

# Health Freedom Lost

Volume 1:  
Eroding Health Freedom

By Thomas J. Lewis, Ph.D.

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## Foreword

"We have given up authority to central bodies of so-called experts who have agendas. The entire process is bought and paid for. If we do not take back our authority as physicians, it is all over concerning the delivery of true health."

"I started a gung-ho prescriber of all these drugs that I now feel are harmful."

- Richard Amerling, M.D.

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The acceptance by doctors of the concept of evidence-based medicine as solely accurate, decided upon by a small panel of experts, must be contested, and this has to be brought before the highest authority. The Supreme Court ultimately has to decide that no one has a monopoly on the truth, especially medical facts. If we reject this notion, a narrow set of experts are the only ones who can define the truth, medicine, and health it lost. However, if we reject this concept and doctors can do what they are supposed to be trained to do for the patient's benefit, that is the essence of Hippocratic medicine. You practice for your patient's benefit according to your best judgment and ability. You do not follow rigid guidelines. There is no word about policies in the Hippocratic Oath. It is all about taking care of your patient, training others, passing on the knowledge, and iteratively improving upon what works. The Hippocratic Oath is this succinct statement of medical ethics, which we have lost. A whole COVID fiasco has just revealed the tremendous extent to which medicine has migrated away from its core mission - to help and save lives.

There's massive over-prescribing, particularly in America, oddly where the foundation of our nation is on freedom. The model we have adopted now is not to reverse the disease but rather to treat those diseases with pharmaceutical products. The current system is so corrupt that we have to start from scratch and build something alongside it as an alternative.

Regarding the question, did we know about stopping transmission before it entered the market? No. We had to move at the speed of science to understand what was taking place in the market, and from that point of view, we had to do everything at risk.

Regarding COVID and the "vaccines," We have known they showed a lack of efficacy and an inability to stop transmission from the beginning. From the first

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day the initial Pfizer study was published, we knew its effect was minimal, and the conclusions were wildly overreaching. The efficacy numbers they came up with were also not germane in the real world because they were relative risk reduction type numbers instead of absolute risk reduction. We knew from the beginning that the study conclusions were problematic. Also, I knew the Pfizer modus operandi because they have been doing this for years with other products such as Lipitor. They never tested to stop transmission or buried that data because it failed. The pivotal trial is the best single look that that drug or product will ever have because the company controls every aspect of the trial and the report's writing.

If the treatment does not pass muster on that first trial, you know it is a bust, and that was clear from the beginning. Subsequent analyses of the study done by Bart Classen first of all, and then Peter Doshi for the British Medical Journal show that the number of severe adverse reactions was higher than those that were prevented by any vaccine effect in terms of decreasing hospitalization or serious illness. We knew from the beginning that this was a disaster. All-cause mortality, as we now know, has gone up by an absolute value in the double digits. Shockingly, they did not start counting vaccinated until either ten days or two weeks after the second shot, which eliminated a bunch of adverse reactions that occurred after the first shot. This is not science; it is data manipulation.

The fact that pharma did not voluntarily release the source data, and had to be forced by the court to drip it out piecemeal, with much of the information redacted, is all you need to know. They wanted to hold onto the bad news forever. Seventy-five years is an eternity and infers severe problems with the study. They did not meet any serious endpoints, and I can imagine the mad conferences that were being conducted in that companies when those results came out, and then the government did the work for them. The government was the one that said that this was going to block transmission. Pfizer never said that.

Pfizer and our governmental officials did drive the coercion campaign to take the jab. The Pfizer CEO is famous for saying, "the vaccine has been proven safe and efficacious, and also I want to tell them (people reluctant to take the jab) that their decision, they need to understand, will not affect only their lives, which at the end of the day, it is their judgment, but will affect the lives of others because if they do not vaccinate, they will become the weak link that will allow this virus to replicate."

Sadly, everybody played along with it and should not have. The media, of course, ran with it as they were told to. But it was clear from the beginning that it was a false narrative and a few brave medical soldiers were trying to inform us, but all that stuff gets censored, and it does not reach a broad audience.

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Strangely, evidence-based medicine is the problem. It created the opportunity to destroy medicine as we knew it before. Medicine is destroyed, and this is what I mean. There are several elements to its destruction.

One of the biggest and first was the loss of professional autonomy. Doctors lost control of their practices. They turned them over to corporations and large insurance companies. They stopped being able to bill directly for their services. They gave that up to the insurance industry. Many became employees more than actual bosses of their own practice, and they had to answer to their corporate or other bosses focused on profits, not care. Most doctors could not practice unfettered medicine as they were trained to. That was a huge thing, the loss of professional autonomy.

Then they lost their scientific roots, which is the evidence-based medicine story. This prescriptive approach does not allow doctors to use their knowledge. And even more important, they lost their ethical mooring. Medical ethics should be forever; instead, it became changeable and fungible with every new law and passing fancy and fad. We are witnesses to the complete destruction of medical ethics, without which you do not have a profession. You may have a trade, but you do not have a profession, and that is why I say the medical profession has been destroyed, but for a relative handful of ethical, science-based doctors out there.

One thing noted during the pandemic is that the “guidance,” which came from the CDC or the FDA around the use of drugs or approaches to COVID in the community, effectively acted as an edict, not guidance. What is evidence-based medicine? It was a construct by a couple of Canadian doctors who said we must introduce a hierarchical system to evaluate the best evidence and then incorporate it into medical practice. It sounded good as initially devised, but something went terribly wrong.

The problem with this so-called evidence system is mainly two things. One, who decides what is the best evidence? And the evidence is not science. Evidence is just something that we use in a scientific process that involves thought, deductive reasoning, and conscious and rational thought. Evidence can be found to support any hypothesis, but a hypothesis is a hope, not reality. Look at vitamin D in the literature, for example. There is evidence for and against it as supporting immunity. There is only one true science but many ways to create evidence.

One of the examples I love is that, according to the so-called evidence, Paul McCartney’s been dead since 1966. I do not know if you remember that whole scare, but it was a conspiracy theory that Paul died, and he was substituted out, and 1966 was the date, and there were all these clues in their songs, and you played certain things backward on the records, and you got hints. You can make up evidence or find evidence for any hypothesis, and that is not science.

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Where evidence-based medicine really went sideways when huge interests became involved in setting the guidelines. The guidance became dominated by industry, not doctors, or at least not doctors funded and supported by the pharmaceutical industry. It works this way today. The pharmaceutical industry creates the study to push their drug. They write the report to market their drug. This has all been very well-documented. We now know that the data, even published in a peer-reviewed journal upon which these guidelines are based, is corrupted, so you cannot possibly use them to practice medicine. Doctors, however, bought into it. It was straightforward. Let's just follow the guidelines. I can turn my brain off at that point and do what they say, thus not facing liability.

Most of the experts are paid by the industry, either as consultants, speakers, or researchers. They are getting money from the industry that they are writing guidelines about. It is inherently corrupt because there are no checks and balances. Their word is final. All of these guidelines should be thrown out. We should just ignore them all. One of the things that I like to say is that if you want to be healthy, do the opposite of what the official recommendations are in terms of diet, sun, exercise, and salt. Do the opposite, and you will be healthy. Eat salt, eat fat. You will be much healthier if you do NOT follow the dietary guidelines.

I grew up in the 50s and 60s before these guidelines were put out, which was the end of the 70s, and everybody was slim back then. The obese people stood out. Now, if you are slim, you stand out. What changed? Well, our genetic makeup did not change. The dietary guidelines pushed everybody to give up animal fat and go with these polyunsaturated industrially-produced vegetable oils like canola and soybean oil. Because they took a lot of the healthy fat out of food, it did not taste good anymore, so they amplified everything with sugar and high-fructose corn syrup, creating a very toxic environment that is very hard to avoid.

If you go to a supermarket, 95 percent of what is on the shelves is toxic. It is sugar-filled and soybean or canola oil-filled. You cannot even find a pretzel that does not have soybean oil anymore. You must work very hard to eat a healthy diet in America today. The vast majority do not, and they gain weight, and eventually, they get metabolic syndrome, type two diabetes, and hypertension, which are all diet-related for the most part. Also, this syndrome is reversible, except the model we have adopted now is not to reverse the disease but rather treat those diseases with pharmaceutical products that make matters worse. It is a fabulous business plan for profits.

The current system is so corrupt that it is impossible to fix. We have to start from scratch and build something as an alternative because if we try to fix what is wrong, we will never finish the task. It is just so bad. We must get all the corrupt influences out; you cannot do that as they are too entrenched. Let's build our own system that will be free from industry influence. We will not have pharma telling us what drugs to give and when. We will not have guideline committees to tell

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doctors how to practice. We will re-instruct doctors to use real science to make clinical decisions.

Doctors must be free to practice what they consider good medicine. They cannot be told how to practice. They cannot be told in California what they can discuss or not discuss with patients. There has to be free and open communication. You have to be able to give informed consent. That is another vital part of medical ethics. If you cannot tell a patient what the risks and benefits of a given procedure are, honestly, you cannot practice real medicine. You become an agent of the state, and I hope the Supreme Court has a moment of clarity and says, "No, you cannot assign a group to determine scientific truth," Otherwise, the current dark ages of medicine will continue.



## Chapter 1. Health Freedom Lost

"In health, there is freedom. Health is the first of all liberties."

– Henri Frederick Amiel

### **Health Freedom Lost**

Summary: We have been losing health freedom for as long as there have been health systems. The common denominator has been and continues to be the control of medicine by small authoritarian groups who have dictated policy over medical delivery despite doctors' superior knowledge on the front lines. The history of medicine reveals great advancements in medical knowledge and technology. Other technologies have and continue to advance, and we enjoy greater functionality at lower costs across many technologies. Medicine is the outlier. In medicine, costs continue to climb exorbitantly, yet chronic diseases, responsible for most morbidity and early mortality, escalate. Only one conclusion may be drawn - the controlled practice of medicine is not based on science.

The concept of health freedom has stunning parallels with key medical concepts. In medicine, there are acute and chronic diseases. Acute diseases are prominent, presenting with clear symptoms. Chronic diseases are long-lasting, insidious, and dangerous, and you may not even know you have one. And the chronic process usually ends in some deadly or debilitating single acute event like a heart attack. Thus, chronic diseases are often misconstrued as being acute in derivation. In health freedom, the parallel to acute diseases is illegal or unfounded mandates where citizens are coerced, against their will, into unproven treatments and restrictions.

The parallel to chronic diseases is a centuries-long or extended loss of health freedom. This slow loss of health freedom has been accompanied by a loss of good health, an underappreciated driver of the COVID-19 pandemic, and emergency use authorizations. This insidious loss of health freedom set us up for the “heart attack” of mandates and forced controls we are experiencing today. The loss of health freedom begins with a global sick care delivery system, not a healthcare system. Understanding how we got here provides clues about escaping its clutches and being healthy again. In such an environment, we are resilient to anything adverse that we encounter.

Health freedom is embodied in The Oath of Hippocrates. An abbreviated modern version of the oath reads,

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"I swear, so far as power and discernment shall be mine, I will carry out regiments for the benefit of the sick and will keep them from harm and wrong; to none will I give a deadly drug even if solicited – into whatsoever house I shall enter, I shall go for the benefit of the sick."

- Eugene McDaniel, M.D.

If our population had access to a science-based healthcare system rather than our current sick care system, COVID-19 death rates would have been substantially lower. We now know that actual death rates associated with this disease were markedly overestimated. Regardless, emergency use authorizations would have been harder to rationalize, and tens of thousands of people would not have died from the COVID injection or, more importantly, dangerous and unnecessary treatments and hospital interventions.

This sinister erosion of health freedom is the root cause of the mandated loss of health and general freedoms we are enduring today. The remainder of this two-volume set of books focuses on how we achieve good health, how we have lost access to it globally, and how we can get it back. We are just some of the ones presenting this concept. In 2020, at the height of COVID fear, The Global Burden of Disease (GBD) Study published its findings in the prestigious journal, *The Lancet*. The information on health and disease was obtained before the SARS-CoV-2 outbreak and illustrated people's general poor state of health today.

The GBD study was produced by a global network of 5,647 collaborators in 152 nations and territories who work in more than 1,100 universities, research centers, and government agencies. The GBD has been used to create and update health policies in numerous nations, local jurisdictions, and international organizations, including the World Bank and the World Health Organization. Here are the key findings and conclusions from that study.

- The GBD study analyzed 286 causes of death, 369 diseases and injuries, and 87 risk factors in 204 countries and territories. It revealed that the world's population was unprepared, in terms of underlying health issues, for the impact of the COVID-19 pandemic.
- It described the current global crisis of chronic diseases and the failure of public health to stem the rise in highly preventable risk factors that have left populations vulnerable to acute health emergencies such as COVID-19.
- GBD concluded that urgent action is needed to address the global syndemic (more than one pandemic at a time) of chronic diseases, social inequalities, and COVID-19 to ensure more robust health systems and healthier people, making societies more resilient to a future pandemic and other health threats.

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- Only six countries have seen the years spent in poor health decrease between 1990 and 2019 - Lesotho, Uzbekistan, Nicaragua, Tajikistan, the Philippines, and Zimbabwe.
- The latest global disease estimates reveal a perfect storm of rising chronic diseases and public health failures fueling the COVID-19 pandemic and those likely to come in the future.

The pandemic of 2019 and the “acute” loss of health freedom have also brought personal freedom to the forefront of concern and dialog among many global citizens concerned about their autonomy. In the acute sense, health freedom is defined by the Health Freedom for Humanity group as freedom from “mandated medical procedures of any kind, medical coercion, or any restrictions on health choice.” It further states that such practices violate fundamental human rights.

Chronic health subjugation is much more insidious than, for example, mandating the vaccine or coercing children, with close to zero risk of dying from the virus, to wear masks and to be vaccinated. And, unlike this sudden emergence of mandates and restrictions, this chronic health subjugation has evolved like slow-growing cancer. Our healthcare system does not deliver health care despite having the knowledge and resources to do so, all for a very high financial premium. Simply put, this health freedom cancer is not a looming mandate – but rather a system that has evolved to limit our choices and forces us down a path of symptom management for chronic conditions that account for 90 percent of human misery and costs. More than 60 percent of adults in America have at least one chronic condition, and chronic diseases account for 90 percent of the more than \$4 trillion annual healthcare expenditure. The result of this restrictive system is that too many of us are consistently unwell, even though we have paid an extremely high price for the “care.”

These concepts of health freedom, acute and chronic, are not separate issues. They are intimately intertwined. In the case of COVID-19, if we, as a society, enjoyed much better health, mainly unavailable to most of us because of the healthcare system design, mortality rates from the pandemic would have been substantially lower than they were in actuality. At some mortality threshold, there would not have been the need to establish emergency use authorizations and a rush to vaccines. The seasonal flu is never considered a pandemic, yet mortality rates for COVID-19 and the flu are similar, with deaths from COVID-19 being lower, especially in younger people. Indeed, if we were healthier, the SARS-CoV-2 outbreak may not have even been classified as a pandemic. In this respect,

"In health, there is freedom. Health is the first of all liberties."

– Henri Frederick Amiel

The key elements that have led to this pandemic and emergency use authorizations include:

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- Loss of health freedom (choice) has eroded slowly and insidiously through controls placed on healthcare delivery over generations by a few authoritarians, most of whom do not practice medicine.
- Our poor state of health has crept in despite enormous technological advancement, the most important of which are not available to us in favor of less effective and expensive alternatives like drugs and surgeries. What we receive, clinically, is an infinitesimally small percentage of general medical knowledge and is dictated by business decisions made by pharmaceutical executives, not their research staff.
- Significant contributions to our poor health have been made from our inadequate healthcare system and other industries, including agriculture, insurance, government, and big oil. Ultimately, money is the driver behind healthcare delivery, not science.
- Health policies restrict doctors from practicing good medicine driven by money over science and evidence.

How did we get here? Chronic diseases are complex. They all involve the interaction of multiple systems resulting in general or specific disease states - a diagnosis, or "dis-ease," a state of poor health without a diagnosis. However, our doctors are trained in very specific silos and stay within narrow "swim lanes." For example, eye diseases are diseases of the eye only, without regard for the possibility that the genesis of the disease lies outside of the eye, and that should be considered the first place to investigate and affect treatment. The silo concept originates in medical schools, and these schools, in the modern era, were created through the control of elite influential people with little medical experience but substantial financial agendas.

Medical advancement and technology exploded over the past century along with other technologies. Most of these impressive technologies employed in healthcare represent a small percentage of what is known to medical research and are, by design, primarily reactive rather than proactive. However, advanced technologies are available for both prevention and treatment. The Japanese, Korean and Singaporean systems are proactive and do not focus on fancy and expensive technologies. Their healthcare costs are one-fourth of that forced on Americans.

As a poignant example, mortality in hospitals goes down during the annual cardiology meetings. The likely reason is that the high-level surgeons and doctors who attend and speak at these conferences typically implement the most advanced procedures and interventions. The document outlining this is in a peer-reviewed publication and summarized in an article in *Cardiology Today* titled, "Mortality Lower for Patients Admitted During National Cardiology Conference Dates," December 23, 2014.

Unfortunately, the spread of influence by the expensive and ineffective American healthcare system and the FDA is vast and global. However, many shining

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examples of reasonably good healthcare systems exist that achieve excellent health in their populations. Examples are few but significant. Japanese women are the longest-lived, with a life expectancy of seven years greater than their American counterparts. The Koreans have implemented a national prevention program, and their aggregate life expectancy is increasing faster than in any other country. Singapore gives healthcare power to the people and has the best healthcare outcome factors compared to any other nation, the lowest cost per person while enjoying excellent health. Countries that reject the American system do well because what constitutes good health is known everywhere through the medical literature and doctor experience and is made available to their citizens. People enjoy good health when they have the freedom to gain access to relevant, science, and evidence-based health knowledge along with its application.

Civilization has advanced over the eons due to the increase and aggregation of knowledge, thanks mainly to the dissemination of information through improved communication. All disciplines of science and technology have benefited as a rising tide lifts all ships. There is knowledge, but there must also be the application of this knowledge. Since the beginning of the twentieth century, advancement in several areas, particularly related to science and technology, has been evident. Examples are skyscrapers, automobiles, airplanes, communication systems, and computers. Medicine is a science-driven technology; arguably, the science of medicine has advanced similarly to other areas of technology. Has the application of medical advancement been based on outcomes? Are we healthier today than in the past? If not, what has held us back?

Our health, particularly our poor chronic disease status, evolved not just through the influence of medical science but by the impact of areas with either little knowledge about health or areas with an agenda other than health. These other areas include the media, agriculture, politics, big oil, the law, government, and finance, to name a few pressures shaping what we receive or do not receive at a clinical visit today.

The medical coding system, the CPT, and the ICD-10 systems are examples of how our medical establishment has lost sight of the impact of multiple systems on general disease. The International Classification of Diseases, Tenth Edition (ICD-10), is a clinical cataloging system. It accounts for modern advances in clinical treatment and medical devices. ICD-10 codes for medical diagnoses offer many more classification options than those found in its predecessor, ICD-9. In 2021, the total number of ICD-10 codes was 72,616. Are there indeed tens of thousands of root-cause drivers of disease? This coding system establishes and controls the delivery of reactive and siloed medicine. If it is not in the code book, a doctor has his or her hands tied. Why? Because the code determines payment. Preventative measures are barely represented in the coding system. Thus, the system is designed to manage rather than prevent disease.

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To understand how the ICD-10 code book restricts medical freedom, we merely need to dissect the purpose and use of this system. Within the healthcare industry, providers, coders, IT professionals, insurance carriers, government agencies, and others use ICD codes to "properly" note diseases on health records, track epidemiological trends, and assist in medical reimbursement decisions. This is the language used to rationalize the coding system. But, as you will see and already know, the system does just the opposite of improving outcomes. Note that there is no statement about using this data to improve health outcomes.

This coding system has become the medical "big brother" that ultimately measures how doctors comply with the standard of care. The standard of care concept is the culmination of all that is wrong with medicine and reflects influences beyond the science of medicine. On the surface, it has the potential to be a brilliant system if used to promote creativity and best-of-breed diagnoses and treatments. Instead, it shackles doctors into compliance by implementing limited approaches that do not evolve with knowledge of outcomes.

Doctors are graded based on compliance with the coding system, translated as the standard of care. A poignant example of this system failing is that of my mentor, Dr. Clement Trempe, a retired ophthalmologist who practiced at Harvard Medical School for 47 years. Before 1980 it became apparent to him that people with eye diseases were systemically sick. He continued to treat his patient's eyes but did extensive whole-body workups on his patients and treated them from a whole-body perspective. Since people have two eyes, it is quite easy to evaluate the impact of treatment.

In macular degeneration, for example, the disease usually starts in one eye - the affected eye - and slowly spreads to the "fellow" eye. The statistics on the rate of spread are well documented: 22 percent in one year and 85 percent in five years. The disease seldom spread in Dr. Trempe's patients, and often the affected eye improved. Standard-of-care ophthalmologists never achieved this remarkable outcome. How was Dr. Trempe rewarded?

- He consistently received average or below-average health grades, mainly because the volume of patients he saw was low compared to standards, and patients had long wait times. It takes time to perform complete evaluations and treatments.
- Other doctors were reticent to refer patients to Dr. Trempe because he was not practicing "standard of care." These cowardly doctors were afraid of liability.

If a doctor does not follow the standard of care and something happens to their patient, liability potential goes sky high. Thus, the doctor does the same thing repeatedly with little regard for the results but staying with the herd protects their career in which they have invested enormous time, intellect, and money. That is why eye diseases are epidemic along with all other chronic diseases. We cannot

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blame the doctors entirely. They are victims of the system. Thus, we must blame the system, tear it down, and build a new one from scratch.

Why is ICD-10 important? This question was adequately answered by TechTarget In an article titled "ICD-10 (International Classification of Diseases, Tenth Revision)," published on 9/28/2018. The answers are illuminating. "ICD-10 codes provide more detailed information for measuring healthcare service quality, safety, and efficacy. Because better data will be delivered via the ICD-10 code set, it has the potential to improve the following:

- value-based reimbursement;
- outcome measurements;
- clinical, financial, and administrative performance measurement;
- the design of payment systems and claims processing;
- reporting on new medical technology;
- improving reimbursement systems; and
- care and disease process management.

The adoption of the ICD-10 code set also allows for more accurate payment for new procedures, fewer rejected claims, fewer fraudulent claims, a better understanding of new procedures, and improved disease management."

This last statement is a tell-all. Do you see anything about health in that statement? We want to maintain disease management. We want to improve health through disease prevention and reversal. Those words rarely appear in these policy documents, and when they do, they have no meat behind them.

Note that most of ICD-10 revolves around payment, not outcomes. Importantly, the term "management" is ubiquitous. Glaringly absent is the bullet that states "continuous improvement in health outcomes." Instead, the keywords are:

- reimbursement;
- measurements;
- claims;
- management; and
- reimbursement again.

Also inferred by this system is that doctors cannot be trusted to do the right thing for their patients. They must be accountable for everything they do and fit within the coding system. So instead, we have a restrictive system that strips creativity away from a profession that arguably comprises the most intellectual individuals in our society. At least, we once thought that!

The coding system is a poignant example of health freedom lost. Doctors have lost autonomy through the implementation of this prescriptive system. The consequences of poor health do not just trickle down to us, the patients. It is more like a tsunami. The evidence and science exist for achieving good health and a

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healthcare delivery system focused on improving our health. A medical history lesson is in order as it exposes (at least) two essential concepts:

- The understanding of good health and technologies to support health are well known, and
- A major cause of morbidity and mortality has been ubiquitous throughout human history: infectious diseases. However, modern medicine views infection as an acute problem and ignores the connection between infection and chronic illnesses that dominate our health landscape.

### **History of Medicine**

How has medicine evolved such that today, we have lost health freedom? History indeed repeats itself. Thus, studying the history of medicine, both the advancement and regression, provides valuable clues as to what controls the application of medical knowledge in modern clinical practice.

Aristotle said:

“We are what we repeatedly do.”

Einstein is credited with saying:

“Insanity is doing the same thing repeatedly and expecting different results.”

Indeed, if what we repeatedly do is not working, it is time to go down a different path. That is what history teaches us.

The roughly 5,000-year history of medical advancement is impressive. A chronological review of that history is included here for two purposes. First, to show how far we have come concerning the sophistication of our most modern tools and knowledge compared to more historical advancements. Second, there are important clues as to the root cause of disease embedded in historic discoveries, many of which are ignored in the modern medical paradigm. Third, to get you to think about what is wrong with the current system because our society is unhealthier than at any other time in history despite all the brilliant achievements.

The historical chronology of medical advancement and regression is broken down into these time segments:

- Ancient Times;
- 4000 BC – Primitive Times;
- 3000 BC – Egyptians;
- 1700 BC – Chinese;
- 1200 BC – Greeks;
- 800 BC – Romans;
- 400 AD – Dark Ages;

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- 800 AD – Middle Ages;
- 1350 AD – Renaissance Period;
- 19<sup>th</sup> Century;
- 20<sup>th</sup> Century.

Ancient Times: People believed that demons and evil spirits caused diseases and illnesses. Treatment was directed towards counteracting or eliminating the demons.

4000 BC – Primitive Times: Herbs and plants were used as medicines. This was a significant advancement in thinking as it inferred that diseases were physiological and could be treated with concoctions. Some of the medicinal used during that era are still with us today. Morphine from the opium poppy is still used as a potent narcotic analgesic. Digitalis, from the foxglove plant, is still used, with modification, as an antiarrhythmic and heart failure drug.

Many other herbs were used medicinally. Formal records were recorded on clay tablets 3000 – 5000 years ago. The Cuneiform script, developed in the ancient Middle East, was used to register the names of 250 plants and recipes for remedies. As an example, aloe leaf was used as a laxative. In some respects, this advancement from ancient times is substantial, ushering in the use of supplements and pharmaceuticals.

3000 BC – Egyptians: These are the earliest people known to keep accurate medical records meaning that they would write down what they did to treat people and the different signs and symptoms observed before and after treatment. Physicians were priests who studied medicine and surgery in the temple medical schools. Magic and medicinal plants were used to treat diseases. However, they still called upon the gods for healing when illnesses occurred. The Egyptians also believed that the body was a system of channels for air, tears, blood, urine, sperm, and feces. If one of these channels became clogged, they would use mainly bloodletting or other techniques to open the channel.

1700 BC – Chinese: They believed in the need to treat the whole body by curing the spirit and nourishing the body (My oh my, how we have moved away from this concept as illuminated by the 77,000+ ICD-10 codes). They believed that by carefully monitoring the pulse, they could determine the body's condition and when the pulse was increased or decreased, that told of something wrong. Then they would endeavor to find the cause. They also used the pulse to determine if a woman was pregnant. Importantly, they began to search for medical reasons for illness, moving away from superstition or just treatment.

A significant advancement by the early Chinese was the development of a recorded pharmacopeia of herbal medications – their type, preparation, use, and outcomes. There was some indication of this in the more ancient Middle East, but the Chinese formalized the practice. In some respects, this may be viewed as the

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emergence of the Standard-of-Care. Ancient Chinese also used acupuncture to alleviate pain and congestion. Blood flow was stimulated (even though circulation wasn't "discovered" for another 3500 years) using moxibustion, a form of heat therapy in which dried plant materials called "moxa" were burned on or very near the surface of the skin. The intention was to warm and invigorate the flow of Qi – the life force or vital energy - and dispel specific undetermined pathogenic influences.

1200 BC – Greeks: They learned from the Chinese and began what closely resembles modern medical science. Observation of cause and effect became an integral part of the Greek approach. They also believed illness resulted from natural causes, as opposed to acts of gods or demons. Emphasis was placed on diet and cleanliness as a way to prevent disease. They used therapies still used today, such as massage and herbal treatments.

Influential thought leaders emerged from the Greek intellectual society. Alcmaeon was a biochemist that identified the brain as the physiological site of the sense. Aristotle dissected animals and is called the founder of comparative anatomy. Hippocrates is considered the father of Medicine. He developed an organizational method to observe the human body and recorded many signs and symptoms of different diseases. He is most well-known for creating a high standard of ethics called the Oath of Hippocrates, which is used, at least in theory, by physicians today. This Hippocratic Oath is recited whenever physicians graduate with their medical degrees.

800 BC – 400 AD – Romans: They treated diseases with diet, exercise, and medication. (Here is an example of medical regression, not progression, as our Standard-of-Care has scuttled any focus on diet and exercise). The Romans were the first to organize medical care, doing so for their injured soldiers, as injuries were a major source of morbidity and mortality during this period of history. For efficiency, they developed the earliest hospitals that were eventually overseen by religious or charitable organizations in which ill people were housed in monasteries or convents. Monks and priests would care for those who were sick or had diseases.

Public health and sanitation systems were developed as a way to prevent disease. Aqueducts were built to carry clean water into the cities and sewers to remove waste materials from populations. Compare this to throwing feces and waste materials out in the street to be carried away. This archaic way of managing waste still impacted "polite" society. At least decades ago, men were taught to walk near the curb while their lady companions would walk closest to the building. Emptying chamber pots of waste through a window was an everyday practice. Those who walked closer to the walls were less likely to get covered in feces. Because, historically, a gentleman was always prepared to sacrifice himself in honor of his woman, he was the one to get his clothes dirty. The Romans

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developed large public bath systems and public bathhouses and developed filtering systems to keep the water clean. The Romans seem to have known that bugs spread disease, as illustrated by the quest for cleanliness. They had a sense, too, that mosquitoes spread disease as they would drain marshes, possibly to reduce the incidence of malaria.

Claudius Galen, a Greek physician living during the Roman Empire, significantly impacted the medical system for hundreds of years. He became very seasoned in the art of treating combat wounds and also gained knowledge of practical human anatomy when human dissection was strictly forbidden. He is said to have described the gladiator's wounds as "windows into the body." He further improved his knowledge of anatomy by performing dissections on apes and monkeys and became uniquely skilled in this discipline.

In the field of pharmacology, he created the system of Galenic degrees, the first recognized attempt to precisely gauge the effects of medicines. He also believed that an imbalance in 4 fluids or humor resulted in illness. As such, he should be considered one of the earliest known clinical researchers. He studied infectious diseases and is regarded as the first to describe symptoms of inflammation. He also forwarded the concept of miasma, or "bad air," and diseases. He may, in this regard, have been the first to explain the underpinning of plagues and pandemics. He died at 87 when the average life expectancy was considered to be 25-35 years of age.

400 – 800 AD – Dark Ages: The dark ages were not just economically, intellectually, and culturally dark. Medicine took steps backward as the study of medicine was prohibited, and emphasis was again placed on saving the soul. This area represents a substantial loss in health freedom. Today, we are in a modern health "dark age" because we have excellent knowledge about health, but much of that knowledge is not applied to our populations.

800 – 1400 AD – Middle Ages: Interest in medical knowledge and practice was renewed. Physicians began to obtain training at medical universities starting in the 9<sup>th</sup> century. Emphasis was on developing an understanding of infectious disease because of high incidences of smallpox, diphtheria tuberculosis, typhoid, the plague, and malaria. Notable, the bubonic plague, also known as the Black Death, spread by flea bites, killed 1/3<sup>rd</sup> of the population of Europe and Asia, with estimates ranging from 10 – 100 million people.

Arab physicians used their knowledge of chemistry to enhance the chemistry of medicine - pharmacology. In Arabia, physicians were required to pass examinations and obtain licenses regulating, for the first time, who could become a physician and actually practice medicine. Rhazes, the Arab "Hippocrates," developed methods to distinguish smallpox from measles. He also suggested that blood was the source of many infectious diseases. He was the first to use animal

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gut for suture material. Avenzoar was a physician of this period who described the mite that causes scabies.

Obtaining and proving medical proficiency can be viewed as nothing short of a substantial advancement. It indicated the use of more global communication contributing to collective medical knowledge. In modern times, however, regulated training omits key learning, thus turning what should be an asset into an impediment.

1350 – 1650 AD - Renaissance Period: The science of medicine took important steps forward. Dissection of the human body provided a vast understanding of anatomy and physiology. The artists Michelangelo and Leonardo da Vinci used dissection to draw the human body in great detail. Also, the development of the printing press allowed knowledge to be spread and amplified. Andreas Vesalius published the first Anatomy book. Isaac Judaeus wrote a book on dietetics.

Notable people from this period and their achievements are included here. The numbers in parenthesis are the lifespan of the individuals. This information is included here because erroneous presumptions about longevity are used to argue the benefits of modern medicine. This is discussed further in Volume 2, where the work of Dr. Paul Clayton on comparative longevity in British history is reviewed.

- Ambrose Paré, a French surgeon, is known as the father of modern surgery. (80)
- William Harvey forwarded the concept of blood circulation in 1615. (79)

William Harvey is a true medical hero. He forwarded the concept of circulation and was convinced that blood has an irreducible life force. He did not publish his findings immediately for fear of retribution and suppression. Harvey's medical notes show that he believed in the heart's role in blood circulation through a closed system as early as 1615. Yet he waited until 1628 to publish his findings in "Exercitatio Anatomica de Motu Cordis et Sanguinis in "Animalibus" or "On the Movement of the Heart and Blood in Animals." Why did he wait so long? Control of medical freedom.

Galenism, or the study and practice of medicine as taught initially by Galen, was almost sacred at the time Harvey lived. No one dared to challenge the teachings of Galen. Like most physicians of his day, William Harvey was trained in the ways of Galen. Conformation was not only the norm but was also the key to success. (Sound familiar?) Rebellious against Galen's teachings could quickly end any physician's career. Perhaps this is why he waited. Today the prescription pad, drug companies, and the standard of care replaced Galen in terms of stymieing medical progress.

Thankfully, Harvey's contribution to medical knowledge was recognized and rewarded. Three years before his death and 40 years after his great discovery, he

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was offered the prestigious Presidency of the College of Physicians, but he refused for health reasons.

- Anton van Leeuwenhoek invented the microscope in 1666 and was the first to see tiny organisms he called ‘animalcules’ in water droplets. (91)
- Gabriel Fahrenheit created the first mercury thermometer in 1714. (50)
- John Hunter, an English surgeon, established standard scientific surgical procedures. (65)
- Benjamin Franklin invented the bifocals for glasses. (84)
- James Lind prescribed citrus juice containing vitamin C to prevent scurvy in 1747. Notably, he was possibly the first to perform a scientifically conducted prospective controlled therapeutic trial proving the cause and effect of a treatment for a disease, in this case, between scurvy and lemon juice (vitamin C). (78)

Lind’s findings saved the lives of millions of people. Estimates of sailor deaths from scurvy are as high as two million. Although Lind's findings on scurvy were recognized then, it was not until more than 40 years later that an official Admiralty order was issued on the supply of lemon juice to ships. With this, scurvy disappeared almost entirely from the Royal Navy. The reluctance of government officials to implement such a simple and harmless treatment and cure at or near the time of its discovery aboard ships led to the untimely death of at least 100,000 sailors.

### 19th Century:

- Edward Jenner is considered the founder of vaccinology in 1796 after he inoculated a 13-year-old boy with the vaccinia virus (cowpox) and demonstrated immunity to smallpox. In 1798, the first smallpox vaccine was developed. Over the 18th and 19th centuries, the systematic implementation of mass smallpox immunization culminated in its global eradication in 1979. (74)
- James Blundell performed the first blood transfusion in 1818. (88)
- Rene Laennec invented the first stethoscope in 1819. (45)
- Ignaz Semmelweis, in the 1840s, encouraged physicians to wash hands with lime juice after performing autopsies and before delivering babies to prevent puerperal (childbirth) fever. (47)

The Semmelweis reflex or "Semmelweis effect" is a metaphor for the reflex-like tendency to reject new evidence or new knowledge because it contradicts established norms, beliefs, or paradigms. Even though the concept is applied generally to any new knowledge, its genesis is medical, and arguably, the preponderance of the Semmelweis reflex occurs in medicine. Clayton Christensen et al., authors of the “Innovators Dilemma,” wrote an article in the Harvard Business Review corroborating this assumption. Christensen, et. al. state:

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“Health care may be the most entrenched, change-averse industry in the United States. The innovations that will eventually turn it around are ready, in some cases – but they can’t find backers.”

“Imagine a portable, low-intensity X-ray machine that can be wheeled between offices on a small cart. It creates images of such clarity that pediatricians, internists, and nurses can detect cracked bones or lumps in tissue in their office, not in a hospital. It works through a patented “nanocrystal” process, which uses night vision technology borrowed from the military. At 10 percent of the cost of a conventional X-ray machine, it could save patients, their employers, and insurance companies hundreds of thousands of dollars every year. Great innovation, right? Guess again. When the entrepreneur who developed the machine tried to license the technology to established healthcare companies, he couldn’t even get his foot in the door. Large-scale X-ray equipment suppliers wanted not part of it. Why? Because it threatened their (lucrative) business models.”

Ignaz Semmelweis is the unfortunate person associated with the “reflex.” He was a Hungarian obstetrician who discovered that often fatal puerperal fever, common among new mothers in hospitals, could be eliminated if doctors washed their hands before assisting with childbirth. He proposed a technique that physicians would wash their hands with an antiseptic solution before assisting in a child’s birth. His recommendation resulted in a significant decrease in deaths. The medical community largely ignored and ridiculed this mandate despite its demonstrated effectiveness. Dr. Semmelweis was dismissed from his hospital post and died in an asylum. There is more to the story, but it is an essential lesson in human behavior. After his death, Semmelweis’ approach eventually earned widespread acceptance, and he is considered a pioneer in antiseptic procedures.

- Elizabeth Blackwell became the first female physician in the US in 1849.
- Florence Nightingale was the founder of modern nursing and established efficient and sanitary nursing units during the Crimean war of 1854.
- Joseph Lister was the surgeon who introduced new principles of cleanliness through sterilization in 1865, which transformed surgical practice in the late 1800s. Widespread acceptance of Lister’s procedures was relatively slow, paralleling the efforts of Semmelweis, as is often the case with revolutionary new ideas. Some busy doctors were unwilling to take the time to try his approach. Some found it difficult to believe in germs because they were too small to see. Others tried Lister’s procedures but did so incorrectly and failed to obtain the desired result.
- Clara Barton founded the America Red Cross in 1881. The international Red Cross was founded in 1863 by the Swiss humanitarian Henry Dunant.
- Louis Pasteur contributed many discoveries to medicine in the mid-1800s. He developed pasteurization and a vaccine for rabies. Of most significance is his original contribution to the relationship between microorganisms

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and disease, referred to as the “germ theory” of disease. Chapter 6 delves deeply into the germ theory as still highly relevant but primarily an ignored disease causation process today.

- Claude Bernard is the most important doctor of the modern era with whom few are familiar. Bernard is credited with “homeostasis” or “internal balance.” Bernard forwarded that your internal terrain is paramount to your health and longevity over all other considerations. He should be regarded as the first true medical scientist.

Informative quotes by and about Dr. Claude Bernard include:

“The fixity of the milieu supposes a perfection of the organism such that the external variations are at each instant compensated for and equilibrated... All of the vital mechanisms, however varied they may be, always have one goal, to maintain the uniformity of the conditions of life in the internal environment... The stability of the internal environment is the condition for a free and independent life.”<sup>1</sup>

“The experimenter who does not know what he is looking for will not understand what he finds.”

On his deathbed, Louis Pasteur reportedly said:

“Bernard was right; the seed is nothing; the soil is everything.”

This last quote by Dr. Bernard may be the most important in medical history and points to the reason behind poor outcomes delivered by the practice of medicine today. We hang our hats on the gold standard, randomized clinical trials, to guide medical policies and procedures. Yet, Bernard implies in his quote that there is often a “rush to judgment.” The experiment or trial is frequently used to justify a preconceived notion or a bias that becomes standard practice, even when the data, interpreted in an alternative way, disputes the interpretation. Since our medical delivery system relies on these randomized trials more than human judgment, the reasonable question is, how often are the conclusions derived from these trials used to guide practice correctly?

The problem of bias in interpreting and reporting scientific data is not new. Manipulating statistics of all types is the making of clichés. For example, Samuel Clements is renowned for this quote,

“There are three kinds of lies: lies, damn lies, and statistics.”

“Not Invented Here Syndrome” is a real concept, and I have personally experienced this when working as part of a “team” in medical research.<sup>2</sup> According to Stephen Watts,<sup>3</sup> “Pride is a double-edged sword. The good side of pride gives us confidence in our abilities and makes us want to strike out on our own to find better solutions. The bad side of pride leads us to ignore the merits of external offerings and contributions. These aspects of pride can lead us to the ‘not-

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invented-here syndrome,' the endpoint of which is inappropriate bias and decay in the rate of expanding knowledge.”

Dr. John Ioannidis is no rookie. He is a professor and chairman at the Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, a tenured adjunct professor at Tufts University School of Medicine, and a Professor of Medicine and Director of the Stanford Prevention Research Center at Stanford University School of Medicine. He has made a career of doing what much of medical research has not - unequivocally validating his work. And that work is the review of the validity of published medical findings. Dr. Ioannidis is known as a meta-researcher and one of the world's foremost experts on the credibility of medical research. He and his team have shown, again and again. In many ways, much of what medical and biomedical researchers conclude in published studies, conclusions that doctors keep in mind when they diagnose or prescribe medications or treatment, is misleading, exaggerated, and often flat-out wrong. His landmark paper, published in 2005, is titled “Why Most Published Research Findings Are False.”<sup>4</sup>

- Wilhelm Koester, a German pathologist, showed that vascular disease is primarily a disease of the small vessels – the capillaries, and he published these results in 1876.<sup>5</sup>

This demonstration by Koester is not known by many but has enormous ramifications for health that are entirely missed by Standard-of-Care medicine today. Cardiovascular deaths continue to be the #1 cause of early mortality in the developed world. Thus, having a deep understanding of the mechanisms of vascular deterioration and disease is paramount to improving the health of a substantial percentage of our population. When you understand the impact of Koester's discovery, you may wonder how medicine, 150 years later – can be so far behind the times.

The discovery by Koester is arguably one of the most important in all of medicine concerning how most chronic and vascular diseases occur. Koester explained that diseases of the vessels start from the outside, in the vasa vasorum region, which is the outermost layer of the blood vessel architecture and works its way inside. The vasa vasorum is the layer of small vessels that nurture the wall of larger arteries. The small vessels, or capillaries, are everywhere because for any cell to live and thrive, it needs to be within three cell diameters of a capillary. Even though the disease starts in and infiltrates the smallest vessels, it is responsible for major vascular diseases, including heart attack, stroke, heart failure, coronary artery disease, and other major vascular diseases.

Plaques result from abnormal neovascularization (new vessel formation) that starts in this vasa vasorum vascular network. Serum proteins, inflammatory molecules, and lipids leak from these abnormal vessels and accumulate in the extravascular space. When this accumulation is suddenly released inside your

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blood vessel, you are highly likely to have an immediate cardiovascular event like a stroke or heart attack. Before it bursts, you may experience symptoms of angina or ischemia as the sack swells into the space of the large vessel wall and your vessel. This occurs from the outside, thus narrowing your lumen, the inside space of the vessel.

Definition: Vasa vasorum are small blood vessels that comprise a vascular network supplying the walls of large blood vessels.

Interpretation: Heart and vascular disease is, first and foremost, a capillary disease, not a large vessel disease.

The consequences of knowing vascular diseases of large vessels are actually a disease of the small vessels (capillaries) that support the large vessels is profound. Important to note that today, every single picture in doctors' offices showing a vessel with plaque precipitating and filling the vessel from the inside is **COMPLETELY WRONG**. Sadly, every doctor proudly displaying the image believes it to be true. This is not just some subtle and inconsequential difference. The two disparate models entirely change the idea of vascular disease causation and treatment of the #1 cause of early mortality in the developed world. This topic will be more thoroughly examined in Chapter 2 of Volume 2. Figure 1.1 shows how vascular disease actually develops compared to what traditional doctors tell you.

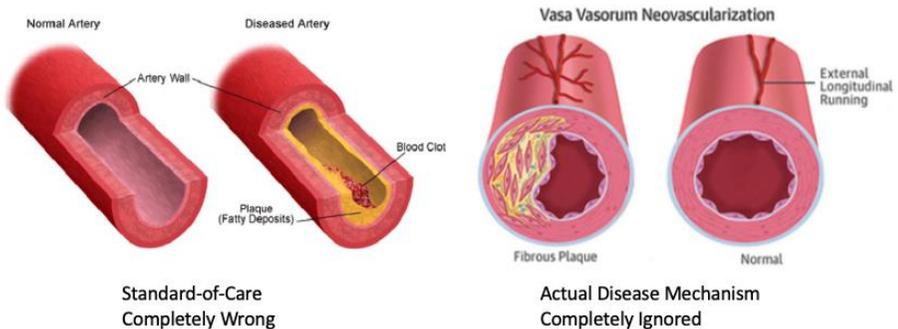


Figure 1.1: The illustration on the left shows an incorrect process of vessel plaque formation. The image on the right shows the correct process of vessel deterioration and plaque formation. The plaque forms from the outside, impinging on the inner space until it bursts, leading to a potentially fatal cardiovascular event.

- Dimitri Ivanofski discovered viruses in 1892.
- Gregory Mendel established the principles of heredity and dominant/recessive patterns.
- Wilhelm Roentgen developed the medical X-ray technique in 1895.

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- Almroth Wright developed the vaccine for typhoid fever in 1897.

These 21 health mavericks from the renaissance period lived an average of >73 years. If this group of 21 had access to certain simple health-enhancing technologies, like clean fuels, better sanitation, and antibiotics, their collective life span would be the same as we experience today, if not longer.

### 20th Century:

The twentieth century ushered in an explosion in the advancement of communication, industry, and technology. In this section, not all great discoveries will be listed. Instead, those most significant from a scientific perspective will be covered, as will those discoveries that help us understand the root causes of disease.

- Walter Reed demonstrated that mosquitoes carried yellow fever in 1900.
- Élie Metchnikoff identified how white blood cells protect against disease.
- Sir Alexander Fleming discovered penicillin in 1928.

The identification of penicillium mold by Dr. Alexander Fleming in 1928 is one of the best-known stories of medical discovery, partially because of its accidental nature but also because penicillin has remained one of the most important and useful drugs in our modern medical arsenal. Penicillin, and antibiotics in general, have saved more lives than any other drug or class of drug. Its discovery triggered research into other invaluable, albeit often misused, antibiotic drugs.

Alexander Fleming, a Scottish bacteriologist in London, made his discovery of penicillin by mistake when he was trying to study staphylococci bacteria. He ran experiments with the bacteria in his laboratory at London's St. Mary's Hospital and set a laboratory dish containing the bacteria near an open window. Upon returning to the experiment, he found mold blown in through the open window onto the dish, contaminating the bacteria. Instead of throwing away his spoiled experiment, Fleming looked closely at it under his microscope. Surprisingly, he saw the mold growing on the staphylococci bacteria and a clear zone around the mold. The penicillium mold, the precursor to penicillin, was killing the harmful staphylococci bacteria. Today we understand that our microbiomes are part of our immune system keeping pathogens at bay. We are now learning that the best antibiotic may indeed be probiotics.<sup>6</sup>

- Francis Crick and James Watson described the structure of DNA and how it carries and communicates genetic information in 1953.
- Jonas Salk developed the polio vaccine using the dead polio virus in 1952.
- Albert Sabin developed an oral live-virus polio vaccine in 1957.
- Christian Barnard performed the first successful heart transplant in 1968.
- Satoshi Ōmura of Kitasato University and William Campbell of Merck are credited with isolating compounds from the avermectin family.

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In 1970, Ōmura isolated a strain of *Streptomyces avermitilis* from woodland soil near a golf course along the southeast coast of Honshu, Japan. According to Crump, “Discovered in the late-1970s, the pioneering drug ivermectin, a dihydro derivative of avermectin, originating solely from a single microorganism isolated at the KITASATO Institute, Tokyo, Japan from Japanese soil, has had an immeasurably beneficial impact in improving the lives and welfare of billions of people throughout the world. Originally introduced as a veterinary drug, it kills many internal and external parasites in commercial livestock and companion animals. It was quickly discovered to be ideal for combating two of the world’s most devastating and disfiguring diseases, which have plagued the world’s poor throughout the tropics for centuries. It is used free of charge as the sole treatment in campaigns to eliminate both diseases globally. It has also been used to overcome several other human diseases. New uses for ivermectin are continually being found.”<sup>7</sup>

- Computerized Axial Tomography (CAT) scan was developed in 1975 mainly by the efforts of Godfrey Hounsfield.
- The first “test tube” baby, Louise Brown, was born in England in 1978
- Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) were identified in the early 1980s.
- Cyclosporine, a drug to suppress the immune system after an organ transplant, was approved in 1983.

Cyclosporine, illustrating the concept of immunosuppression, ushered in the development of many immunosuppressing drugs. These drugs have found new applications beyond avoiding rejection to treat disease symptoms by reducing various inflammatory cytokines. COVID-19 has illuminated the concept of rampant cytokines as a causal factor in severe disease outcomes. Indeed, controlling inflammation may be a key component of treatment. But COVID-19 also reminds us that there is an underlying cause of the cytokine storm. Many biologics are prescribed to treat “inflammation” without any effort to understand and treat the reason for the elevation of the activity of our immune system. Indeed, a cytokine storm may kill, but without the antigen, there is no storm.

- The first gene therapy to treat disease occurred in 1990. Four-year-old Ashanthi de Silva became the first gene therapy success story. She was born with severe combined immunodeficiency (SCID) due to a lack of the enzyme adenosine deaminase (ADA). Without ADA, her T cells died off, leaving her unable to fight infections. Injections of a synthetic ADA enzyme helped, but only temporarily. Doctors decided to deliver a healthy ADA gene into her blood cells using a disabled virus that cannot spread in the body. Their success spurred more trials in the 1990s for the same form of SCID.
- Dr. Hans Vink discovered the relationship between the glycocalyx and vascular health in 2010. Dr. Hans Vink is a pioneer in the study of the

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endothelial glycocalyx. He was one of the first researchers to study the glycocalyx when he focused his expertise on medical imaging. As a result, Dr. Vink and his team were one of the first research groups to capture realistic images of the glycocalyx and focus on its significance. He had been studying the microvascular system since the 1980s. It was in the mid-1990s that technological advancements enabled peering deep inside the capillaries to take pictures. The discovery of a very thick glycocalyx, and the development of new techniques to take early pictures, have led to ongoing research to determine how a compromised glycocalyx is linked to diseases and conditions.

The average life span of those featured in the 20th century: 75.9 years.

There has been a medical revolution over the centuries. Advancement was slow at first and, following how nature works, accelerated following a log-linear relationship. This is just the concept of doubling. This example shows how advancement works when information is collected, shared, and expanded upon.

Which would you rather have, \$1,000,000, or be given a penny today, two pennies tomorrow, and receive double the number of pennies on subsequent days for a total of 30 days? Accepting a penny instead of a million-dollar check seems like a foolish move, indeed. Even on day 10 of 31, you have only collected a total of \$10.23 – ugh! On day 20, things look more promising, but your total of \$10,485.75 pales compared to \$1,000,000. Day 26 looks much brighter, where your total in pennies is now \$671,088.63. Finally, on day 30 – congratulations – you have collected a total of \$10,737,418.23, or 10 times more than the person who went straight for the cash. The point of this exercise is that very little change is noted at first. At the end of this process, there is an explosion in value. This is how nature works, and advancement in technology parallels this concept.

The 20<sup>th</sup> century marked an explosion in value, with the value being knowledge. The “Industrial Revolution” was a knowledge revolution, with all ships (areas of knowledge) rising with the tide of general and specific knowledge. Medical knowledge is no exception. When used collectively, the combined knowledge of our medical forbearers contributes to a profound new understanding of health, as the historical view of medical achievement documents. Now we know so much about the human body compared to the days of demons and disease.

Advancement in knowledge without proper application is like the cliché about the tree falling in the woods without anyone within earshot. There are many examples of how collective knowledge has led to transformative advancements. Importantly, these advancements have made a considerable impact on the way we live today. Here are some poignant examples.

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- Mass communication. We have gone a long way from Monks writing on scrolls to the printing press, telephones, television, satellite communication, to cellular technology.
- Location. The compass facilitated early navigation and travel. Today we have extraordinarily precise tools like satellites and global positioning systems for the public, and who knows what the military has?
- Currency. Cryptocurrency, Apple pay, and connected banking are significant advancements compared to barter and trading goods like livestock. This may be an exception if corrupt governments use centralized systems to take away our freedoms. However, it represents technological advancement nonetheless.
- Building materials: Steel and advanced materials allow for skyscrapers compared to caves, thatch, and mud structures.
- Electricity. The first refrigerator appeared in 1899. In the 1930s, men delivering ice was not uncommon. Our founding fathers wrote the Declaration of Independence either under the sun or candlelight. Rockefeller launched his empire by distributing kerosene to run lamps. The example of refrigeration and lighting barely scratches the surface of the impact of electricity on human advancement through technology.
- Magnification. This may seem like an unremarkable advancement, but the microscope, radio telescopes, X-rays, and other allied technologies have offered us a glimpse into everything from distant stars and galaxies to the minute workings of living cells and sub-atomic structures.
- Transportation. Our evolution from foot to boat, to horses, to the steam engine, to the internal combustion engine, and now to advanced battery-driven vehicles show a magnificent exponential upswing in technology. A poignant example is air travel, where we have quickly gone from Icarus to the Wright Brothers, to Pan Am, to the moon launch, and now to SpaceX. Compare a horse and buggy used to travel down fifth avenue 100 years ago to a Tesla or a bullet train.
- The transistor. The central consideration here is the constant improvement in the efficiency and speed of these devices. The number of transistors in integrated circuits doubles nearly every two years, a phenomenon known as Moore's Law. Their remarkable impact on technology will only continue to grow. These advancements set the benchmark for what technology can achieve when applied in the right direction, even though many of us still are impatient with how fast our computer reboots.

Humans tend to think linearly. We do one thing, and we expect to get a corresponding result. But nature does not behave linearly. Instead, it subscribes to the asymptotic or exponential curve. Simply put, it follows the bell curve (gaussian curve). Knowledge and technological advancement have followed this log-linear relationship too. After all, we are still part of nature.

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In 1965, Gordon Moore made a prediction that would set the pace for our modern digital revolution. From careful observation of an emerging trend, Moore extrapolated that computing would dramatically increase power and decrease relative cost at an exponential pace. Moore's Law insight became the golden rule for the electronics industry and a springboard for innovation. As a co-founder, Moore paved the way for Intel to make the faster, smaller, and more affordable transistors driving our modern tools and toys. Notably, Moore's Law is accelerating, consistent with log-linear or exponential growth or improvement, Figure 1.2. Significantly, the price per transistor has decreased at about the same rate that performance has increased.

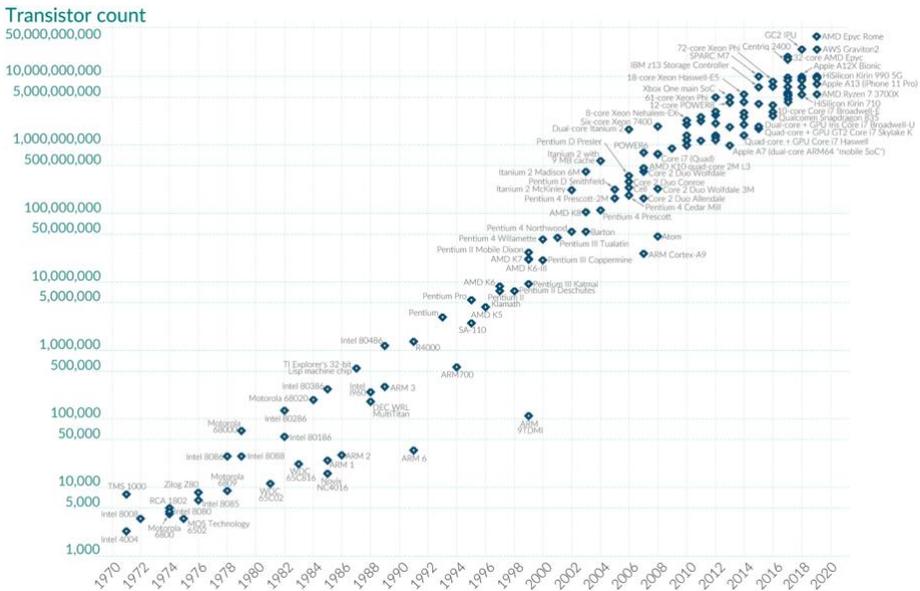


Figure 1.2: Exponential increase in transistors on integrated circuits and concomitant improvement in performance.

Compare this technological trend to healthcare, also driven by technological advancement. Is our healthcare system displaying an increase in power (outcomes) and a decrease in relative cost at an exponential pace? Figure 1.3

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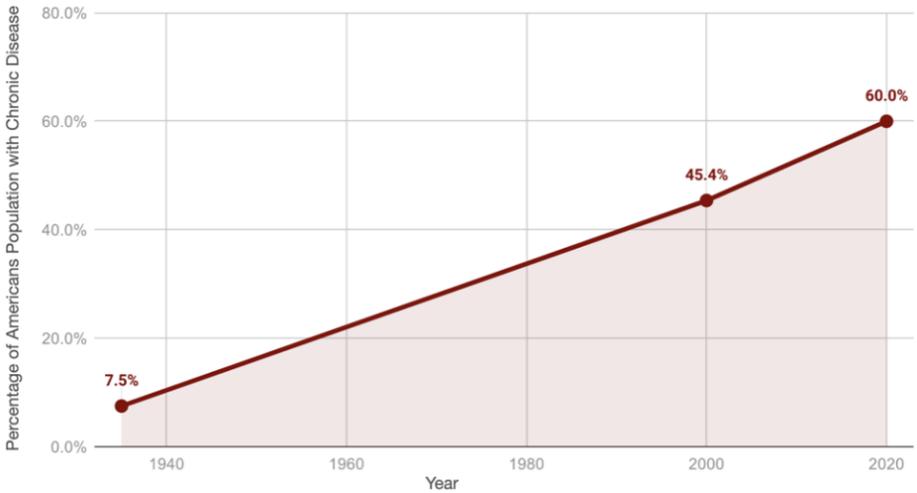


Figure 1.3: Number of people with chronic conditions in the United States by percent of population and numbers of people impacted, reported by year.

Healthcare trends are changing but in the wrong direction. Importantly, according to GBD, the prevalence and cost of chronic disease in the United States are growing and will continue to grow, not just due to the Baby Boomer generation aging but also due to increased disease prevalence among children and younger adults. Despite all our advancements in technology and knowledge, global populations are becoming less healthy. The U.S. is leading the way to poorer health in the developed world. According to the CDC, 60 percent of American adults have at least one chronic condition. And we are paying a heavy financial price for that poor health.

Moore's law includes two (2) factors:

1. Increase in power
2. Decrease in costs

U.S. healthcare's "law" is upside down compared to Moore's law and what science and technology should deliver to its patients, that is us.

1. Increased adverse outcomes: Americans live 2.5 years less compared to the average of the people of the other 35 developed nations.
2. Decrease in affordability: Americans pay 2.5 times more for the privilege of being less healthy over our lifetime and dying younger.

In healthcare, America fares the worse when considering these two types of factors compared to the 36 most developed nations. It turns out that the U.S. is dead last, Figure 1.4.

### OECD Nations: Life expectancy at birth and health spending per capita, 2013

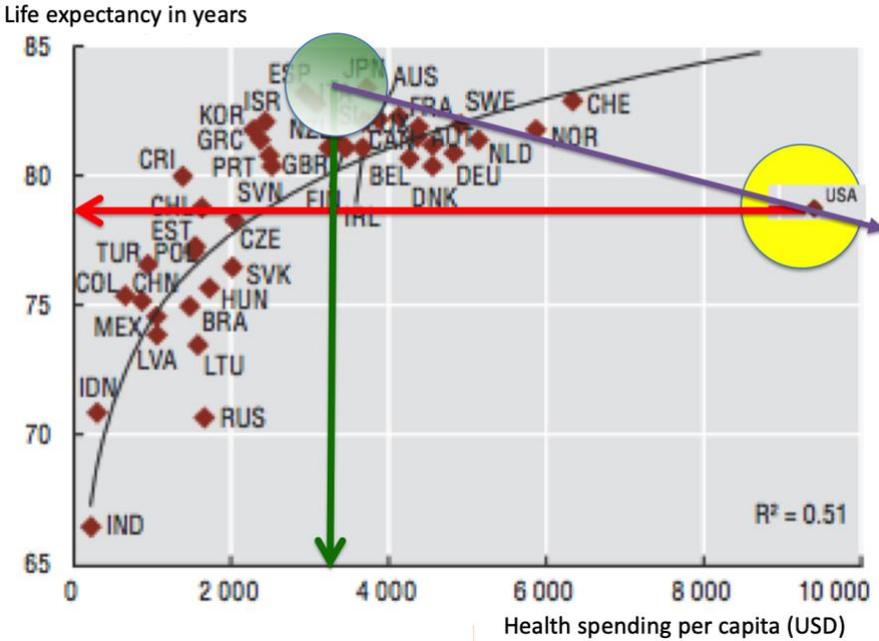


Figure 1.4: Life expectancy by the country for the 36 most developed nations on earth versus the cost of healthcare on a per-person basis

When analyzing figures 1.2 - 1.4, it is clear that healthcare is going in the wrong direction compared to other areas despite advancing science and technology. The only conclusion to be drawn:

Healthcare is NOT driven by scientific or technological advancement. If not science, then what?

“A broken system will not fix a broken people.”

— Kingsley Opuwari Manuel

### **Health and Care Lost**

Summary: Health Insurance is NOT healthcare. Health insurance is a manifestation of a command-and-control system that severely restricts what doctors can deliver to patients. However, health insurance is just the tip of the iceberg. Health accreditation agencies, the pharmaceutical industry, medical schools, agriculture, the media, and governmental regulatory agencies all deliver disinformation and perpetuate poor health.

Healthcare is killing you. So, should it be called healthcare? "Sickcare" is a term often associated with the standard of care in the United States. But it still has the word "care" associated with it. Are you getting "care" or getting the "hustle?" Some people are saved by healthcare, but compared to its potential, the overall impact of healthcare is a distinct negative. That is not care or caring, and that is not the delivery of health. SOP stands for Standard Operating Procedure. Healthcare is using a failed SOP - the "standard of care." In this chapter, I will refer to traditional healthcare delivery as SOP, but in this context, it means the "standard of profit." In no way is the word "care" applicable. Another phrase for what we receive from the so-called healthcare system is the sub-standard of care.

The long and slow leadup to what has become SOP medicine is now ingrained into the delivery of medicine that even the most elite of our society cannot find good or life-saving care. Steve Jobs, Paul Allen, John Warner, and Bernard Tyson are just a few examples of how repeatedly doing the same thing - SOP medicine - has led to a regression in medical expertise, so no one is being saved. Bernard Tyson is a particularly poignant example. When he died of a massive heart attack at the age of 60 was the Chairman and CEO of the Kaiser Permanente healthcare system. This system, at least in theory, should promote good health. It offers both sides of the healthcare equation - the delivery and payment of medicine. The incentives for good outcomes are aligned between the payer and the doctors. And yet their leader could not be saved. How can you be saved?

John Warner is another example. At the time of his massive heart attack, he was in his early fifties and was the head of the American Heart Association. Surely he was receiving the best care and diagnostics. He was most likely on "lifesaving"

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statin drugs, a low-fat diet, and all the other recommendations for heart health issued by his organization. Shortly after the heart attack, the media became aware of the incident. They downplayed it (aka lied) by saying, "The president of the American Heart Association, Dr. John Warner, had a minor heart attack Monday during the organization's scientific conference in Anaheim, California." The heart attack happened at the American Heart Association meeting! Later, the EMT revealed that it saved Warner's life; the resuscitation lasted 8 minutes. This was admitted by the association about a month and a half after the event. CNN obviously got their fact wrong - again. Lesson learned? If you want a heart attack in your fifties, follow the SOP promoted by large medical associations.

Many people have documented the loss of life caused by the medical system. Iatrogenic deaths, caused by medical errors, are 3rd on the list of annual deaths of any cause, only exceeded by those from heart disease and cancer. According to Statnews, "Injury or illness caused by the healer is called iatrogenic harm. It's so widespread, so frequent, massive, and continuous that it rarely makes headlines. And unlike a plane crash or a building collapse, the vast majority of iatrogenic deaths can be kept under wraps, and they are."<sup>8</sup> John Ioannidis, M.D., of Stanford Medical School, is famous for discussing medical "evidence-biased" medicine. He states that 75 percent of published research in the medical arena is falsified to some degree.<sup>9</sup> The landmark paper explaining this has been viewed almost three million times, but nothing has changed. If anything, in the COVID era, it is safe to assume that evidence biases in medical journals significantly exceed the 75 percent mark.

Iatrogenic deaths are not the entire picture regarding deaths caused by medical wrongdoing. The article "How American Health Care Killed My Father"<sup>10</sup> explains that in-hospital infections account for at least another 100,000 deaths annually. The headline quote from the report states, "After the needless death of his father, the author, a business executive, began a personal exploration of a healthcare industry that for years has delivered poor service and irregular quality at an astonishingly high cost. It is a system, he argues, that is not worth preserving in anything like its current form. And the healthcare reform now being contemplated will not fix it." The author, David Goldhill, states, "One hundred thousand deaths are more than double the number of people killed in car crashes, five times the number killed in homicides, and 20 times the total number of our armed forces killed in Iraq and Afghanistan. Another victim in a building American tragedy."

The number of deaths caused routinely by SOP medicine pales compared to the number of deaths caused by the COVID jabs and coercion to prevent early treatment. Those numbers, when properly counted, may be in the eight to nine-figure range. Currently, the high end of estimates relying on published data is around 30,000,000 over two years.<sup>11</sup> We do not know yet the long-term death toll caused by the jab and the spike protein. We know that most of these deaths would

have been preventable if our governments and the most corrupted SOP in history did not interfere with care.

In the modern era, the financial misalignment between the patient and doctor was created by the marriage of the petroleum industry to pharmaceuticals and medical school education dominated by big pharma. It is reasonably well appreciated that the cause of the health delivery crisis that the United States and the developed world are afflicted with is tied to an outrageous financial connection between governments and wealthy pharmaceutical giants. Specifically, the Flexnor report of 1911 led to the consolidation of medicine into tight and restricted SOP silos that intensely squelched innovation.

Innovation was the strength of the United States over the last one hundred years based on the number of patents issued. However, medical doctors practicing medicine have had little to say about the ultimate delivery of care. Instead, an entirely new medical research industry emerged at the universities, funded by you know who and you know what. Impactful works have evolved from individuals and the collective concerning medical research, as documented in Chapter 1. However, the major impediment has been the control over the medical "translator." That is the intermediary that brings the research finding into the clinic. Specifically, it is the same set of culprits, pharma and our governments.

In the past, the lines of demarcation between research, translation (testing and validation), and clinical delivery were blurred. Now they are in very tight silos, and God forbid a doctor in the clinic should suggest a new treatment. Ultimately, as explained in the first chapter, medicine is not based on science. The explanation is simple. Only drug companies have the finances to run the required clinical trials to get approval for anything new from the governing bodies. And since so much money is involved, the only treatments that make it to the clinic must compensate for the expenditure, that being high cost "on patent" drugs, devices, and surgeries. We now know that anything that threatens SOP (remember, "P" is for profit) leads to threats against those who dare. Thus, in the COVID era, repurposed yet safe and effective approved drugs were forbidden - or else.

For further reading on the Flexnor report and how this one report impacted your care leading to SOP, go to the following reference materials:<sup>12</sup>

### **Tail Wagging the Dog**

At one time, insurance was for catastrophic events for which you would be financially drained or even bankrupt if you did not have the insurance. In these instances, insurance made and still makes sense. It is a pooling of risk among many rather than hoping that a single event does not impact you. The insurance company is just a broker to manage the pooled monies. However, insurance today is creeping into little things, for example, paying an extra \$3 to insure a \$90-dollar

item. Companies underwriting these types of policies realize how profitable insuring a large pool of people can be, especially when the risks are easily defined and good statistics help the underwriting insurer calculate what their costs are likely to be. That is why big financial institutions and high-net-worth individuals like Buffet and Soros are firmly implanted in the insurance industry. It is literally an ATM for these people and organizations.

There was a time, say about 60 years ago, when many Americans did NOT have health insurance. Instead, they paid their doctor cash for a visit and did not fear an untenable bill they could not afford. However, healthcare inflation has been so significant that now a health event requiring support from the health industry is so expensive that most of us cannot even imagine having the financial means to cover the cost of medical bills. Healthcare costs are the number one reason for bankruptcies in the United States.

Why is auto insurance so expensive? One part of the reason is medical liability. The litigious nature of our society also plays a major role, but that subject will not be discussed in this book. Instead, my focus is on evaluating specialty medicine and the enormous costs associated with diagnoses and treatments. This is the area of medicine that has led to high healthcare and auto insurance premiums. In the United States, we pay two and a half times more for healthcare compared to the 35 other developed nations, and we live two and a half years less than these nations. The math is simple - the more we pay for healthcare, the shorter we live.

Healthcare, particularly health insurance, is the largest cost that strips us of disposable income. It is disposable income that gives us the freedom to experience life to its fullest in our connected world, afford basic necessities, or the best possible education for our children. The high cost of healthcare is imprisoning the majority of Americans. Dave Chase of the Health Rosetta is famous for his video titled "How Healthcare Stole the American Dream."

Freedom lost and health freedom lost is a tale of two things:

- exorbitant healthcare costs; and
- ineffectual healthcare delivery that perpetuates the high costs.

**Why "freedom lost?" Because health is the first of all liberties.**

Where did it all start? Chapter 1 clearly establishes that medical technology advanced along with other sciences in a way that benefited humanity until about 100 years ago. Indeed, there have been remarkable advances in the science and technology of medicine. Still, since our chronic health and lifespan have not reflected the benefits of this technology, it is of little consequence. Science and technological advancements to which we have access have been chosen by those with the power (Machiavellian) to provide the most profit while not losing customers. A cured patient is a lost customer. Even though health freedom was eroded over millennia, the lack of health improvement performance over the last

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100 or so years during the science and technological revolution is nothing short of criminal. Only over this period has the following truly happened, particularly in America, and sadly is spreading globally like cancer.

- Healthcare cost inflation has been exorbitant. See Figure 2.1. and 2.2.
- Overall, population health has declined. See Figure 2.3.

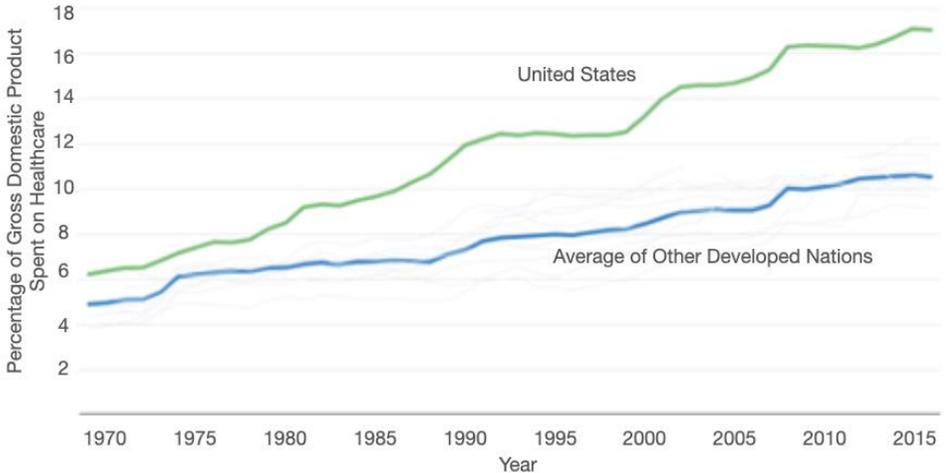


Figure 2.1: Health expenditure as a percentage of the gross domestic product in the United States compared to the average for thirty-five other developed nations. Source: Organization for Economic Cooperation and Development (2016).

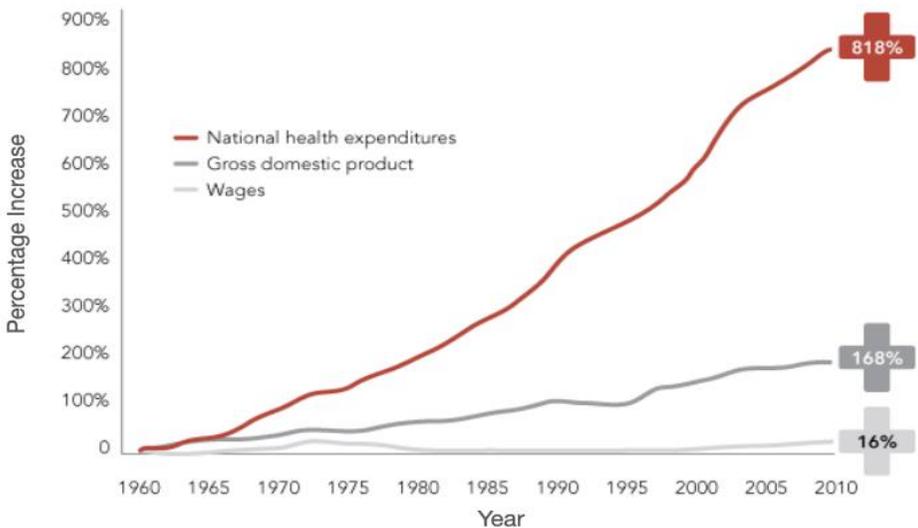


Figure 2.2: Percentage increase in wages, gross domestic product, and national healthcare expenditures in the United States by year. Source: McKinsey, "Accounting for the Cost of U.S Healthcare" (2011).

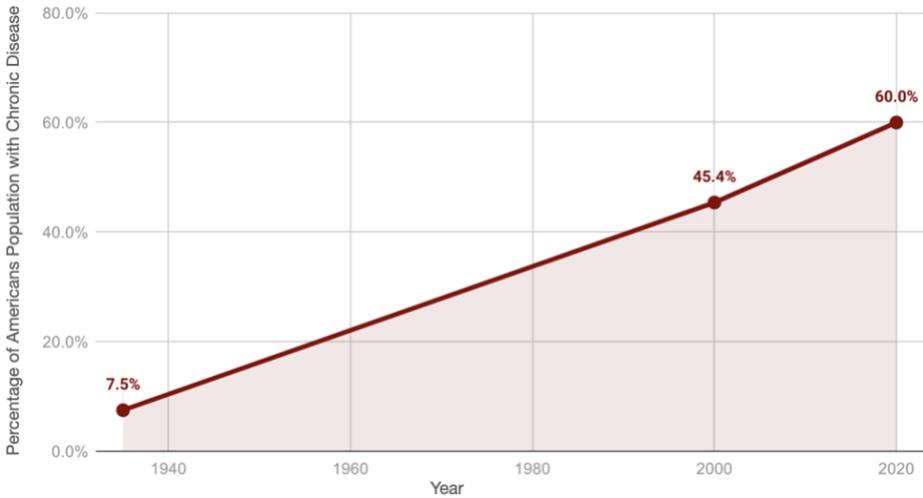


Figure 2.3. Percentage of Americans with at least one chronic disease by year. Source: CDC "Chronic Diseases in America" (2021).

### Not Just Evil Pharma - Insurance Too

Interestingly, the escalation in costs coincides well with the introduction of Medicare, HMOs, and the growth of the BUCAs, which are the big health insurance giants. Which came first? The way to find the answer to this is by determining how insurance companies gain profits.

The Center for Media Democracy's PRWatch published an article in 2011 titled, "Blue Cross, Blue Shield Getting Richer, Like Corporate Insurers."<sup>13</sup> This article, reproduced here, explains why healthcare has become so expensive. The healthcare industry makes up a certain percentage of the total cost of healthcare. Therefore, they are incentivized to make healthcare as expensive as possible. The greater the cost, the more money they make. Insurance companies yield way too much power and influence over healthcare delivery.

"I've written frequently in recent weeks about the eye-popping profits the big, publicly-traded health companies have been reporting. Last year -- as the number of Americans without health insurance grew to nearly 51 million -- the five largest for-profit insurers (Aetna, CIGNA, Humana, UnitedHealth, and WellPoint) had combined profits of \$11.7 billion. But that was in 2010.

If the profits those companies made during the first three months of this year indicate things to come, 2011 will likely be the most profitable year ever for these new darlings of Wall Street.

But lest you think only those big New York Stock Exchange-listed corporations have figured out how to make money hand over fist while their

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base of policyholders is shrinking, take a look at the so-called nonprofit Blue Cross and Blue Shield plans.

Don't think for a minute that the Blues are any more interested in your health and well-being than the companies that at least own up to being in business to make hefty profits off of insuring the healthy and shunning the sick.

According to a report by Carl McDonald of Citi Investment Research and Analysis, last year was the most profitable year in history for the Blues plans. They enjoy significant tax advantages because they claim to be nonprofit and terrific community citizens. The Blues reported more than \$5.5 billion in net income in 2010.

Furthermore, the Blues now have more than five times that amount in capital above what state regulators require. As McDonald noted in his report, maintaining such a vast reserve should make regulators think twice before approving rate increases in the future."

"Our analysis of the financial position of 33 Blue Cross plans suggests that their capital position has reached a level that's difficult for the nonprofits to justify, and if sustained, will lead to significant tension between the nonprofit Blues, regulators and consumer activists," McDonald wrote. "According to our data, the nonprofit Blues held a total of \$52 billion in capital at the end of 2010 or more than \$29 billion above minimum regulatory requirements."

"One of the ways the Blues have been able to amass such fortunes is by avoiding paying for care in exactly the same way the big for-profit companies do. They are rapidly moving their policyholders into high-deductible plans and spending far less on medical care - and far more on overhead - than they have in the past.

How much insurance firms spend on medical care is measured by what is called the medical loss ratio.

In 1993, the average medical loss ratio in the health insurance industry was 95 percent, meaning insurers spent 95 cents out of every dollar they collected in premiums on medical care. In their quest for profits, all insurers have been spending less on care in recent years, regardless of their tax status. The average medical loss ratio is now closer to 80 percent.

McDonald found that some of the Blue Cross companies are spending far less than that these days. For example, the medical loss ratio at the Texas Blues was just 64.4 percent last year.

Beginning this year, due to the healthcare reform law, insurers will have to maintain medical loss ratios of at least 80 percent. Had that provision of the law been in effect in 2010, McDonald says the Texas Blues plan would have

had to price its policies for individuals about 12 percent lower than it actually did.

McDonald found that some Blues are much greedier than others regarding making profits and building up big surpluses.

It turns out that the Blues plans that have to compete with the big for-profit companies behave, well, just like the big for-profits. In other words, the competition works against the interests of policyholders. The profit margins and the size of the surpluses of the Blues in states where the for-profits have a significant presence were considerably higher than in states where the for-profits don't have as much market share.

So much for the myth that competition among insurers results in lower premiums.

Health insurance is one part of the U.S. economy where the free market works beautifully for the insurers and a few executives (and shareholders of for-profit companies) but horribly for the rest of us."

### **Practically Useless Labs Run on Everyone**

Most articles on health insurance assert that the lack of health insurance is killing you. However, the opposite is true. Dr. Carter is on the advisory board of the Black Health Trust, an organization created by Dr. Randall Maxey, MD, Ph.D., former President of the National Medical Association. A poignant example of this thesis occurred during an advisory meeting where we discussed biomarkers not commonly obtained by your primary care doctor or specialist.

I explained markers like D-Dimer, Fibrinogen, C-reactive protein, and creatine kinase. One brave doctor interrupted my explanation by saying, "we used to run markers like these 40 years ago." Another doctor chimed in and stated, "I am not sure I would know what to do if one of these markers was elevated." Clichés like "you cannot see the forest for the trees" applies well here. Testing covered by insurance lack precision and depth.

In my family, my mother was being evaluated for cognitive decline, and my son was undergoing a physical to participate in a cross-country running summer camp. They both got the exact same tests, even when my mom was referred to a specialist. The standard tests were and continue to be a metabolic panel, lipids, and A1C. These are the only tests allowed without a diagnostic code in most office visits. Who lords over these tests? The insurance companies, at least in part. They will only pay for these tests. Doctors and their administrative teams have given up trying to get paid for any test not officially reimbursed.

You can rarely get valuable exploratory and preventative tests ordered and paid for. You must have one or more diagnostic codes to even marginal tests ordered and paid for by United States health insurance. This is upside down. Today,

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medicine acts as if you are in only two health states – perfectly healthy or sick. The concept of a health continuum is not in the healthcare language. Few doctors are willing to stick their necks out and have labs ordered that do not correspond to a given diagnostic code.

My mentor, Dr. Clement Trempe, bucked the tide, making him an exceptional doctor indeed. He dared to face the medical industrial complex 60 years ago. As an ophthalmologist for 47 years at Harvard, he learned how to see the early formation of disease in the eye. He was then able to assign a diagnostic code to eye conditions that enabled reimbursed blood tests beyond the SOP. But essentially all other doctor types cannot “see” the disease process. Thus, their hands are tied. They cannot or will not stray from the basic lab panels that have proven, over modern medical history, to be ineffective at predicting or understanding disease processes.

Dr. Trempe performed a very thorough medical workup on all his patients. What other clinicians matched his levels of investigatory prowess? Dr. Carter, my medical doctor partner, sees patients of all ilks daily. They are black, white, Hispanic, young, middle-aged, old, male, female, sick, and healthy. They all come to him with the same standard and useless labs. He has to start from scratch with every patient, even though these folks have paid substantial monies into the SOP system.

Running standard labs is likely done for economic reasons. But sickness is expensive, and the labs Dr. Trempe ran are very inexpensive and add extraordinary predictive value to a patient's health status. More importantly, Dr. Trempe developed healing protocols based on good labs. Ask your current doctor who takes insurance what their protocol is for reducing elevated C reactive protein. They will not have an answer; thus, they avoid this test. A major reason for the labs routinely obtained and not obtained is simple. First, let's look at the cost. To add a CBC with differential adds about 2 dollars in cost. Next, note in Table 1 below the alignment between a lab and a drug.

<b>Biomarker</b>	<b>Routine</b>	<b>Drug to Treat?</b>
A1C	Yes	Yes
Glucose	Yes	Yes
Insulin	No	No
Cholesterol	Yes	Yes
Chemistry	Yes	Maybe
Immune cells (WBC counts)	No	No
RDW	No	No
Inflammation markers	No	No
Blood pressure	Yes	Yes

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Table 1. Example blood tests illustrate how the tests that are routinely run have an associated drug if the value is elevated. Tests with no drug associated with its elevation are not routinely run.

The opaqueness of health insurance becomes more apparent when you look at the most prescribed drugs. This is the top 10 list from 2021 according to goodrx.com.

1. Lipitor / statin drugs for lowering “cholesterol.” Interestingly everyone gets a “cholesterol” test but not more essential tests like a measure of innate immunity, for example.
2. Lisinopril for high blood pressure. Everyone gets a blood pressure measurement and rightfully so, but few are told why their blood pressure is up and what they can do about it without Lisinopril.
3. Albuterol for bronchospasms. Have you been told that bronchospasms and asthma may be related to oral pathogens or chlamydia pneumoniae and other infections?
4. Levothyroxine for thyroid support. But what about root causes of thyroid dysfunction, including leaky gut, malabsorption, or other factors that may create autoimmunity, like periodontal pathogens, that can be solved without drugs?
5. Amlodipine for high blood pressure. See #2 above.
6. Gabapentin for seizures. Johns Hopkins Medical School has used the Ketogenic diet for seizures, with the development of that approach having an over 100-year history.
7. Omeprazole for acid reflux. Repair and recovery are critical to health and are linked to gut integrity. Nothing impacts digestion, absorption, repair, and recovery more than these harmful drugs.
8. Metformin. Diabetes is ultimately a lifestyle disease and is easily solved without any drugs. Even though metformin is widely prescribed, exogenous insulin is the most profitable. This type of insulin makes diabetes worse.
9. Losartan for high blood pressure. See #2 above.
10. Hydrocodone / Acetaminophen for pain. Look for oral pathogens, spine arrangement, chlamydia pneumoniae, and gut problems, all of which may be the source of pain.

Do you see the pattern? If there is a drug to prescribe, then do the test. If not, defer until the case becomes critical. Blood pressure could be considered an outlier and very necessary. I agree to some extent. However, treating this as a symptom illustrates medical ignorance and incompetence. Many seniors report feeling woozy on blood pressure meds. Some fall and break a hip because of the unnatural over-regulation of blood pressure. This is a life-ending event in many cases.

Sadly, doctors are treated like schoolchildren in detention. They are not trustworthy to do right by the patient, so they are overregulated. And the

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consequence of going against regulation or even a hospital-based policy is the potential loss of license to practice. It would be no big deal if these were high school-educated people - find another job. But these people have gone through and paid for 7-8 years of post-graduate work.

One insidious rule that prevents doctors from doing adequate workups is the vague concept of medical necessity. The American Medical Association (AMA) and Medicare have guidelines and regulations on medical necessity. Would not preventing the epidemic of chronic disease be deemed a medical necessity? This is a great concept as long as the doctor knows what is wrong with the patient first. But do they ever? Does anyone? If you are not testing, you are guessing. And a good guess is that the pharmaceutical and insurance industries want costs high, so deferring a good diagnosis is a great place to start.

Here is an explanation of medical necessity. AMA Policy H-320.953: Definitions of "Medical Necessity" is: "Health care services or products that a prudent physician would provide to a patient to prevent, diagnose or treating an illness, injury, disease or its symptoms in a manner that is: (a) by generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily ... for the convenience of the patient, treating physician, or other health care provider."

It sure looks like doctors are free to practice based on this definition, but insurance coverage is only available in a few instances.

The concept of medically necessary treatment is also incorporated into Medicare's coverage limitations, where coverage is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury," 42 USC 1395y(a)(1)(A). "No payment may be made under part A or part B of this subchapter for any expenses incurred for items or services. . . which. . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Medicare rules and regulations make it clear that tests not justified by an appropriate diagnosis are not considered medically necessary and are not reimbursable. For example, the Medicare Claims Process Manual clearly states, "tests performed in the absence of signs, symptoms, complaints, personal history of a disease, or injury are not covered except when a statutory provision explicitly covers tests for screening as described."

A physician includes a diagnostic code, currently known as an ICD-10 code, on a test requisition form to indicate the patient's current health status to justify the medical necessity of the ordered test(s). An ICD-10 code correlates with a specific condition the patient is currently suffering that purportedly warrants performance of the requested test(s)." Thank goodness a doctor only has to know 68,000 codes.

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God forbid the doctor looks at the patient as a human, tests the patient, helps the patient, and gets paid for doing this.

Of course, codes for prevention a few and far between. One of the keys to getting reimbursed for a medical expense is understanding what an insurance policy classifies as a medical necessity. Even though there are lists of some typically accepted procedures or preventative care that may fall under the category of medical necessity, sometimes, whether something meets the criteria needs to be clarified. And most, if not all of us, have experienced dramatic delays in insurance reimbursements, with doctor practices heading this list. Once insurance has your money, they do not want to part with it. The cost of getting delayed payment is exorbitant. By some estimates, the average medical practice overhead is between 60 and 70 percent of revenues.<sup>14</sup> One would think the cost of evaluating a patient would be at least 50 percent or more. But today, administrative activities double the cost of healthcare.

Do the feds or the associations mandating SOP have the experience and knowledge to really dictate "reasonable and necessary" to the doctors actually seeing the patients? Millions have been harmed or killed during COVID due to callous or premeditated control of doctors. If you start to think that societies might have the requisite information to drive good care, remember that one of their presidents had a massive heart attack at 52. Do you really want these people controlling your doctor? They are.

Has there been fraud by doctors? Of course. Dr. Trempe told me about an ophthalmologist who trained under him at Harvard and indicated he would return to his native country, the Dominican Republic, and offer his newfound skills to his countrymen. Instead, he bolted to Miami and racked up Medicare billing of \$21,000,000 in 2012.<sup>15</sup> How could this have been prevented? Here is a short list of actions.

1. Test people more thoroughly over time and offer solutions so they stay healthy. Healthy people are less frequent and costly healthcare consumers.
2. Rip apart medical specialties and put most emphasis on primary care as the way to solve most problems at much lower costs. Some European nations do this; their healthcare costs are 40 percent of ours.
3. Reinstate medical schools and professionals eliminated by the Flexnor report.
4. Items 1-3 would significantly reduce medicine costs so the individual could afford to pay cash for treatment like we used to sixty years ago. Under such circumstances, price gouging would be much more difficult. A patient paying directly to their local doctor is much less likely to be bilked than by some amorphous governmental and insurance systems.

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The control of medicine by the payer has negated much of the vital training doctors receive. As a result, doctors are surprisingly bad at reading blood tests. This is the title of an article in the Washington Post.<sup>16</sup>

This article was written by a healthcare professional, not a paid health assassin of the criminal Gates. The author, Daniel Morgan, is an associate professor of epidemiology, public health, and infectious diseases at the University of Maryland School of Medicine and chief of hospital epidemiology at the Baltimore VA Medical Center. Here is a quote from that article.

"In a paper from 2016, my colleagues and I interviewed more than 100 doctors to gauge their understanding of the risks and benefits of 10 common medical tests or treatments. We found that nearly 80 percent of our subjects overestimated the benefits. Strangely, the doctors acknowledged this, with two-thirds rating themselves as not confident in their understanding of tests and probability. Eight out of 10 said they rarely, if ever, talked to patients about the probability of test results being accurate."<sup>17</sup>

Andrew Gelman is a professor of statistics and political science at Columbia University. He wrote a paper explaining how HMOs have corrupted the delivery of healthcare through misaligned incentives.<sup>18</sup>

"Back in the 1970s, I occasionally read a newspaper or magazine article about this mysterious thing called an HMO—a “health maintenance organization.” The idea was that the medical system as we knew it (you go to the doctor when you’re sick and pay some money, or you go to the hospital if you’re in terrible shape and pay some money) had a problem because it gave doctors and hospitals a motivation for people to be sick: as it’s sometimes said today, “sick care,” not “health care.” The idea is not that healthcare providers would want people to be sick but that they’d have no economic incentive to increase the population’s general health. This seemed in contradiction to Deming’s principles of quality control, in which the goal should be to improve the system rather than to react to local problems.

In contrast, the way HMOs work is that you pay them a constant fee every month, whether or not you go to the doctor. So, they are motivated to keep you healthy, not sick. Sounds like a great idea. But something happened between 1978 and today. We all have HMOs, but there’s even more concern about screwed-up economic motivations in the healthcare system. This time the concern is not that they want us to go to the doctor too much. They want to perform too many tests on us and overcharge us for ambulance rides, hospital stays, aspirins they give us while we’re in the ambulance or the hospital, etc. I guess this arises because much of the profit for HMOs comes not from our monthly fees but from those extra charges.

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What's my point in writing about this? I'm not an expert in healthcare research, so I don't have much to add in that direction. Instead, I'm coming at this as an outsider. The most straightforward message here is: "Ha! Unexpected consequences!" Or, to get more granular, you could say that as long as there's loose money floating around, operators will figure out how to grab it. Still, it's interesting to me how HMOs solved a problem of counterproductive incentives, but this led to a new issue of counterproductive incentives."

### **Substandard Medical School Education**

There are other major factors impacting patient care and the lack thereof. Medical school education plays a big role in unexpected ways.

- First, there is the Flexnor report that eliminated competition and stymied innovation.
- Second, the pharmaceutical industry is allowed to participate in medical school education. Whom are we kidding? Pharma runs medical school education.
- Third, the high cost of medical education and the time commitment by doctors to this one profession creates indentured servants. It is not like a doctor could switch and become an engineer overnight.
- Forth are the State and National regulatory bodies that set the SOP and control licensing and discipline. God forbid a doctor goes against the SOP and gets sent to the principal's office of the regulatory bodies. After all, doctors have put into their careers; this could be the unraveling of their professional and personal lives.
- Fifth is the health narrative by the medical societies about fat, cholesterol, their ultimate endorsement of big agriculture, and other untold but known lies. The USDA, through lobbyists, is also culpable. The New York Times published an informative piece titled "How the Government Supports Your Junk Food Habit." I would be happy to provide a reference, but it appears this article is a victim of censorship, no doubt internally driven by the Times. The point of this article and many others is that junk food crops that support the low fat and poor health agenda are subsidized, making them more affordable to the poor to perpetuate their equally poor health.

Shame everywhere.

"Dying to be Free: How America's Ruling Class Is Killing and Bankrupting Americans, and What to Do About It," by Dr. Leland Stillman, explains that more young doctors are becoming disenchanted with what they are allowed to do medically. However, few see a way out. "They've made it incredibly hard, by design, to start your practice," Stillman says. "They really want to keep all of the physicians corralled." A significant part of that "prison" is debt. Debt can reach half a million dollars when a doctor is licensed to practice. Thus, many opt for a

secure income, which means working for a hospital. That is yet another way they are entrapped to practice SOP.

### **Insurance Companies Are NOT Doctors**

One of my best friends is the head of cardiology at Mercy Hospital in Portland, Maine. I developed atrial fibrillation due to Lyme disease, and Craig, my doctor friend, took over my care. He prescribed a specific drug to help control the arrhythmias. On my return from Maine to Massachusetts, I discovered that Blue Cross, my insurer (now I will never have traditional health insurance), would not cover that specific drug. It turns out their medical "committee" (aka actuaries) made that decision overriding my doctor, who had actually seen me. I was very naive at the time - 20 years ago. I called Blue Cross and was told about the denial. I fumed a bit and called them back, threatening to drive to their headquarters in Quincy, Ma. and make a stink they would never forget - in person. I was heading in that direction when I got a return call indicating that their "medical team" (aka public relations group) changed their mind and granted the prescription as filed. I did not know that this was more common than not and was one of the more insignificant aspects of SOP (remember, SOP = Standard of Profit). If you read about your healthcare provider's denial and appeal process, you will realize that my experience was very unusual. Happy endings are not the norm.

It is interesting that, in many cases, even doctors are denied care when they are on the patient side of the ledger. Money is money, doctor or not. Here is a doctor's story about trying to do right for his patients, and even his daughter, but failing. It is titled, "Insurance companies aren't doctors. So why do we keep letting them practice medicine?" Even within the system, the insurance "tail" is "wagging the dog." This article was originally published in the Washington Post and reproduced here.<sup>19</sup>

"We know how important it is to have insurance to get health care. As a physician, parent and patient, I cannot overemphasize that having insurance is not enough. As a gastroenterologist, I often prescribe expensive medications or tests for my patients. But for insurance companies to cover those treatments, I must submit a "prior authorization" to the companies, and it can take days or weeks to hear back. If the insurance company denies coverage, which occurs frequently, I can set up a special type of physician-to-physician appeal called a "peer-to-peer."

Here's the thing: After a few minutes of pleasant chat with a doctor or pharmacist working for the insurance company, they almost always approve coverage and give me an approval number. There's rarely a back-and-forth discussion; I'm just saying a few keywords to ensure the denial is reversed. Because it ends up with the desired outcome, you might think this is reasonable. It's not. On most occasions, the "peer" reviewer is unqualified to assess the specific services. They usually have minimal or incorrect

information about the patient. Not one has examined or spoken with the patient as I have. None of them have a long-term relationship with the patient and family, as I have.

The insurance company will say this system ensures patients get the proper medications. It doesn't. It exists so that many patients will fail to get the medicines they need. I've dealt with this system from the patient side, as well. My daughter has a rare genetic disorder called Phelan-McDermid Syndrome, which causes developmental delay, seizures, heart defects, kidney defects, autism, and a laundry list of other problems (sounds like vaccine injury, does it not?). She receives applied behavior analysis therapy, an approach often used for autism, which has successfully improved her skills and communication. But recently, our health insurer reduced the therapy they thought she needed.

While I know what levers to pull from the physician's side, a patient's options are entirely unclear. I probably have better access than almost anyone else can get. Yet, the ability of my daughter's providers to mitigate denials for services they deem appropriate is slow and often ineffective. My daughter can languish for months or years, not receiving the care that every highly qualified person who treats her agrees she needs. While we wait, the window to give her a little more function, a little bit less suffering, and a little better life gets smaller.

Consumers have a right to appeal denials for healthcare services, but regulations focus primarily on the process, not the content. For instance, insurers must notify you in writing of a denial, and patients have the right to an internal appeal; if that fails, some states also allow for an external review. This sounds good, as most denials are related to specific provider choices or contractual issues, which are relatively easy to remedy (but a problem nonetheless). But other denials are a judgment of some test or treatment as "not medically necessary."

Insurance companies know that many patients don't bother to appeal at all. A smaller fraction asks for an internal review, and still fewer seek or even know about external review options available in most states. Of the cases that end up under external review, almost a third of all insurer denials are overturned. This proves that whatever process insurers have to determine medical necessity is often not in line with medical opinion. A study of emergency room visits found that when one insurance company denied visits as being "not emergencies," more than 85 percent met a "prudent layperson" standard for coverage.

Some might argue that having two doctors discuss a case makes sense and then come to a consensus on the most cost-effective approach for an individual. That's not what is happening. This system saves insurance

companies money by reflexively denying medical care that a physician has determined necessary. And it should come as no surprise that denials disproportionately affect vulnerable patient populations, such as sexual-minority youths and cancer patients.

We can do better. If physicians order too many expensive tests or drugs, there are better ways to improve their performance and practice, such as quality-improvement initiatives through electronic medical records. When an insurance company reflexively denies care and makes it difficult to appeal that denial, it makes healthcare decisions for patients. In other words, insurance officials are practicing medicine without accepting the professional, personal or legal liability that comes with the territory.

We don't have to put up with this. Health care in the United States is shockingly opaque; it's time to take insurance companies out of our decision-making process."

### **When Doctors Truly Sold Medicine to Insurance Companies**

Doctors and society were forewarned of the evils of health insurance back in the 1960s when Medicare was coming into being.<sup>20</sup> On July 30, 1965, President Lyndon Johnson traveled to the Truman Library in Independence, Missouri, to sign Medicare into law. His gesture drew attention to the 20 years it had taken Congress to enact government health insurance for senior citizens after Harry Truman had proposed it. Medicare's history dates back even further. On November 1945, Harry Truman sent Congress the first comprehensive federal health insurance proposal.

Dr. Eugene McDaniel explained, in a passionate letter, the consequences of giving medicine away to insurance companies. He did that in 1964 as Medicare was about to impose itself on the future of health insurance. Here is that letter.

"Since the beginning of time, human ills have afforded mankind more insurmountable problems than any other force or combination of forces, unless it is the force of gravity; but man, in his struggle with gravitation, has soared to great heights and has entered the stratosphere at speed much faster than sound. Who knows that before long, some daring pilot may pierce this stratosphere and land on some distant unknown orb? But human ills are still with us. To struggle with and overcome these human ills, we must have men with unhampered and unrestrained minds, with free and unfettered hands, to carry on this great scientific work that has done so much for humankind.

The human mind knows no limitations, and the desire to excel forever opens the doors of progress. When the human mind can function in its own right, we always have a more significant measure of progress. The human initiative, rugged individualism, and the desire to excel have made the

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science of medicine what it is today: the science that has contributed more to the well-being of mankind than any other source. Progress, not only in medicine but in any other line of work, can go forward in no other way than that of common sense and sound reasoning. The history of medicine will prove this fact.

The history of medicine had its beginning thousands of years before Christ. The Egyptians were the first to record the uses of bark, herbs, roots, spices, and other medicaments for treating human ills. The practice of medicine was strictly centralized in the hands of the church, and all medical practice was performed by the church's priests or by those delegated by this authority. There was no appreciable advancement in medicine for nearly four thousand years; no one was allowed to dispute the authority of this centralized power.

Medicine was based purely on mysticism; today, it is based upon tried and proven scientific facts, at least in theory. Those healing priests assumed no responsibility. The gods brought the disease; those gods and only those gods could relieve the disease. They had no incentive to seek the cause of the illness or to search for means of cure and prevention. Under such a system of medicine, no progress could be made.

Two thousand years later, in about 450 B.C., a man was born in Greece by the name of Hippocrates. He was a man of vision with a burning determination to fight for the liberation of medicine and place it as a scientific fact. He was challenged; he met this challenge, and with this compulsion in his mind and heart, he preached revolt. The revolt was targeted against medical dogma, and the results of his labors separated medicine from the church and religion and supplied a philosophy and ethics that were destined to be the tremendous guiding influences of future medicine. Therefore, today, Hippocrates is called the father of medicine.

Hippocrates gathered all the stones of the ages with the crude carvings thereon, placed all his findings together, applied the wisdom of reason, and coordinated them into a flexible science. He was the first to sit beside his patients and painstakingly seek out the symptoms and record them. He founded the bedside method. He classified the different symptoms, thus establishing the art of diagnosis. He kept a balanced relationship between science and art, a distinguishing quality of all great clinicians of all ages. He said, "To know is one thing; merely to believe one knows is another. To know is science, but merely to believe one knows it is ignorance. Life is short, and art is long, the occasion fleeting, experience fallacious and judgment difficult." With these great things in his mind and heart, he wrote the Hippocrates Oath, the oath that lived today, that permeates the lives and practices of our present-day physicians.

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Less than one hundred years after Hippocrates' death, 371 B.C., his scientific teachings began to decline. Medicine was soon in the hands of the church again, and as Greece began to decline, medicine crumbled into the dark ages. This was the era of regimentation and complete absolutism, demonstrating the environment's influence in shaping men's characters and lives. And the atmosphere was one of submission to recognized authority - unquestioning submission to the church, and feudal lord preached and exemplified before the child from birth. Potential genius was suppressed or directed into channels barren of practical results. Until the sixteenth century, there was little or no progress.

During the fifteenth century came the fall of Constantinople, which brought an end to the Byzantine empire. The capture of that city sent hundreds of fugitive Greek scholars into western Europe. Freedom of thought emerged rapidly. The teachings of Hippocrates had been hidden by the powers that came into being. In their travel and writings, they preached revolt against dogma and for the return to the scientific standards of centuries before. And they won! Let us not take our advancement in medicine for granted. Let us not believe it has been possible without struggle. Many have lost their lives because they defied authority and struggled for freedom of thought. Less than six hundred years ago, men were burned at the stake because they dared to fight for the liberation of thought in the cause of medicine.

In 19th century France, Pasteur and Bernard ushered in a new era of scientific thought and discovery. Pasteur founded the science of bacteriology. He made it possible to prevent the spread of disease by infection. Before Pasteur's discovery, scientists believed that lifeless matter had come to life by spontaneous generation. He proved that the germs that caused disease were in the air and could be killed, and their spread could be controlled.<sup>1</sup>

During the closing decade of the nineteenth century and the opening of the twentieth, many great men from this allied field showed that the mosquito is the carrier of malaria and yellow fever, that ticks are intermediary agents of Texas fever in cattle, that the Tsetse fly is the fatal agent of sleeping sickness; that the flea transmits Bubonic Plague and the louse carries Typhus. Since man has had the freedom to work and go forward without bureaucratic control, he has brought medicine out of the state of mysticism. He has placed it in the realm of science in the two most important areas of medicine; diagnosis and prevention.

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<sup>1</sup> Note that the primary approach to disease control was, and still is, hygiene. Dr. Peter McCullough famously stated that he was unaware of the power of protecting and cleaning barriers as the crucial part of early treatment of COVID-19. John Snow found the source of Cholera and stopped the epidemic.

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A brief sketch of medical history is offered to familiarize the reader with the accomplishments, and the rapid progress medical science has made since man has been free to use his endowed wisdom of reason and common sense. We cannot progress in medicine or any other line of work unless we retain this freedom and human incentive to pursue the line of work we choose and to pursue it unhampered by controls from any source. The testimonials from all great physicians, chemists, and scientists regarding their professions, show their great desire to do good, unhampered and unrestrained, by making "Free America" a better place to live for our children and their posterity.

Among the many signs of our times, among the many subjects of public interest and discussion, there are few, if any, which are more significant and essential to business, professional, and laboring men and women - to the people as a whole - than the increasing tendency of the federal government to curb, to restrain, and restrict, to bind and to limit, and even to prescribe and direct the operations of private enterprises. Going far beyond that regulation of businesses which is admittedly desirable, the government seems to be reaching out to restrain the individual from exercising his rightful freedom of action. If this trend of government continues, and the last election indicates that it is not improbable, we may see the day when the government will take control of medicine. You will then see this great science which has contributed so much to mankind, regimented and placed in the hands of a few politicians who know seemingly very little about medicine and its associated arts.

From the writings of Mr. Ewing, I cannot find where he has made the science of medicine his profession. Instead, he is here to tell you what you should have and that a pivoted chair should govern the health of you and your children in Washington. How distant this may be, how far-fetched the idea may seem, this can happen. It is called for by your president, whether he believes in it or not. In this great country of ours, we all have an opportunity - anything can happen to a free child born in this great country - and let us keep it that way.

The Insurance Economics Survey's Report: There are roughly 165,000 physicians and surgeons in the United States. American medicine, except for certain restrictions on harmful drugs, has always been free from government meddling. These 165,000 physicians and surgeons are today taking care of the sick and injured in America and rendering a better service than any other country. American medicine has risen to its present high level because the American doctor has been capable, earnest, and ambitious and has a heightened sense of duty. It happened, too, because they were practicing medicine in a free country where, as yet, the government bureaus have been prevented from extending their tentacles over the care of the sick.

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The government can claim no credit for medicine's astounding advancement. The contrary is true; political control has been stultifying and disastrous in those countries where the medical profession has been placed under the dictation of the state. Politicians, at the instance of the Marxist schemers, have long had their eye on this business of the care of the sick.

Great Britain has now politicalized her medicine, which means that political bureaus have stepped in and will, from now on, teach doctors, dentists, nurses, pharmacists, and patients what to do to the last detail. And the same political move threatens here and now in the United States. A supreme effort is being made to convert our magnificent system of caring for the sick into a government-run machine of political medicine. The fate of 165,000 physicians is at stake. But more important is the fate of the 150,000,000 people they minister to. They wish to destroy the freedom of American medicine by placing it under the political management and control of government - THIS IS THEMSELVES. They want to destroy the most successful medical system the world has ever seen and substitute for it a system that has failed everywhere else.

The proponents of socialized medicine tell us that our medical practice does not work. They grabbed with glee the report that so many of our young men were unfit for military duty and that so many were rejected for military service. They tell you that it was a lack of medical attention. The socializers in Washington are telling us that these men were rejected by the army because medical treatment was lacking, even though a significant percentage of those rejected were from the wealthy class. These socializers will tell you anything, for they are hell-bent not only on socialized medicine but want to socialize everything.

Why should anyone want to tell the American people they needed socialized medicine when it was socialized and directed by a supreme authority for more than 4,000 years, and no progress has been made? As soon as the government lays its hands on medicine, it will be at the peril of your loved ones. What has the army done to hasten the progress of the medical profession when they have had all the money needed to launch to complete any project they may have wished to undertake? Why, when we have the most remarkable scientific medicines in the world today, do they want us to adopt the philosophy of controlled medicine that Russia has? Look at the degree of superiority of our great medical men today compared to those in Russia. For what reason did we fight two great wars? Why sacrifice the lives of hundreds of thousands of our finest young men on the battlefields, spend billions and billions of dollars, and then return to embrace and adopt the ideologies we found so valiantly against?

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If we allow medicine to be socialized, everything will be socialized in a few more years. You will be regimented; the thoughts of your children and mine will be directed into channels of absolutism, and the state will supersede the lives of all men, women, and children. We will have lost our freedom while we slept at the crossroads. Let these socializers go to Russia - they have their countries mixed. This is AMERICA, not Russia.

To socialize medicine would place an additional burden of taxes upon the already strained pocketbooks of the working man. Some of our greatest economists estimate that it would cost at least 20 percent of every dollar earned to defray this great bureaucratic expense by placing a million and more on government payrolls. Our government is bulging with employees now. In 1939 there were 900,000 employees on our government payroll. Today there are 2,100,000 (1965), and just before the last national election, 80,000 more were added to these figures. This is an increase of nearly 300 percent within the last decade.

In an address before a medical society, Senator William Robertson warned that many American workers might be taxed as much as \$40. per month, in addition to all other taxes, to finance programs of social benefits and socialized medicine recommended by President Truman. A full 10 percent additional tax on gross income is a considerable burden. Senator Robertson added that the exact cost of the president's program as a whole could not be estimated in terms of individual payments. Still, he recalled that economists in testimony before the ways and means committee had put total payroll taxes at 20 percent. If the taxes should reach that proportion, then the Senator continued, persons with income of \$4,800 annually would be required to put up an additional 10 percent of their gross income.

Senator Robertson asserted that the tremendous financial burden of the proposed program would be reflected in increased costs on manufactured goods because employers would add their tax expense to the selling prices. "I feel there is no reason to assume that the abolition of the private profit incentive will not be harmful to medicine as it has been to the production of goods and services in general."

Quoting Dorothy Thompson from "Federal Medicine Boob Trap," "I have lived under such systems in England, Austria, and Germany, and they are awful. The great jokers in all these schemes are put forward as FREE, meaning something for nothing. Let their proponent at least tell the truth. What is advocated is compulsory insurance. Every worker in the country will have the cost subtracted from his pay envelope and added to the price of everything he buys. He will be paying for unused aspirin (or jabs) when he needs money for oranges. He will support innumerable filing clerks and exorbitant paper staff for the entire population. When and if he gets ill and

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finds that under the slap-happy methods of overworked doctors, fees are assured anyhow, he gets no better but worse; he finally will, in desperation, consult one of these private physicians who refuse to join the assembly line. Atop all, he has already put up, week by week, paying a private fee (functional medicine). How do I know this? Because I have experienced it.

Why this most inventive country seems compelled to copy social measures originating elsewhere is indeed baffling blindly. Before Congress passes legislation falsely called "health" insurance, it owes it to the American people to tell them precisely what a person with low income is going to have to pay over a working life of 40 years to take care of his illness and just what service the government guarantees him in return for his money. Will it, for instance, sign on the dotted line that if his wife is in labor, the government guarantees a bed and a physician at the critical moment? Do not make me laugh; I've lived under these schemes."

In New Zealand, where political medicine was set up less than ten years ago, the expense today absorbs 40 percent of all revenues collected by the government, and deficit financing has been resorted to in a desperate attempt to furnish the benefits promised. Forty percent of the comparable revenues of the United States is an unfathomably high number.

Against all sinister forces working together for the enactment of political medicine, those striving to defeat it have on chief reliance - that is, in the innate good sense and love of liberty of the American people and the American doctor. The American people do not have to have this scheme - fathered by communism, mothered by socialism, and wet-nursed by power-hungry bureaucracy imposed upon them. It is not inevitable so long as enough free men and women dare to stand up and fight against it.

Socialized medicine means:

- loss of initiative,
- loss of responsibility,
- inferior medicine,
- delayed attention,
- a number instead of your name, and
- an abundance of taxes.

Wake up America and live. Let us keep this country so we can still pledge allegiance to our flag and keep it so we can still sing "AMERICA," yes, the land of the free and the home of the brave.

"My God, grant us the knowledge to see and the wisdom to act. We owe this to our children if to no one else."

- Eugene P. McDaniel

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What has happened? Exactly what Dr. McDaniel predicted. Now we have to expend more energy and shed more blood than if we averted this catastrophe in the first place to get proper healthcare back. Lord knows enough blood has been shed as COVID-19 and the falsified need for emergency use authorizations have taken a death toll far beyond modern wars.

“You are what you eat, so do NOT be fast, cheap, easy, or fake.”

– Unknown

### **The Journey from Food! to Food?**

Summary: Many of us no longer eat food, at least in a natural and unprocessed form. Those consuming these Frankenfoods products are becoming nutrient deficient yet calorie rich. Commercial agriculture plays a significant role in providing a product lacking essential ingredients. However, government subsidies for this industry incentivize large farmers to produce unhealthy crops. Authorities from the medical establishment also play a major role by promoting unhealthy eating practices, including low-fat and low-salt diets, without taking a noticeable stance against processed foods. Hmm... fat is natural, salt is natural, but processed foods are synthetic.

Our ancestors ate an omnivorous diet consisting of both plant and animal food. We know this for sure, looking as far back as the Pleistocene era that ended about 12,000 years ago.<sup>21</sup> Historic eating patterns determine what is optimal for our health today based on the lengthy process of genetic adaptation. Science is increasingly compiling evidence showing how the evolution of our species has interacted with the availability of different kinds of nutrition to shape the genetic framework of our metabolism. The prestigious Nature Magazine published “The influence of evolutionary history on human health and disease” in 2021, where the authors determined, “Nearly all genetic variants that influence disease risk have human-specific origins; however, the systems they influence have ancient roots that often trace back to evolutionary events long before the origin of humans.”<sup>22</sup>

The point of all this “science-speak” is that we cannot escape our past, including our distant past. Food has changed dramatically in just a few generations, and our genetics have not and will not catch up in time to save us from maladaptation. Just spend a day “people watching” in Walmart for confirmation. The current state of global ill health that results from this state of maladaptation is the epidemic of rampant chronic diseases.

The Pleistocene era foods shared commonalities with today’s foods but also had substantial differences. Their foods were wild and unprocessed as they did not have the technology to process them. In most cases, whole food processing leads

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to the removal of nutrient value. Today, too much emphasis is placed on calories for energy. But micronutrient content is more important compared to calories in most instances. Micronutrients, not macronutrients, play a crucial role in keeping us healthy by supporting cellular and tissue repair and recovery.

Compared to today, ancient people ate only local food but also ate a much wider variety of foods than we consume today. With ancient populations living in warmer climates, roots, berries, fruits, lizards of all types, antelope, fish, birds, and arachnids (insects) were all part of their diet. So, if Klaus Schwab makes us eat insects, thank him because we are much more adapted to them than a twinkie. Waste was not an option as most of their existence centered around survival, with food gathering being their most important and time-consuming activity. They literally ate everything down to the brains and broke bones to eat the marrow rich in monounsaturated fats. They certainly could not establish a diet style; they ate what was available. Thus, they consumed as much meat as was available and little else during the dry seasons or, upon moving north, the cold season.

Humans have proportionally much larger brain sizes compared to primates. Additionally, our guts are proportionally much smaller. Migration to higher latitudes may account for this difference and speaks to a change in nutrition associated with this movement. The large guts imply the need for the more efficient digestion of foods low in nutrients. There was a trade-off to evolving a large brain at the expense of reducing our gut size. The brain is the most active organ and metabolically uses more ATP than any other organ in the body. The brain's energy demands are about ten times that of other tissue. Thus, a big brain requires more calories and nutrients, therefore, better absorption. Chimpanzees closely related to early man ate fruit primarily and, to a lesser extent, plants. Today chimpanzees have much smaller brains than humans, and the types and preparations of foods consumed by humans and chimpanzees are the primary reason for this difference.

Moving away from the equator meant shorter seasons for fruits and harvestable plants. Humans started eating more meat which is more calorically and nutrient-dense, especially when the entire animal was consumed. Slowly, our brains enlarged, and we became more capable of catching and harvesting food. A key point of demarcation is 40 degrees latitude, where the ground freezes and foraging for anything but roots and nuts are curtailed, but animals, as a food source, were still abundant.

Veganism and vegetarianism were not part of our food consumption history. This eating style is potentially lethal unless it is supplemented with vitamin B12, for example. Also, brain development is impaired by the all-vegetable diet due to a lack of healthy fats the brain relies on as a primary fuel. The modern argument for the value of veganism is the hippopotamus and the gorilla, both of which are impressively muscled. However, humans stand out among the animals for brain

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size and function compared to overall body size. Table 1 shows the brain size of various animals in relation to their weight. Even though gorilla is much larger than the average human, their brain is only one-third the size.

<b>Animal</b>	<b>Brain to body mass ratio</b>
Hippopotamus	1:2789
Gorilla	1:360
Chimpanzee	1:113
Human	1:40

Table 1. The brain-to-body mass ratio in selected animals and humans.

Historically, due to food availability, less than fifteen percent of societies obtained more than half of their foods from plants. At 69 degrees north latitude, Eskimos living in Greenland consumed between 80 to 96 percent animal foods and only 4 percent plants. They probably consumed significantly more plant food during the month or two of the year when these foods were available.

In the United States today, about 70 percent of calories come from four or five different foods; bread, dairy, refined vegetable oils, and sugar, based on research published in the American Journal of Clinical Nutrition.<sup>23</sup> Prevalent foods like cereal, cookies, doughnuts, and crackers have roughly the same combination of these ingredients. The Western diet lacks variety, micronutrients, fiber, and healthy fats. It is common for people, creatures of habit, to eat the same things daily. Our foods today are nutritionally less dense than diets before the industrial revolution, with much fewer vitamins, minerals, phytochemicals, and unnatural fatty acid profiles. Many of these deficiencies are due to modern mechanized agricultural processes that have reduced soil nutrients. To make matters worse, these cheap foods displace natural foods like meats, fish, fruits, and vegetables. This does not even consider the nutritional value lost in modern meats, largely farm-raised on low-quality mass-produced foods that are also the basis of today's junk foods.

The agricultural revolution, which began about 5,500 years ago, led to a more dependable food supply but also impacted our health. The first report of domesticated animals extends back 10,000 years. Dairy came on the scene about 9,000 years ago. Beer, wine, and salt became available about 6,000 years ago. On an evolutionary timescale, this is a relatively short timeframe compared to our overall existence, roughly 30 generations. This is approximately 10 percent of modern human generations. We still have substantial genetic makeup from the stone age. That means humans have genes, bodies, and digestive systems that are very well adapted to the foods we have consumed, dating back to the extensive part of our history before more modernized agricultural processes.

A key inflection point was the production of sucrose which was first produced in India about 2,500 years ago, and of course, it was not refined, so it contained some

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nutrients. Initially, it was not exported worldwide, and only a relatively small population had access to it. The Industrial Revolution in the mid-to-late 1800s changed everything. Dr. Paul Clayton's work showed a substantial change in health, mainly due to two things related to the industrial revolution: shipping and canning.<sup>24</sup> These two advances ushered in the era of inexpensive, low-quality, but storable processed foods.

Our diets changed due to the convenience associated with dependable foods that were inexpensive and had long shelf lives. Fatty meats ubiquitous in our early diets were replaced with canned meats from highly domesticated animals fed cheap feedstocks. Thus, our diet, even though containing meats, became derived from refined grains. And our intake of white bread and white rice increased because of technological innovations. All of this transpired within the past 3-4 generations, which is less than 2 percent of our evolutionary genetic window.

From a generational perspective, our genes do not change substantially in the three or four generations in which these foods have been introduced. Humans today have the same genes that people had ten thousand years ago, so garbage foods are an onslaught to our physiology and health. Our genes just do not adapt to this sudden change, and we cannot manufacture vital and essential nutrients unavailable in these new foods. The organisms prevalent in nature and our bodies, the microbiome, have not adapted well either, as an untold but high percentage of the population consuming junk foods have gut issues. These organisms may never adapt to consuming these foods because they are not really foods. They are better defined as chemicals or drugs – unnatural substances.

You may question the concept of adaptation and argue that three generations allow our genetic makeup to change. Here is a visual example for you to consider. The difference between a European American and African American is skin pigmentation. The dark skin of the ancestors of the African Americans is our true ancestors because none of our ancient ancestors were born wearing fur coats. Thus, the European Americans are the ones whose ancestors adapted. And they adapted from their darker-skinned African ancestors.<sup>25</sup> Do you note any lightening of skin color in African Americans who migrated north in the last four generations? I did not think so. The process, in this case, is called "natural selection."<sup>26</sup>

When comparing adaptation to natural selection, indeed, we have adapted, to some degree, to unnatural foods. However, we have done so only as a survival mechanism, whereas the selection process is about thriving.

Modern technology has allowed food production efficiency to serve a rapidly expanding population. A critical development was synthesizing refined vegetable oils that are inexpensive to produce, come from prolific plants like soybean and corn, and have substantial shelf lives to reduce waste by dramatically extending shelf lives. In nature, foods decompose because different species, like fungi, can

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extract nutrients. These normal processes do not occur with the unnatural processed oils, implying that these organisms do not view them as food, yet humans do.

The Twinkie is a good reflection of the change in our food supply. When Twinkies first appeared on supermarket shelves in the 1930s, their shelf-life was just two days. Today, the shelf life is reported to be 25 days, boosted by a large number of processed oils in the product. But they do not decompose like a typical food being consumed by organisms. This food is sterile and turns rock hard because of moisture loss and other chemical changes. This is not the natural way foods “go bad.” The food industry funded a campaign to “dispel the myth” about Twinkie’s shelf life to make it appear that this is actually food, not a chemical. However, there is a substantial difference between spoiling and losing texture. They can go a long time without spoiling, with estimates of up to 30 years, but has anyone tested them out to 100 years yet?

High fructose corn syrup (HFCS) is unnatural. Robert H. Lustig is an American pediatric endocrinologist. He is a Professor Emeritus of Pediatrics in the Division of Endocrinology at the University of California, San Francisco, where he specializes in neuroendocrinology and childhood obesity. He delivers his message through videos and podcasts, with an impactful one titled “The Bitter Truth.” He is the most passionate spokesman against HFCS. Fructose was initially thought to be a better choice for diabetics due to its slightly lower glycemic index. But only your liver cells can process fructose, and that is where the problems begin.

Fructose goes straight to your liver and starts a fat production factory. It triggers the production of triglycerides that is part of the “total cholesterol” calculation, so the “cholesterol” number goes up on fructose, putting you at risk of being prescribed a statin drug. These drugs make you more susceptible to diabetes, creating a vicious cycle pushing you further into diabetes. The initial statin prescription usually leads to more drugs, including metformin, other diabetic drugs, and blood pressure medications. This combination of 3 drugs is prolific in overweight people with or heading to diabetes. Remember that it is actually the sugar, not the fat, that causes weight gain and metabolic syndrome.

Fructose is handled entirely differently in the liver compared to other refined sugars. A key step in metabolism is called the phosphofructokinase process, which regulates the flux of sugars through the liver. Fructose can bypass this process, allowing for the unlimited flow of this sugar into our circulation. In the liver, fat, among other things, is produced. This way of processing fructose, which is high in fruits, is important evolutionarily. Fruits are only available seasonally, and storing the fruit calories as fat for later use was essential for the survival of hunters and gatherers. However, with unlimited supplies of fructose available and consumed daily, this rapid storage process leads to high glucose levels, insulin

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resistance, diabetes, and a myriad of other chronic diseases tied to excess glucose and the inflammation the excesses of glucose produce.

"Fructose is like rocket fuel. Eat fruits and other natural high-fructose foods when you are a rocket!"

- Thomas J. Lewis, Ph.D.

Even though the synthesized HFCS is similar to, or the same as, the fructose in fruits, the fruits contain micronutrients while the HFCS does not. This matters because consuming and utilizing any food requires energy and nutrients. The fruit has a complete complement of nutrients, while the HFCS does not. The result is, consuming HFCS puts your body into a state of nutrient deficiency. Any deficiency drives hunger. Thus, even though the HFCS provides enormous amounts of calories, the consumer is likely to remain hungry and continue consuming more HFCS.

An equally severe health consequence of HFCS consumption is what it does to your gut. It is not a natural substance broken down by the digestive process. Instead, it can damage the lining of the intestinal tract, causing intestinal permeability or "leaky gut syndrome." This allows foreign food proteins and bacterial proteins to enter the bloodstream, which triggers inflammation, causes weight gain, triggers various autoimmune conditions, including joint pain, brain fog, and lack of energy and contributes to type 2 diabetes. And fructose often causes hunger by spiking insulin, creating a vicious cycle of increasingly poor health.

Corn subsidies, sponsored by the USDA, led to sugary fructose syrup becoming a more affordable option for incorporation into foods and beverages. Thus, corn subsidies begat cheap corn, making corn-derived sweeteners cheaper than sugar. Voila: HFCS takes over the soda market.

Why are junk foods consumed at such high rates? As explained above, nutrient-deficient foods, like HFCS, keep you hungry, often for more junk food with HFCS. But why are people choosing the HFCS food as opposed to a carrot? You may be thinking it is evident that the world now has a sweet tooth, and a carrot does not quell the desire for sweets. But there are other reasons. A major driver in food decisions is economics. At a time when almost three-quarters of United States citizens are overweight or obese, it comes as no surprise that junk foods are the largest source of calories in the American diet. Topping the list are grain-based sweet foods like cookies, doughnuts, granola bars, sodas, energy drinks, and other beverages like sweet tea, a staple of the south with the highest obesity and diabetes rates compared to any other region.

The federal government reports that bread, sugary drinks, pizza, pasta dishes, and dairy desserts like ice cream are among Americans' top 10 sources of calories. A common denominator among these foods is that they are composed of significant

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quantities of one or more of corn, soybeans, wheat, rice, sorghum, and milk. All these foods are heavily subsidized by the federal government, ensuring that junk foods are cheap and plentiful. Stores favor them because of their highly extended shelf life. For store owners, what food is better to stock, a candy bar with over a year shelf life or a banana that shows signs of rotting in 2 days?

The consequence of the USDA subsidy policy is that a snickers bar, loaded with HFCS, is half the price of a competitive product made with healthy nuts, chocolate, a modest amount of sugar as a binder, and sweetness. Sweetness is the expected flavor; without that, snacks will not leave the shelves. This subsidy program sets up quite a contradiction. The federal government recommends that people fill half their plates with fruits and vegetables to help prevent obesity, but only a tiny percentage of subsidies support the production of fresh produce. The vast majority of agricultural subsidies go to commodity crops that are processed into foods that are causing obesity, diabetes, and the chronic disease crisis.

People, particularly the poor, consume snacks and highly processed foods at artificially discounted prices and can conserve their budgets. But the subsidies are costing all of us financially. There is no free lunch. The subsidies damage our people's health and increase medical costs. For many, those medical costs are subsidized by the Government, which means taxpayers are paying significantly for the food subsidies. According to the U.S. Public Interest Research Group, a nonprofit consumer advocacy organization, "taxpayers are paying for the privilege of making our country sick."<sup>27</sup>

"Taxpayers are paying for the privilege of making our country sick."

The subsidy program did not start to encourage the poor to eat junk. Instead, it was created decades ago to support struggling farmers and secure America's food supply. Since its inception in 1995, over a trillion dollars has been poured into this program. The program no longer serves its original purpose. Instead of supporting small farmers who grow fruits, nuts, and vegetables, the program primarily helps large producers grow profitable crops, including grains, corn, sorghum, and oilseeds like soybeans. These companies do not need subsidies to be profitable. The specialty farmers that grow nutritious foods account for three-quarters of the country's cropland but receive just 14 percent of government subsidies. Large agribusinesses specializing in growing the major commodity crops represent 7 percent of the cropland and receive about half of all subsidies. At one point, the farm bill prohibited farmers from using subsidies to grow fruits and vegetables. Fortunately, that has changed. Figure 3.1 shows what the USDA subsidies are.



Figure 3.1: Farm subsidies provided by the USDA by the percent subsidy per crop and food.

### The History of Junk Food

The history of junk food is long and storied. This timeline shows the introduction of America's favorite cheap, low-nutrient value foods.

- 1886: Coke;
- 1900: Hershey bar;
- 1902: Pepsi;
- 1902: Cornflakes;
- 1906: Crisco;
- 1913: Oreos;
- 1921: Wonder bread;
- 1921: Rice Krispies;
- 1928: Corn chips;
- 1931: M&Ms;
- 1969: Pringles.

If our transition to junk and processed foods, high in carbohydrates, was just a macronutrient issue – that is, excess carbohydrates replacing healthy fats and proteins –our health status would not be as dire as it is today. However, micronutrients are severely lacking in most foods afforded farming subsidies. The food industry knows that people are easily addicted to sugar.<sup>28</sup> Sugar has been scientifically proven to be more addictive than cocaine and nicotine.<sup>29</sup> Salt also provides a highly desirable flavor characteristic. If you have not tried junk food like Kentucky Fried Chicken, one bite will confirm this. The odor emanating from the establishment is the soybean oil prolific in the food.

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Excessive sodium is blamed for hypertension in junk food consumers. However, most diseases are caused by deficiencies. In this case, potassium deficiency is an important driver of elevated blood pressure, and junk food consumption loaded with sodium is just a sign of low potassium intake. Potassium is arguably the most neglected of the critical minerals. Estimates of Americans who are potassium deficient range from 50 to 98 percent.<sup>30</sup> Not surprisingly, it is considered to be a "nutrient of public health concern" according to the 2015-2020 Dietary Guidelines for Americans since its underconsumption in the US population is associated with adverse health effects, including hypertension and cardiovascular diseases.<sup>31</sup>

Processed foods are stripped of micronutrients and are also devoid of dietary fiber. Fiber consumption is often an afterthought in good nutrition. However, with the advent of a new understanding of the importance of the microbiome and digestion, fiber now rises to the top of the list of critical food components. We were taught, "you are what you eat," but that is only partially true. You actually "are what you absorb." Fiber, the food that supports the microbiome, plays a vital role in health. The primary reason is that not all food is absorbed equally well, and micronutrients are the hardest to extract from foods, thus being absorbed in adequate quantities.

Junk and processed foods, in general, are considered "pre-digested" because complex food substances and hard-to-absorb nutrients are not part of these foods. Therefore, they are digested quite readily. Whole foods are often composed of complex structures that are not easily broken down, except in an optimally working digestive system that few people in the developed world have. The challenge is that it is not easy to measure gut health, that is, establish where you lie on the gut health continuum. Asymptomatic people may still have some level of gut dysbiosis, thus, inefficient digestion. This leads to what is called "junk food syndrome," where people are eating well but absorbing poorly.<sup>32</sup>

An important question becomes, what food types absorb readily and which ones are more difficult to break down and absorb their nutritional content? This may not be obvious, but it becomes more apparent through simple observation. Compare a sweetened beverage to a piece of kale. Continuous glucose monitors illuminate the abruptness with which a sudden spike absorbs the fructose and sucrose in these beverages in glucose levels. On the other hand, the kale is broken down and absorbed much more slowly and does not cause an abrupt change in glucose levels.

An experiment you can do at home explains what is digested and absorbed quickly. Food must be liquified to be absorbed into the bloodstream through the intestinal lining. Place sugar, a granola bar, and a piece of kale in separate glasses of water and come back in about three hours. The sugar will be completely dissolved, some of the constituents of the granola bar, the sugary parts, will be

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dissolved, and the kale will be wet, with nothing obvious being dissolved. You can tell by tasting the water in each glass. Water represents a poor digestion environment, yet sugars are easily dissolved in this solution. Thus, in people with poor gut health, sugars are absorbed while the more complex and nutritious ingredients of foods are not. On average, this process of breaking down foods into liquified bioavailable components must be completed in 3.5 hours. Thus, even if you are eating highly nutritious foods, but your gut health is not optimal, you are essentially eating junk food.

"If your gut function is not optimal, even if you are eating high-quality, nutritious food, your physiology receives the equivalent of junk food."

Cooking (heating) foods should be the first step in digestion. Cooking "tenderizes" by breaking down complex food structures. That is what digestion does, too, except in digestion, the food is completely liquified. Cooking kale to create a softer, more palatable form takes quite a while. It is very "starchy" and resists the action of heat and digestion to break it down. Harvard primatologist Richard Wrangham weighs in on the importance of cooking and how it advanced humans over other creatures.<sup>33</sup> He states,

"The biggest revolution in the human diet came not when we started to eat meat but when we learned to cook. Our human ancestors who began cooking sometime between 1.8 million and 400,000 years ago probably had more children who thrived."

Wrangham says.

"Pounding and heating food "predigests" it, so our guts spend less energy breaking it down, absorb more than if the food were raw, and thus extract more fuel for our brains. Cooking produces soft, energy-rich foods. Today we cannot survive on raw, unprocessed food alone, and we have evolved to depend upon cooked food."

Compared to a cow, which eats raw grasses and has four large compartments in its stomach, humans have just one small one. Cooking is a substantial reason for that difference. Cows are large, and so is their stomach. However, proportionally, the cow's stomach is fifty times larger than a human's.

Although the bioavailability of some nutrients is relatively well understood, for other nutrients, the scientific understanding of uptake, absorption, and bioavailability in humans is still at a nascent stage. And, not all micronutrients are well absorbed, even in seemingly healthy people. Many presumed healthy people have mild gut issues that impact the rate and efficiency of digestion and do not even know it. More than good analytics to measure digestion efficiency are needed. This presents a problem in the absorption of, for example, green leafy vegetables. These foods are rich in iron, but the bioavailability of iron is relatively low, around 12 percent, as indicated in some studies. This average value is higher

in those with good digestion but lowers in those with poor digestion. A sign of poor digestion is any common gut-related issue, including diarrhea, constipation, gas, bloating, and acid reflux. According to Melse-Bonstra, in an article titled, “Bioavailability of Micronutrients from Nutrient-Dense Whole Foods: Zooming in on Dairy, Vegetables, and Fruits,”<sup>34</sup> “The low bioavailability is attributed to the indigestibility of cellular components such as chloroplasts and mitochondria where iron is stored. Poor absorption of micronutrients creates a deficiency that affects physiological processes leading to a myriad of diseases.”

Poor iron absorption may lead to anemia, the blood disease associated with low iron levels in the blood. Anemia is a common disease that affects ~1.6 billion people worldwide, especially infants and women. The World Health Organization (WHO) has estimated that the global prevalence of anemia in women is nearly 30 percent.<sup>35</sup> Mayo Clinic states,<sup>36</sup>

“A shortage of iron in your body causes this most common type of anemia. Your bone marrow needs iron to make hemoglobin. Without adequate iron, your body can't produce enough hemoglobin for red blood cells. Without iron supplementation, this type of anemia occurs in many pregnant women. It's also caused by blood loss, such as from heavy menstrual bleeding; an ulcer in the stomach or small bowel; cancer of the large bowel; and regular use of some pain relievers that are available without a prescription, especially aspirin, which can cause inflammation of the stomach lining resulting in blood loss. It's important to determine the source of iron deficiency to prevent recurrence of the anemia.”

Could the many causes listed by Mayo not be the predominant root cause of anemia? Based on the science of digestion and absorption being in its infancy, is it possible that the most prevalent cause of anemia is poor digestion? Taking an iron supplement in pill form may not solve the problem because it may not be broken down and absorbed, just like iron in food. Our medical professionals, who focus on gut health, indicate that many cases of anemia resolve when improved digestion is the focus of their therapeutic interventions.

Cereal grains constitute about a quarter of our calorie intake. Unfortunately, the type of cereal grains consumed in the United States is refined and has a high glycemic load. Our hunter-gatherer ancestors did not eat cereal grains. It was impractical for them because the amount of energy required to harvest them offset the energy they provided. Cereal grains are the seeds of grasses, and in their wild state, they are tiny and difficult to harvest. Once harvested in their natural form, that is not edible. They must be ground and cooked; otherwise, the starch and protein they contain are not bioavailable through digestion. Crude grinding stones were used roughly ten to fifteen thousand years ago, which led to grains being slowly introduced to a limited population. The industrial revolution leading to more sophisticated grinding devices led to the broader availability of flour as a

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food. Waterwheels that turned gears that ground stones together to make flour led to mass production and wide availability of this food. Still, flour did not have evolutionary adaptation connected to it. The high consumption of flour occurred just recently.

Wheat has reasonable nutritional value tied up in the germ and the bran. Modern technological developments increased wheat processing throughput, removing the germ, bran, and micronutrients they contain. Whole wheat kernels have a low glycemic index, but refined flour products have a high glycemic index. In addition, these foods disrupt a proper acid-base balance in the gut and blood. The correct pH is critical to health, and these grains interfere with this balance. All grains are net acid-yielding, and these foods promote osteoporosis, indicating poor mineral availability influenced by gut and acidic blood pH. Fruits and vegetables are the few alkalinity-producing foods, and insufficient amounts of these foods are consumed to overcome the acidifying effect of wheat-based foods. Thus, the Western diet is net acid-yielding. Acidity in the blood promotes inflammation and infection.

Osteoporosis is actually the least of the conditions caused by an acidic milieu. Dr. Otto Warburg, the winner of the Nobel Prize in 1931, discovered that cancer cells are not fueled by oxygen, as are normal cells. The high levels of oxygen found in healthy, alkaline bodies are toxic to cancers. He found that cancers get their energy from sugars and a process of fermentation in acidic environments. He empirically proved the relationship between cancers, acidic body pH, and cellular oxygen starvation.<sup>37</sup> His findings demonstrated that cancers are merely a symptom of acidosis; therefore, it is impossible to truly cure any cancer without first fixing the underlying acidosis.

John Kellum, author of “Determinants of Blood pH in Health and Disease,” explains three key factors that regulate blood pH.<sup>38</sup> One of the “big three” is “relative electrolyte concentrations.” Electrolytes mean minerals, and it is clear that minerals are difficult to absorb. Thus, our society has a cascade of ailments driven by improper blood pH. Kellum states:

“An advanced understanding of acid-base physiology is as central to critical care medicine as an understanding of cardiac and pulmonary physiology. Intensivists spend much of their time managing problems related to fluids, electrolytes, and blood pH. Recent advances in the understanding of acid-base physiology have resulted from applying basic physical-chemical principles of aqueous solutions to blood plasma. This analysis has revealed three independent variables that regulate pH in blood plasma. These variables are carbon dioxide, relative electrolyte concentrations, and total weak acid concentrations. All changes in blood pH, health, and disease occur through changes in these three variables. Clinical implications for these findings are also discussed.”

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The salivary pH in patients with chronic generalized periodontitis is more acidic than in the control group. This explains why many cancers are associated with poor oral health and periodontal bacteria. Charles Mayo, the founder of the Mayo Clinic, focused a substantial portion of his medical career on the impact of infected teeth on chronic health. Mayo used the term “focal infection” to explain that diseases caused by periodontal bacteria outside the mouth were not necessarily systemic but rather localized. Kevin J. Carlin brings our understanding of focal infections to a new level and is related to physiological pH levels.<sup>39</sup>

“Why do certain infections tend to recur in the same area? For certain, at least part of the explanation is the opportunity with the infectious agent's location close at hand or an enhancing delivery system. Also, specific adaptations by the infectious agent occur, leading to particular locations. But perhaps there is an additional unknown preference that, at least on occasion, may be involved. Few are surprised *Candida albicans* episodically grow on the skin, in urine, and in the female vagina since these areas are all known to be acidic at times, and *Candida* prefers an acidic environment for growth. But we do not use the same logic, for example, when an infectious agent grows in the adrenals or bone well away from the original lung location.”

Not surprisingly, lower blood pH, tied to poor mineral absorption and low nutrient density consumption, is a decisive prognostic factor for fatal outcomes in critically ill COVID-19 patients. Kieninger et al. explain that pH and arterial pressure are more important compared to other risk factors in COVID-19 patients.<sup>40</sup>

“In this retrospective cohort study, we analyzed the first 59 adult critically ill Covid-19 patients treated in one of the intensive care units of the University Medical Center Regensburg, Germany. Using uni- and multivariable regression models, we extracted parameters that allowed for prognosing in-hospital mortality.

Within the cohort, 19 patients died (mortality 32.2 percent). Blood pH value, mean arterial pressure, base excess, troponin, and procalcitonin were identified as highly significant prognostic factors of in-hospital mortality. However, no significant differences were found for other parameters expected to be relevant prognostic factors, like low arterial partial pressure of oxygen or high lactate levels. In the multivariable logistic regression analysis, the pH value and the mean arterial pressure turned out to be the most influential prognostic factors for a lethal course.”

These data present a strong argument for optimizing gut microbiome, digestion, and micronutrient intake, emphasizing foods high in mineral content to combat the most serious diseases. This information rationalizes why a group from

Harvard Medical School indicates that the gut microbiome has the potential to reshape the cancer therapy paradigm, Figure 3.2.<sup>41</sup>

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# The Potential of the Gut Microbiome to Reshape the Cancer Therapy Paradigm

## A Review

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Figure 3.2. Image of a peer-reviewed paper on the importance of the microbiome by a team of Harvard Medical School researchers.

Dr. Mat Lalonde is an expert on foods and their micronutrient density. He holds a Ph.D. in Organic Chemistry from Harvard University. He evaluated many modern dietary styles for nutrient density and determined that most claims about dietary nutrient values were flawed. He created a scale using evidence-based algorithms, and included weighting factors for each - all based on micronutrient levels, as opposed to macronutrient density.<sup>42</sup> Table 2 presents his findings.

Category	Nutrient Density
Organ meats and oils	17.05
Herbs and spices	16.78
Nuts and seeds	10.28
Cacao	7.97
Fish and seafood	1.16
Pork	0.69
Beef	0.31
Eggs & dairy	-0.56
Vegetables (raw)	-0.7
Wild game	-1.19
Poultry	-1.71
Legumes	-2.86

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Processed meat	-3.1
<b>Category</b>	<b>Nutrient Density</b>
Vegetables (cooked,)	-4.84
Plant fats and oils	-5.41
Fruit	-5.62
Animal skin and feet	-6.22
Grains	-6.23
Refined processed fats	-6.43
Animal fats and oils	-6.88
Grains (canned)	-7.04
Processed fruit	-8.12

Table 2. Nutrient density scores for various foods.

As important as consuming high nutrient-density food is, optimizing digestion is even more critical.

#### History of Sugar

Refined sugar is consumed at an alarming rate in the developed world, particularly in the United States. About 20 percent of the calories there come from these sugars. Hunters and gathers would have consumed sugar in the form of honey whenever and wherever they could. Sugar is, in the context of food, rocket fuel, and the hunter and gathers, being constantly on the move, needed high-energy food. Importantly, because access to food was not guaranteed back then, they needed to be able to store food in anticipation of times of deficiencies. Since they did not have refrigeration or freezers, storing food on their bodies as fat was essential for survival. Honey was not constantly available, so the ancient people would consume it in relatively large quantities, based on its availability, and tuck some of the calories away as fat for future use.

During the industrial revolution, refined sugar consumption increased from about 5 to over 100 pounds per person per year, a highly unusual intake trend over such a short period. Starting in about 1970, fructose, derived from corn starch, became readily and economically available. The high fructose corn syrup (HFCS) product, ubiquitous in modern society, is about 50 percent sweeter than sucrose; thus, less is required to provide the same level of sweetness. The move to HFCS was entirely financial. By 2000 sucrose and HFCS were used at the same level. After another decade, through the media efforts of authorities like Robert Lustig, MD, and others, information about diseases associated with refined sugars, especially HFCS, became more appreciated. Certain cancers, including those of the breast, colon, and prostate, were being blamed on refined sugar intake and the type 2 diabetes high sugar intake caused.

Medieval Islamic scholars declared sugar a panacea for all medical ailments. Sugars are a necessary part of the diet, but the dose makes the poison. When food

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supplies are uncertain, storing sugar as fat is vital for survival. In the 16th century, it became a profitable item of luxury. By the 18th century, however, Quaker William Fox denounced it, saying, "for every pound used, we may be considered as consuming two ounces of human flesh" He recognized that in the cases of sedentary lifestyles, too much sugar is deleterious. The unfortunate journey to consuming too much sugar is neither short nor sweet.

Since ancient times, desires for the sweet taste of sugar have spurred global trade exchanges and exploration of lands and technologies to produce large amounts of sugar. People from varying social strata gained access to sugar and escalated its demand leading to the expansion of the deplorable practice of slavery. Exploring the history of sugar reveals a world transformed by mass migrations and widespread dietary changes linked to an inexorable demand for its sweetness. Human brains are geared towards calorie-dense foods as part of an inbuilt survival mechanism against starvation. Still, sugar was not part of the evolutionary process as its mass consumption is a relatively modern phenomenon.

Throughout ancient history, honey was the primary sweetener but was available to few and was consumed over a relatively short period when it was first available for harvest. This is how sugar is naturally intended to be used. During times of bounty, humans needed to store calories in their bodies in preparation for times of shortage. Around 8000 BC, the people of New Guinea encountered sugar cane, a tall grass that, when chewed, released a burst of sweetness. Explorers from this region helped spread sugar cane to the Philippines and India around 6000 BC as part of their trade exchanges involving tools, arts, and crops. Evidence of sugar production in India appeared in the fourth century B.C. document "Natyashastra," which mentioned sugarcane juice being processed into semi-solid sweeteners around 300 BC. Military encounters with Alexander of Macedon led to the spread of sugar from India to his Hellenistic empires.

Exchanged in small amounts as a medicine, sugar soon sparked industries in Persia and Egypt. In the seventh century AD, the Arab Empire became enamored by its sweetness and purported medicinal value. They explored ways of growing sugarcane in their Mediterranean territories. This period was marked by technological advancement targeted to improve irrigation for sugarcane fields. The waterwheel was employed to maximize sugar production. The rapid expansion of the Arab Empire led to sugar industries across the Mediterranean Basin. The 11th century marked the beginning of the Crusades and the spread of sugar to European nations. According to Albert von Aachen, a 12th-century chronicler, "it was on this sweet-tasting sugarcane that people sustained themselves during the sieges."<sup>43</sup>

European merchants eagerly cultivated sugarcane on lands won in battle. However, the Mediterranean sugar industry encountered setbacks due to an unfavorable growing climate, war, and the black death of the 14th century, which

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drastically reduced its labor force. To this point, sugar remained an expensive item of luxury. It was not uncommon to see lavish sugar sculptures adorning the homes of the wealthy who coveted them. Eager to grow their sugar, Spain and Portugal explored the Madeira and Canary Islands in the Northeast Atlantic in the 15th century. The climate there was better suited to growing sugar cane, and Atlantic sugar soon gained a stronghold in European markets.

Crucial to the success of making sugar was the availability of a large workforce obtained by forced labor, as the process of manufacturing sugar was laborious. In the Middle Ages, this work was mainly done by peasant laborers or prisoners of war. The colonization of the Madeira islands and East Africa in the 15th century promoted African slavery. The proximity of these islands to Western and sub-Saharan Africa made it easier for Portuguese sugar traders to begin a slave trade that continued for centuries.

When Christopher Columbus encountered the Caribbean islands in 1492, a route to explore a whole new world for sugar production opened up. He brought sugarcane home on his second voyage and realized the land was ideal for such a crop. This ushered in the “Columbian Exchange,” a period that witnessed an extensive exchange of animals, plants, and diseases between the Americas and Afro-Eurasia. Exploration of the new world led to Portugal establishing the largest sugar industry in their colony of Brazil, for which the Atlantic slave trade provided cheap labor. Brazil is well-known to be the primary user of slaves historically. The 1600s saw the creation of English, Dutch, and French colonies in the Caribbean, leveraging lucrative trade in cash crops such as tobacco, cotton, and sugarcane. This marked the start of the infamous Atlantic triangular trade exchange of enslaved people, raw materials, and manufactured goods between the Americas, Europe, and Africa. Millions of Africans were captured and sold as slaves.

Working conditions were very harsh, particularly in parts of the Caribbean where sugar was grown. Adjusting to the climate was difficult, creating a vicious cycle where laborers died and had to be replaced. Around the 1840s, the British Caribbean colony of Barbados was transformed into a phenomenal sugar industry due to its rich volcanic soil and easy maritime access. Hordes of indentured Irish laborers driven from their land formed the workforce. Initially, the rising costs of Irish labor got Britain involved in the African slave trade. Laborers in sugar colonies encountered exhausting work and brutal treatment; however, slave labor was instrumental in the success of the sugar industry.

The inconvenient truth is that the desire for sweet sugar was a major driver of the African slave trade, ultimately leading to major mass consumption. Millions of slaves suffered and died in the development of sugar mass production. Now, countless people are suffering from chronic diseases and dying prematurely due to excess sugar consumption. There is no free lunch.

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By the 18th century, British sugar became affordable to the working class and became incorporated into other foods to enhance their desirability and increase their consumption. Coffee and tea became more popular with the addition of sugar, and soon drinking tea became an English national habit while ale houses were exchanged for coffee houses throughout Europe. In 1791, Britain encountered growing protests against the slave trade. Sugar boycotts gained momentum, forcing Britain to abolish slavery in its colonies in 1833 finally. However, the popularity of sugar remained undiminished even when enslaved Africans could no longer be forced to work when slavery was abolished. After all, sugar has a desirable flavor and is addictive. In the British Empire, during the period of the 1830s and up until World War I in 1917, about 500,000 indentured Indian contract laborers came to England as the next wave of cheap labor for sugar production. They completely changed the demographics of these lands through mass migrations.

During the 1800s, sugar served as fuel for the Industrial Revolution. Workers consumed tea and coffee sweetened with sugar to boost energy before their long hours in factories. However, since they labored hard, they "burned" rather than stored the sugar. This marks the period where sugar consumption began its meteoric widespread rise. The early 1800s also witnessed the prolific production of beet sugar, which was initiated in France under Napoleon's rule. Both sugar sources are predominantly sucrose. However, in the United States, sugar beets are typically genetically modified organisms (GMOs), though it is possible to find non-GMO organic beet sugar. Most sugarcane is non-GMO, though some countries have started growing GMO sugarcane.

The Haitian Revolution in the French colony of Santo Domingo and a trade embargo with Britain during the Napoleonic Wars ended the supply of West Indian cane sugar to France; hence Napoleon encouraged exploration into beet sugar technology to meet the pressing demand for sugar. This allowed sugar to become cheaper and accessible to people of all classes. Sweetened jam and bread became a staple of the common person's diet. Sugar started to be incorporated into foods instead of being an additive. The content in the average slice of processed bread varies but can be as high as 3 grams. Some sugar is formed naturally in baking, but it is also a common additive in refined bread products.

In 1820, the per capita annual sugar consumption was around 5 pounds. Today that figure is over 150 pounds. That is a 3000 percent increase and is equal to 3 pounds (or 6 cups) of sugar consumed in one week. Nutritionists suggest that Americans should get only 10 percent of their calories from sugar or roughly 30 pounds per year, but that is an outrageously high number considering our history with sugar and our evolution. And before technology, pure cane sugar was consumed and contained nutrients that are now removed in the sugar refining process. Molasses, removed from cane sugars, is a significant source of calcium, iron, magnesium, manganese, potassium, thiamin, niacin, pantothenic acid, and

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Vitamin B6, whereas refined sugar does not have these micronutrients. Molasses offers a 1/3<sup>rd</sup> reduction in calories compared to refined sugar. Importantly, these nutrients are needed to metabolize sugar. When they are absent in refined sugar, these nutrients are still needed, and their use in metabolism leads to deficiencies.

For the prolific poor, towards the end of the 19th century, much of their calorific intake came from refined sugar. The lack of vitamins led to malnutrition and diseases because of their poor immune status. The surge in sugar production led to the development of a broad array of sugar-containing products. The candy industry became prominent, and chocolate became a highly popular confection. The food industry used the popularity and low price of sugar to increase sales by adding it to many foods, which increased the food's acceptance. This realization by food producers led to sugar being included in nearly all processed foods today, leading to extraordinarily high sugar intake. The journey of sugar from a rare commodity to an everyday, highly overconsumed product and its desirability propelled global trade, exploration of lands, and technologies for its mass production. Although accessible to the poor, no class is exempt from its addictive allure. Thus, it is a ubiquitous staple of the Western diet, rich or poor.

Sugar is an addictive drug. If people were attracted to sugar for its sweet taste, then emerging information about its detrimental consequences on health may be enough motivation to reduce its intake. But the trend to eat more sugar, despite health concerns, is a strong barometer of its addictive properties. Addiction is a reflex to a change in brain chemistry. In a testimonial on a Ted Talk, Laura Marquis admitted,

“I was eating everything, and I'm not talking about one or two pieces of dessert here and there. I would eat a dozen cookies at a time or nearly a whole pie at once, and I couldn't stop myself. I was desperate to come up with a solution because I was gaining weight and wasn't feeling great about myself. So, I took just one bite of the dessert and then threw the rest into the trash. For sure, this would help, but I was wrong. I knew it was still there and until recently, I never thought I'd share this part of my addiction because it's pretty embarrassing and not the proudest moment of my life. My addiction got to the point where I would actually take the half-eaten dessert out of the trash and finish it.”

After decades of observations about potential addiction, in 2008, sugar was scientifically proven to be chemically addictive, and more so compared to well-known addictive substances like cocaine, alcohol, and nicotine.<sup>44</sup> The statistics bear this out from a global perspective by looking at overweight and obesity statistics, with 1/3<sup>rd</sup> of adults overweight. When sugar is viewed as an addictive substance rather than just a desirable foodstuff, a monumental problem arises.

Consider alcoholism. Many alcoholics, to be successful at overcoming this addiction, must go “cold turkey” at eliminating the substance. This is similar in

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smokers. And, one drink or puff is apt to rekindle the addiction. Over 30 percent of people who attempt to stop drinking relapse in their first year of sobriety, and more than 70 percent of people struggling with alcohol abuse will relapse at some point. Fruit contains sucrose and fructose and could potentially trigger a relapse in the desire for more sweet foods. How, in a world full of sugar, can anyone undergo abstinence from this addictive substance?

It is possible to avoid sugar, but it is substantially harder than other addictive substances because it is everywhere and often hidden on labels. Only about 50 percent of people truly understand how to read a food label, if we even take the time to review this “fine print”. Food labels generally list only total sugars, a combination of sugars naturally in foods and those added by processors. Most people have no idea how much extra sugar they consume. Looking at the ingredients list may offer a few clues to the number of caloric sweeteners that have been added to the product since manufacturers can list items like high-fructose corn syrup, honey, fruit syrup, molasses, and barley malt, and never use the word sugar.

Natural versus processed sugars in foods makes a big difference to our health. Our hunter-gatherer ancestors obtained the trivial amount of sugar they consumed mainly from fruits. However, they worked off the quickly absorbed calories because they constantly moved. Importantly, the sugars naturally present in fruit and milk, for example, come naturally laden with essential nutrients. Added sugar brings in nothing but calories. When added sugar calories are present in a person's diet, there is less room for nutrient-rich foods that can help to prevent serious chronic diseases. But this is only one half of the story.

Digestion is a demanding process requiring nutrients. According to Dr. Natasha Campbell-McBride, an apple naturally supplies the nutrients necessary to assist in its digestion; however, a fructose-containing processed food does not. Thus, your body has to sacrifice the meager nutrients it has if you are a processed food consumer, to digest that food, further exacerbating malnutrition. Your immune cells, just like the rest of the cells in your body, require nutrients to perform optimally. Deficiencies in nutrients caused by consuming empty calories may be the single biggest driver of the single most significant disease category in the developed world – chronic diseases.

"Sugar alone is not the cause of major health problems associated with its consumption. The lack of nutrients from consuming sugar rather than nutritious foods makes us vulnerable to disease."

- Thomas J. Lewis, Ph.D.

### **Harmful Oils**

Inflammation is the underlying driver of most chronic diseases. Two major drivers of inflammation are:

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1. High sugar consumption causes a lack of adequate micronutrients, and
2. Processed and inflammatory seed oil is artificially high in omega-6 fatty acids and unhealthy synthetic fats.

Omega-6 fatty acids from various sources, including seed oils, are crucial to health, as is a little sugar. However, when taken in excess or from chemically manufactured sources, thus not natural, the seed oils are very harmful to your health.

During the same period that consumption of refined sugars escalated, refined vegetable oil consumption skyrocketed to 20 percent of the calories Americans consumed. Before the advancement of technology in recent years, producing vegetable oils involved difficult and expensive processing. Steel express expellers and solvents capable of efficiently pulling oils from sweet corn on the cob are a relatively recent advancement. The problem faced from a marketing perspective is that these new oils were intended to replace butter, a solid oil product, but they were liquid, diminishing their acceptance. But the industry was motivated to overcome this problem because, like refined sugar, they were readily available and inexpensive, ensuring favorable profit margins.

Hydrogenation of vegetable and seed oils turned them into solids, and this process first became available around the turn of the 20<sup>th</sup> century. Hydrogenated oils are well known as trans fats or trans fatty acids. Peer-reviewed studies on health proved that these fats are detrimental to health. However, they were ubiquitous in the modern food supply 80 years before the information on adverse health became widely appreciated and disseminated. Humans did not have time to slowly adapt to the tremendous increase in intake of trans fats as the time frame from essentially no such oils in our diets to being well over 20 percent of our calories occurred in a scant three human generations.

### **Linoleic acid (LA)**

The harm to human health created by vegetable oils and the trans fatty acid versions is due to a high linoleic acid content (LA). LA is an omega-6 fatty acid. Omega-6 fatty acids, while an essential component of the makeup of specific cells, are highly pro-inflammatory in excess. Linoleic acid is the most abundant dietary polyunsaturated fatty acid (PUFA) and accounts for approximately 90 percent of dietary omega-6 PUFA intake.<sup>45</sup>

Confusion is abundant about vegetable and seed oils because the name of the anti-inflammatory omega-3 oil,  $\alpha$ -linolenic acid (ALA), is so close in spelling to the inflammatory one.

- A beneficial anti-inflammatory vegetable- and seed-based oil is  $\alpha$ -linolenic acid (ALA).

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- A potentially harmful pro-inflammatory vegetable- and seed-based oil is linoleic acid (LA).

The expression “the dose makes the poison and the cure” is apropos for any substance regarded as toxic or even beneficial at the right dose. That is why clichés like “too much of a good thing” are common in our culture. The discipline of toxicology, the study of the interaction of substances with human physiology, dates back thousands of years. Paracelsus, who lived in the 16<sup>th</sup> century, expressed the classic toxicology maxim,

"All things are poison, and nothing is without poison; the dosage alone makes it, so a thing is not poison."

The ubiquitous use and associated harm created by LA and processed soybean oil are related to its excessive use in processed and fried foods, with the latter being mainly in fast food restaurants. Soybean oil is the most common oil used in most restaurants. It turns up in large amounts in so-called healthy food items like salad dressings. When of my favorite foods is duck. I ordered a fried duck breast appetizer at a respected restaurant in Waynesville, NC. I asked the waitress what oil was used for frying the duck. The answer: soybean oil! Ugh. Duck is so fatty; I don't know why they could not use duck fat. Time is money is the most likely answer. It is a lot easier to dump soybean oil from a jug than to harvest duck fat.

Soybean oil, along with other vegetable and seed oils like canola, sunflower, grapeseed, corn, safflower, peanut, and rice bran oil, is loaded with omega-6 linoleic acid (LA), which acts as a metabolic poison when consumed in excess, as explained by Paracelsus. Anything over 10 grams per day is potentially toxic. Ten grams is a small quantity. Squeeze a serving of French fries from a fast-food restaurant, and over 30 grams will be obtained. About 20-25 percent of the mass of a cooked French fry will be oil. An order of large fries weighs about 150 grams and contains 30-40 grams of oil. One tablespoon of oil is about 15 grams. Is anyone open to swallowing two tablespoons of soybean oil? The answer is a decided "yes" when it is hidden in our foods.

Seed oils are processed. Thus, these products used in foods are not natural. Drugs are synthesized substances; in some ways, the common seed oils should be viewed as drugs, not as foods. The definition of food varies depending on the source. The Oxford dictionary defines food as,

“Any nutritious substance that people or animals eat or drink or that plants absorb to maintain life and growth.”

Britannica defines food as

“A substance consisting essentially of protein, carbohydrate, fat, and other nutrients used in the body of an organism to sustain growth and vital processes and to furnish energy.”

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Soybean and other oils technically meet the definition of food and can be included in our food supply. However, the FDA has considered the term "natural" to mean that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food." Thus, these oils, all of which are highly processed and modified, cannot be considered natural, whereas avocado oil and butter are.

Seed oils are pro-inflammatory and drive oxidative stress. Soybean oil has been shown to cause irreversible genetic changes in the brains of mice.<sup>46</sup> This is true for unmodified soybean oil and soybean oil modified to be low in the dangerous LA-containing product. Both produce pronounced effects on the hypothalamus, which regulates metabolism and stress responses emanating from the brain.

Several genes in the mice fed soybean oil were not functioning correctly, including a gene that produces oxytocin, the "love hormone." About 100 other genes also were shown to be affected. Any changes to the brain with a "drug" often lead to toxicity and disease.

The label of any oil product, including olive oil and avocado oils, must be scrutinized as they are commonly adulterated with cheaper seed oils, and even pure olive oil is loaded with LA. Additionally, be aware of the LA content in oils considered pure, independent of added cheap oils. Table 3 lists the linoleic acid oil content in various foods. Many of the oils on this list are not processed and are preferred over modified soybean and other vegetable oils. We need some LA in our diet because omega-6 fatty acids constitute the "lipid" portion of cell membranes. However, if you consume processed and fried restaurant foods, LA's total "dose" may be too high and thus harmful.

<b>Oil Type</b>	<b>% Linoleic acid</b>
Safflower oil	78%
Grape seed oil	73%
Poppy seed oil	70%
Sunflower oil	68%
Hemp oil	60%
Corn oil	59%
Wheat germ oil	55%
Cottonseed oil	54%
Soybean oil	51%
Walnut oil	51%
Sesame oil	45%
Rice bran oil	39%
Pistachio oil	33%
Peanut oil	32%
Canola oil	21%
Egg yolk	16%
Linseed oil	15%
Lard	10%

<b>Oil Type</b>	<b>% Linoleic acid</b>
Olive oil	10%
Palm oil	10%
Cocoa butter	3%
Macadamia oil	2%
Butter	2%
Coconut oil	2%
Avocado oil	2% - 17%

Table 3. List of oils and their linoleic acid (LA) oil content by percent.

To add to the confusion on LA, the scientific community is uncertain about the proper intake of this fatty acid. An article on this topic is appropriately named “Linoleic Acid: A Nutritional Quandary.”<sup>47</sup> The abstract is reproduced here:

“Over the course of the twentieth century, there was a 20-fold increase in consumption of vegetable oils resulting both from their increased availability and from recommendations to consume these oils to lower blood cholesterol levels. This dietary change markedly increased linoleic acid consumption to current levels of approximately 6 percent of total dietary energy. While considerable research has focused on the effects of dietary linoleic acid on cardiovascular health, questions about optimum dietary levels remain. For example, meta-analyses disagree about the role of dietary linoleic acid in atherosclerosis. Recent publications indicate that linoleic acid’s reduction of blood cholesterol levels does not predict its effect on the development of atherosclerosis. Further, there are also detrimental effects of elevated dietary linoleic acid on human health related to its role in inflammation and its activity as a promoter of cancer in animals.”

At the proper levels, unadulterated LA is essential for human health. After all, it is a lipid, and the membranes of all cells are composed of the phospholipid bilayer, and a lipid that constitutes this bilayer is LA. The best suggestion is to consume foods on the list above in moderation and avoid fried foods and any modified oil, especially soybean oil. Grocery shelves are loaded with LA oil-containing products. In the peer-reviewed publication titled “Linolenic Acid,”<sup>48</sup> Whelan et al. state:

“Linoleic acid is the most highly consumed PUFA in the human diet. On consumption, linoleic acid has four primary fates. Like all fatty acids, they can be used as an energy source. It can be esterified to form neutral and polar lipids such as phospholipids, triacylglycerols, and cholesterol esters. As part of membrane phospholipids, linoleic acid functions as a structural component to maintaining a certain level of membrane fluidity of the transdermal water barrier of the epidermis. In addition, when released from membrane phospholipids, it can be enzymatically oxidized to various derivatives involved in cell signaling.”

Soybean oil and partially hydrogenated soybean oil contain substantial amounts of trans fat linked to heart disease. Consumption and digestion of this oil lead to harmful metabolites called advanced lipid oxidation end products (ALEs) and oxidized LA metabolites (OXLAMs) that can cause significant damage at the cellular level. For example, an ALE called 4HNE is a mutagen (causes genetic mutations) known to cause DNA damage. Studies have shown a definite correlation between elevated levels of 4HNE and heart failure.

Harvard Medical School weighs in on the dangers of trans fats in an article titled “The truth about fats: the good, the bad, and the in-between.”<sup>49</sup>

“For decades, fat was a four-letter word. We were urged to banish it from our diets whenever possible. We switched to low-fat foods. But the shift didn't make us healthier, probably because we cut back on healthy and harmful fats. You may wonder if it isn't fat bad for you, but your body needs ample fat from food. It's a major source of energy. It helps you absorb some vitamins and minerals. Fat is needed to build cell membranes, the vital exterior of each cell, and the sheaths surrounding nerves. It is essential for blood clotting, muscle movement, and reducing inflammation. For long-term health, some fats are better than others. Good fats include saturated, monounsaturated, and polyunsaturated fats. Bad ones include industrial-made trans fats.”

Trans fats have no known health benefits, and there is no safe level of consumption. Therefore, they have been officially banned in the United States and were banned in European countries years before this occurred in the United States. Early in the 20th century, trans fats were found mainly in solid margarine and vegetable shortening. As food makers learned new ways to use hydrogenated vegetable oils, they appeared in everything from commercial cookies and pastries to fast-food French fries. Eating foods rich in trans fats increases the quantity of blood levels of C-reactive protein, a marker of inflammation that is linked to heart disease, stroke, diabetes, and other chronic conditions. They contribute to insulin resistance, which increases the risk of developing type 2 diabetes. Even small amounts of trans fats can harm health: for every 2 percent of calories from trans fats consumed daily, the risk of heart disease rises by 23 percent.<sup>50</sup> Fortunately, these types of fats are removed from our food supply, but not entirely.

### **Saturated Fats**

In the ancestral diet, there were no dairy products. No one approached a wild animal and attempted to extract milk. Today, after the domestication of animals, 10 percent of calories consumed are from dairy. The first evidence of dairy consumption date to about 9,000 years ago. The fats in dairy are primarily saturated. Since the 1950s, based on an incomplete, flawed report by Ancel Keys, saturated fats have become demonized as an alleged cause of heart disease. However, that opinion, initially accepted globally, has slowly eroded. But leave

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it to the U.S., and the American Heart Association (AHA) in 2017, to issue a warning about coconut oil, a source of mostly saturated fat, as a cause of heart disease. Coconut oil has gained a considerable following since the beginning of the 21<sup>st</sup> century. After the AHA warning, many people began to question using coconut oil. And the warning was not based on studies but simply on the basis that coconut oil is rich in saturated fats. There were no studies referenced in the AHA warning. Coconut oil contains saturated fats. Therefore, it is bad - period.

Dr. Fabian Dayrit wrote a passionate response to the actions of the AHA that was published in a scientific journal.<sup>51</sup> The article's title is “The Warning on Saturated Fat: From Defective Experiments to Defective Guidelines.”

"Coconut oil has been adversely affected by the current dietary guidelines that advocate lowering total fat and replacing saturated fat with polyunsaturated fat. This recommendation originates from the saturated fat-cholesterol-heart disease hypothesis that Ancel Keys first proposed in 1957. This hypothesis became an official recommendation with the publication of the Dietary Guidelines for Americans in 1980 and has been adopted by many other countries and international agencies. The dietary recommendations also warn against coconut oil.

Recently, the American Heart Association re-issued this warning in its 2017 Presidential Advisory. However, a critical review of the experiments that Keys conducted has revealed experimental errors and biases that cast serious doubt on the correctness of his hypothesis and the warnings against coconut oil. Further, the recommendation to decrease saturated fat effectively means increasing unsaturated fat in the diet. The result has been increased omega-6 fats and a high omega-6 to omega-3 fat ratio. This unhealthy ratio has been linked to heart disease, the disease that the AHA wants to target, and cancer and inflammatory diseases. Defective experiments have led to faulty guidelines.”

The term “The French Paradox” is known in medical research circles. This apparent paradox is that French people live much longer than Americans and have one-third the heart disease. Yet, they consume the most saturated fats compared to any developed nation and twice the amount compared to Americans. Additionally, they smoke at twice the rate of Americans. Essentially, they do many things in complete opposition to what the American Heart Association says is “heart friendly.”

The French Paradox is easy to explain by doctors who practice “root-cause” medicine and turns out not to be a paradox after all. Healthy fats are protective against inflammation, and saturated fats – chemically the most stable form of dietary fats – cannot drive inflammation or oxidative stress due to their stability. A paper titled “Dietary patterns in the French adult population” provides a credible summary of the many health-enhancing attributes of the French lifestyle,

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some of which are attributable to high saturated fat intake.<sup>52</sup> Only about 13 percent of the French population, mostly younger people, subscribe to a Standard American Diet (SAD) high in sugars and low in healthy fats. The attributes common to the other 87 percent of the French are:

- They consume full-fat foods.
- They do not have a reliance on processed foods.
- They eat fish regularly.
- They imbibe wine modestly and regularly.
- Consume fresh foods without preservatives.
- Snacks are much healthier compared to American counterparts.
- The French do not provide subsidies for junk food constituents.
- Basic foods are consistently consumed, including cheese, eggs, potatoes (with sauces including butter), butter, yogurt (full fat – not processed), animal fat, organ meats, and bread without preservatives. Note that dairy, eggs, and organ meats are high in menaquinone (K2), which activates proteins to chelate calcium from soft tissue.<sup>53</sup>
- Smoking is a social and less addictive behavior.
- Grains, advertised as heart-healthy in the United States, are not a big part of the French diet (sorry, Mr. Quaker).
- Bread is fresh and not high in gluten, like in the United States, where wheat is genetically modified for shelf life. French bread is stale by noon.

Have you been to a French boulangerie? The French consume bread with lots of butter. But if you arrive at the boulangerie afternoon, the entire product is gone, except for a few sticks of bread that are too stale to consume. Their bread is very low in gluten compared to that produced in the United States and quickly becomes stale. American bread stays pseudo-fresh for weeks. This is not natural.

Indeed, adopting French eating habits in the United States will improve health, but there is slightly more to it than is captured in these bullets. There is a complete absence of commercially grown GMOs in French agriculture.<sup>54</sup> Although there is industrial farming, many farmers have decided to use traditional techniques and banned glyphosate, a known toxic herbicide.

The French eat micronutrient-dense meats, with Pâté (liver and other organ meats) being a staple. The French government banned sales of beef parts susceptible to diseases, like brains and spinal cords, for human consumption in 1996, but “exotica” animal body parts are once again becoming chic. According to the “Offal-Eater’s Handbook,”<sup>55</sup>

“Among Europeans, at least, no one relishes organs more than the French, and their restaurants in the States tend not to shrink from serving them. Don’t forget; it was the French who invented foie gras, an intense liver

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preparation that involves forcibly cramming provender down the throat of a goose.”

Few Americans are up to this dietary challenge but often suffer from the consequences of micronutrient deficiencies.

Another fascinating observation about the French is their smoking addiction. Twenty-eight percent of French adults smoked in 2020 compared to 14 percent of American adults. And French smoking controls are relatively new, meaning that heart disease statistics are based on even higher rates of French smokers. We know smoking is a significant risk for inflammation and heart disease. This provides anecdotal evidence that having many healthy habits may counteract the adverse effects of a single risk. Our bodies are in a constant state of repair. Abundant micronutrients - like the French consume - help with that repair process and keep them ahead of decay caused by a few bad habits.

Cheese consumption is another food vice of the French, according to the AHA. In general, the saturated fat content of cheese is 5-6 grams per ounce or roughly 20 percent of the food. The French top the list of most prolific cheese-consuming nations, with an amount consumed almost double compared to United States citizens. Interestingly, the strong correlation between cheese consumption, life expectancy, and coronary heart disease death rates is precisely the opposite of what the AHA promotes based on the saturated fat content of cheeses, Figure 3.3.

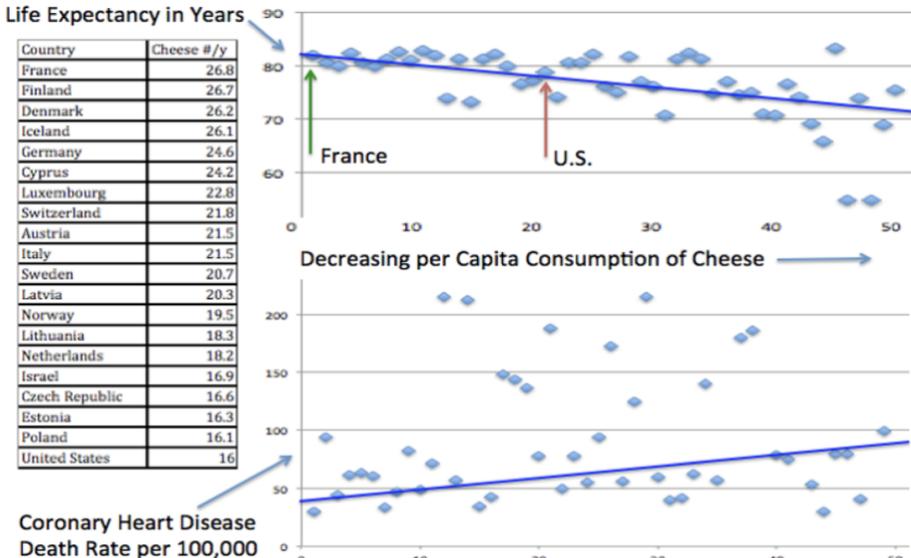


Figure 3.3: National Cheese consumption, life expectancy, and death rates due to coronary heart disease.

The trend is apparent, eat more cheese, live longer, and decrease mortality from coronary heart disease. Will someone please inform the AHA that France, a

country of 67,000,000 people, provides much better health data than the 6,000-person Framingham study with “selected” data used to draw the conclusions authorities want? The Framingham study and the Keys report started the entire low-fat trend in the United States, and our national health has consistently deteriorated since that time.<sup>56</sup>

The real reason for the so-called French Paradox is that the French consistently enjoy a wide range of good healthful foods and beverages as staples, including saturated fats and high nutrient-containing organ meats. And, they are not a paradox compared to other nations, the citizens of which consume healthy, whole food diets like Korea and Japan. The people of these nations all enjoy the same low cardiovascular disease mortality rates at ~28 deaths per 100-person years compared to the U.S. at ~77 deaths on that same scale.

The “American Paradox” is real, while the “French Paradox” is a fabricated concept. The French are remarkably similar to other developed nations that enjoy good health, like Finland, German, Japan, Spain, and many more. In fact, it is the U.S. that is the outlier. The Organization of Economic Cooperation and Development (OECD)<sup>2</sup> compiles data, including health statistics, on the 36 most developed nations on the planet. America ranks near the bottom in health but first in spending per capita by a wide margin. The most important health attribute is a long life. And the benefit of long life is a longer “health span.” People who live to 100 experience a lifespan of 20 years over someone who passes at 80, but their health span is 30 years longer.<sup>57</sup> Thus, the most important statistic for root-cause doctors is longevity.

Life expectancy for the U.S. population in 2015 was 78.8 years, a decrease of 0.1 years from 2014.<sup>58</sup> Fish and fermented food-eating countries like Korea are seeing steady and significant increases in longevity. The article, “Future life expectancy in 35 industrialized countries: projections with a Bayesian model ensemble,” published in *Lancet*<sup>59</sup>, indicate that women in South Korea, France, Spain, and Japan have a high probability of living to 90, on average. American women die seven years sooner compared to their Japanese counterparts. Of the 35 countries studied by the OECD, the USA, Greece, Macedonia, and Serbia have some of the lowest projected life expectancy gains for both men and women. These countries are seeing a decrease in overall longevity, despite heroic and expensive end-of-life interventions common in the U.S.

The “Food Pyramid”<sup>60</sup> and the more recent incarnation, “My Plate”<sup>61</sup>, were the marketing platforms that fostered the erroneous low-fat dogma that indoctrinated our children about the presumed hazards of fat in the diet. These policy recommendations led to a continuing trend of increasing levels of chronic diseases, now suffered by at least 60 percent of our adult population.

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<sup>2</sup> <http://www.oecd.org/els/health-systems/health-data.htm>

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Americans must face the facts. Citizens of the United States are among the least healthy in the developed world. While individuals are ultimately to blame for their choices, the healthcare system and the Federal Government are the root cause of this health catastrophe. The narrative must change to the “American Paradox” that is captured in the following statement:

“America has the worst chronic health outcomes and the highest medical costs compared to thirty-five developed nations - by far.”

- Thomas J. Lewis, Ph.D.

"Let food be thy medicine"

– Hippocrates

### Missing Nutrients

**Summary:** Our foods are deficient in nutrients. Several essential nutrients are seldom discussed by healthcare providers, including those that are more functionally oriented. Some key nutrients that are largely ignored and often present in foods at inadequate levels are discussed.

#### **Boron**

Do you have osteoporosis, joint pain, arthritis, or another bone disease? Has your doctor performed a bone scan and recommended Fosamax because of low bone density? If so, do you have a Fosamax deficiency, or is it something else?

Boron is an underappreciated nutrient that plays a vital role in bone and teeth health. It is classified as an essential micronutrient meaning your body does not produce it. Thus, you have to consume boron daily. And boron is needed in our bodies at relatively high concentrations, so it is not a micronutrient by definition. The need for boron is similar to magnesium, chloride, sodium, potassium, and calcium. Boron is found in the body at particularly high levels in the parathyroid glands.

Boron, in nature, is found in trace quantities. Plants do concentrate boron to some degree, as this nutrient is essential to plant growth. I first learned about the need for boron from gardeners. Foods highest in boron include apples, plums, grapes, avocados, vegetables, nuts, and legumes. But boron levels are often low in foods including these listed, depending upon where you live, leading to physiological insufficiencies in many of us. For example, apples are considered to be a good source of boron. However, to attain the minimum 3 mg daily intake of boron that is generally suggested, about eight apples must be eaten daily. This nutrient needs to be supplemented unless you can determine that the foods and water you access have reasonable levels of boron. Blood testing for boron is available but has yet to be performed commonly.

**Boron Quick Facts:**

- supports parathyroid health;

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- helps calcium absorption and balance;
- reduces the risk of arthritis; and
- reduces the risk of osteoporosis.

The parathyroid glands' primary function is tightly controlled calcium levels in the bloodstream. Calcium levels are generally very stable when boron is available in sufficient amounts. Calcium must be balanced to ensure that the nervous system and the body's muscles work correctly and that boney substances remain strong. Calcium management is vital as too much calcium in the bloodstream can lead to the hardening of the arteries, also known as atherosclerosis.

The main target organs where the parathyroid hormone exerts its effects are the bones and the kidneys. When calcium levels are low, parathyroid hormones are released by the parathyroid glands into the blood, causing bones to release calcium and increase levels in the bloodstream. It does this to keep your heart beating. It also causes the kidneys to stop calcium from being lost in the urine and stimulate the kidneys to increase vitamin D metabolism. Boron prevents vitamin D deficiency by increasing its biological half-life, meaning it prolongs the time vitamin D stays in your body in a functional form.

Boron is a regulator of vitamin D and calcium.

Boron must be consumed in food daily as it has a half-life of 21 hours which means it is being excreted quickly. As with any substance, the dose makes the poison and the cure. The lethal dose of boron is thought to be about 15 to 20 grams. In many areas of the world, the level of boron in food and water is negligible. It is not detrimental at low concentrations but certainly is harmful because it is needed to regulate calcium.

The Mojave Desert, parts of China, Tibet, Jerusalem, and Turkey are regions high in soil boron levels. In these places, boron intake may be as high as 130 milligrams per day. Compare this value to the 3-6 mg recommended daily by knowledgeable functional doctors. The FDA does not have a boron-recommended daily allowance (RDA).<sup>62</sup> Go figure.

Interestingly, Jamaica has very little boron and has high incidences of arthritis in adults. Boron intake in Turkey is the most well-studied. There, specific water sources have about 30 milligrams of boron per liter. On average, people consume two liters of water or 60 milligrams of boron. Interestingly, the citizens of Turkey have very low incidences of arthritis in contrast to Jamaica, where the estimated incidence is 70 percent. Contrast that to the United States, where boron intake is <3 Milligrams/day, on average, and the incidence of arthritis is around 20 percent.<sup>63</sup> Based on population studies, the optimal boron intake is between 10 and 30 milligrams per day.

Historically, natural boron spas have been used as therapy for arthritis. New Zealand is one country where spas known to be high in boron were noted as being

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able to help people overcome arthritis. Some of the hot springs contain substantial amounts of boron in the water.<sup>64</sup> Table 1 provides estimates of boron intake and the incidence of arthritis in various regions.

Country	Estimated intake of B [mg/day]	Appr.ox arthritis incidence [% arthritis]
Jamaica	<1	70
Mauritius	<1	50
Fiji (Indians)	1	40
Fiji (Natives)	3-5	10
United States	1-2	20
United Kingdom	1-2	20
Australia	1-2	20
Transkei (rural Xhosa)	2-5	3
Transkei (urban Xhosa)	1-2	20
Australia (Carnarvon)	6-10	1
Israel	≥10	0.7
New Zealand (Ngawha)	>10	None

Table 1: Estimated boron intake by country and their approximated incidence of arthritis. There is a strong association between low boron intake and a high incidence of arthritis.

Boron is not just about the parathyroid gland and calcium homeostasis. It also has a regulatory role in at least 26 enzymes, including energy metabolism. Boron is also essential for plants, including the regulation of sugar transport. Boron, in nature, is what helps plants become sweeter. Did you ever bite into a carrot, and it tasted like wood, but another one was sweet? Boron levels in the soil may be the explanation for the difference.<sup>65</sup> Additionally, boron improves the uptake of other nutrients by plants. It is involved in the growth of hairy roots, the little tentacles that extend into the soil like capillary blood vessels, finding and absorbing nutrients in the ground.

Boron helps to reduce inflammation. Proof of this is its effect on arthritis, an inflammatory disease. Early medicinal scientists understood the concept of inflammation and joint pain, and they provided patients with the bark of the willow tree from which aspirin is made. They also used the borage plant. In the 1930s, it was determined that this plant concentrates boron from the soil, which was the anti-inflammatory constituent. The American Indian witch doctors knew about this long before it was determined that joint pain is partially a boron insufficiency.

Tooth loss is due to jaw bone decay supporting the teeth' roots. Boron supports bone health, repairs tooth enamel, and may be applied in tooth tissue re-engineering.

Boron at sufficient levels improves wound healing. A study titled "Treatment of deep wounds with loss of tissue. Value of a 3 percent boric acid solution"<sup>66</sup>

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showed that a dilute boric acid treatment on deep wounds reduced the overall healing time by two-thirds. Since that publication, further research shows that boron helps wounds through specific action on the most common enzymes in animal tissues: collagenase, alkaline phosphatase, and elastase.

Additionally, boron activates osteoblasts<sup>3</sup> in the bones and fibroblasts<sup>4</sup> in the skin and tissues.

Interestingly, there is emerging evidence that boron has some effect on lowering prostate cancer incidence. This illustrates the diversity of the biological effects of boron. Life Extension magazine has followed the research on boron as a protective agent in prostate cancer. Their November 2015 article titled "Boron Reduces Prostate Cancer Risk" is reproduced, in part, here. The report was scientifically reviewed by Dr. Gary Gonzalez, MD, in May 2022 and written by: Michael Downey.

"Compelling evidence indicates that the trace mineral boron plays an important role in protecting men against deadly prostate cancer by selectively killing prostate cancer cells while leaving healthy cells unharmed. Adequate boron levels are associated with a 64 percent reduced risk of prostate cancer and a reduction in PSA levels.

Compelling evidence accumulates that the trace mineral boron protects men against deadly prostate cancer.<sup>67, 68, 69</sup> As men grow older, their risk for prostate cancer skyrockets, and metastasis outside the prostate is "uniformly lethal." Fortunately, eye-opening studies demonstrate that boron has been found to kill prostate cancer cells while leaving healthy cells unharmed selectively.<sup>70</sup> Also, boron has been found to lower PSA, which was previously believed to be only a marker for prostate cancer. More recent research shows that elevated PSA is a causative factor in prostate cancer progression.

Adequate boron levels are associated with a 64 percent reduced risk of prostate cancer, but obtaining protective levels of boron from food alone is difficult.<sup>71</sup> This means that supplementation with low-cost boron could be a lifesaver for aging males at risk for prostate cancer and other health benefits provided by this vital mineral.

### **Boron Preferentially Targets Prostate Cancer Cells**

"The idea that supplemental use of boron might reduce the risk of prostate cancer was first brought to the attention of scientists following a 2001 study

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<sup>3</sup> An Osteoblast is a specialized mesenchymal cell that synthesizes bone matrix and coordinates the mineralization of the skeleton

<sup>4</sup> A fibroblast is a type of cell that contributes to the formation of connective tissue, a fibrous cellular material that supports and connects other tissues or organs in the body. Fibroblasts secrete collagen proteins that help maintain the structural framework of tissues.

on dietary patterns of prostate cancer patients as reported long ago in *Life Extension* magazine. This study compared the diets of 76 prostate cancer patients with 7,651 men without cancer. Researchers found that men who ingested the greatest amount of boron from their diets were 64 percent less likely to develop prostate cancer than those who consumed the least.

Interestingly, while there was a significant decrease in cancer risk in the group that consumed the most boron, those in the highest intake group only consumed 2.5 additional servings of fruit and one additional serving of nuts per day compared to those in the lowest boron intake group.

A subsequent study confirmed these findings. The researchers compared the dietary boron intake of 95 prostate cancer patients with 8,720 healthy male controls. Researchers controlled for age, race, education, smoking, body mass index, dietary caloric intake, and alcohol consumption. They found that men with the highest boron intake showed a substantially lower risk of prostate cancer than those with the lowest intake.<sup>72</sup> Also, they noted that increased dietary boron intake was associated with a decreased risk of prostate cancer in a dose-response manner.

These findings not only underscored the remarkable, broad-spectrum health benefits associated with consuming fruits but also suggested that boron may be responsible for some of these protective benefits. Encouraged by these epidemiological findings showing a connection between dietary intake of boron and reduced risk for prostate cancer, scientists set out to determine if supplementing with boron could protect against prostate cancer. Initial animal studies indicate that the answer is yes.

In a validated animal model of prostate cancer, researchers found that oral administration of various concentrations of a boron-containing solution substantially decreased tumor size. It also lowered levels of prostate-specific antigen or PSA—the most abundant protein synthesized in the prostate gland—suggesting a possible mechanism for these anticancer effects.<sup>73</sup> In this animal model, researchers orally administered various concentrations of a boron-containing solution to test subjects and found that this decreased prostate tumor size by 25 percent to 38 percent. Remarkably, PSA levels dropped by an astounding 86 percent to 89 percent in the animals that received boron.

These findings suggested that supplemental boron may have both preventive and therapeutic effects, helping shrink prostate tumors and decrease levels of PSA."

### **Boron: Novel Protective Mechanisms**

"The finding that supplemental boron can help shrink prostate tumors while decreasing levels of PSA is particularly exciting. At one time, PSA was

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viewed primarily as a blood indicator of prostate cancer, infection, or inflammation. However, evidence now reveals that PSA plays a critical role in the progression and metastasis of prostate cancer, thus opening up new therapeutic pathways for preventing and treating this epidemic disease with PSA-lowering nutrients such as boron.

Scientists now believe that elevated PSA breaks down the protein surrounding the cells (called the extra-cellular protein matrix) within the prostate gland. The breakdown of these cellular barriers by excess PSA may be what enables prostate cancer cells to more readily invade healthy tissue and spread themselves beyond the prostate gland, with potentially lethal consequences.<sup>74</sup> This remarkable data provides further understanding as to how we may prevent or slow down prostate cancer by reducing PSA levels. Published evidence further suggests that higher intake of boron-containing compounds can inhibit PSA activity and lower the risk of prostate cancer by reducing intracellular calcium signals and storage."<sup>75</sup>

An excellent article that explains the importance of boron in agriculture is titled "Boron the Mighty Micronutrient!."<sup>76</sup> It explains that boron deficiency in soils is widespread in North America.

"Boron is one of the 17 essential nutrients (considering cobalt as an essential nutrient). Continuous/aggressive cropping with high-yielding varieties, without additions of micronutrients, including boron, leads to increased micronutrient deficiencies in crop plants. Boron deficiency is fairly widespread in North America. Response to boron application has been reported from at least 43 states in the USA and throughout Canada.

- it is required in small amounts in the plant's tissue, and
- it is removed in small amounts by crop plants from soils
- its deficiency in soils and crops can cause serious physiological damage, retard plant growth and substantially reduce crop yields even when other nutrients are applied in sufficient quantities. The deficiency symptoms of boron are not readily seen in crop plants. For example, in legumes, boron deficiency, without any visible symptoms, can reduce the legumes seed yield by 40-50 percent."

Boron also has a role in brain health. James G. Penland is with the United States Department of Agriculture, Agricultural Research Service. He wrote an article titled "Dietary Boron, Brain Function, and Cognitive Performance" in 1994.<sup>77</sup>

"Although the trace element boron has yet to be recognized as an essential nutrient for humans, recent data from animal and human studies suggest that boron may be important for mineral metabolism and membrane function. To investigate further the functional role of boron, brain electrophysiology and cognitive performance was assessed in response to dietary manipulation of boron (0.25

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versus 3.25 mg boron/2000 kcal/day) in three studies with healthy older men and women.

Spectral analysis data showed the effects of dietary boron in two of the three studies. When the low boron intake was compared to the high intake, there was a significant increase in the proportion of low-frequency activity (of the brain) and a decrease in the proportion of higher-frequency activity (of the brain) in the low boron group, an effect often observed in response to general malnutrition and heavy metal toxicity.

Performance (e.g., response time) on various cognitive and psychomotor tasks also showed an effect of dietary boron. When contrasted with the high boron intake, low dietary boron resulted in significantly poorer performance on tasks emphasizing:

- manual dexterity;
- eye-hand coordination;
- attention;
- perception;
- encoding and short-term memory;
- and long-term memory.

Collectively, the data from these three studies indicate that boron may play a role in human brain function and cognitive performance and provide additional evidence that boron is an essential nutrient for humans. These studies provide converging evidence that relatively short periods (42-73 days) of restricted boron intake can affect brain function and cognitive performance in otherwise healthy older women and men."

"The Physiological Role of Boron on Health" is an extensive review of the importance of boron.<sup>78</sup> The section titles within this article, reproduced here, illustrate the diversity of the effects of boron on health. The section titles are:

- Occurrence, Source, and History of Boron;
- Requirement of Boron in Microorganisms and Plants;
- Role of Boron in Animals and Humans;
- Boron and Growth Performance;
- Boron and Meat Quality;
- Boron and Bone Development;
- Boron and Liver Functions;
- Boron and Embryonic Development;
- Boron and Brain Activity;
- Boron and Hormonal Effects;
- Boron and Wound Healing
- Boron and Oxidative Stress;

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- Boron and Anti-inflammatory or Immune Response;
- Boron and Cancer Treatment;
- Interaction of Boron with Other Nutrients;
- Metabolic Effects of Boron;
- Pharmacokinetics of Boron;
- Mechanism of Action for the Bioactivity of Boron;
- Toxic Effects of Boron.

As you can see, boron has pleiotropic properties (producing more than one effect). Considering rampant chronic diseases, many of which are potentially prevented or reversed by the various modes of action of boron, it makes sense to measure for and, if necessary, supplement with boron.

The conclusion of this article is reproduced here.

"Recent findings have reinforced the significance to the health of adequate boron status. The effects of boron are multiple and versatile, demanding further studies to elevate the benefits and lessen the hazards of this influential trace mineral. When administered at an effective dose, boron shows remarkable properties, and its nutritional value cannot be underestimated.

Experimental boron administration in animals and humans has marked improvement in immunity, antioxidative effects, growth, and embryonic development. Boron also facilitates improvements in brain function, hepatic development, osteoporosis, cancer therapy, and wound healing."

### **Organ Meats and Oils**

Cod liver oil (CLO) is the most important superfood you should take daily, and no, it is not disgusting to do so. Just do some root-cause analysis on your preconceived notions about taking it. Why do you think cod liver oil is repulsive? Is it the odor, taste, texture, past experiences, veganism, or a combination of all these factors?

There is no sense in talking about the benefits of CLO and other liver foods if you will not consume them. Europeans eat much greater amounts of organ meats compared to United States citizens. They also live longer - by 2.5 years on average - and pay only 40 percent of what Americans pay for healthcare. This is more than just an association. There is strong scientific evidence behind the anti-inflammatory value of fish oil and the anti-infective activity of vitamins A and D found in CLO. Other organ meats are highest in nutrient density which is key to rebuilding damaged tissue.

The liver generally has the highest nutrient density compared to any other food. Harvard University organic chemist Dr. Mathieu Lalonde created a scale that puts the liver at the top of the list for the Ancestral Health Symposium in 2012 that

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ranks foods according to their available nutrients. He used the essential nutrients as accepted by the USDA.<sup>79</sup> Therefore, if you want optimal health, you must eat liver. Here is how I got over my repugnance of beef liver. My objection was the taste, texture, and odor of liver and onions my mother made for my dad. I solved each of these by making pate or buying liverwurst. Here is my pate recipe:

- Start with fresh grass-fed beef liver ~1/4 pound, sliced into small pieces.
- Add fresh vegetables of all types, sliced and chopped ~3/4 pound. I use whatever is available at the time.
- Add all the ingredients in a saucepan with butter and coconut oil and simmer on low heat for about 20 minutes, covered. Add as many spices as you like, including; sage, turmeric, oregano, salt, pepper, ginger, and a Braggs Sea Kelp seasoning are my usual ones, but more is better as herbs and spices are very high in nutrient content.
- Toward the end of the simmering, add coconut milk to have more liquid which is necessary to create the right consistency of the pate.
- Let the mix cool, and then blend in a food processor. Add more coconut milk, as needed, to create a consistency similar to hummus.

The pate made this way freezes and thaws well for later use so you can make a big batch. Add something like salsa or another favorite condiment when you serve this. All objections I had are easily overcome, resulting in a highly nutritious meal that is low cost, easy to prepare, and easy to store for later use. Most importantly, it no longer tastes, feels, and smells like liver!

The objections to cod liver oil are even easier to overcome. Start with the liquid version, for which several high-quality brands are available. Have a meal, preferably dinner. Right after dinner, fill 1/2 of a shot glass full of cod liver oil liquid. This is about 15 grams. This is the minimum amount you want to combat serious diseases like arthritis, Alzheimer's, and eye diseases. Next, "shoot" the CLO and chase it with something acidic. The CLO is chemically a base, so taking in a little acid quickly neutralizes the flavor and rinses it down your throat. My preferred acid solution is diluted apple cider vinegar, kombucha, another fermented beverage, or a slice of grapefruit. Ta-da! The cod liver oil is consumed, and your tissues, particularly those of your brain and eyes, will thank you for years to come.

Today, we need to count our blessings because over 100 years ago, cod liver oil was much less palatable. The man with a fish on his back was the decal on cod liver oil bottles back in the day, Figure 4.1. It is also the name of an article describing the history of cod liver oil.<sup>80</sup>

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Figure 4.1: Cod liver oil from over 100 years ago. Compared to this product, modern cod liver oil is free from the oxidized oil responsible for foul taste and smell. Many modern cod liver oils are flavored to mask the mild odor of the oil.

In that article, the early manufacture of cod liver oil was described as "cut out the fish livers with gallbladders, throw them into barrels, and let them decompose. Fishermen often applied heat to extract the last bits of oil from the smelly, decaying mass." Reference was made to a pharmacist who wrote, "cod-liver oil was not a desirable article of consumption; indeed, to put the matter plainly, it was an abomination, and no one could have taken it willingly, even once, not to speak of day after day and month after month. Nevertheless, many people did take it, and the only reasonable explanation is that the oil must have given strikingly favorable results."

Cod liver oil must have given strikingly favorable results.

The method of "chasing" the cod liver oil with something more palatable is almost as ancient as cod liver oil itself. Some early ideas for taking this elixir included:

- mixing a little preserve for children, some fruit, a biscuit, or a drop of Bordeaux or Sherry wine;
- mixing into coffee, milk, or brandy;
- taking the oil with smoked herring, tomato ketchup, or in the froth of malted beverages; and
- Those with an "insurmountable aversion to the taste" could take the oil by enema.

People went to great lengths to take cod liver oil for a reason.

We have it good today with the highly refined and purified versions of cod liver oil widely available. Capsules overcome all issues with taste, odor, and texture. The only issue is potential reflux or other digestive issues that could cause the oil to come back up. However, as you will see, the truly beneficial amount of cod liver oil is at least 5 grams/day, with doses of up to 50 grams/day being used therapeutically in very ill patients. A capsule contains about 1 gram. The proper

dosing requires at least five capsules daily, with 15 being a common recommendation. The amount you should take depends upon many variables, including your omega-6 to omega-3 ratio.

### **Animal Liver and Other Organ Meats**

Surprising is the number of people who justify not consuming animal organs due to toxicity. This is more urban legend than fact. Populations and their good health show that organ meats are healthy. The French and most other European citizens eat approximately twice as much organ meats as United States Citizens. The French consume the most, smoke at twice the rate of Americans, yet live about three years longer. Protective nutrients, in part from organ meats, are part of the reason behind this divergence.

My Alma Mata, MIT, weighed in on organ meats in an article titled "Offal Good."<sup>81</sup> Here are some insights on organ meats from the world's top science and engineering school.

"Offal is nearly a whole class of food in itself, encompassing everything from an animal's heart, liver, lungs, and entrails to the tail, feet, and head, each part with its own unique and, yes, delicious flavors. The word "offal" actually comes from the Old English "off" and "fall," referring to the pieces that fall from an animal carcass during butchering. Various dictionaries refer to offal as "refuse" or "rubbish" or "waste parts," when in fact they have much to offer nutritionally and gustatorily."

"In much of the world, France, Italy, and China especially, the tradition of preparing organ meats reflects resourcefulness and economy on the cook's part, as nothing is wasted. While offal has never been a big hit in the U.S. (and it certainly does not help that the word is pronounced "awful"), viscera have gained a foothold in restaurants and kitchens in the past couple of years which attests to the broadening tastes of American diners as well as the savoriness of the offal dishes themselves. Most of this country's best chefs list offal as one of their favorite meals to cook and eat."

"With offal, the challenge is only in your head. So, before you summarily dismiss one of the most delicious foodstuffs animals have to offer, I urge you to give them a shot. Who knows, you might find them offal-ly tasty."

Chris Kresser, M.S., is a renowned expert and top educator in functional medicine and ancestral health and the New York Times-bestselling author of *The Paleo Cure*. He wrote an article titled "How to Eat More Organ Meats."<sup>82</sup> He admits he is inclined to avoid organ meats but recognizes their nutritional value. He gives recipes for heart, liver, and tongue. If you have not had tongue or heart, you are missing two more delicious and tender cuts of meat. And this has nothing to do with Shakespeare! Although classified as organ meat, these two should be in the muscle meat category. Is that enough to get you to try some?

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Kresser throws down the gauntlet in his conclusion, challenging people to be more adventurous in consuming organ meats. He stated, "Once you've started eating liver regularly, maybe you'll be interested in trying other unorthodox cuts of meat and less popular parts of the animal. Mark Sisson has written about eating heads, feet, tails, and everything in between. Perhaps you'll give tripe a try or attempt a kidney recipe. Maybe you'll even get the guts to try some of the more adventurous animal parts, such as "sweetbreads" (pancreas), blood, or maybe even "oysters" (testicles). No excuses... and no fear!"

The liver of any animal is the warehouse for the raw materials needed to rebuild tissue. According to the Hepatitis C Trust website<sup>83</sup>, "The liver acts as a storage site for some vitamins, minerals, and glucose. These provide a vital energy source for the body, which the liver transforms into glycogen for more efficient storage. The liver stores vitamins and minerals when lacking in the diet. It can store enough vitamin A and vitamin B12 for four years and enough vitamin D for four months."

Johns Hopkins School of Medicine has this to say about the liver.<sup>84</sup> "The liver regulates most chemical levels in the blood and excretes a bile product. This helps carry away waste products from the liver. All the blood leaving the stomach and intestines passes through the liver. The liver processes this blood, breaks down, balances, and creates the nutrients, and metabolizes drugs into easier forms for use by the body. More than 500 vital functions have been identified with the liver. Some of the more well-known functions include the following:

- Bile production helps carry away waste and break down fats in the small intestine during digestion.
- Production of certain proteins for blood plasma.
- Production of cholesterol and special proteins to help carry fats through the body.
- Conversion of excess glucose into glycogen for storage (glycogen can later be converted back to glucose for energy) and to balance and make glucose as needed.
- Regulation of blood levels of amino acids that form the building blocks of proteins.
- Hemoglobin is processed to use its iron content (the liver stores iron).
- Conversion of poisonous ammonia to urea (urea is an end product of protein metabolism and is excreted in the urine).
- In clearing the blood of drugs and other poisonous substances.
- In the regulation of blood clotting.
- Making of immune factors and removing bacteria from the bloodstream.
- Clearance of bilirubin, also from red blood cells. The skin and eyes turn yellow if there is an accumulation of bilirubin.

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The land animal liver is generally rich in water-soluble nutrients, while CLO and other marine animal livers tend to be higher in fat-soluble nutrients. We need to take in high levels of nutrients to be optimally healthy, and consuming organs from land and sea organisms is the best natural way to achieve this goal.

Micronutrients play a crucial role in the repair and recovery of tissue. This mechanism is arguably the most important process that sustains our good health. The liver, as a food, is at the top of the nutrient density list, as explained by Dr. Mat Lalonde. It makes sense when you look at how nutrients pass from the soil to foods. The soils provide the micronutrients necessary to build plants. The earth is the "gut" of the plant, and the gut of animals is their "soil." Here is the process:

1. Soil contains minerals and other micronutrients.
2. Plants require minerals and micronutrients to grow through the process of photosynthesis. Roots absorb nutrients and water from the soil. Plants also deliver substances to the soil to help break it down and become more bioabsorbable.<sup>85</sup>
3. The plant is mostly carbohydrate but has the micronutrients used to build its structure. The plant also synthesizes specific vitamins.<sup>86</sup>
4. Animals eat plants.
5. Humans, particularly Americans, eat the muscle meat of animals.
6. Most essential micronutrients are concentrated in the liver and other organs, not the muscle meat.
7. Americans have worse health when compared to other developed nations.

That is why this section begins with ways to consume more liver. Vegans can hate this concept, but our large brains are due to cooking and an omnivore style of eating. Proof, with an "n" of 1, is Michael Greger.

Beef liver has a particularly "strong" flavor and unusual texture that contribute to our reticence to consume it. Instead, try chicken or duck liver, both of which are much milder and easier for the neophyte to consume.

### **Medicinal Cod Liver Oil**

Cod liver oil gained popularity not as a snake oil but as a true medicinal. Historically, cod liver oil contributed to the resolution of serious diseases. Key examples include:

- Arthritis, dating back to the Viking era, where topical and internal intake improved the condition.
- Tuberculosis, in the 1800s, where very high intake reduced mortality by 50 percent.
- Rickets, a rampant bone disease prevalent at the turn of the 19th century, was all but eliminated by taking cod liver oil.

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The resolution of Rickets is the reason your grandmother or great-grandmother gave you or your mother and father cod liver oil.

In modern times, evidence-based solid studies show that taking cod liver oil improves many chronic conditions while enhancing overall health. Poignant examples include a reduction in early childhood mortality, blindness, and increases in IQ. It can help resolve these varied problems because, at their root, it is a surprising commonality. The fat-soluble vitamins and fatty acids in cod liver oil have immune-enhancing, anti-inflammatory, and antibiotic properties.

### **Cod Liver Oil and The Brain**

The omega-3 components of cod liver and fish oils profoundly impact brain wiring. The "3" of omega-3 fatty acids refer to the location of "unsaturation" in the long-chain fatty acid. The unsaturated part of the fatty acid chain is the reactive part of that molecule's backbone. The "6" of omega-6 fatty acid means that the "unsaturation" occurs at a different place along the fatty acid chain. The seemingly slight difference has significant consequences for brain function. Most publications on fish oils and brain health are not very scientific. Here are a few technical paragraphs explaining how vital these omega-3 fats are to brain health.<sup>87</sup>

"Omega-3 fatty acids have the potential to influence neurogenesis (growth of new brain cells) through at least two distinct mechanisms. First, omega-3 fatty acids are incorporated into neuronal membranes, which influence membrane proteins' structure, some of which act as transporters and receptors. They also can alter membrane fluidity, which is important for neurotransmitter binding and signaling within cells. For instance, lipid fluidity modulates the binding of serotonin to neuronal membranes. As serotonin stimulates neurogenesis, a change in the efficacy of this modulator could influence the levels of neuronal proliferation (replication and expansion). Therefore, omega-3 fatty acids may alter (enhance) the rate of neurogenesis via their contributions to the dynamic structure and function of neuronal membranes."

"Enhancing immune function is a second potential pathway by which these omega-3 fats may influence neurogenesis. For example, EPA (only concentrated in fish) inhibits the release of inflammatory substances. Omega-3 fatty acids also influence levels of neurotrophins, molecules that promote neuronal survival and growth. Neurotrophins are associated with improvement in neurogenesis and neuronal survival."

"These connections between the omega-3 fatty acids, inflammation, neurotrophins, and neurogenesis are also intriguing from the clinical perspective. Inflammation appears to play a potentially critical role in depressive illness. Stress can cause an elevation in inflammation. Therefore, the same molecules that regulate neurogenesis are also implicated in major

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depressive illness. Although there is inadequate data to make a conclusive statement regarding the functional relationship between neurogenesis and clinical depression, these associations suggest pathways by which omega-3 fatty acids may simultaneously influence neurogenesis and depressive illnesses."

A remarkable benefit of taking fish oil and cod liver oil is its impact on mood. Prison populations arguably are people with mood issues greater than the general population. And in some countries, they are accessible populations to study as long as the intervention is a "do no harm." There is evidence that prisoners consume diets lacking essential nutrients, which could adversely affect their behavior. As processed foods, low in nutrient density, have become more heavily consumed, many members of society, not just the prison population, experience substantial brain-related ailments.

One study on prisoners and essential fatty acids is titled "Influence of supplementary vitamins, minerals and essential fatty acids on the antisocial behavior of young adult prisoners: Randomized, placebo-controlled trial."<sup>88</sup> According to the authors,

"Both omega-6 and omega-3 essential fatty acids are deficient among violent offenders.<sup>89</sup> For this reason, an essential fatty acid supplement was also employed. 'Efamol Marine' provides omega-6 and omega-3 essential fatty acids without an obvious after-taste, a factor that could otherwise have compromised the blinded study. The daily dosage was four capsules providing 1260 mg linoleic acid, 160 mg gamma-linolenic acid, 80 mg eicosapentaenoic acid, and 44 mg docosahexaenoic acid. A vegetable oil-based placebo of identical color and clear placebo of identical color and clear gelatin shell was used."

This is interesting because it is not really a comparison between a test substance and a placebo. Instead, it is a comparison between plant-based oil and fish-based oils. Let's see what happened.

The authors concluded,

"This research strongly suggests that the effect of diet on antisocial behavior has been underestimated, and more attention should be paid to offenders' diets. It should be noted, however, that the current dietary standards by which dietary adequacy is judged barely consider behavior. Thus, having demonstrated an effect on antisocial behavior empirically, we are only at the start of understanding the potential of this intervention."

Someone with mood disorders should take cod liver oil at the dose that is effective at reducing the severity of Tuberculosis, which is 15 - 50 grams daily until the problem is resolved. See the section below.

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The Guardian magazine looked at the link between junk food and violence in an article written in 2006. It is titled "Omega-3, junk food and the link between violence and what we eat."<sup>90</sup> Here is a most interesting quote from the article.

"That Dwight Demar is able to sit in front of us, sober, calm, and employed, is "a miracle," he declares in the cadences of a prayer-meeting sinner. He has been rocking his 6-foot-2-inch bulk to and fro while delivering a confessional account of his past into the middle distance. He wants us to know what has saved him after 20 years on the streets: "My dome is working. They gave me some kind of pill, and I changed. Me, myself, and I, I changed.

Demar has been in and out of prison so many times he has lost count of his convictions. "Being drunk, being disorderly, trespass, assault and battery; you name it, I did it. How many times I been in jail? I don't know, I was locked up so much it was my second home.

Demar has been participating in a clinical trial at the US government's National Institutes for Health near Washington. The study investigates the effects of omega-3 fatty acid supplements on the brain, and the pills that have affected Demar's "miracle" are doses of fish oil."

### **Cod Liver Oil and Tuberculosis**

Tuberculosis is a severe and often fatal lung disease caused by the bacterium tubercle bacillum. Late-stage deadly tuberculosis infection is called "consumption." The name "consumption" describes the disease because it "consumed" the lungs. In the 1800s, consumption killed one in seven out of all people who lived. It was initially thought to be a disease of genetics, not infection, and many consumptive patients pursued relief in sanatoriums alongside leprosy patients. The belief was that rest and a healthful climate could change the course of the disease. The actual benefit was undoubtedly due to vitamin D production on the skin and melatonin production in the mitochondria at the high altitudes where UVB, red, and near-infrared exposure is higher compared to sea level.

In 1882, Robert Koch's discovery of the tubercle bacillum revealed that TB was infectious, highly contagious, and somewhat preventable through proper hygiene. As is usually the case with a new discovery, the medical community was slow to accept Koch's findings as deaths mounted. This continues to be a recurring story, with h-pylori, Lyme disease, and SARS-CoV-2 being examples. Cancer is also an example but is not often viewed as having an infectious component. When this connection is generally made, it will usher in an approach of prevention rather than waiting for and treating the tumor.

According to the Mayo Clinic, Tuberculosis, which should be eradicated entirely, has come back in the modern era.<sup>91</sup>

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"Tuberculosis (TB) is a potentially serious infectious disease that mainly affects the lungs. The bacteria that cause tuberculosis are spread from person to person through tiny droplets released into the air via coughs and sneezes.

Once rare in developed countries, tuberculosis infections began increasing in 1985, partly because of the emergence of HIV, the virus that causes AIDS. HIV weakens a person's immune system, so it can't fight the TB germs. In the United States, because of more robust control programs, tuberculosis began to decrease again in 1993. But it remains a concern.

Many tuberculosis strains resist the drugs most used to treat the disease. People with active tuberculosis must take many medications for months to eliminate the infection and prevent antibiotic resistance."

Cod liver oil, with its natural mixture of vitamins A and D, is a treatment for TB. Since TB is a highly virulent pathogen, cod liver oil is not a cure but significantly reduces morbidity and mortality. In a study carried out by physicians at the Hospital for Consumption in 1848 in England, 542 patients with the disease received standard treatment with added cod liver oil. These patients were compared with 535 'control' patients who received standard treatment alone, without cod liver oil.<sup>92</sup> The disease stabilized in 18 percent of the patients given cod liver oil compared with only 6 percent of those in the control group. That, in relative terms, is a 300 percent improvement. This is what modern drug companies would claim. However, in absolute terms, the real benefit was a 12 percent improvement. This is impressive considering the most prominent drug class in history, statins, have an aggregate net of ZERO percent benefit.

Deterioration or death occurred in 33 percent of patients given standard treatment alone but in only 19 percent of those given cod liver oil, an absolute reduction of 14 percent. Today the benefit of most drugs is given in relative statistics, so, for the sake of comparison, the relative reduction in deaths on cod liver oil was 74 percent. Using either statistic, the improvement in health outcomes afforded by cod liver oil was impressive.

Do you have asthma, COPD, a chronic cough, or other lung issues? If so, take high doses of cod liver oil. Do you want to live a long healthy life with an alert mind? If so, take high doses of cod liver oil. The right dose matters, however. When a drug company studies a new pharmaceutical, billions are spent on its approval. A substantial portion of those funds looks at dosing studies to find the level of the drug that provides the greatest statistical benefit. Many studies on fish oils, including cod liver oil, use an unscientific dose of 1 gram, and when the results are paltry, the conclusion is that fish oil provides no benefit. The TB study of the 19th century provides the proper dose based on the admirable outcomes. The 542 inpatients with consumption treated with cod liver oil were given a dose

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of 1 drachm (3.6 ml) three times a day, gradually increasing, in some cases, up to 1.5 ounces (42 ml) per dose.

The proper dose, based on the British study on Tuberculosis, is:

- Healthy people for health maintenance: 10 grams/day (2 teaspoons). This is equivalent to the lowest dose given to consumption patients - 3.6 ml (approximately 3.6 grams) three times per day. This is equivalent to 10 standard capsules of oil per day.
- For people with any type of lung issue, up to 124 grams per day (42 ml three times per day) is recommended. This is equivalent to 124 standard capsules per day.

Indeed, 124 grams per day is quite a lot of cod liver oil, but it sure beats having a chronic lung problem. This dose may provide too much vitamin A, which can express toxicity at levels that are too high. Also, fat-soluble substances can be stored in fat for months and possibly years, so taking them daily can lead to bioaccumulation. Dr. Trempe recommended 15 grams per day for people with glaucoma or macular degeneration and sometimes started these patients on 30 grams per day for the first month and then had them reduce the dose to 15 grams per day. In many instances, he had them drop their daily dosage to 5 grams/day after three months. Dr. Trempe, a true medical scientist, never guessed. He measured for vitamin A, D, and omega 3 and 6 levels in red blood cells and made his recommendation based on the test results.

### **Cod Liver Oil and Rickets**

The disease called Rickets, a painful disease of the bone, cured by cod liver oil, provides evidence that bone health is not just about calcium. Rickets is a disease of vitamin D deficiency and is thought to be rarely seen today. However, it is still a ubiquitous condition. At the turn of the 20th century, rickets was particularly rampant among the poor children living in industrialized and northern cities. Lack of exposure to sunshine was the cause and was and continues to be especially noted in people with high levels of skin pigmentation.

The popular belief is that rickets is just a bone or skeletal disease, easily fixed with vitamin D supplementation. However, there is also an extraskeletal component to Rickets that is deadly, while the skeletal component is debilitating. This extra skeletal feature includes seizures caused by a general lack of calcium absorption and a decrease in neurotransmitter release and muscle contraction facilitated by calcium. The other manifestation is cardiomyopathy which is a disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body. Cardiomyopathy is related to a calcium imbalance and can lead to heart failure. Now you may understand why Boron was the first missing nutrient discussed because it plays an even more primary role in calcium balance than cod liver oil.

"A Brief History of Nutritional Rickets"<sup>93</sup> explains how vitamin D deficiency causes heart and muscle problems. The key points made in the article include the following:

- An adequate serum concentration of Vitamin D is required for optimal absorption of calcium from the gastrointestinal tract.
- This vitamin D concentration or status is maintained by either production following ultraviolet B (UVB) irradiation of the skin, or
  - Supplementation/fortification as diet alone is unlikely to meet normal daily requirements.
- When Vitamin D deficiency occurs, calcium absorption is reduced, and furthermore, when accompanied by low dietary calcium intake can lead to total body calcium deficiency and compensatory hyperparathyroidism.
- Elevated parathyroid hormone concentrations result in low serum phosphate levels with resultant abnormal bone mineralization. Boron keeps the parathyroid hormone in balance, just like iodine maintains a healthy thyroid gland.
- Rickets is specific to children due to their open growth plates and results from a combination of poor mineralization of the primary and secondary spongiosa (bone) and the lack of chondrocyte terminal differentiation caused by hypophosphatasemia.
- There are multiple causes of rickets, but vitamin D deficiency, usually in concert with dietary calcium deficiency, is thought to be the leading cause, with an incidence of between 3 and 10/100,000.
- As calcium is essential for normal nerve and muscle function, low serum calcium, or a calcium imbalance, can result in neuromuscular excitability, which in severe cases can result in convulsions.
- Low calcium muscle problems can also manifest in cardiac problems and lead to death, but rarely.

Cod liver oil provides a superior form of vitamin D supplementation for Rickets prevention and for obtaining sufficient blood vitamin D levels. Vitamin D found in cod liver oil is similar to that made by photosynthesis on your skin and includes up to six different forms, not just vitamin D3. The exact nature of vitamin D in cod liver oil remains not well-defined. Vitamin D supplements contain the precursor solely to 25-hydroxyvitamin D that is produced in the liver. This version is actually considered an inactive form of vitamin D. However, it is converted to the active form, 1,25-dihydroxy vitamin D, in the kidneys, Figure 4.2.

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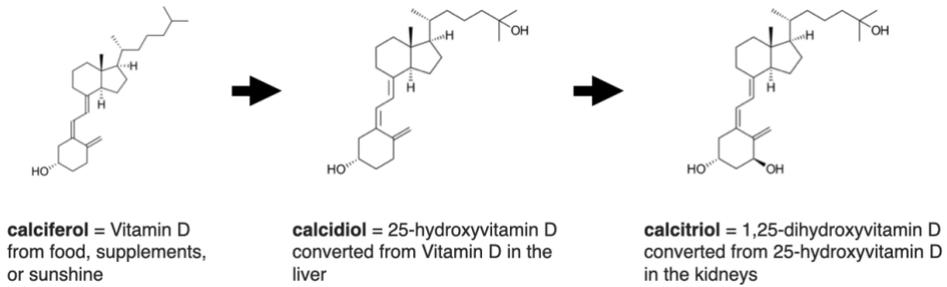


Figure 4.2 The conversion of vitamin D from external sources to the storage form, 25-hydroxyvitamin D, in the liver and finally to the active form, 1,25-dihydroxy vitamin D, in the kidneys.

Cod liver oil is reported to have some of the active forms of vitamin D not found in supplements. The active form of vitamin D in cod liver oil is available because the liver and kidneys of the cod fish possess the enzymes that convert the inactive form to the active form. In some respects, the vitamin D from cod liver oil may be better than that produced on your skin because the cod liver carries out the conversion for you. This is not scientifically proven at this time.

Harvard Medical School published an article titled "Vitamin D and your health: Breaking old rules, raising new hopes."<sup>94</sup> Here are some key excerpts from that article.

"Although vitamin D is firmly enshrined as one of the four fat-soluble vitamins, it is not technically a vitamin. True, it is essential for health, and only minuscule amounts are required. But it breaks the other rules for vitamins because it is produced in the human body, it is absent from natural foods except for fish and egg yolks, and even when it is obtained from foods, it must be transformed by the body before it can do any good."

"Vitamin D is not one chemical but many. The natural type is produced in the skin from a universally present form of cholesterol, 7-dehydrocholesterol. Sunlight is the key: It is ultraviolet B (UVB) energy that converts the precursor to vitamin D<sub>3</sub>. In contrast, most dietary supplements are manufactured by exposing a plant sterol to ultraviolet energy, thus producing vitamin D<sub>2</sub>. Because their function is almost identical, D<sub>2</sub> and D<sub>3</sub> are lumped together under the name vitamin D - but neither will function until the body works its magic."

"The first step is in the liver, where vitamin D picks up extra oxygen and hydrogen molecules to become 25-hydroxyvitamin D, or 25(OH)D. This is the chemical that doctors usually measure to diagnose vitamin D deficiencies. But although 25(OH)D is used for diagnosis, it cannot function until it travels to the kidney. There it acquires a final pair of oxygen and hydrogen molecules to become 1,25 dihydroxy vitamin D; scientists know

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this active form of the vitamin as 1,25(OH)<sub>2</sub>D, or calcitriol, but for ordinary folks, the name vitamin D is accurate enough."

"It used to be simple: just get a "healthy" tan, and your body will make all the vitamin D it needs. Desk jobs and sunscreen have changed all that, just as research is underlining the importance of vitamin D and suggesting its possible role in preventing many health problems. That makes vitamin D a dilemma of modern life that has a modern solution: eating fish and drinking some low-fat fortified milk, along with judicious doses of vitamin D supplements."

Ugh! Typical of Harvard to get most of it right and then revert back to a long-standing misinformation dogma. Drinking some low-fat fortified milk? Really? Dr. Trempe was a member of Harvard Medical School staff for 47 years, and he knew the right way to get vitamin D. He was recommending 15 grams of cod liver oil daily in the 1980s. He also knew the importance of sunshine, but people are actually more compliant with taking CLO.

### **Cod Liver Oil, Vitamin A, Eyes and, Childhood Mortality**

Dr. Alfred Sommers is an ophthalmologist, as was Dr. Trempe. They know things most of the rest of us do not know about the retina and vitamin A. Vitamin A is a mixture of retinal and retinol. Eye doctors study and treat the retina. Is there a coincidence in the similarity of the names?

Retina definition: "innermost coating of the back of the eyeball;" from Medieval Latin retina "the retina," probably from Vulgar Latin (tunica) retina, literally "net-like tunic," on resemblance to the network of blood vessels at the back of the eye, and ultimately from Latin rete "net." This definition shows how advanced our predecessors truly were. The choroid of the retina is filled with blood vessels that bring oxygen and nutrients to the eye, and it has the highest density of capillaries in the body. The eye, after all, works very hard converting light to electricity all day long.

Vitamin A is a mixture most commonly associated with beta-carotene. However, its true composition is a group of organic compounds that includes retinol, retinal (also known as retinaldehyde), retinoic acid, and several provitamin A carotenoids, most notably, but not exclusively, beta-carotene. Vitamin A deficiencies have specifically been linked to blindness, which is how the discovery of these retinoids came about. Ancient Egyptian, Greek, and medieval medicine have all shown evidence of using animal liver, where vitamin A is most abundant, to treat night blindness. Thus, vitamin A was named after the retina.

In general, everyone should obtain their vitamin A through cod liver oil because it is a food that contains many other important fat-soluble nutrients, several of which support the action of vitamin A and vitamin D. Yes, cod liver oil today is

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processed, but so is every supplement you obtain in pill, liquid, or capsule form. If you want the best cod liver oil, obtain cod livers rather than supplements.

Here is Dr. Sommer's story as told by his institution, Johns Hopkins School of Public Health. The article is titled "The Story of Dean Sommer and Vitamin A."<sup>95</sup>

"The landmark work on vitamin A by Alfred Sommer, MD, MHS, dean emeritus of the School of Public Health, has been credited with saving the lives of millions of children around the world. In 1976, Dr. Sommer, who had just finished his residency in ophthalmology at Johns Hopkins' Wilmer Institute, began a series of complex intervention trials in Indonesia that revealed that even mild vitamin A deficiency (VAD) dramatically increases childhood mortality rates, primarily because VAD reduces resistance to infectious diseases such as measles and diarrhea.

In fact, the survival of children randomized to vitamin A was so much greater than that of children not receiving vitamin A that many scientists considered the study flawed and the results too good to be true. Before Sommer undertook these studies, scientists knew that VAD could lead to blindness; they were unaware, however, that a vitamin A-deficient child faces a 25 percent greater risk of dying from a range of childhood ailments such as measles, malaria, or diarrhea. As a result of his research, night blindness is viewed not today as a mild, early sign of VAD but as evidence of late, severe deficiency.

To definitively prove the link between even mild VAD and pediatric mortality, Sommer and his colleagues ran a number of large-scale, community-based, randomized trials from 1983 through 1992. Keith West, Ph.D., professor of International Health and Ophthalmology; Joanne Katz, ScD, professor of International Health; and James Tielch, Ph.D., professor of International Health, among others still at the school, all played major roles.

Their work showed that ensuring adequate vitamin A intake can mitigate the effects of common diseases such as measles and diarrhea, reduce child mortality in at-risk populations by 23 to 34 percent to avert up to one million deaths a year, and prevent as many as 400,000 cases of childhood blindness each year. By 1992 the World Health Organization (WHO), UNICEF, the Food and Agriculture Organization of the United Nations, and the Convention on the Rights of Children had all declared the control of VAD a global goal.

Sommer and his team then set themselves the task of demonstrating that oral, high-dose, vitamin A supplementation—a treatment tailor-made for developing countries since it does not require a sterile injectable preparation—could effectively, quickly, and cheaply treat the debilitating

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consequences of VAD. As a result, the World Development Report (World Bank) declared vitamin A supplementation one of the most cost-effective of all health interventions.

With vitamin A capsules costing only 2 to 3 cents each, increasing vitamin A intake is now recognized as one of the most cost-effective public health interventions for child survival. The full cost of delivering the capsules to children ages six months to five years at six-month intervals is about 50 cents per child per year. Moreover, a World Bank study estimates that for every dollar invested in supplementation, more than \$100 would be returned in increased productivity associated with reduced childhood mortality, lower healthcare costs, and improved worker performance.

In 1995, out of 72 countries where VAD was prevalent, only six had adequate vitamin A supplementation rates. In 1998, the year the WHO and its major partners launched the Vitamin A Global Initiative, vitamin A supplements were delivered through national immunization days to more than 12 million vitamin A-deficient children in 40 countries.

Today, thanks in large part to Dr. Sommer's work, more than 40 countries are reaching the large majority of their children with at least one high-dose vitamin A supplement a year. UNICEF estimates that between 1998 and 2000, as many as 1 million child deaths may have been prevented because of this global vitamin A supplementation program. The most recent studies by Dr. Sommer and his colleagues have shown that supplementing women of childbearing age with vitamin A or beta-carotene reduces maternal mortality by an average of 45 percent by improving their resistance to infection and reducing anemia."

In the 1800s in the United States, up to 30 percent of children died before their first birthday, and 43 percent did not survive past their fifth birthday. If the child lived to ten, they still only had a 60 percent chance of surviving to adulthood. A small sampling of death records illustrates the common causes of death among children: consumption (tuberculosis), croup, whooping cough, smallpox, measles, cholera, typhus, typhoid fever, diphtheria, influenza, and scarlet fever. Every one of these diseases is infectious in nature. These are the types of conditions contributing to blindness and early childhood mortality that Dr. Sommers confronted head-on in the third world with vitamin A.

The important takeaway from this work is that vitamin A, the mixture, is a highly effective antibiotic. Early childhood blindness and the major eye diseases today are infectious diseases that vitamin A can help prevent and treat. However, cod liver oil which is rich in vitamin A has many other health-promoting substances making it the preferred source of vitamin A.

### **Brief History of Cod Liver Oil**

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The history of cod liver oil explains much about what we need to know about the benefits of cod liver oil, its production, and its dosage. An article titled "What the History of Cod Liver Oil Teaches Us About Omega-3 Potency"<sup>96</sup> produces an excellent summary and is reproduced here. It was written by Bo Martinsen, MD, an omega-3 specialist, innovator, and advocate for natural foods.

"In 1937, surgeon M. B. Daver noticed something odd while using cod liver oil to treat burns and pus-filled sores. "Crude" cod liver oil helped his patients heal quickly. But refined cod liver oil did not have the same wound-healing benefits. Did the refining process destroy the properties that made cod liver oil effective, Daver wondered and published his thoughts in a British Medical Journal memorandum.

Eighty years later, Daver's question is increasingly relevant. Omega-3s have evolved into a \$4 billion industry, including everything from natural liquid fish oils to refined prescription pills. These products differ wildly in their nutrient profiles, dosages, and even chemical makeups. Yet, they all usually get lumped together in reviews of omega-3 supplements."

Such generalizations make it confusing to read nutrition news. One week, headlines declared that fish oils have no heart health benefits and may even increase the risk of atrial fibrillation. The next week, studies show omega-3s fight cancer tumors. How can we make sense of the conflicting findings? To get a better understanding, let's take a closer look at fish oil's long history and how today's refining trends affect fish oil benefits.

Fish liver oil has a long history of medicinal use. In ancient Greece, Hippocrates described using dolphin liver oil to treat skin issues. The Vikings prized fish liver oil as "the gold of the ocean," thanks to its healing properties. Cod liver oil remained a popular folk remedy in Northern Europe for centuries. As early as 1782, English physicians began studying cod liver oil and prescribing it for rheumatism. During the 19th century, cod liver oil became a widely accepted treatment for rickets, tuberculosis, joint and muscle pain, and skin wounds.

Though cod liver oil was popular, 19th-century scientists did not understand why it worked. Did cod liver oil contain some special unknown ingredients? Were known components working together to deliver synergistic benefits? In the 1910s, biochemists thought they had found the answer when they discovered two essential nutrients in cod liver oil: vitamins A and D. Soon, scientists began extracting these vitamins from cod liver oil, believing them to be the sole reason for the oil's potent effects. In the 1940s, however, scientists began to wonder if cod liver oil offered something else besides the two fat-soluble vitamins. After all, in rat studies, other oils containing even more vitamins A and D did not prove as effective as cod liver oil.

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In the early 1970s, researchers Bang and Dyerberg seemed to uncover the missing puzzle piece. They determined that fish and fish oil contained two omega-3 fatty acids called eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Since their discovery, EPA and DHA have become some of the best-studied nutrients in history, with over 30,000 scientific papers to their names. EPA and DHA have been researched for everything from heart disease to rheumatoid arthritis. Scientists have also learned that these fatty acids reduce inflammation, support healthy nutrient exchange, and influence gene expression.

While EPA and DHA are vitally important, they represent just two members of a much larger fatty acid family found in fish and fish oil. Most of these other fatty acids have not been extensively researched. However, initial studies indicate they have potent benefits, too. These findings suggest that EPA and DHA may just be part of fish oil's evolving nutrition story, much like vitamins A and D were one century ago. While EPA and DHA represent only two kinds of omega-3 fatty acids in CLO, the true count is now over 30 other polyunsaturated omega-3s.

Today, fish oil is practically synonymous with the word 'omega-3s.' Besides EPA and DHA, natural cod liver oil contains a good amount of lesser-known omega-3 fatty acids, like DPA omega 3. While DPA has not been researched as much as EPA and DHA, studies show that it has potent anti-inflammatory effects and cardiovascular benefits. Cod liver oil also delivers a range of other healthy fats besides omega-3s. In a teaspoon of cod liver oil, you will find saturated and monounsaturated fats similar to the ones in extra virgin olive oil and avocados.

Depending on how cod liver oil is made, it may contain vitamins A, D, and E – as well as co-factors like melatonin. (In most products, however, these vitamin levels are significantly reduced after the oils are purified of pollutants). Though natural fish oils contain many nutrients, the omega-3 industry is increasingly focused on isolating just EPA and DHA. For pharmaceutical companies, it is lucrative to obtain new patents by concentrating specific omega-3s into prescription medications. Your best advice is to avoid these and buy and consume wild cod livers.

Concentrating omega-3s has a dose but not a diversity advantage. In the United States, omega-3 supplements usually come as oil pills. Therefore, the more concentrated the oil is, the fewer pills consumers theoretically have to swallow to get an effective omega-3 dose. Sadly, highly concentrated omega-3 products retain only a fraction of the nutrients found in natural fish oils. Some concentrates contain EPA exclusively; others contain only DHA. Of the products that provide both EPA and DHA, the fatty acid ratios can differ tremendously. How these products are concentrated and their resulting chemical forms and purity also vary. Today, there are ethyl ester omega-3s, omega-3-carboxylic acids, and more. These chemically modified versions of EPA and DHA do not exist in nature.

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Highly concentrated fish oils and prescription omega-3s typically contain just a fraction of the nutrients found in natural fish oils.

As omega-3 research has progressed, the efficacy and safety of omega-3 supplements occasionally come into question. Some studies indicate significant benefits, while others find no improvements or even adverse effects. Scientists have many theories to explain the conflicting results. But, one fundamental problem is that omega-3 studies use products with disparate nutrient profiles, chemical forms, dosages, and freshness levels. Given all these variations, it is not surprising that “fish oil supplements” as a group fail to perform consistently.

Cell and mice studies have revealed that formulations made with varying ratios of EPA and DHA affect inflammation differently. Studies also show that an omega-3 oil’s chemical form influences how well it is absorbed. And dose and freshness impact results, too.

As omega-3 research evolves, it continues to uncover new nutrients in fish oils like DPA, SPMs, omega-7, and wax esters. These findings invite familiar questions. Are EPA and DHA alone what make fish oil beneficial? Or do we suffer from the same tunnel vision as the vitamin A and D-obsessed scientists at the start of the 20th century? There is no doubt that studying isolated fatty acids has its merits. Besides making research easier, it gives us better insight into how these nutrients work in the body.

In reality, the human body does not just rely on one or two nutrients to function. Usually, several different molecules interact with each other to create beneficial effects. That is why counting on just one drug or synthetic fatty acid to fix a problem is NOT logical. Other industries seem to have understood this. With extra virgin olive oil, we know that excessive processing negatively impacts health benefits. Similarly, hemp manufacturers regularly discuss the entourage effect, which explains why the multitude of nutrients in full-spectrum hemp oil performs better than extracts. Interestingly, these oils are also usually taken in liquid form, not as capsules.

The Weston A. Price Foundation considers cod liver oil the number one superfood. They state, "Once a standard supplement in traditional European societies, cod liver oil provides fat-soluble vitamins A and D, which Dr. Price found present in the diet of “primitives” in amounts ten times higher than the typical American diet of his day. Cod liver oil supplements are a must for women and their male partners, to be taken for several months before conception, and for women during pregnancy. Growing children will also benefit greatly from a small daily dose.

Dr. Price always gave cod liver oil with high-vitamin butter oil, extracted by a slow centrifuge from good quality spring or fall butter. He found that cod liver oil on its own was relatively ineffective but, combined with butter oil, produced

excellent results. We now know that butter oil is an excellent source of vitamin K, which is needed to balance vitamins A and D in cod liver oil. Other good sources of vitamin K in western diets are aged cheeses and the fat and livers of ducks and geese. Other sources include butter and egg yolks. Without the balance of vitamin K, fish oil could lead to heart troubles, bone problems, tooth decay, and gum disease. Fortunately, cod liver oil does contain some vitamin K, but science has not established if it is adequate. Nature probably better answers that question.

Likewise, the omega-3 fatty acids in cod liver oil require balance by omega-6 arachidonic acid (AA), found in butter, meat fats, organ meats, and egg yolks. Without the balance of AA from animal fats, cod liver oil could contribute to skin problems and digestive problems.

It IS all about balance! Be sure that when you take cod liver oil and include sources of animal fats into your diet.

The Weston A. Price Foundation gives recommendations on cod liver oil dosing in an article titled "Cod Liver Oil Basics and Recommendations."<sup>97</sup> I continue to take cod liver oil regularly. Because I have been taking it for 20 years, my current dosing is 15 - 20 grams two to three times a week. But I do eat fish at least five times per week.

The best advice, based on the information presented by Dr. Martinsen and the Weston A. Price Foundation, is to take cod liver oil but rotate the brands. Also, include natural wild-caught cod livers into your diet, recognizing that only the real food is unprocessed.

### **Sulfur**

Sulfur is an underappreciated nutrient, and we need a lot of it. In this regard, it is not a micronutrient; rather it is a critical nutrient. Sulfur, after calcium, chloride, and phosphorus, is the most abundant mineral element found in our bodies. Sulfur plays an instrumental role in many bodily functions. Methionine, cysteine, homocysteine, and taurine are the four prevalent sulfur-containing amino acids, but only the first two are incorporated into proteins which are the building block of life. Sulfur is available to us in our diets, with sulfur-containing proteins being a major source.

Sulfur is incorporated into amino acids in the form of the "S-H" bond or group, and this structure is critical to advanced life as we know it. The S-H group is called a mercapto or a sulfhydryl group. It is a reactive group, able to undergo chemical reactions with ease to form robust disulfide bonds. Cysteine, by virtue of its ability to form disulfide bonds, plays a crucial role in protein structure and in protein-folding pathways. This "folding" phenomenon turns a string of proteins into a complex bioactive formation. The key word here is "bioactive."

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"Are we getting enough sulfur in our diet?"<sup>98</sup> is a peer-reviewed article that explains our sulfur needs and its value in our physiology. The article is a "must read" and includes some key information. Key facts on the value of sulfur include:

- Proteins contain between 3 and 6 percent of sulfur amino acids.
- Sulfur-containing methionine and cysteine are both required for protein synthesis, and diets must provide these two amino acids.
- Thiamin and biotin are sulfur-containing vitamins.
- The necessary intake of methionine may be as high as 3 grams/day,
- Sulfation is a major pathway for the detoxification of pharmacologic agents, heavy metals, and other toxins by the liver.
- Sulfur is necessary for glutathione production to protect cellular energy pathways and glycosaminoglycans that are involved in cartilage health.
- Glutathione is a key metabolite, intracellular antioxidant, and storage form for sulfur.

The form and structure of proteins determine what physiological activities they are able to perform. Proteins do not form into flat amorphous shapes. Instead, they assemble into elegant and beautiful structures, all with a purpose. Figure 4.3.

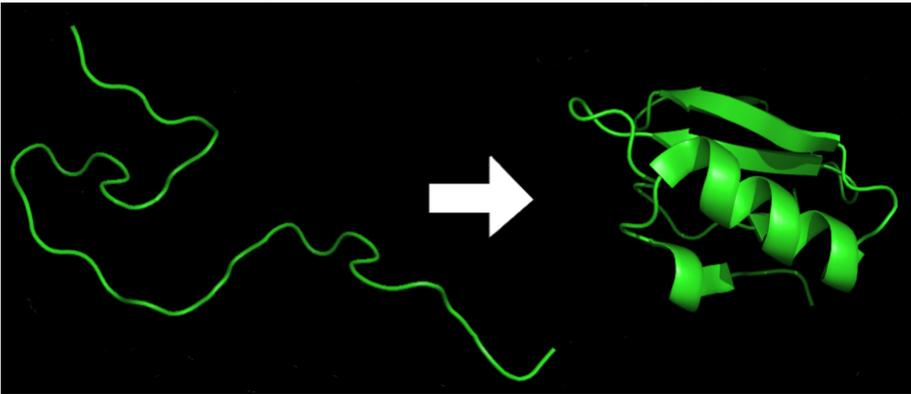


Figure 4.3: Protein before and after folding. The folding occurs primarily through the formation of disulfide bonds between sulfur-containing amino acids in the protein chain.

Sulfur, the sulfhydryl groups on amino acids, and the disulfide bond all play critical roles in forming functional proteins. Alzheimer's is an example of a disease associated with a change in the structure of a protein. The beta-1-42 protein is a hallmark of Alzheimer's disease. For a long time, this disease had and continues to be referred to as a disease of a "misfolded" or "unfolded" protein response. This change in form, regardless of the name, does not happen without changes in disulfide bonding units within the protein.

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Amyloid protein formations, like cholesterol, are considered toxic to our bodies by most people in the medical field. Amyloidosis is considered a disease of abnormal proteins. Are they really abnormal or an appropriate response by an active immune system? WebMD calls amyloidosis “a serious health problem that can lead to life-threatening organ failure.” Sources like Mayo Clinic claim, “Amyloidosis is a rare disease that occurs when a substance called amyloid builds up in your organs.” Are they right or just professing the current dogma?

In the case of Alzheimer’s amyloid beta 1-42, nearly \$1 trillion dollars have been spent in efforts to dissolve it or curb its formation. After hundreds of clinical trials that successfully reduced the levels of "misfolded" beta-amyloid proteins, not one study participant with Alzheimer’s showed any improvement. These Alzheimer’s amyloid plaques may actually be part of the immune system, a new study has revealed. Sulfur to the rescue! Folded proteins appear to be ready to change to help us fight disease.

It is time to rename these so-called misfolded or unfolded amyloid proteins. They are best described as "refolded" proteins.

Research carried out at Harvard Medical School indicates that amyloid-beta may be the first line of defense against infection in the brain and other tissues. The Harvard team reported, “members of this evolutionarily ancient family of proteins, collectively known as antimicrobial peptides (AMPs), share many of the amyloid’s purportedly abnormal activities.”<sup>99</sup> In this case, the term "abnormal" actually means beneficial.

Individuals with severe, chronic inflammatory conditions lasting several years deposit amyloid in many tissues, and this is a fairly common condition despite prevailing doctrine. Cataract, a very common eye condition, is a protein that is unusually folded. Its removal and replacement with an artificial lens is the #1 surgery performed throughout the world. A cataract is an example of an amyloid formation that is there for a good reason.

In the image in Figure 4.4 below, note the white cataract formation in the center of the eye of this 5-year-old child. She was infected with Ebola and survived. Research from Harvard Medical School dating back to 2003 shows that cataracts are a type of amyloid, and they actually form to protect us from infection. It is highly likely that this child has amyloid formations throughout her body, but there is no simple test for systemic amyloid. The eye is unique, affording a window to view pathology within its transparent tissue, non-invasively from the outside.



Figure 4.4: Five-year-old Ebola sufferer. The nuclear cataract is a protein that has refolded into what is classified as an anti-microbial peptide. This cataract development is part of the innate immune response against, in this case, the Ebola infection.

The disulfide bond is critical to the formation of refolded proteins by creating connections across amino acid segments and providing stability to the new configurations. Amyloids, especially the beta-sheet structure, are still regarded as toxic or harmful. However, these structures are now called “functional amyloids” that are created for predetermined or beneficial purposes.<sup>100</sup>

Sulfur in amino acids of proteins is critically important because the bonds they form are convertible. That is, they can be broken and reformed based on the state of the environment and the physiological need of the organism. In the case of humans and the 1-42 beta amyloid formation, this happens in an attempt to wipe out the infections causing the disease. Amyloids, as with cholesterol, are like fire trucks being observed at the fire. God forbid if the fire department does not show up.

Beyond amyloids, the building of disulfide bonds within proteins creates cells, tissues, and hormones in our bodies that all contribute to their individual functions. Sulfur is an extremely versatile element, with its main benefit being the rebuilding of tissue everywhere in the body.

Can we consider an element clever? Sulfur definitely qualifies. We now know that sulfur, in the form of the sulfhydryl group, is reactive, able to form crosslinks within a protein, and the process is reversible. However, reactive substances like the sulfur-containing group are generally reactive. How is it that these moieties remain available to do the exact chemical construction work needed at the right time and right place? This is where another sulfur compound enters the picture.

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Glutathione is a key sulfur-containing molecule that functional doctors, in particular, call the master antioxidant. Glutathione is a tripeptide, which is not classified as a protein but is a string of 3 amino acids; cysteine, glycine, and glutamic acid, with cysteine being the sulfur-containing amino acid. It is found in surprisingly high concentrations in most cells, at levels similar to those for potassium, glucose, and cholesterol. Clearly, this is an important substance for sustaining our health; otherwise, it would not be so prevalent. Interestingly too, the cholesterol molecule keeps showing up in high concentrations essentially everywhere in the body.

Truth be told, unless I research something very thoroughly, like the glutathione molecule, I remain skeptical of the claims made by others. However, after studying glutathione, I now believe it plays a very important role, just like those other substances found at similarly high concentrations in all cells. Why else would they be there? That being said, it probably does not need to be taken as supplemental since it is not classified as an essential nutrient. That is, our bodies can manufacture glutathione, presumably in sufficient quantities. The key consideration with respect to glutathione is reducing it to an active form. This is discussed in the Energy Medicine chapter of Volume 2.

The most important aspect of glutathione is its specific anti-oxidation capabilities, with emphasis on the term “specific.” Importantly, it scavenges excess free radicals from cellular energy production. Free radicals in the right place are beneficial, but in the wrong place can be harmful. Metabolism is an oxidative process. White blood cells and antibodies produce reactive oxygen species to fight infection. In these instances, oxidation is crucial.

Glutathione is a smart antioxidant. It apparently gets its intelligence from sulfur. Glutathione cleans up the damage of combustion from the mitochondria. It also plays the sacrificial role of protecting the sulfhydryl groups so they are available to create crosslinking bonds within proteins that allow them to be built into the form and function needed. The chemistry of protein disulfide bond formation is directly influenced by three key factors:

1. The spatial accessibility/physical proximity of the partner cysteine residues forming the disulfide bond determines how the proteins fold and into what shapes.
2. The difference between the pKa (acid and base value) of the involved thiol groups and the pH of the local environment facilitates bond formation.
3. The oxidation/reduction (redox) environment determines how energy is produced in the mitochondria, which is where glutathione plays its crucial role.

The redox environment is controlled by the ratio of oxidized glutathione (GSSG) to reduced glutathione (GSH). Without glutathione and its perfectly tuned redox properties, the right conformational formations of protein would not be possible,

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and our world would look very different indeed. Based on the way glutathione works, it regulates the most important mechanisms in health and disease. The key mechanisms are included here.

- Repair and recovery processes through the formation of complex folded protein structures that we call enzymes.
- Fighting infection through the formation of complex folded protein structures that we call antimicrobial peptides.
- Anti-oxidation of oxidative substances created by our mitochondria energy plants.

This is not the entire story of sulfur and glutathione, but it is a big part of our health picture, and that is why sulfur is the 4th most abundant mineral nutrient but all too often the one in which we most likely suffer a deficiency.

Another use of sulfur that makes our modern world possible again revolves around the disulfide bond. What would our world look like without rubber tires? The strength and pliability of rubber have everything to do with sulfur and its ability to crosslink as it does in proteins. In this case, the process is called vulcanization. Vulcanization is a chemical process that converts natural rubber and other polydiene elastomers into cross-linked polymers. Sulfur is the key vulcanization agent. It forms bridges between individual polymer molecules when heated with the rubber. The next time you go anywhere, thank sulfur. Rubber tires sure beat the wooden spoked wheels our forefathers (and mothers) rode upon.

### **Sulfur and Detoxification**

Detoxification is also an important process that contributes to healthy longevity. Another key role fulfilled by sulfur includes detoxification. It helps the human body to safely digest or expel medication, food additives, and even the toxic metals that are present in the things we consume. Chemists use elemental sulfur as a binding agent for mercury to clean up a spill. Sulfur also helps to keep blood healthy and prevent coagulation. Here are summaries from peer-reviewed papers discussing sulfur and detoxification.

- "Heavy-metal detoxification using sulfur compounds."<sup>101</sup> "The development of sulfur compounds for use in heavy-metal detoxification has resulted in the preparation and use of compounds that are highly effective for this purpose because of the great stability of many types of metal-sulfur linkages. The ability of many of these compounds to penetrate cellular membranes has made them useful in situations in which the more readily ionized oxygen-based chelating agents are quite ineffective. This review describes the use of mono-, di-, and polythiols, cysteine derivatives, and dithiocarbamates for the **detoxification of arsenic, mercury, lead, cadmium, and copper**, with some attention to other types of sulfur compounds and other toxic metals."

Note that thiol means the sulfur atom in a molecule in a certain form.

- "Possible roles of plant sulfur transferases in detoxification of cyanide, reactive oxygen species, selected heavy metals, and arsenate."<sup>102</sup> "Plants and animals have evolved various potential mechanisms to surmount the adverse effects of heavy metal toxicity. Plants possess low molecular weight compounds containing **sulfhydryl groups (-SH) that actively react with toxic metals**. Furthermore, heavy metals induce reactive oxygen species (ROS), which directly or indirectly influence metabolic processes. Reduced glutathione (GSH) attributes as an antioxidant and participates in controlling ROS during stress."
- "Detoxification and the mineral Sulfur"<sup>103</sup> "Another benefit of sulfur in our daily diet is the production of the protective molecule, Metallothionein, found in our intestines. This digestion system protector binds with mercury and other toxic metals that enter our digestive tract resulting in its excretion."

Certain foods that are high in sulfur have been shown to be useful in detoxification because of a mutual affinity between the heavy metal and sulfur to bind, forming a new compound. This new metal complex is more soluble, enabling the body to eliminate it through urine or stool, thereby reducing the concentration of the toxic metal.

Good sources of sulfur-containing foods are garlic and onions, and other allium vegetables, the brassicas family, also known as cruciferous vegetables, including; broccoli, brussels sprouts, cabbage, cauliflower, Bok chow, and turnips. Ginger, egg yolks, and molasses are also good sources of sulfur. The sulfur-containing vegetables hold sulfur in the form of sulforaphane which possesses reported anti-cancer properties in addition to being good detoxifiers of heavy metals. This may explain why a short-term vegan diet has shown benefits for cancer. Garlic has prevented cadmium-induced kidney damage and decreased free radical damage due to lead in animal models.

Glutathione, as a sulfur-containing mini-protein, has heavy metal detoxification properties. Humans naturally make glutathione from the ingestion of three amino acids found in food glutamic acid, cysteine, and glycine. The limitation of glutathione in detoxification is its consumption as an antioxidant in cells and as a general detoxifying agent for substances like acetaminophen and other harmful agents. This may leave insufficient amounts of glutathione to perform the heavy-metal detoxifying function.

Certain supplements, beyond the base amino acids, support the formation of glutathione. The most prominent one is the sulfur-containing supplement MSM. Other substances that boost glutathione synthesis include alpha-lipoic acid, N-acetyl cysteine, L-glutamine, and milk thistle, which contains a glutathione-producing flavonoid known as silymarin. Importantly, taking pre-formed

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glutathione has not been shown to be useful at increasing blood levels of the substance, as it is poorly absorbed from the gut.

Other sulfur-containing amino acids may provide help with detoxification and certainly are sources of sulfur as a raw material. These include taurine and methionine. We normally have ample methionine from consuming protein-rich foods, methyl folate, and methylcobalamin. Taurine, also known as 2-aminoethanesulfonic acid, is the most abundant amino acid in the heart muscle and may play a key role in helping to prevent congestive heart failure. It also has documented ability to detoxify the body of certain heavy metals.<sup>104</sup>

Sulfur is the 4th most abundant mineral in the human body. It is there for a myriad of reasons, with detoxification, anti-oxidation, and tissue repair being paramount. You need a lot of it, so you must be eating nutrient-dense foods high in sulfur every day. If not, supplementing with MSM is essential to ensure healthy longevity.

### **Iodine**

Iodine is a critical nutrient, yet there is substantial controversy about the actual daily need. There is a presumption that iodine is just valuable in supporting thyroid health. In fact, the recommended daily allowance for iodine is based on preventing goiter, which is the irregular growth of the thyroid gland. Evidence is mounting that low iodine is linked to numerous ailments and diseases, including breast cancer and developmental deficiencies of the brain. Unfortunately, there is no consensus in conventional or alternative medical circles as to the right level of iodine required to support overall health, not just thyroid health. And there is uncertainty as to the value of iodine testing. The 24-hour urine test, performed at regular intervals, is probably the best way to assess iodine sufficiency.

In essence, the entire discussion about iodine intake revolves around the support of the thyroid gland and the production of the hormones T4 and T3, where the numbers reflect how many iodine atoms are attached to the molecules. However, iodine has many more uses than activating energy hormones. We all know iodine is an effective antiseptic, for example. Optimal iodine intake and physiological levels should be based on total body health and not just thyroid health.

The conservative approach to iodine intake and supplementation is based on a concern about Hashimoto's Thyroiditis, an autoimmune condition of the thyroid. Indeed, there is compelling evidence that adding supplemental iodine can create or exacerbate Hashimoto's. However, this does not occur in everyone. And it probably occurs in a small minority of people. Health is a continuum and applies to susceptibility to Hashimoto's as well. Therefore, when considering Hashimoto's risk, all factors need to be considered and corrected, then iodine supplementation may become less of a concern or even irrelevant with respect to Hashimoto's. The only way to know for sure is through proper testing.

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The protocol for iodine supplementation and avoidance of Hashimoto's is provided at the end of this section. But first, let us look at the different positions experts have with regard to iodine and its appropriate intake.

Iodine RDA and accepted limits are provided by the Institute of Medicine (US) Panel on Micronutrients.<sup>105</sup>

"Iodine is an essential component of the thyroid hormones that are involved in the regulation of various enzymes and metabolic processes. Thyroid iodine accumulation and turnover were used to set the Estimated Average Requirement.

- The Recommended Dietary Allowance (RDA) for adult men and women is 150 µg/day.
- The median intake of iodine from food in the United States is approximately 240 to 300 µg/day for men and 190 to 210 µg/day for women.
- The Tolerable Upper Intake Level (UL) for adults is 1,100 µg/day (1.1 mg/day), a value based on serum thyrotropin (TSH) concentration in response to varying levels of ingested iodine."

Note that the Institute of Medicine states that iodine is involved in processes beyond the thyroid, yet iodine intake limits are based on the needs of the thyroid. This approach could lead to an iodine deficiency in non-thyroid tissues. Also, our own data on people taking more than ten times the UL have normal TSH values in most cases.

Iodine is concentrated in the ocean and thus in sea flesh and vegetables. Iodine plays a key role in the maintenance of healthy breast and ovarian tissue in women and in fostering optimal neurocognitive development in babies. Adequate levels of iodine have been shown to prevent cancer and are anti-viral, anti-bacterial, and anti-fungicidal.

Some doctors who have studied iodine indicate that daily consumption of iodine, on a global basis, with few exceptions, is highly insufficient. According to Jorge Flechas, MD, a world authority on iodine, most people have iodine levels that are virtually undetectable. David Brownstein, MD agrees and explains his view on iodine in the book titled, "Iodine, why you need it, why you can't live without it." Even with this type of messaging, iodine supplementation is not represented in the top 20 most consumed supplements. Try buying an iodine or kelp supplement at Walgreens or CVS. Most people get their iodine from food alone, and most Westerners are not consuming sea foods and particularly sea vegetables which are the highest in iodine content by far. Thus, Dr. Flechas's assertion about iodine deficiency is supported well by consumption patterns of both foods and supplements.

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Here are some key facts about iodine, its availability, and potential reasons that many people are deficient in iodine.

- In the United States, the ground, and hence the crops grown in it, is depleted of iodine.
- Diets without ocean fish or sea vegetables such as seaweed are lacking in iodine.
- Inadequate use of iodized salt from low-salt diets or use of unrefined sea salts that do not have added iodide salts.
- Diets high in pasta and bread, which contain bromide, inhibit the body's absorption of iodine. Many spas use bromine substances to control microbial growth.
- Fluoride, such as that in drinking water and oral products, may contribute to the inhibition of iodine binding.
- Vegan and vegetarian diets are lacking in Iodine unless they include sea-based vegetables.
- Sucralose that contains chlorinated table sugar may displace iodine.
- Medications, especially inhalers and selective serotonin reuptake inhibitors (SSRIs), are iodine antagonists.
- Soy products are also classified as iodine antagonists, as are flax seeds and raw cruciferous vegetables (broccoli, Brussels sprouts, cauliflower, and cabbage). They contain goitrogens that counteract iodine.

Due to the controversy surrounding iodine and the wide variety of iodine recommendations, what follows is information on iodine requirements from various sources.

What is not controversial is that iodine is a critical nutrient, and the amount of iodine an individual should be obtaining is very individual. Thus, two non-controversial considerations are:

- Iodine levels should be routinely measured.
- Thyroid function should be routinely measured.

Determining your actual intake of iodine is very important, so the results from the tests recommended in this section can be interpreted based on true iodine intake, and adjustments to that intake are made based on testing, not guessing. There is some evidence that iodine from food is better compared to that obtained from various supplements, so these two sources, supplements and foods, should be distinguished when determining daily iodine intake.

As you read through these various sources, recognize their inclusion here does not reflect an endorsement. Instead, it is intended to provide information and an appreciation for the variability in iodine intake recommendations. However, we do offer a solution to this controversy at the end of this section.

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As a refresher, the thyroid, upon activation by the thyroid stimulating hormone (TSH), produces metabolically active hormones called T3 and T4, using shorthand for their real names. The numbers are for the quantity of iodide atoms found in each hormone molecule. The entire process of producing these metabolic hormones is shown in Figure 4.5.

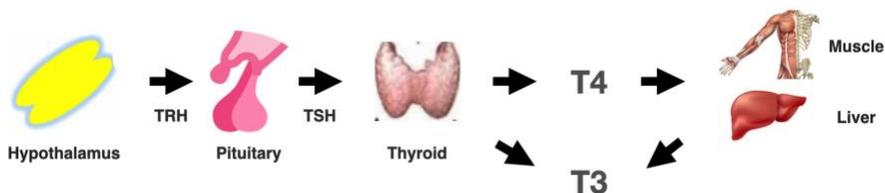


Figure 4.5. The production of the active thyroid hormones T4 and T3.

Iodine is not stored in the body like the fat-soluble vitamin D is fat-soluble and available in times of deficiency. Instead, a large percentage of iodine, with some estimates as high as 90 percent, is shed daily in urine and sweat.

### **Source 1:**

An article titled "Iodine, Iodine metabolism and Iodine deficiency disorders revisited" gets right to the point.<sup>106</sup>

- "Five grams of iodine are sufficient to meet the lifetime needs of an individual with a life span of 70 years.
- Iodine is mostly concentrated in the thyroid gland,
- A healthy adult body contains 15-20 mg of iodine, 70-80 percent of which is stored in the thyroid gland,
- Daily intake of iodine by individuals amounts to roughly 500 micrograms but is very variable,
- Daily physiological requirements during adult life are 150 micrograms,
- During pregnancy and lactation period, the daily requirement jumps to 200 micrograms,
- Normally about 120 micrograms of iodide are taken up by the thyroid gland for the synthesis of thyroid hormones."

Is it possible that the requirements for iodine are that narrow across a world with such great diversity? Iodine is shed by athletes in perspiration, and their metabolism may be elevated dramatically for hours each day. Note there is no accommodation for these individuals.

"Oceans are the world's main repositories of iodine, and very little of earth's iodine is actually found in the soil. The deposition of iodine in the soil occurs due to volatilization from ocean water, a process aided by ultraviolet radiation. The coastal regions of the world are much richer in iodine content than the soils further inland; here, the problem gets more compounded by

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the continuous leeching of iodine from the soil. Therefore, the crops grown in such soil remain iodine deficient; even groundwater in these areas is deficient in iodine. This explains the endemic distribution of Iodine Deficiency Disorders (IDD) in the world."

"Traditional food of Japan contains significant amounts of dietary iodine, with citizens possibly consuming at least 7000 mcg of iodine daily from kombu alone. It has been estimated that the Japanese consumption of dietary iodine exceeds the upper safety limit of 1 mg by approximately 5-14 times. These higher levels appear to have no suppressive effect on the thyroid function in normal individuals, yet intake of excess iodine could cause problems in patients with thyroid nodules, hyperthyroidism, and autoimmune thyroid disease. On the contrary, it has been interestingly observed that Japanese women who consume a high iodine content diet have a low incidence of benign and malignant breast disease."

### Source 2:

Chris Kresser, M.S., L.Ac., is a renowned health expert and top educator in the fields of functional medicine and ancestral health. Here is Mr. Kresser's view on iodine from his website.

"Iodine deficiency is the most common cause of hypothyroidism worldwide. Once researchers realized this, health authorities around the world began adding iodine to table salt. This strategy was effective in correcting iodine deficiency. But it had an unanticipated and undesired effect. In countries where iodine has been added to table salt, the rates of autoimmune thyroid disease have risen.

Why does this happen? Because increased iodine intake, especially in supplement form, can increase the autoimmune attack on the thyroid. Iodine reduces the activity of an enzyme called thyroid peroxidase (TPO). TPO is required for proper thyroid hormone production.

On the other hand, restricting the intake of iodine can reverse hypothyroidism. In one study, 78 percent of patients with Hashimoto's regained normal thyroid function with iodine restriction alone. However - and this is a big "however" - it appears that iodine may only pose a problem for people with Hashimoto's and other autoimmune thyroid diseases in the presence of concurrent selenium deficiency.

In the study above, where rats developed goiter while receiving excess iodine when they were given adequate selenium, they did not develop the goiter. Other studies have shown that selenium protects against the effects of iodine toxicity and prevents the triggering and flaring of autoimmune diseases that excess iodine without selenium can cause.

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In my practice, I always test for both iodine deficiency and Hashimoto's when a patient presents with hypothyroid symptoms. If they are iodine deficient, I will start them on a trial of iodine and selenium together. In most cases, patients see a significant improvement. In a minority of cases, they cannot tolerate supplemental iodine even with adequate selenium intake.

Unfortunately, the blood test for iodine that your doctor might run is not very accurate. The best way to determine iodine status is with a 24-hour urine loading test. This involves taking a large dose of iodine and collecting your urine for 24 hours afterward. If you are iodine deficient, you will retain more of the ingested iodine than you should, and the level of iodine excreted in the urine will be lower than expected. The two labs I recommend for this test are Doctor's Data and Hakala.

That said, if your doctor or health care practitioner will not order these tests, you can simply begin an iodine protocol. This involves starting with a low dose of iodine (I start my patients with kelp tablets that contain 325 mcg of iodine per tablet) and increasing very slowly over time. As I've described in this article, it is crucial that you also take 200 mcg of selenium per day during this protocol to protect against the potentially adverse effects of iodine supplementation, especially if you have autoimmune thyroid disease.

- Start with 325 mcg of iodine/day.
- Include 200 mcg of selenium as an iodine cofactor.

Physicians that specialize in treating hypothyroidism with iodine (such as Dr. Abraham and Dr. Brownstein) suggest doses as high as 50 mg per day may be necessary to restore iodine levels in those that are deficient. I have used doses this high in my practice, but it is imperative that patients build up to such high doses very slowly, and I do not recommend doing it without the supervision of a clinician experienced with iodine treatment. Be aware that high doses of iodine can lead to a transient increase in TSH levels, which can be mistakenly interpreted as a sign of hypothyroidism.

Finally, it is important to keep in mind that a minority of patients with Hashimoto's confirmed by biopsy (the gold standard) never test positive for thyroid antibodies. This is probably because their immune systems are so depressed that they can no longer produce antibodies. If you have a combination of hyper- and hypothyroid symptoms, I would still suspect Hashimoto's even if your thyroid antibody tests are normal. It is wise to be cautious with iodine if you have any signs of autoimmune thyroid disease, even without a confirmed diagnosis."

### Source 3:

At Self-Decode, Dr. Puya Yazdi is a physician-scientist with 14+ years of experience in clinical medicine, life sciences, biotechnology, and nutraceuticals.

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He medically reviewed the information on iodine and thyroid health on the self-decode website.

"It is crucial not to take too much iodine as well. The safe upper limit for iodine intake in adults is 1,100 µg daily. In a study carried out in Liaoning Province, China, the intake of iodine that exceeded 250 – 499 µg/L led to iodine deficiency disorder and subsequent hypothyroidism. This is due to the so-called Wolff–Chaikoff effect, when an excess of iodine leads to a decrease in hormone production by the thyroid gland.

The thyroid gland in the baby develops during weeks 10-12 of pregnancy, and in the case of excess iodine intake by the pregnant mother, hypothyroidism can develop in children as well. There was a report on mothers that overdosed on iodine during pregnancy. The children of those three mothers were diagnosed with hypothyroidism. The correction of the condition was achieved by stopping this overdose coming from supplements."

Here is a case where limiting iodine is absolutely incorrect. IQ is intimately intertwined with iodine intake by the pregnant mother. The solution is to solve mom's Hashimoto's and keep the iodine sufficient for fetal brain development.

### Source 4.

Dr. David Brownstein is a Board-Certified, family physician. He is one of the foremost practitioners of holistic medicine and is the Medical Director of the Center for Holistic Medicine in West Bloomfield, Michigan.

Dr. Brownstein, through his book, "Iodine: Why You Need It. Why You Can't Live Without," provides dosage guidelines. There is a presumption that Dr. Brownstein only recommends very high doses of iodine. But, as you will soon see, that is not always the case.

"Now that we have established that the RDA for iodine (approximately 150mcg/day) is inadequate, how much iodine should you take? There is some concern in the conventional literature that too much iodine can harm the thyroid gland and cause other problems in the body.

The question of dosage cannot be answered without reviewing the iodine intake of the Japanese. It has been estimated that the mainland Japanese ingest approximately 13.8mg of iodine per day, which is approximately 100 times the RDA. The Japanese receive most of their iodine from seaweed, which is known to concentrate iodine."

(Note: Dr. Brownstein indicates that the Japanese take in 5 to 10 times more compared to other references on Japanese average iodine intake).

What is the effect of ingesting this larger amount of iodine? The Japanese who consume these large amounts of iodine have remarkably lower levels

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of breast, endometrial, and ovarian cancers. In addition, as compared to American women, there is a significantly lower amount of fibrocystic breast disease in Japanese women. Mainland Japanese men have lower rates of prostate cancer as compared to the U.S. male population, including Japanese males who have migrated to the United States. The medical literature has pointed out a possible relationship between all of these cancers and iodine deficiency.

There is some concern that the ingestion of iodine in excess of the RDA of 150 mcg/day will cause adverse effects. With the proper monitoring and dosing, iodine in milligram doses is safe and effective. There are seven major concerns with using iodine in excess of the RDA. Many practitioners feel that milligram doses of iodine may cause:

- Iodine allergy;
- Autoimmune thyroid disease
- Detoxification reactions;
- Iodine-induced hypothyroidism and goiter;
- Iodine-induced hyperthyroidism;
- Iodism (metallic taste);
- Thyroid cancer.

Dr. Brownstein addresses each one of these presumed issues in his book. Associations are not causations. Only deep studies that establish causation should be used. Everything else is a guess.

According to Dr. Brownstein, his clinical experience has shown that in an iodine-deficient state, higher doses of iodine are an effective and safe way to treat autoimmune thyroid illness without appreciable side effects. Remember, the best results are achieved as part of a comprehensive, holistic treatment plan, including proper testing.

According to Dr. Brownstein, "How much iodine should you take in? There is no perfect dose for everyone. The best way to properly dose iodine is to test the body for its iodine status. This can easily be accomplished with an iodine-loading test. The instructions for the loading test are detailed below.

### Iodine-Loading Test

1. First-morning urine is discarded.
2. Take 50 mg of iodine/iodide (Iodoral®) with a glass of water.
3. Collect 24-hour urine. Include the first-morning sample at the end of the 24-hour collection.
4. Send a sample of the 24-hour urine for the evaluation of iodine status.

"The principle behind using the iodine-loading is well established. If the body was saturated with iodine, one would expect that most of the 50mg of

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iodine ingested for the loading test would be excreted. If, on the other hand, there was an iodine deficiency present, then more of the iodine would be absorbed.

Research has shown that a 90 percent excretion (or 45mg of iodine) of a 50mg iodine-loading test would indicate an iodine-sufficient state. Levels below 90 percent (or <45mg) would signify an iodine-deficient state. In this case, iodine supplementation can begin, and a retest can be performed in the future.

Once an iodine-deficient state is determined, iodine supplementation can be implemented. I recommend using a combination of iodine and iodide. This can be found in liquid or tablet form. Iodine concentrates in all of the trillions of cells in the body. Not only does it concentrate in the thyroid and breasts, but it also accumulates in the prostate, salivary glands, skin, intestines, and all the red and white blood cells throughout the body. Proper iodine supplementation may address health problems in all of these tissues. Approximately 12mg of iodine has been established as the optimal daily dose of iodine/iodide for the breast and thyroid gland. However, this may not be adequate to address the needs of the rest of the body.

Also, due to the contact with so many goitrogenic substances such as bromide, fluoride, and cruciferous vegetables, the daily iodine requirements may be elevated for some. Depending on the iodine status of the body, my experience has shown that the RDA for iodine is inadequate not only for the thyroid gland but for the rest of the body as well.

We live in a toxic society and are continually exposed to increasing amounts of goitrogens in our environment. The increased poisonous load and goitrogen exposure will necessitate increased ingestion of iodine. Although the dose should be individualized, my experience has shown that the dose can vary from 12-50 mg/day for most adults. This is the daily dose that Dr. Guy Abraham, my mentor on iodine, recommended. Some may need higher doses, particularly those with cancer or disease of the thyroid, ovaries, uterus, breast, and prostate. This higher iodine dose can easily be followed by periodically checking an iodine-loading test. A proper history and physical exam can also help guide the dosing of iodine.

When iodine is taken orally, it is absorbed into the bloodstream. Iodine is transported into the target cells of the body by an energy-dependent process. One atom of iodine is transported into the cells, and two atoms of sodium are transported out of the cells via the sodium/iodide symporter (NIS). Recently a second mechanism for the transport of iodine into the cells has been observed, the chloride/iodide transporter known as pendrin.

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Iodine may be absorbed through the intestines resulting in an elevated serum level of iodine, but the target cells are unable to uptake the iodine. This can occur if the NIS and/or the pendrin transporter systems are damaged. Certain goitrogens, such as bromide, can bind to the NIS, causing damage to the transport system. The end result of this damage would be iodine deficiency in the target cell.

One way to determine if the transport mechanism for iodine is working is by measuring the saliva/serum iodide ratio. If the transport mechanisms for iodine are properly functioning, the saliva levels of iodine will significantly increase relative to the serum. A saliva/serum iodide level has been used in neonates to diagnose a congenital iodide symporter defect.

We (Drs. Abraham, Brownstein, and Flechas) have been evaluating saliva/serum iodide levels in a series of patients. Initial results show that the normal saliva/serum iodide level is approximately 42. That means that when iodine is being properly transported into the cells, the salivary fluid should have 42 times the iodine level that is found in the serum. If the saliva/serum levels are low, especially less than 20, a thorough search for a reason for the poor transport of iodine must be undertaken."

How common is iodine deficiency? Every few years, the U.S. government measures vitamin, mineral, and toxicity levels in the U.S. population. This National Health and Nutrition Examination Survey (NHANES) has found that iodine levels fell by more than 50 percent between 1971 and 2008. The World Health Organization reports that 72 percent of the world population is iodine deficient. Among the nearly 6,000 patients that Dr. Brownstein has tested in his practice, more than 96 percent of them were iodine deficient when evaluated by the iodine loading test.

### Source 5:

Dr. Isabella Wentz is trained in functional medicine through The Institute for Functional Medicine, Kalish Functional Medicine, and the American Academy of Anti-Aging Medicine. She is a Fellow of the American Society of Consultant Pharmacists and holds certifications in Medication Therapy Management as well as Advanced Diabetes Care through the American Pharmacists Association. In 2013, she received the Excellence in Innovation Award from the Illinois Pharmacists Association.

"Iodine is a controversial topic with regard to thyroid health. While I've discussed the dangers of high doses of iodine for Hashimoto's in my books, I wanted to address the topic in an article and make sure that the conversation doesn't turn into a debate about a single nutrient, as Hashimoto's is a multi-factor and full body condition.

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While some thyroid advocates will propose that taking high doses of iodine is helpful for everyone with Hashimoto's, unfortunately, I have not found that to be the case for most. As a pharmacist, I am often reminded that "the only difference between a medicine and a poison is the dose." This is a wise old quote from Paracelsus, who is credited as the father of modern toxicology.

Thus, not surprisingly, while physiological doses of iodine can benefit thyroid function, research has shown that excessive doses of iodine can trigger (and worsen) Hashimoto's in people who are genetically predisposed to Hashimoto's and may have certain "vulnerabilities," such as a fixable selenium deficiency. Furthermore, temporary iodine restriction may actually improve and even normalize thyroid function in some individuals."

The critical question that needs answering about the statements of Dr. Wentz is the magnitude of "some individuals." Specifically, what percentage of people have Hashimoto's, and what percentage of them are impacted by doses of Iodine > 150mcg/day? When these questions are answered, the debate about iodine may give way to good science.

Because it is a necessary nutrient for thyroid health, some people have assumed that supplementing with high doses of iodine can help the body make more thyroid hormone, thereby improving hypothyroidism and Hashimoto's; and many conventional health books and doctors often recommend it. However, they do not understand that iodine is what pharmacists call a "Goldilocks" nutrient, meaning that, while low levels are necessary for thyroid health, higher levels can have a negative effect. In my practice, I have seen iodine harm people with Hashimoto's, so I need to caution people about supplementing with high doses of this nutrient unless they have a known deficiency. However, even in the case of deficiency, taking too much at once can be toxic.

Note - This statement only applies to people with Hashimoto's disease, representing a small percentage of the population. Dr. Wentz sees people mainly with Hashimoto's disease because of her renowned expertise in this area. Thus her population is not representative of the general public.

"Initially, a person given iodine may experience more energy but then crash and feel worse. This is because iodine, given to a subset of people with *Hashimoto's*, can make the thyroid produce more hormone initially. Still, unfortunately, in doing so without having enough selenium and antioxidants on board, the increased hormone production creates lots of free radicals, which can flare up the attack on the thyroid gland. Lab tests will reveal that their "new energy" comes from destroying thyroid tissue, which dumps thyroid hormone into circulation. Reports will show elevated TSH, elevated

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thyroid antibodies, and in some cases, low levels of active thyroid hormones.

This is why I don't generally recommend iodine supplements to people with Hashimoto's. I don't believe that the short-term artificial boost in energy is worth destroying your thyroid gland!

This has to do with how iodine is processed in the body. The thyroid gland processes iodine from foods and supplements so the body can properly use it. During this process, hydrogen peroxide, a free radical, is released. In cases when the body has adequate levels of selenium and it is appropriately used, the selenium neutralizes the hydrogen peroxide. However, excess hydrogen peroxide can cause oxidative damage to the thyroid gland in cases of iodine excess. When not enough selenium or glutathione is present to neutralize the hydrogen peroxide, oxidative damage can lead to inflammation and autoimmunity.

Researchers have studied the effects of excess iodine on those with thyroid disease. In Germany, for example, a low dose of potassium iodide (250mcg) was given to 40 people who tested positive for anti-thyroid (TPO) antibodies or had a thyroid ultrasound showing a hypoechogenic (more dense tissue) pattern consistent with Hashimoto's. A group of 43 subjects with similar characteristics served as a control group.

Nine patients from the iodine group developed thyroid abnormalities, compared with only one from the control group. Seven of the nine patients in the iodine arm developed subclinical hypothyroidism; one became hypothyroid, and another hyperthyroid. Positive changes were also seen in TPO antibody levels and thyroid ultrasound. Three of the seven subclinical hypothyroid patients and the hyperthyroid patient regained normal thyroid function after iodine withdrawal.

Indeed, the iodine group has some hypo- and hyperthyroidisms, but did they also have benefits? This is not discussed. For example, avoiding breast cancer is certainly more important than developing hypothyroidism, which often can be reversed, independent of iodine intake.

"While testing a low iodine diet can be helpful to many people, and iodine deficiency is relatively rare in those with Hashimoto's, it's important to note that for some people, addressing an iodine *deficiency* may be key to improving one's thyroid health. Some potential factors that may lead me to suspect an iodine deficiency include the following:

- eating a vegan diet;
- eating a diet low in seafood;
- having fibrocystic breasts (though this could be caused by magnesium deficiency);

## Chapter 4: Missing Nutrients

- having low reverse T3 on a lab test; or
- experiencing a negative reaction to selenium (which is very rare).

I often get the question about testing for iodine deficiency. Do blood, urine, or “spot” tests (where you paint yourself with iodine until it disappears) actually work? Are they accurate? Unfortunately, these tests cannot reveal an iodine deficiency or excess. Instead, they will be reflective of your recent iodine intake. That said, iodine testing can help determine if your average diet and lifestyle contain excess iodine. The most helpful test involves checking one’s urinary iodine to creatinine ratio. The amount of iodine in your urine is compared to the amount of a normal kidney protein called creatinine.

This urinary iodine to creatinine ratio is tested with a urine collection and can be done at home and mailed in for convenience. The test will not tell you how much iodine you are taking. Still, if you are working to reduce iodine levels to help your thyroid function, it can help you determine if you have eliminated enough hidden sources of iodine. The urinary test results are reported as an mcg of iodine per gram of creatinine, abbreviated as mcg/G.

- If your levels are over 100 mcg/G, you have not eliminated enough hidden sources of iodine.
- The goal is to be under 100 mcg/G. The higher your scores are above this range, the more iodine you are still ingesting.
- You can use this as a clue to find and eliminate other sources of iodine in your diet or personal care products.

In the case of a deficiency of iodine, I recommend iodine supplements but only in the dose of the RDA. If exposed to the high doses of iodine recommended by others, taking a selenium supplement (up to 600 mcg per day) may be helpful to negate the adverse effects of the iodine excess."

Common sources of iodine include:

- high iodine foods (kelp, dulse, spirulina, chlorella, seaweed, fish, shellfish, egg yolks, dairy products, and commercial baked goods);
- iodized table salt
- iodine in skin care products such as shampoo, conditioner, sunscreen, facial moisturizer, and skin creams (watch out for ammonium iodide, potassium iodide, sodium iodide, iodoform, PVP-iodine, hydroxypropyl bistrimonium diiodide, TEA-hydroiodide, ethiodized oil, iodopropynyl butylcarbamate, and the following seaweed extracts: Fucus vesiculosus extract, Laminaria digitata extract, kelp extract)
- supplements, including multivitamins, prenatal vitamins, and some supplements marketed as “thyroid support” blends;

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- medications (many oral, topical, and injectable drugs contain iodine)
- oral medications: amiodarone, benziodarone, calcium iodide, diiodohydroxyquin (Yodoxin), R-Gen, echothiophate iodide ophthalmic solution (phosphine), hydriodic acid syrup, iIodochlorhydroxyquin (Entro-Vioform), iodinated glycerol (Iophen), idoxuridine ophthalmic solution (Herplex), isopropamide iodide (Darbid), potassium iodide (KI), Mudrane, Lugol's Solution, niacinamide hydroiodide, Ponaris nasal emollient, supersaturated potassium iodide (SSKI)
- injectable solutions: sodium iodide;
- topical antiseptics: diiodohydroxyquin cream (Vytone), iodine tincture iodochlorhydroxyquin cream (Vioform), Cellasene, iodoform gauze (NuGauze), povidone-iodine (Betadine);
- radiology contrast agents: diatrizoate meglumine sodium (Renografin), iodized oil, iopanoic acid (Telepaque), ipodate (Oragrafin), iothalamate (Angio-Conray), metrizamide (Omnipaque), ethiodized oil (Lipiodol).

### **Iodine, Breast Health, and Cancer**

There is no doubt that iodine is present in female breasts during pregnancy and lactation. The debate revolves around iodine at "adequate levels" as a breast cancer preventative agent. A peer-reviewed article clarifies the conditions required for iodine to express an effect on breast cancer risk.<sup>107</sup> The background and conclusions of the study are provided here.

"Iodine has been suggested to protect against breast cancer, but there are no epidemiologic studies on individual risk. High iodine intake has been proposed to lead to a low risk of breast cancer in Japanese women. An early correlation study indicated that a high iodine intake is protective. A study from Spain found an inverse association between iodine intake in different geographical areas and breast cancer mortality. Still, there have been no studies on iodine levels and breast cancer risk in individual women. Interestingly, a recent meta-analysis reported that women treated with radioactive iodine (RAI) for thyroid cancer had a relative risk of breast cancer of 0.61 (a 39 percent reduction) compared with patients with thyroid cancer not treated with RAI.

There is strong biological evidence of a potential protective effect from iodine regarding breast cancer. Iodine receptors, such as the sodium/iodide symporter (NIS), Pendrin, and sodium/monocarboxylate transporter (SMCT), are present in breast tissue, which enables the uptake of iodine. Iodine is necessary for normal breast development, and iodine deficiency in rats causes breast cell abnormalities and pre-cancerous cell formations, reversible with iodine supplementation. Iodine has also been proposed to act as an antioxidant to have antiproliferative effects and to stimulate apoptosis in breast tissue.

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Iodine metabolism is closely related to selenium, for example, in the regulation of thyroid hormones, and selenium has also been implicated as a protective factor for breast cancer. Two reviews that included 17 separate studies reported no association between selenium and breast cancer risk and were confirmed by a Cochrane analysis. An interesting finding is that breast cancer mortality in the United States (on average, low iodine and high selenium levels) and Europe (low iodine and low selenium) is about 4–5 times higher than in Japan, where both selenium and iodine are high.

This study aimed to investigate the association between pre-diagnostic serum iodine levels and subsequent breast cancer risk and whether selenium levels modify this potential association in over 1000 patients. The study concludes that a combination of high serum iodine levels and high selenium levels was associated with a lower risk of breast cancer of at least 25 percent. There was no statistically significant reduction in breast cancer rates when either of these nutrients was considered to be found at moderate or low levels as measured in serum (blood).

Since the early 1960s, we've known iodine deficiency was related to breast disease, including breast cancers. Carcinomas are most likely to develop in the ductal tissues that normally should be concentrated in iodine.<sup>108</sup> When these tissues are iodine-deficient, they are actually more sensitive to the stimulatory and proliferative effects of estrogen.”

### **Iodine and Athletic Performance**

Just a few peer-reviewed articles address iodine intake and athletic performance. One such piece is titled "Iodine uptake and loss. Can frequent strenuous exercise induce iodine deficiency?" The abstract is reproduced here.

"Most of the daily dietary iodine intake (approximately 90 percent) will be excreted in the urine; measurement of urinary iodine excretion is thus routinely used as an index of dietary iodine intake. However, urinary excretion is not the only means of iodine loss. Subjects such as athletes or those participating in vigorous exercise can lose a considerable amount of iodine in sweat, depending on environmental factors such as temperature and humidity. In areas of lower to moderate dietary iodine intake, loss in sweat can equal that in urine.

Although electrolyte loss in sweat is well-recognized and replacement strategies are adopted, there is less recognition of potential iodine loss. Crude calculations reveal that if sweat iodide losses are not replaced, dietary stores could deplete an athlete undergoing a regular training regime. The significance of these losses could be increased in areas where dietary iodine intake is lower in the summer months. Although there is little doubt that excessive sweating can induce a relative iodine deficiency state, there is no

## Chapter 4: Missing Nutrients

case yet for iodine supplementation in those who participate in regular vigorous exercise. However, sustained iodine loss may have implications for thyroid status and possible consequences for athletic performance.<sup>109</sup>

Although it is standard practice to replace fluid and electrolytes lost during vigorous exercise, replacement requirements seldom exist for minerals such as iodine. Iodine is essential for producing thyroid hormones; hence, inadequate dietary intake leads to diminished thyroid hormone levels. Based on the published sweat iodine content of 35–40 µg/L and a potential sweat loss of 4–5 liters following vigorous exercise, daily iodine losses in sweat equivalent to the WHO-recommended adult daily intake (150µg) might be expected. When added to urinary iodine excretion, such losses would result in a significant diminution in the body's iodine stores."

Previous reports have suggested that sweat iodine content is independent of dietary intake, but data indicate that this may only apply to those with adequate iodine status. In a study, the administration of potassium iodide to subjects with borderline iodine intake showed an increase in sweat iodine. Under such conditions, it is postulated that sweat iodine may increase until it reaches an optimal level and plateau thereafter. In the absence of definitive evidence that iodine loss through excessive sweating can induce a relative iodine deficiency with consequences for thyroid hormone synthesis, there is not yet a case for iodine supplementation of those involved in vigorous exercise. However, the calculated levels of potential iodine loss through excessive sweating in the absence of adequate replacement at least raise the question of the implications of exercise-induced iodine loss for thyroid status and possibly consequential athletic performance.

Vigorous exercise is a stressor but is one of just many that life dishes out. Therefore, this information on iodine loss and athletics overlaps with other areas of life, including relationships, finances, and pandemics.

I have a personal story related to iodine and exercise. In December of 2021, I had a severe case of COVID. I was bedridden for two weeks and had a peak temperature of 103.5 F. After I "recovered," I was abysmally weak for months. I fought back hard to regain weight and strength. No matter how sickly I felt, I did a short gym routine, walked, or rode my bike around the neighborhood.

"I was not going to let the SOBs catalyze my health decline!"

By June, I participated in and finished a 115-mile bike trek over the mountainous Cherohala Skyway and finished respectably. In September and October, I had the fastest time of all participants in 101-, 103-, and 85-mile events. One day in July, I felt pretty fatigued. It was a Sunday, and I usually rode for 3 hours on Sundays. My son came into my room asking for something minor. I told him I was not feeling well, so do not expect much from me. I then decided to test the

## Chapter 4: Missing Nutrients

iodine/athletic performance theory on myself. I took one capsule of a 10.5 mg iodine supplement and left for a 3-hour ride. I felt great!

Since this experience, I have taken approximately 800mcg of iodine from a kelp supplement daily. Of note, I have NOT experienced unexplained days of lethargy and poor performance since being regular with iodine supplementation.

Those interested in learning more about the role of the thyroid and energy are referred to as "Thyroid Hormone Regulation of Metabolism."<sup>110</sup> In some respects, the thyroid is between regulating digestion and delivering nutrients to cells.

### Summary Points:

- Sweating in the course of vigorous exercise involves the loss of not only fluid and electrolytes but also minerals such as iodine.
- An adequate supply of dietary iodine is essential to produce thyroid hormones and control metabolic processes whose optimal function is necessary for the top-performing athlete. But this also applies to people experiencing other stressors.
- In the case of iodine losses induced by stress, if not adequately replaced, it eventually results in diminished thyroid hormone production, with fatigue being an impactful ramification.
- Sweat iodine concentration of 35–40 µg/L and losses of 4–5 liters would lead to overall losses to the recommended adult daily iodine intake level.
- Iodine losses in sweat may not be independent of dietary iodine intake.
- Over a prolonged exercise period, sweat iodine losses would substantially deplete iodine availability and stores.
- Under stress, iodine deficiency, thus hypothyroidism, may be transient but explain occasional fatigue.

The potential impact of extreme athletics iodine level is transient hypothyroidism, with the emphasis on transient, which may persist during training or an event, but be corrected at the next meal. It is reported that transiently decreases in the active hormone T3 do occur.<sup>111</sup> However, no solid studies demonstrate long-term thyroid suppression from elite training levels. A 24-hour transient suppression of T3 production may differentiate between winning and losing for competitive athletes. My own experience is that iodine supplementation before competitive endurance events convey a noticeable, if not subjective, improvement in my performance. After all, SOMETHING is rate or performance limiting.

### **Iodine Protocol**

As you can see, most discussions about iodine intake revolve around Hashimoto's thyroiditis. But what about most people where this condition does not exist nor is a potential issue? Hashimoto thyroiditis affects 1 to 2 percent of people in the United States. Dr. Wentz, for example, sees people who predominantly have thyroid issues, so her population is not representative of the general population.

Iodine plays a broader role than just supporting the thyroid. Thus, the intake of iodine must not be dictated by the potential for Hashimoto's disease.

The Holistic Primary Care website agrees.<sup>112</sup> Here is what this group has to say about iodine beyond the thyroid.

"Say the word "iodine," and most physicians automatically think, "thyroid."

While the thyroid gland is an unquestionable iodine sponge, and iodine is a key constituent of thyroid hormone, it has other important physiologic effects, among them the maintenance of healthy breast and ovarian tissue in women and fostering of optimal neurocognitive development in babies.

Less than 30 percent of the body's total iodine load goes to the thyroid (other references indicate that 90 percent of total iodine goes to the thyroid). Between 60–80 percent of total iodine is non-hormonal and concentrated in extrathyroidal tissues.<sup>113</sup> This fact is sadly overlooked by most clinicians, to the detriment of their patients, says Sherri Tenpenny, DO, a Strongsville, OH, a holistic physician with a primary focus on women's and children's health.

"Braverman's "The Thyroid," one of the bibles of endocrinology, says in the very first chapter that iodine is important for the eyes, prostate, breast, and ovaries. But medicine has largely ignored these tissues for decades. The FDA never even bothered to give a total body RDA for iodine beyond the anti-goiter recommendation of 150mcg per day (in lactating women, it is 220–290mcg) established in the 1920s."

"Since the early 1960s, we have known iodine deficiency was related to breast disease, including breast cancers. Carcinomas are most likely to develop in the ductal tissues that normally should be concentrated in iodine.<sup>114</sup> When these tissues are iodine-deficient, they are more sensitive to estrogen's stimulatory and proliferative effects."

Also, most discussions on iodine just consider levels of intake. However, there is inadequate consideration of iodine loss. The point is that one must consider a "mass balance" on iodine based on the following:

- intake;
- co-factors (selenium, for example);
- antagonists;
- excretion and loss of iodine; and
- risk for Hashimoto's.

Even Hashimoto's risk must be weighed against the benefits of iodine beyond the thyroid. In this regard, Iodine intake becomes personal. Thus, the solution has everything to do with personalized testing. Internal iodine levels are safe over a broad range. Figure 4.6 below shows an iodine intake "U" curve. This is not intended to be a guide to follow but rather an illustration of how iodine levels

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cannot be ascribed to such a narrow range as is currently occurring, that being close to the RDA of 150mcg/day.

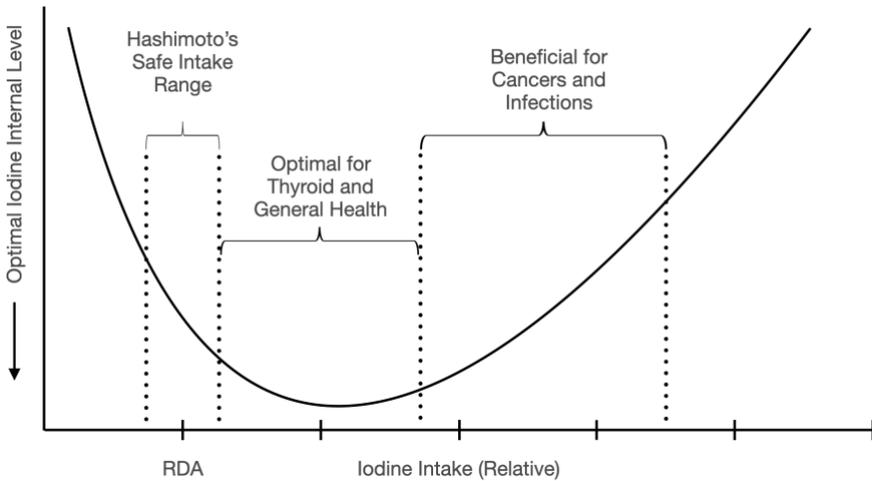


Figure 4.6: Optimal iodine intake and physiological levels. People with Hashimoto's Thyroiditis or risk factors for this condition should consider limiting iodine intake to RDA levels. People with chronic infections or cancer should consider a higher intake of iodine.

"It is not about Iodine for the Thyroid - it is about the Thyroid for the Iodine."

- Thomas J. Lewis, Ph.D.

This means we do not want the Thyroid "tail" to wag the Iodine "dog." Hashimoto's thyroiditis is now considered the most prevalent autoimmune disease and the most common endocrine disorder. It was initially described in 1912 but rarely reported until the early 1950s. However, Hashimoto's thyroiditis affects just 1 to 2 percent of people in the United States. Dictating iodine intake based on the low prevalence of Hashimoto's is inappropriate 98+ percent of the time. Further, Hashimoto's is a diagnosable and often reversible condition. Thus, those who need to be restricted in iodine intake to the RDA diminishes to less than 1 percent.

Autoimmune disease is when your immune system mistakenly attacks your body. In most cases, there is a presumption that this happens without some underlying pathology. If that were the case, we would not survive as a species. In reality, there are very quantifiable causes of autoimmune diseases.

- Intestinal permeability caused by:
  - H-pylori,<sup>115</sup>
  - Parasites,<sup>116</sup>
  - Incomplete digestion,<sup>117</sup> and

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- Food sensitivities.<sup>118</sup>
- Chronic, often stealth, infections, including:
  - Bacterial diseases, including Lyme disease and periodontal infections,<sup>119</sup> and
  - Viruses.<sup>120</sup>

Like every other aspect of health, Hashimoto's is best represented as a continuum. A person's position on this continuum dictates safe and optimal intake levels of iodine, Figure 4.7.

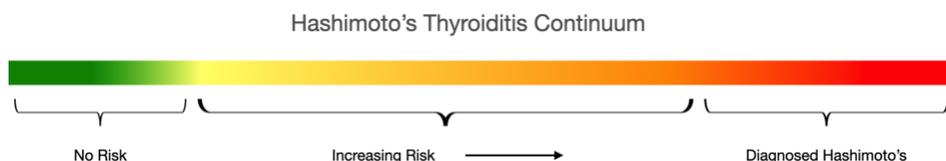


Figure 4.7. Hashimoto's disease is a continuum. The disease impacts approximately 1-2 percent of people. More may have risk factors for the disease that can be corrected when root causes are identified and treated.

### **Specific Protocol for the Intake of Optimal Iodine - Above the RDA**

Step 1: Perform a complete evaluation of thyroid health. These are the biomarkers that must be obtained:

- TSH;
- Thyroxine (T4);
- Triiodothyronine (T3);
- Triiodothyronine (\*T3), Free;
- T4, Free (Direct);
- Reverse T3, Serum;
- Thyroid Peroxidase (TPO) Antibodies;
- Thyroglobulin Antibodies.

If there is no indication of Hashimoto's thyroiditis, then iodine intake above the RDA is most likely safe, effective, and recommended. The upper daily limit we recommend is 3 mg/day. For perfectly healthy individuals on a whole-food diet, 0.5 mg/day (500 mcg/day) is adequate. Athletes and those who experience substantial daily stressors should double these recommendations.

Step 2: If there IS an indication of Hashimoto's thyroiditis, test for and remediate causes. Even people without Hashimoto's should consider this before increasing their current iodine intake levels. Some applicable tests include:

- Complete blood count with differential with an interpretation focused on low-grade viral or bacterial infection.

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- Erythrocyte sedimentation rate. The results from this test should be <3mm/hr. Anything above that infers some level of gut dysbiosis that may be resolved with a probiotic diversification approach.
- H-pylori blood test. If this organism is found, even if below standard reference ranges, it should be treated to bring it down to the lowest possible levels. It contributes to intestinal permeability and gut dysbiosis.
- Oral pathogen test. Oral pathogens festering below the gum line may contribute to Hashimoto's.
- Stool test to determine microbiome health.
- Food sensitivity testing.
- Internal temperature measurement (<https://careclinic.io/thyroid-temperature-chart/>).

Work with a practitioner to get these tests and correct any issues uncovered.

Step 3: After appropriate protocols are completed, at a minimum, retest the panels in Step 2. If these tests are now optimal, retest the comprehensive thyroid panel.

Step 4: Adjust your iodine intake by measuring iodine levels and excretion. This is a serum and urine test but is somewhat imperfect because some iodine is lost through sweat. This is why athletes should consider higher doses of iodine than sedentary people.

- Test for serum iodine.
- Test for urine iodine (spot and 24 hours).
- Adjust iodine intake.
- Retest for iodine levels.
- Continue to monitor the core temperature.

Ideally, it would be best to plot the iodine excretion levels versus iodine intake. This type of chart will help you determine your physiological need.

Finally, assuming you have increased your iodine intake above the RDA, periodically test the full thyroid panel. If antibodies are present, reduce iodine intake and redo testing for factors that potentially cause Hashimoto's and fix them.

Do NOT limit your iodine intake because of a reversible underlying condition.

Iodine is a crucial nutrient. Consider taking in more iodine than is dictated by the presumed need of your thyroid and the potential for Hashimoto's thyroiditis. Testing, as always, is the key to getting it right - to the extent anyone can when it comes to the complexities of human physiology.

“Knowledge is freedom, and ignorance is slavery.”

- Miles Davis

### **Cholesterol is Essential to the Function of ALL Cells**

Summary: Every cell membrane of every cell type in our body is composed of a phospholipid bilayer. This structure is key to both the integrity and function of our cells. Cholesterol is arguably the most important lipid in cell membranes. Every doctor does or did know the importance of cholesterol, yet it is and continues to be the most demonized of all human physiological substances. The cholesterol-lowering industry has eclipsed \$1 trillion in revenues. That is just the "tip of the iceberg," as these drugs cause or exacerbate the most prolific diseases we face today.

- The cholesterol misinformation campaign is one of many that prepared our society to accept something as insidiously dangerous as the unproven and untested COVID "vaccines."
- Fight back and tell your doctor NEVER to use the word "cholesterol." Instead, force them to use the term low-density lipoprotein or LDL. Cholesterol is NOT what is being treated. We must not accept the infiltration of any disinformation.

The cholesterol paradigm has enslaved us. Citizens are enslaved, and doctors are coerced. Doctors are not to blame in many cases. They are required to follow the standard of care. A healthcare professional's deviation from the "standard of care" can lead to a medical malpractice lawsuit. Also, doctors are rated based on their execution of the standard of care. Not prescribing drugs that are part of the standard of care will sometimes lead to bad scores.

However, doctors must take some risks to help their patients. How many of you with elevated "cholesterol" who have resisted statin (cholesterol) treatment have been chided by your doctor?

"Don't you want to protect your heart?"

"What are your children going to do when you are gone?"

These are actual statements by doctors to patients. This must stop in the face of new (and old) information on the true value of statin drugs.

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The benefit of all drugs is given in relative statistics. This information is meaningless to you. Here is a simple example to explain the difference.

This year, three people in America were killed by a lightning strike. Last year only two people died from lightning. Here are the statistics.

- Relative statistics: 2 died last year, 3 died this year; therefore, the relative increase is  $(3-2)/2 * 100 = 50$  percent increase.

Are you worried about being struck by lightning and dying? You would have no concern when you know the absolute statistics.

- Absolute statistics: There are 331,000,000 Americans as of 2022. Therefore, your absolute risk - your real risk - of dying from a lightning strike is  $(3-2)/331,000,000 * 100 = 0.00000003$  percent

Compare 50 percent (relative risk) to 0.00000003 percent (real risk, also known as absolute risk). This shows how dramatically irrelevant relative statistics can be. If the true threat of a lightning strike that kills you is 50 percent annually, the entire population of the United States would be reduced to less than 1,000 people in just 20 years!

Never base any health or life decisions based on relative risk or relative statistics.

They are meaningless.

Absolute statistics are real, accurate, and relevant. In medicine, absolute statistics are expressed as "numbers to treat (NNT)." This is the absolute (actual) value for the efficacy of any drug. The NTT for statins is paltry, Figures 5.1 and 5.2.<sup>121</sup>

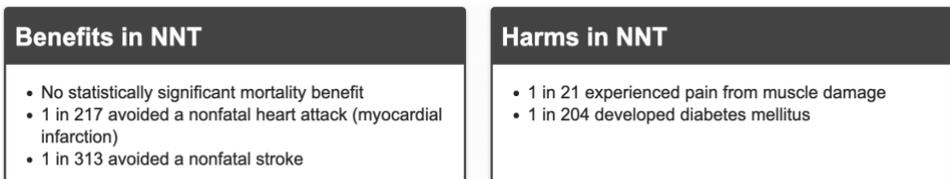


Figure 5.1: Statin benefits and harm in Numbers to Treat.

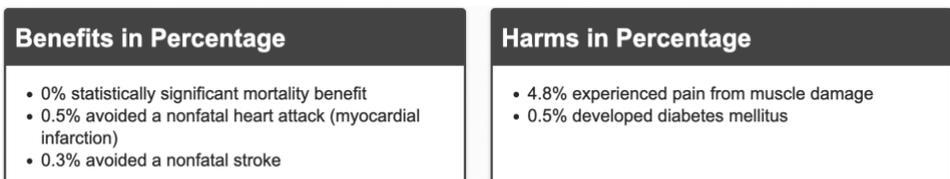


Figure 5.2: Statin benefits and harm in absolute percentages.

The number of people studied to derive these values is enormous. An entire organization has arisen based on numbers to treat as the foundation of evidence-

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based medicine. The organization is a group of physicians that have developed a framework and rating system to evaluate therapies based on their patient-important benefits and harms, as well as a system to evaluate diagnostics by patient signs, symptoms, lab tests, or studies. This organization only uses the highest quality, evidence-based studies (frequently, but not always Cochrane Reviews) and accepts no outside funding or advertisements. Concerning statin drug value, they conclude,<sup>121</sup>

"The CTT meta-analysis, which included 22 trials with more than 130,000 patients, showed no statistically significant mortality benefit from statins in the two low-risk groups (lower than 10 percent and lower than 20 percent 10-year risk), separately and combined. Conversely, the USPSTF, pooling data from 15 trials with more than 70,000 patients, found that 0.4 percent fewer patients taking a statin died than patients taking a placebo (number needed to treat [NNT] = 250). Importantly, some of the trials in the USPSTF analysis included high-risk patients or patients with cardiovascular disease."

Translation: Statins do not provide a more extended life benefit for most people. Less than 0.4 percent of high-risk people live longer.

The cholesterol industry is extraordinarily powerful. Sales from statin drugs have reached US \$1 trillion.<sup>122</sup> The marketing budget to promote this narrative is daunting, and they have made the cholesterol molecule the most demonized of all substances in the body. Because of the power behind this movement, the industry can get away with saying completely unscientific things by presenting their data in meaningless relative statistics, and worse! Because of the revenue collected from the various drugs to lower cholesterol, they have the finances to manipulate data through randomized control trials in subtle and overt ways.

Reminder: According to the Chaired Professor from Stanford University Medical School, John Ioannidis, M.D., "most published research is false."<sup>123</sup>

Manipulated published research on cholesterol is the rule, not the exception.

An example illustrates how blatantly duped we are regarding knowing our cholesterol numbers. Any third grader with adequate knowledge of addition and subtraction, when given this example, scratches their head and says, "huh?" Please read on.

Your total cholesterol number is the summation of your LDL and HDL values plus 20 percent of your triglyceride number.

Total cholesterol (TC) = LDL + HDL + 20 percent Triglycerides

Here are three scenarios.

Patient	Total cholesterol	LDL	HDL	20% Triglycerides
1	245	140	85	20

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2	195	140	35	20
3	150	70	30	50

If you are a doctor, before reading on, please imagine the recommendations you might make in each case.

At great risk of creating confusion, here are the incorrect definitions for "cholesterol" used by doctors who practice standard of care. The correct definitions are provided after the analysis of these three scenarios. MedlinePlus provides the definitions that are universally used but are misnomers at best.<sup>124</sup>

- Total cholesterol - a measure of the total amount of cholesterol in your blood. It includes both low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol.

Of course, this is an entirely incorrect definition of total cholesterol. Cholesterol is NOT measured as part of "total cholesterol."

- LDL (bad) cholesterol - the main source of cholesterol buildup and blockage in the arteries.

This, too, is wrong. LDL is made with cholesterol, but the actual cholesterol molecule is not measured. No one on planet earth knows the actual amount of the cholesterol molecule in their blood. No one!

- HDL (good) cholesterol - HDL helps remove cholesterol from your arteries.

The way this statement is written infers that HDL is a savior of your arteries. This is not correct. HDL is a lipoprotein that moves excess fats back to the gut for disposal or reprocessing. Cholesterol is NOT a lipoprotein.

- Triglycerides - another form of fat in your blood that can raise your risk for heart disease, especially in women.

According to the Mayo Clinic, the "healthy" values for the cholesterol numbers are shown in Table 1.

<b>Cholesterol levels for adults, ages 20 and over</b>				
AMOUNT (mg/dL)	TOTAL	LDL	HDL	TRIGLYCERIDES
Ideal	<200	<100	>60	<150
Borderline	200–239	130–159	Women: 40–59 Men: 50–59	150–199
Too high or low	>240	High: 160–189 Very high: >190	Women: <40 Men: <50	High: 200–499 Very high: >500

Table 1. Cholesterol levels for adults ages 20 and over. Source: Mayo Clinic and U.S. National Library of Medicine.

Comparing patient 1 with patient 2

When the doctor sees the "high" total cholesterol of 245 in patient 1, red flags quickly go up. When the doctor sees the "normal" total cholesterol in patient 2, there is much less concern. However, what makes absolutely no sense, is that in patient 1, the "good" cholesterol is high, and in patient 2, the good cholesterol is low.

If HDL is the "good" cholesterol, and in patient 1, the good cholesterol is nice and high, why does it make the total cholesterol score worse? And too many doctors prescribe statins and other cholesterol-lowering drugs on TC.

Translation: As your "good" HDL cholesterol increases, your total cholesterol score worsens, and you are much more likely to be put on a statin drug.

Let's review the 3rd-grade cholesterol math. In general, if you want to calculate the net "good" in your life, you would subtract the number of "bad" from the number of "good" to get a net good. Thus, in general:

$$\text{Net Good} = \text{Total Good (minus) Total Bad}$$

In the cholesterol calculation, why is the "bad" LDL added to the "good" HDL?

This is when any 3rd grader says, "this does not make sense." But your doctor, with 20 years of education, writes a statin prescription.

This is how duped we have become when the drug industrial complex can fool us by twisting 3rd-grade math. We are partially to blame, but statin drugs that lower LDL profoundly impact cognition.

Let's take a look at patient 3.

When the doctor sees total cholesterol of 150 in patient 3, green lights flash, indicating "perfect" cholesterol numbers, according to the American College of

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Cardiology.<sup>125</sup> Patient 3 is actually the least healthy of the three and most likely is on a statin or other cholesterol-lowering drug. Total cholesterol values are seldom 150 mg/dL in healthy people. Patient 3 has a low "bad" LDL value. If the analysis is just on LDL and total cholesterol, the person's actual health status is missed - completely because the total cholesterol value is calculated under a false pretense.

The "good" HDL cholesterol of patient 3 has tanked, and the 20 percent of triglycerides value is high. Their actual triglyceride level is 250 mg/dL. People with a triglyceride level of 250 are diabetic or close to being so. The Cleveland Clinic says, "A healthy number for triglycerides is below 150 milligrams per deciliter (mg/dL)."<sup>126</sup> The Mayo Clinic states, "A triglyceride level of 250 mg/dL is considered high. High triglycerides can put you at greater risk for heart disease and can also be a sign of serious conditions including type 2 diabetes, prediabetes, metabolic syndrome, and hypothyroidism."<sup>127</sup>

What? But the total cholesterol number is perfect! How can Mayo Clinic say this person is at higher risk for heart disease and diabetes?

The Mayo Clinic also offers help to raise your HDL levels in an article titled "HDL cholesterol: How to boost your 'good' cholesterol."<sup>128</sup> In essence, they are showing you how to raise your total cholesterol and be put at risk of being prescribed a statin drug.

Being put on a statin is often the beginning of a vicious cycle. It becomes a statin drug merry-go-round. As you will see later in this chapter, Statin drugs increase the risk of type 2 diabetes by at least 50 percent, on average. Translation: Taking statins can increase your triglycerides, thus your heart disease risk. Now you may realize why patient 3 is most likely on a statin drug. Therefore, one of many statin merry-go-rounds is related to diabetes.

- As a person trends toward diabetes, their blood glucose goes up.
- As their glucose goes up, so do their triglycerides.
- As their triglycerides go up, their total cholesterol number goes up.
- A large portion of those on statins is on blood pressure medications.
- As the cycle continues, their diabetes status worsens, and they are put on insulin therapy.
- Their triglycerides go up further, increasing the total cholesterol number, and they are regularly put on a higher statin dose.
- Many people on statins still have an adverse event precipitated by the statin drug contributing to the diabetic condition.

Do you know what your doctor or cardiologist does if you have a heart event of some type in this situation?

They put you on an even higher statin dose - if you can tolerate it, Figure 5.3.

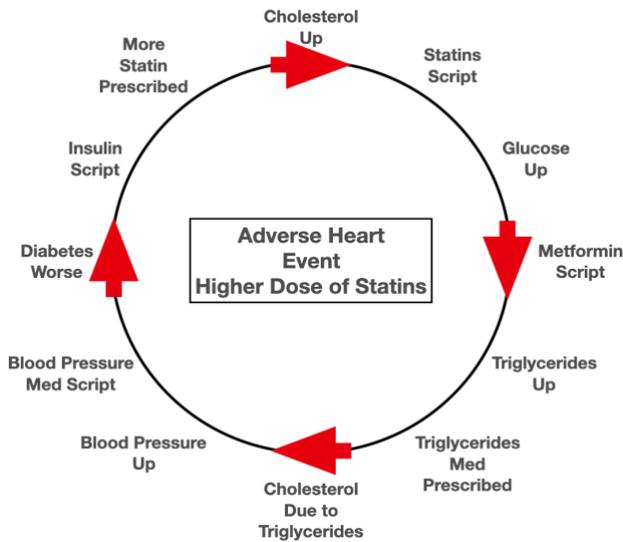


Figure 5.3: The statin prescription merry-go-round.

Some type of procedure, a stent, angioplasty, or other invasive intervention, is next. The approach to heart disease is just one thing - elevated cholesterol - nothing else. If it were just one thing, that would be wonderful. Successfully treat it in everyone, and the disease goes away. Cardiovascular disease remains the number one killer of United States citizens.

“The whole secret lies in confusing the enemy so that he cannot fathom our real intent.”

-Sun Tzu

What causes heart disease if not cholesterol? Please refer to the chapter on stealth infections to see a powerful cause-and-effect link.

Charles Mayo, the founder of the Mayo Clinic, dedicated a substantial portion of his medical career to educating the world on the link between periodontal infection and many chronic diseases, especially those of the heart. An article by the Samaritan Ministries provides a concise overview of Mayo's work.<sup>129</sup> Here are some highlights from that article:

- "Dr. Charles Mayo, the founder of the famous Mayo Clinic, believed in the “focal infection” theory of disease, something so archaic that almost no one has heard of it today. The theory basically states that oral infection can influence the entire body's health. Addressing the Chicago Dental Society in 1913, Mayo said, “The next great step in preventative medicine must come from the dentists.”
- Mayo appointed Dr. Edward C. Rosenhow to head a team of researchers dedicated to focal infection theory. From 1902 to 1958, Rosenhow

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conducted experiments and published more than 300 papers, 38 of which appeared in the Journal of the American Medical Association. During the same period, Weston A. Price, founder of the National Dental Association research institute, published his findings indicating that dental and oral infections were often the primary cause of disease.

- These two medical pioneers established a simple but profound fact. If you pull an infected tooth, the patient will often recover from serious disease, from chronic fatigue to cancer, dermatitis to diabetes, from hemorrhoids to heart disease.
- He took teeth with root canals that he extracted and sewed them under the skin of a rabbit. The rabbit invariably died from the same disease that had plagued the person. If the patients had kidney trouble, the rabbits developed kidney problems; if they had eye trouble, the rabbits' eyes became affected; heart trouble, rheumatism, stomach ulcers, bladder infections, ovarian diseases, phlebitis, osteomyelitis, whatever the condition, rabbits promptly became similarly affected. Dr. Price claimed he never found an exception to this rule.

Numerous studies show that cholesterol levels are elevated with periodontal infections. Mechanistically, it all makes sense. The Infection causes damage, and cholesterol repairs damage as it is a critical constituent of new cells. Of course, it will go up. The brain holds the most cholesterol on a "per mass" basis because it is highly metabolically active and needs more cholesterol to repair the damage caused by its constant and piqued activity. Selected titles asserting the cholesterol-periodontal link are included here.

- The association between hyperlipidemia and periodontal infection.<sup>130</sup>
- Association between periodontal pockets and elevated cholesterol and low-density lipoprotein cholesterol levels.<sup>131</sup>

This paper's conclusion is to the point.

"In this large cohort study, the presence of periodontal pockets as measured by Community Periodontal Index of Treatment Needs (CPITN) was positively associated with total cholesterol and LDL-cholesterol. The study's findings support the reports linking increased prevalence of cardiovascular mortality among patients with periodontal disease."

- Hidden tooth infections increase heart disease risk by almost three times.<sup>132</sup>

Our plant manager client was obsessed over the potential for a heart attack. He complied with the doctor's orders to take his statin drug. Over eight years, his total cholesterol never exceeded 160 mg/dL. He had a major dental extraction and, three weeks later, suffered a massive heart attack. His white blood cell count at the hospital was 14,000 cells per mL. He was prescribed a higher statin dose by

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his cardiologist. The elevated white blood cells were ignored. After all, white blood cells just reflect the action of innate immunity. How could this possibly compare to a presumed elevation of physiological soap? Statins are known to promote infections, and this plant manager developed severe oral infections. Here is just one example reference titled,

"Statins: The severe infection 40 percent more likely to occur among statin users - study warning."<sup>133,134</sup>

When going to their doctor and have "elevated cholesterol," how many people are asked about their teeth or referred for a thorough dental evaluation?

### **Your Actual Cholesterol Number**

Do you know your actual cholesterol number? If you answer 240 or 175 or some other number in this range, you are wrong. There are 7.9 billion people on earth as of April 2022. Not a single person on earth knows their cholesterol number - not even one person out of 7.9 billion. How can this be? Look at the definition of "total cholesterol" above. Where is the actual cholesterol number in that equation? It is NOT there. We have been duped.

Cleveland and Boston Heart Labs perform extensive "cholesterol" testing. Consider calling either of these labs and asking if they run a test for the cholesterol molecule. The person answering the phone will say something like, "We do this; we measure "total cholesterol." Then explain that "total cholesterol" is not the cholesterol molecule, but you want your actual cholesterol measured. There will be silence on the other end of the phone. Then ask to speak to one of their scientists. None will be available, and you will never get a return call. This is actually what happened to me.

Do you find it mind-boggling that a molecule that is not even measured becomes the most known and feared of all physiological substances?

Granted, both LDL and HDL contain the cholesterol molecule, so there is a correlation between these values and the amount of cholesterol they are transporting. But, both these lipoprotein molecules do so much more than carry cholesterol. Figure 5.4 shows the chemical structure of the cholesterol molecule and the LDL particle. They are clearly not the same. And the HDL particle is very similar in construction to the LDL particle.

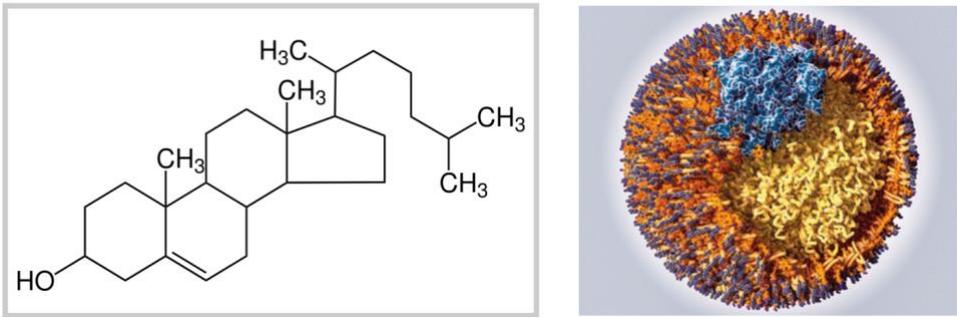


Figure 5.4: Cholesterol molecule on the left and low-density lipoprotein (LDL) on the right.

Harvard Medical School expresses strong accolades for the cholesterol molecule.

"Cholesterol is essential for human health. It is the building block of steroid hormones, including the stress hormone cortisol, and the male and female sex hormones, including testosterone and estrogens. Cholesterol is also an essential component of the membranes that surround all human cells. More than simply holding cells together, these membranes have a crucial role in regulating cell function and allowing chemicals to pass into and out of cells. Because cholesterol is so vital, the body does not rely on diet to provide it. Most of the cholesterol in the blood is manufactured in the liver."

You can no longer find this statement published by Harvard in 2007. They took it down in 2019. My best guess is that it contradicts the "cholesterol is bad" narrative. I used this article to help many people get off of statin drugs. Do you believe in God? I received a message that this article would be removed from the internet in 2018, so I downloaded the full article referenced here.<sup>135</sup>

The actual cholesterol molecule is not the target of the drug companies through their statin and biological drugs. The \$1 trillion in revenue is from lowering the LDL particle, the one on the right side of the figure above. Therefore, we all should know what is this "bad" substance.

LDL, it turns out, is a 4-letter word - SOAP. Yes, the drug companies have grossed 1 trillion dollars by demonizing soap. You have been duped. Or maybe not. Do you need soap in your body?

### **LDL is a 4-letter word: SOAP**

"The human brain is nearly 60 percent fat. We've learned in recent years that fatty acids are among the most crucial molecules that determine your brain's integrity and ability to perform."<sup>136</sup>

The actual cholesterol molecule is often defined as a waxy substance. This term sheds a negative light on the substance. Even the word "fat" has a negative connotation. However, in human physiology, cholesterol is properly classified as

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fat. For the sake of an example, consider the words "fat," "oil," and "grease" to have the same meaning. Grease is more of a cooking term, oil is more of a chemical term, and fat is more of a physiology term which all define the same class of substance.

Blood plasma contains 91 to 92 percent of water. The brain is 60 percent fat (oil). The grease remains when you wash a greasy (oily) dish with water. Upon adding soap, the oil magically disappears. Where does it go? The oil gets pulled into the soap molecule, Figure 5.5.

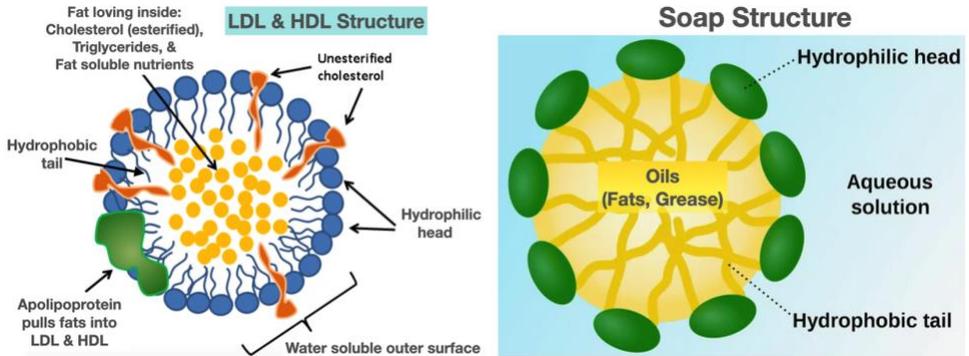


Figure 5.5: The similarity between the LDL and HDL particles and soap.

Liji Thomas, M.D., explains lipoproteins.<sup>137</sup>

- Lipoproteins are special particles made up of droplets of fats surrounded by a single layer of phospholipid molecules. They are distinctive in being amphipathic, meaning they have polar and non-polar ends.
- In a lipoprotein, the polar ends of all the phospholipid molecules face outwards to interact with water, itself a polar molecule. This enables the lipoprotein to be carried in the blood rather than rising to the top, like cream on milk or the oil in a vinaigrette salad dressing.
- The non-polar fat balled up inside the phospholipid layer at the center of the lipoprotein is thus transported to the place where it must be stored or metabolized, through the bloodstream, despite being insoluble in blood.
- Thus, lipoproteins (LDL and HDL) are molecular-level trucks to carry fats wherever they are required or stored.

Here is the definition of soap.

The soap molecule has two different ends, one that is hydrophilic (polar head) that binds with water, and the other that is hydrophobic (non-polar hydrocarbon tail) that binds with grease and oil. Soap is an emulsifier capable of dispersing one liquid into another immiscible liquid. This means that while oil does not naturally mix with water, soap can suspend oils, grease, and fats in such a way that they can be transported through water.

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LDL and HDL are soap molecules that transport fats through your water-based bloodstream.

### **Cholesterol Demonized**

Please name any substance your brain regulates and your liver produces that causes you to die young.

A 2018 article explains that the evidence against cholesterol-lowering drugs has been suppressed and exaggerated.<sup>138</sup> The author, Maryanne Demasi, completed a doctorate in medical research at the University of Adelaide and worked for a decade at the Royal Adelaide Hospital as a research scientist specializing in rheumatoid arthritis research. She has also worked as an advisor to the South Australian Government's Minister for Science and Information Economy. The abstract from her paper titled, "Statin wars: have we been misled about the evidence? A narrative review" is provided here.

"Statins are the most widely prescribed cholesterol-lowering drugs in the world. Despite the expiration of their patents, revenue for statins is expected to rise, with total sales on track to reach an estimated US \$1 trillion by 2020.

A bitter dispute has erupted among doctors over suggestions that statins should be prescribed to millions of healthy people at low risk of heart disease. Concerns exist that the benefits have been exaggerated and the risks have been underplayed. Also, the raw data on the efficacy and safety of statins are being kept secret and have not been scrutinized by other scientists.

This lack of transparency has led to an erosion of public confidence. Doctors and patients are being misled about statins' true benefits and harms, and it is now urgent that the raw data from the clinical trials are released."

The entirety of the paper is provided at the end of this chapter.

LDL is NOT just a carrier of the cholesterol molecule. Any fat, healthy or unhealthy, is transported through the water-based bloodstream in LDL. Livestrong wrote, "What's the Connection Between Cholesterol and a Weight-Loss Diet?"<sup>139</sup> Triglycerides, the molecules produced from excess glucose in the bloodstream, are stored in fat cells. The fatty acids carried by LDL are important because these fats can be used as fuel for cells. Triglycerides are best thought of as the means for storing and transporting the fatty acids we need for fuel. Fuel cannot be burned unless delivered to the furnace, and lipoproteins like LDL are the delivery vehicles.

When LDL is lowered with a statin drug, triglycerides are less able to be transported to be burned as fuel in cells. The consequences are:

- A greater dependence upon sugar as a fuel

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- Inability to lose weight because stored fats, converted to triglycerides, cannot be transported to be burned, so they stay stored as fat.
- Being unable to burn fats efficiently leads to insulin resistance and diabetes. There is a well-documented association between statin use and diabetes. Now you know how those drugs contribute to diabetes.

Not everyone appreciates this process, even those at the highest level of medicine. The Livestrong article quoted Roger Blumenthal, MD, a professor of cardiology at Johns Hopkins and director of its Ciccarone Center for the Prevention of Cardiovascular Disease. He said, "Most people who lose weight also improve their dietary choices, eating more fruits and vegetables, for example. But theoretically, if you lose weight on a diet of cheeseburgers and fries, you could raise your LDL."

Comments like this are not helpful and infer that LDL only transports harmful fats. This is not the case. Vitamin A, a vital nutrient for the brain and eyes, is transported by lipoproteins. The brain, predominantly composed of fats, is nurtured with fat-soluble nutrients like vitamin A and omega-3 fatty acids, and the lipoproteins carry these building blocks to the brain. Other fat-soluble nutrients that lipoproteins transport include: Vitamins D, E, and K and important fats, including fish oils and the essential fatty acids EPA and DHA.

Here is an interesting coincidence. The brain is very active but less so during sleep. Imagine if your bicep was always active, curling a weight all day. By the end of the day, it would be exhausted and relish a good night's sleep to recover. That is your brain every day.

Consequently, brain cells use roughly ten times more oxygen than the average of the rest of the cells in the body. Your bicep would also use more oxygen if it exercised all day long. Two simple facts explain the importance of the cholesterol molecule and LDL that transports cholesterol to the brain.

1. The brain uses ~25 percent of the oxygenated blood leaving the heart. The brain is only about 2.5 percent of the mass of the body. Thus, it uses ten times more oxygenated blood, on average.
2. Twenty-five (25) percent of the cholesterol found in the body is in the brain.

Isn't it interesting that 25 percent of the oxygenated blood and 25 percent of the cholesterol are in the brain? Coincidence?

Cholesterol, per Harvard, is a critical component of all cells. When cells are very active, they are more likely to break down and be rebuilt, just like an active muscle. "No pain - no gain." Pain results from breaking down cells that rebuild stronger than the ones replaced. Consider the bicep example and the soreness you would experience the next day if you curled a weight all day. Due to its constant

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activity, the brain needs more repair substances, and cholesterol is the most important of the lot.

Oxygen consumption and cholesterol levels go together. Where there is "fire," there is a need for repair.

Generally, the discipline of cardiology studies and administers drugs for the heart. Every once in a while, other groups publish data that crosses into areas like the cardiovascular arena. A case in point is the discipline of neurology. The NY Times wrote, "When 'Bad' Cholesterol Gets Too Low, Stroke Risk May Rise."<sup>140</sup> The article states, "LDL levels below 70 were tied to an increased risk of hemorrhagic stroke." But the American College of Cardiology, responsible for setting LDL targets, states, "High-risk patients should be treated to lower LDL, achieving a target level < 70 mg/dL.

Translation: The ACC target for LDL increases stroke risk by at least 50 percent.

The NY Times article is based on a peer-reviewed paper in the journal Neurology.<sup>141</sup> The conclusion to that paper states,

"We observed a significant association between lower LDL and higher risk of ICH (intracerebral brain hemorrhage) when LDL was <70 mg/dL, and the association became nonsignificant when LDL ≥70 mg/dL. These data can help determine the ideal LDL range in patients at increased risk of both atherosclerotic disease and hemorrhagic stroke and guide planning of future lipid-lowering studies."

The study also looked at very low LDL values in the range your cardiologist would be delighted with. In particular, the study shows that at an LDL of < 50, stroke risk increases by 270 percent. The NY Times summarized the data with the following statement. "They found that compared with people in the range of LDL 70 to 99 milligrams per deciliter of blood, people who had an LDL of 50 to 69 had a 65 percent higher risk of hemorrhagic stroke. For people with an LDL below 50, the risk nearly tripled."

The study on low cholesterol and stroke was substantial, following over 96,000 people for nine years. However, when this study is presented to cardiologists and primary care doctors, they tend to dismiss the findings. You see, neurologists, not cardiologists, published this paper. I have observed that doctors put more value on the source of information than on the data itself!

Note that a range for LDL of 70 - 99 mg/dL is NOT normal. The ideal range for LDL is 100 - 140 mg/dL. As you will see later in this chapter, the optimal total cholesterol level is around 220 mg/dL. Recall that total cholesterol is an aggregate of the LDL, HDL, and 20 percent of the triglyceride level. Therefore, an ideal total cholesterol value broken down into these three pieces is more like this:

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- LDL - 140 mg/dL;
- HDL - 70 mg/dL;
- Triglycerides - 50 mg/dL (20 percent of that is 10).

$$\text{Ideal total cholesterol} = 140 + 70 + 10 = 220 \text{ mg/dL}$$

Even though I criticized adding HDL and LDL together previously in this chapter, I am now adding them - just like your ignorant doctors. Have I lost my marbles, or is there another explanation?

HDL and LDL are both good,  
as is a total cholesterol value above 200 mg/dL.

However, the fraud that is not relieved by this realization that LDL is not bad is the phrase "total cholesterol."

- Triglycerides are NOT cholesterol;
- LDL is NOT cholesterol (it does contain some);
- HDL is NOT cholesterol (it does contain some);
- Total cholesterol is NOT total cholesterol.

What is "total cholesterol?" There is no such thing. It is an attempt to measure specific types of lipids (fats). Triglyceride fats are carried in LDL and HDL lipoproteins, as are many other fatty substances. Therefore, how can we specifically determine the quantity of the cholesterol molecule?

The Total Cholesterol calculation is of no value and is deceiving by implying it is something it is not and should not be calculated or used.

### **If not "total cholesterol," then what?**

A major health problem in the developed world is diabetes. It is viewed as a sugar issue. This is a naive view because there is almost always a yin and yang consideration. If the yin is sugar (glucose or triglycerides), then the yang is fat. Sugars in the body are easy to measure either through HbA1C, fasting glucose, fasting insulin, or triglycerides.

How are fats measured in the body? Here is a simplistic but accurate view of fat distribution and balance in the body. The circulatory system is our connected system through which all nutrients and wastes pass, including fats. In general, LDL carries fats to tissue, and HDL recycles waste and unused fats back to the kidneys and liver. HDL, in this sense, reflects fat deficiency or sufficiency. If HDL is low, fats are mostly consumed. When HDL is high, excess fats are available. In this respect, it is no different compared to any other nutrient. We do not just want the bare minimum of sodium, for example. We always need a reserve.

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Clever researchers have developed a vague biomarker they call the "atherogenic index of plasma" to determine cardiovascular health and risk. It is elegant in its simplicity and is quite predictive of vascular outcomes. Importantly, the mechanism reflected in its high or low values is understandable regarding the driver of diabetes and vascular disease.

The atherogenic index of plasma (AIP) =  $\text{Log Triglyceride value} / \text{HDL}$

I understand your eyes glaze over when there is a trigonometry symbol, so let's simplify this:

Diabetes and heart disease risk is proportional to the ratio of:

sugar (measured by triglycerides)

divided by

fats (measured by HDL)

Higher AIP numbers are associated with worse vascular outcomes. How simple is this relationship? As sugars go up and fats go down, diabetes and heart disease worsen. What is this fundamental mechanism?

- Sugars promote inflammation and damage. As sugars increase (triglycerides in this instance), the damage worsens.
- Fats promote healing. The actual cholesterol molecule builds and rebuilds all cell membranes. HDL is a measure of fat and cholesterol sufficiency. If HDL is low, the repair and rebuilding of damaged tissue are compromised.
- The AIP value takes both of these circumstances into consideration. The AIP is the yin and yang of diabetes and cardiovascular disease.

My team calculates the AIP of all our participants, and we use its value as a benchmark for improved health. Here is one of a few key articles on the AIP value, in this case, published in *The Mayo Clinical Proceedings* by a group from Johns Hopkins and the University of Mississippi.

"Atherogenic Index of Plasma and Triglyceride/High-Density Lipoprotein Cholesterol Ratio Predict Mortality Risk Better Than Individual Cholesterol Risk Factors, Among an Older Adult Population."<sup>142</sup>

Please ignore your phony "total cholesterol" number and focus on your AIP value. It should be well less than 0.24.

The study, "Heart disease: the greatest 'risk' factor of them all,"<sup>143</sup> supports the concept that the current trends in heart disease mortality have little to do with "cholesterol." The authors state,

"By the turn of the last century, flying in the face of over a hundred years of research and clinical observation to the contrary, medicine abandoned

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the link between infection and atherogenesis; not because it was ever proven wrong, but because it did not fit in with the trends of a medical establishment convinced that chronic disease such as heart disease must be multifactorial, degenerative and non-infectious. Yet it was the very inability of 'established' risk factors such as hypercholesterolemia, hypertension and smoking to explain the incidence and trends in cardiovascular disease that resulted in historically repeated calls to search out an infectious cause. This search began more than a century ago.

Today, more than half of US heart attack victims have acceptable cholesterol levels, and 25 percent or more have none of the "risk factors" associated with heart disease, including smoking, high blood pressure, elevated total cholesterol, or obesity, most of which are not inconsistent with being caused by infection.

UCLA Health looked at hospitalization for heart attacks.<sup>144</sup> "A national study has shown that nearly 75 percent of patients hospitalized for a heart attack had cholesterol levels that would indicate they were not at high risk for a cardiovascular event, based on current national cholesterol guidelines. Specifically, these patients had low-density lipoprotein (LDL) cholesterol levels that met current guidelines, and close to half had LDL levels classified in guidelines as optimal (less than 100 mg/dL)."

One might think that since 50 percent of heart attack victims have "elevated cholesterol," it is a major risk factor. However, a group from the University of California at San Francisco (UCSF) explains this is not the case. Cholesterol is needed to repair damaged tissue, such as heart disease. Thus, its number will go up under such circumstances. The UCSF group explains this.<sup>145</sup>

"The changes in lipids and lipoproteins that occur during inflammation and infection are part of the innate immune response and therefore are likely to play an important role in protecting the host. The guidelines for managing lipid disorders and the standard risk calculators for predicting cardiovascular disease (ACC/AHA and Framingham) underestimate the risk in patients with inflammation. It has been recommended to increase the calculated risk by approximately 50 percent in patients with severe inflammatory disorders. Of note statins, fibrates, and fish oil have anti-inflammatory properties and have been reported to have beneficial effects on many of these inflammatory disorders."

Key points from the UCSF article include:

- The total cholesterol value is part of innate immunity.
- People with inflammation are at high risk for heart disease.
- Statins have meager anti-inflammatory properties.

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These researchers subtly indicate that any benefit from statin drugs is NOT derived from their "cholesterol" lowering capability. Instead, statins act as anti-inflammatories. The term "anti-inflammatory" is very broad. Inflammation measures the body's response to an insult mainly from infection. Traumatic injury is an exception. Inflammation is a treasure to our bodies. It is what keeps us from dying in a hostile world. Inflammation is a measure of our innate immune response. Some drugs reduce inflammation. In general, these drugs suppress the immune system. Other drugs classified as anti-inflammatories reduce the cause of inflammation, which a substantial percentage of the time is infectious in nature.

Importantly, any benefit derived from statin drugs has nothing to do with lowering LDL. Instead, it is their antibiotic properties that provide the benefit.

### **Statin Drugs are Antibiotics**

Most of us are antibiotic-phobic. We will tolerate a 10-day treatment for Lyme disease or acute infection. However, would you take antibiotics for life? If you take statin drugs, you are doing just that. Steven Schmidt is a medicinal scientist who worked for Warner-Lambert on the development of Lipitor. Pfizer eventually bought Warner-Lambert and Lipitor became the most profitable drug of all time until recently surpassed by the COVID-19 injections. When Dr. Trempe of Harvard Medical School suggested to Schmidt that statins were antibiotics, he replied, without hesitation, "we know that."

Here are some recent research titles that add credibility to the idea that statins are (and work because they are) antibiotics that reduce infection and inflammation.

- "Studies on the antibacterial effects of statins-in vitro and in vivo." <sup>146</sup>
- "Antimicrobial action of Atorvastatin and Rosuvastatin." <sup>147</sup>
- "Antibacterial activity of statins: a comparative study of Atorvastatin, Simvastatin, and Rosuvastatin." <sup>148</sup>
- "Antimicrobial Effect and Immunomodulation of Atorvastatin." <sup>149</sup>
- "Nontraditional Anti-Infectious Agents in Hemodialysis." <sup>150</sup>
- "Effect of statin therapy on mortality from infection and sepsis: a meta-analysis of randomized and observational studies." <sup>151</sup>
- "View of statins as antimicrobials in cardiovascular risk modification." <sup>152</sup>
- "Antimicrobial Effect and Immunomodulation of Atorvastatin." <sup>153</sup>
- "Unexpected antimicrobial effect of statins." <sup>154</sup>
- Anti-tuberculous Effects of Statin Therapy: A Review of Literature." <sup>155</sup>
- "Repurposing of Existing Statin Drugs for Treatment of Microbial Infections: How Much Promising?" <sup>156</sup>

This last article includes some profound statements about the action of statins. "In the medical literature, various studies have reported some encouraging results regarding the antimicrobial use of existing statin drugs. Further, some clinical studies have also shown statin drugs' inconsistent and meager protective effect in

reducing morbidity is due to action against chronic infectious agents, but a complete understanding is still lacking. Thus, there is a need for a better understanding of the use of statin drugs, especially in the context of antimicrobial effects."

Interestingly, the term "antibiotic" is not in any of these titles. Instead, synonyms are used. Thus, these researchers are "softening the blow" to the statin industry. Another interpretation is that the statin drug industry is powerful enough to squelch that term in any publications or even deny the publication of a paper with this term. Yes, this happens. However, anti-infectious, antibacterial, and antimicrobials are all terms for antibiotics.

Is the meager absolute reduction in cardiovascular deaths due to cholesterol reduction or their anti-inflammatory/antibiotic actions? David R. Nalin,<sup>157</sup> a "Science Hero," weighs in on statins. He authored "*Comment on Unexpected antimicrobial effect of statins.*"<sup>158</sup> He astutely pointed out that statins may have an antibiotic effect against *Chlamydia pneumoniae* and that testing should be done. *Chlamydia* organisms are well documented to be in the plaques of cardiovascular disease (and Alzheimer's). He concludes that "the demonstrated benefits of certain statins in reducing the progression of atheromatous (heart) disease may partly relate to their antimicrobial efficacy against chlamydial organisms and their immunomodulatory and anti-inflammatory properties."

The problem with Dr. Nalin's suggestion is there are known and better drugs and drug combinations for battling chlamydial infection without the profound side effects attributable to statins. We need to stop our romance with statins and ask doctors to carry out the right tests, make the right diagnoses and choose the right treatments for cardiovascular diseases. Cardiovascular disease may show declining trends and stop being the number one killer.

Healio is a medical news journal that provides education and information for physicians and health care practitioners. Steven Lome, Cardiologist at the Community Hospital of the Monterey Peninsula, CA contributed an article titled, "Statins are Antibiotics...is THAT the Pleiotropic Effect?"<sup>159</sup> His article is reproduced here.

"Statins have pleiotropic effects, i.e. the ability to slightly reduce heart disease risk and cardiovascular death via an unknown mechanism, certainly beyond the LDL cholesterol lowering they can achieve.

Researchers have known for quite some time about these beneficial effects of HMG-CoA reductase inhibitors (also known as "statins," such as atorvastatin and rosuvastatin). However, the physiology behind this phenomenon remains unclear. Why statins have these pleiotropic effects is largely unknown, but let me throw out an interesting theory, and you form your own opinion.

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Statins are antibiotics that kill the undiscovered organism responsible for the entire process of atherosclerosis.

Let's look at some facts first. Many don't know that the first statin, mevastatin, was discovered in 1971 in the fungus *Penicillium citrinum*. As the name implies, this is the same fungus from which the first antibiotic, penicillin, was found. What was the role of penicillin in this fungus, you ask? To kill the surrounding bacteria, so they do not invade the fungi's space, allowing the *Penicillium citrinum* species to grow and spread more easily ... survival of the fittest!

Then, what is the role of mevastatin in this fungus? According to researchers, it is the same: Blocking cholesterol synthesis in the invading bacteria and other fungi, acting like an antibiotic.

Think about this, as well: It takes decades for atherosclerotic plaques to form, and it is an inflammatory process. We know that the early use of statins immediately during an Acute Coronary Syndrome (ischemia) slightly reduces mortality in only very high-risk individuals according to multiple clinical trials, including PROVE IT-TIMI 22 and the MIRACL trial. This benefit is thought to be from acute plaque stabilization, decreased thrombogenicity, and decreased inflammation that occurs immediately after statin administration.

How does this make any sense if the only thing statins do is reduce LDL levels through inhibition of HMG-CoA reductase? How should short-term administration improve long-term outcomes, considering the chronic nature of atherosclerosis? Why do these beneficial effects occur? Why is inflammation reduced so quickly? Again, maybe statins are antibiotics!

Quite an intriguing theory, that statins are antibiotics and kill the pathogenic cause of atherosclerosis, isn't it? Of course, I was not the first to think that atherosclerosis may occur from an infection. The organisms contributing to atherosclerosis include *Chlamydia pneumoniae*, cytomegalovirus (CMV), and *Helicobacter pylori*. Here is a look at some studies that test this theory."

Interesting side note: Mevastatin caused liver tumors and severe muscle problems in animal studies and therefore was never brought to market (although it is one of the naturally occurring statins in red yeast rice extract, which millions take ... not good).

We know that CRP is a measurable inflammatory marker that is significantly elevated during states of inflammation, including atherosclerosis, acute coronary syndrome, inflammatory arthritis, and, of course, during infection (including sepsis). We know that statin therapy reduces CRP marginally, independent of reductions in LDL cholesterol. So, putting these together, infection increases CRP

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and statins decrease CRP. This association, of course, does not prove the antibiotic theory but is a bit intriguing.

Statins have been shown in more than one analysis to decrease the incidence of sepsis (severe infection with a systemic inflammatory response, usually bacterial) and decrease mortality in patients with bacteremia - a bacterial disease of the blood.

Please appreciate that our immune system is decidedly antibiotic in nature thus, antibiotics may be helpful against a wide range of diseases. However, due to their pleiotropic properties, statin drugs, exert more than one effect and can cause and prevent infections. Earlier in this chapter, skin and oral infections were shown to be worsened by statins. They also lower CoQ10. So, when are statins beneficial, and for whom? Nobody knows. What we do know is the risk-benefit ratio is so low.

The enlightened country of Switzerland considers statins to provide insignificant benefits even though they are relatively inexpensive. The quality-adjusted life year or quality-adjusted life-year (QALY) is a generic measure of disease burden, including the quality and the quantity of life lived. It is used in economic evaluation to assess the value of medical interventions. One QALY equates to one year in perfect health. The Swiss Medical Board (SMB) reports that costs per quality-adjusted life years are extremely unfavorable (\$225,000/QALY) for statins in primary care in Switzerland when administered for 5 years.<sup>160</sup>

Translation: Statins, although cheap, are a waste of money and harmful simultaneously.

### **Infections, Inflammation "Cholesterol," and Heart Disease**

*Chlamydia pneumoniae* has the most data to show a correlation with atherosclerosis. This pathogen enters through the respiratory tract and is thought to be the third leading cause of upper respiratory tract infections worldwide, with an estimated 50 percent of the population exposed. Circulating monocytes then bring the organism into the vascular wall and induce inflammation. Animal studies with mice and rabbits show that *Chlamydia pneumoniae* infection, a contributor to hypercholesterolemia (elevated total cholesterol), can induce atherosclerosis. Moreover, giving azithromycin blocks this effect.

Translate this to humans. One study of 220 patients after a heart attack showed that positive *Chlamydia pneumoniae* antibody titers increase the risk of future events and that treating those patients subsequently with azithromycin reduces the risk down to the level of patients with negative antibody titers (the chlamydial organism no longer detected).

Immunization for Heart Disease

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How about the prospect of developing an immunization against one of these organisms? Could a cure for *Chlamydia pneumoniae* actually result in a cure for atherosclerosis?

Nobody knows the answer to that question. Researchers are indeed in the process of developing an immunization for heart disease! Interestingly, it has nothing to do with *Chlamydia pneumoniae*. A protein antigen that inflammatory T cells react to is being targeted to prevent the inflammatory response they create. I believe we know how that will go based on COVID. Sucker beware!

Pleiotropic Effects of Statins - So what's the deal?

In my search to see if HMG-CoA reductase inhibitors (statins), in laboratory models have ever been studied to see if they eliminate *Chlamydia pneumoniae*, I came up empty. Also, no data in patients with vascular disease determines if statin therapy is more effective in those seropositive for *Chlamydia pneumoniae* than seronegative individuals.

Dr. Nalin continues. "OK, fine, maybe it is a bit far-fetched to say that there is, perhaps, one lone organism causing all of atherosclerosis. Multiple factors likely contribute, causing the endothelial injury that starts the process, but infection probably plays a role somewhere along the line. However, could you imagine if there was ONE predominant infectious etiology? A potential cure for heart disease, stroke, and peripheral vascular disease could be developed! I see a Nobel Prize opportunity ... discover the real reason for the pleiotropic effects of statins!"

When you read the chapter on infection, you will see that the Nobel Prize work has already been completed. It is not the least bit "far-fetched." It just has not been recognized in the modern medical system as yet.

### **Cholesterol and Mortality**

The major emphasis of the standard of care is on the number one killer, heart disease. This is evident by the "cholesterol" measurement being performed on everyone who visits their doctor. How has it worked out? The Wall Street Journal reported that deaths from cardiovascular disease increased by 4.3 percent from 2011 to 2016, Figure 5.6.<sup>161</sup>

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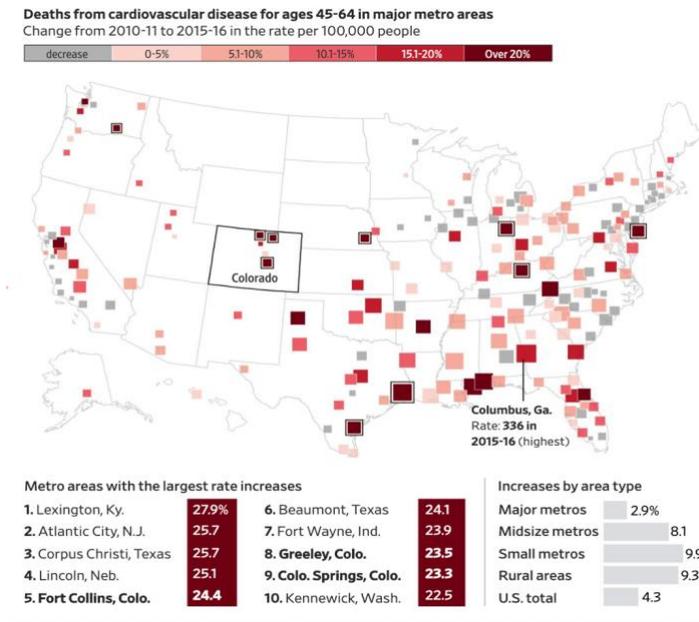


Figure 5.6. Death from cardiovascular disease for ages 45-64 in major metro areas of the United States.

Surprisingly, some of the highest increases in cardiovascular death occurred in healthy Colorado. This can only lead to one conclusion; medicine is looking in the wrong place. A study published in 2003 may explain part of the mortality increases in Colorado, if not in other locations. The article's title is "Rocky Mountain Spotted Fever, A Clinician's Dilemma."<sup>162</sup> The authors state,

"Rocky Mountain spotted fever (RMSF) is still the most lethal tick-vector illness in the United States. We examine the dilemmas facing the clinician who is evaluating the patient with possible Rocky Mountain spotted fever, with particular attention to the following 8 pitfalls in diagnosis and treatment:

1. waiting for a petechial rash to develop before diagnosis;
2. misdiagnosing as gastroenteritis;
3. discounting a diagnosis when there is no history of a tick bite;
4. using an inappropriate geographic exclusion;
5. using an inappropriate seasonal exclusion;
6. failing to treat on clinical suspicion;
7. failing to elicit an appropriate history; and
8. failing to treat with doxycycline.

Early diagnosis and proper treatment save lives."

They go on to say,

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"*Rickettsia rickettsii* elicits a moderately severe to life-threatening systemic illness in its host by infecting endothelial cells lining small vessels of all major tissues and organ systems" *Rickettsia rickettsii* is the pathogen that causes RMSF. Even though the disease is named "Rocky Mountain," according to the CDC, RMSF cases have been reported throughout most of the contiguous United States. Heart disease, of course, is also reported throughout the United States."

If you are not testing, you are guessing, and cholesterol is the wrong guess.

Smoking is arguably the greatest risk factor for heart disease. That narrative is replaced by high cholesterol and blood pressure in the modern era. Are these new risk factors the root cause? Figure 5.7 shows the trends in cardiovascular disease mortality rates versus smoking trends. As people smoked more, deaths from heart disease increased, but with a lag reflecting the time it takes for heart disease to develop to the point of causing death. As cigarette smoking decreased, the heart-related death trend also started to decline. However, around 1990, that trend reversed. Statin drugs, supposedly a cure for heart disease, were first introduced in 1987. Hmmm.

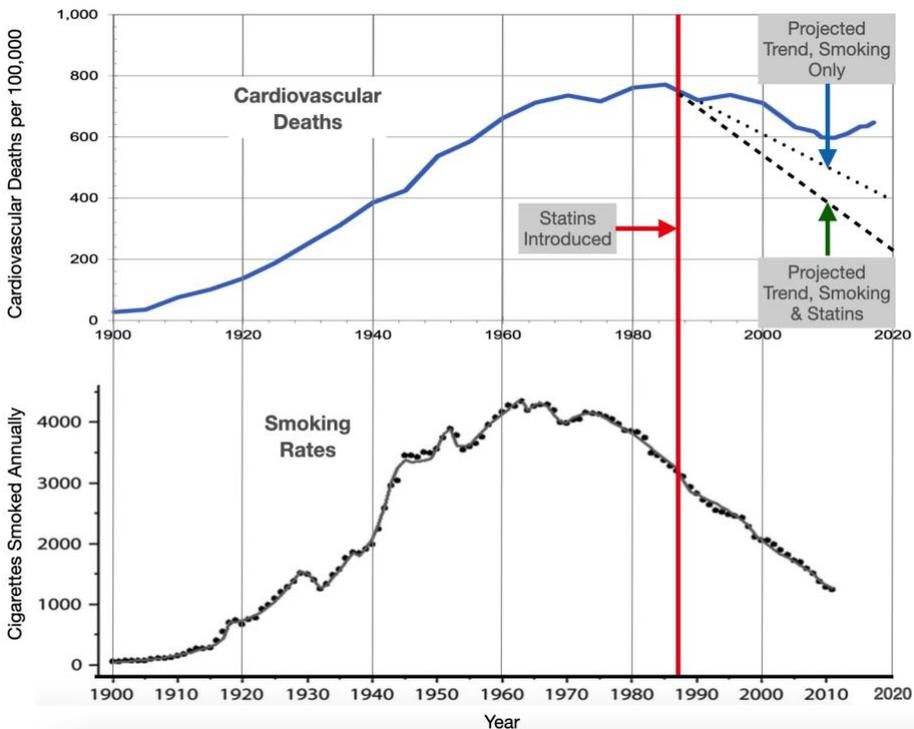


Figure 5.7: Trends in cardiovascular disease deaths and smoking trends. Statin therapy was introduced in 1987 (red line), and the trend toward lower cardiovascular mortality following smoking tendencies ended shortly after that.

If statins are truly a cure for heart disease deaths, reported to reduce them by at least 20 percent (remember, this is an irrelevant "relative" statistic), and smoking rates were going down substantially, shouldn't deaths from heart disease also drop? The data does not lie. Cardiovascular disease deaths significantly increase when considering cardiovascular death rate trends before statin introduction and downward smoking trends. Figure 5.7 shows a complete lack of any benefit in cardiovascular mortality rates. Based on trends just before their introduction, there is at least a 20 percent increase in mortality rates upon the introduction of statin drugs. Any downward trend after 1987 reflects a continuation of the smoking reduction trend, as statins were not immediately universally prescribed.

### Cholesterol-Lowering is NOT a Cure

A picture is worth a thousand words. A cure eradicates a disease. Treatment lowers the incidence of a disease. It is quite clear from Figure 5.7 that statins drugs, in particular, and cholesterol-lowering drugs, in general, are neither a cure nor a treatment.

Pellagra is a vitamin deficiency disease most commonly caused by a chronic lack of niacin (vitamin B3) in the diet. Thus, the cause is well known, and so is the treatment. Pellagra is a deadly disease, and Figure 5.8 presents a death rate trend curve that shows what a true root-cause cure can do to mortality rates.<sup>163</sup>

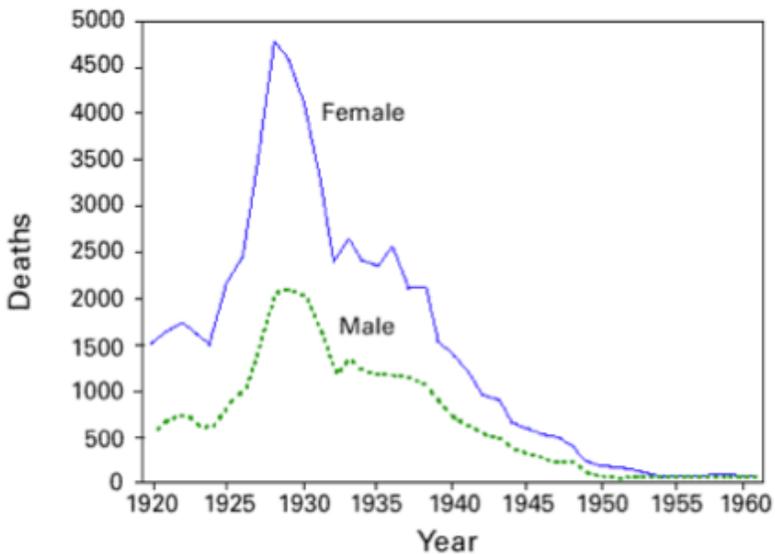


Figure 5.8 Number of reported pellagra deaths in the United States, 1920-1960.<sup>164</sup>

Note that death rates fall precipitously to nearly zero. This is what a medical cure looks like.

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Tuberculosis or TB (short for tubercle bacillus) was common, and in many cases lethal, infectious disease caused by various strains of mycobacteria, usually *Mycobacterium Tuberculosis*. Tuberculosis typically attacks the lungs but can also affect other body parts.

The TB death rate curve, Figure 5.9, shows the power of knowing the cause of the disease and treating it. However, there is some complacency or lack of understanding about TB as it is making a slight comeback in the 21<sup>st</sup> century.<sup>165</sup> Also of note, the introduction of antibiotics and vaccines in the 1940s and 1950s show a meager change in mortality rates for TB. The effect of the antibiotic at least showed some change, but the vaccine's effect was zero.

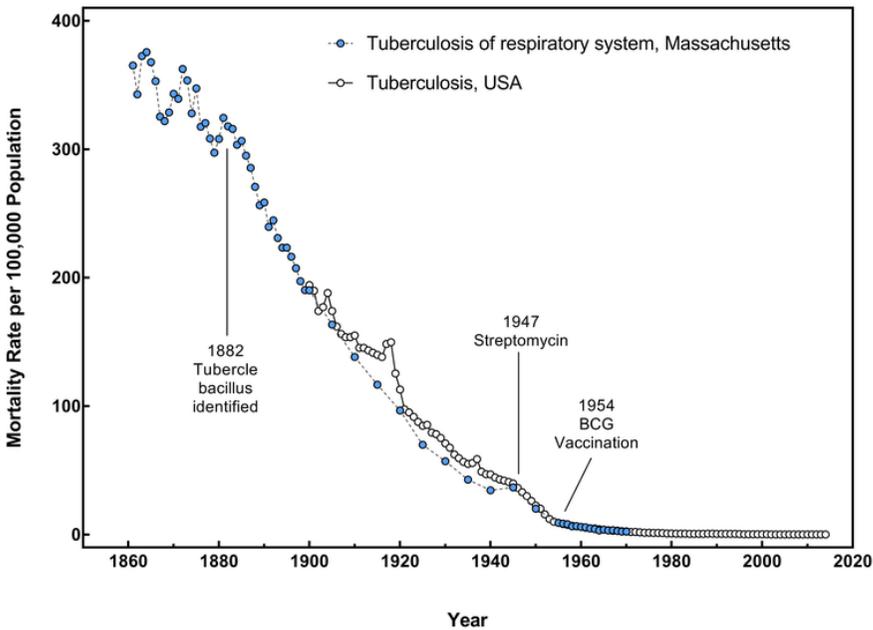


Figure 5.9: Massachusetts and the United States tuberculosis death rate per 100,000 population, 1860-2020.

Typhoid fever, also known as typhoid, is a common worldwide bacterial disease transmitted by the ingestion of food or water contaminated with the feces of an infected person that contains the bacterium. It is treated (cured) with antibiotics. However, improved hygiene practices had the greatest impact on mortality rates, Figure 5.10.<sup>166</sup> This is obvious from the figure because antibiotics did not see widespread use until the 1950s at the earliest.

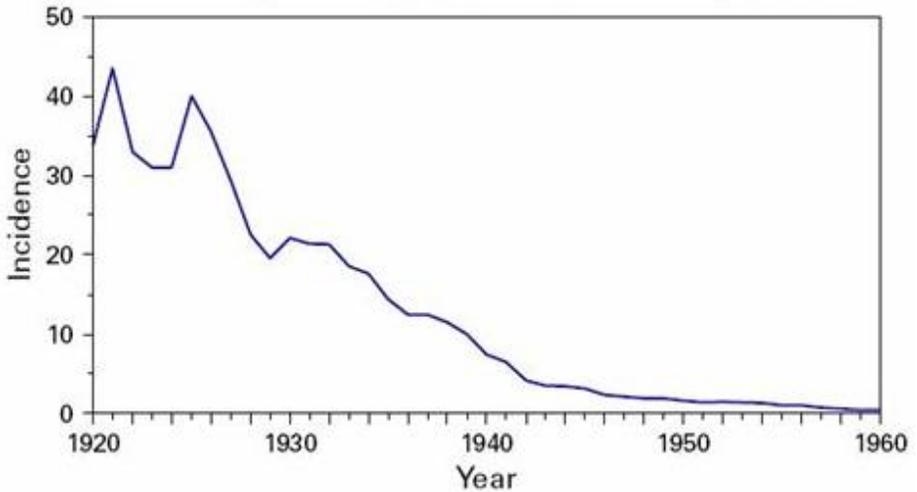


Figure 5.10: Incidence of typhoid fever per 100,000 population – U.S., 1920-1960.

Compare the cardiovascular disease mortality curve in Figure 5.7 to the three actual cures. It is strikingly obvious that statin therapy provides no benefit and appears to cause more harm than good. Statin therapy to “cure” cardiovascular disease began around 1987, and other cardiovascular drugs have also been introduced in the past 50 years. These include beta-blockers, ACE inhibitors, and ARBs. Over 40 million Americans are on statin drugs today. The aggregate impact on mortality from all these standard-of-care treatments is nil at best.

How much proof is needed that standard-of-care cardiovascular treatments do not work?

The New England Journal of Medicine (NEJM) and Nature are the most respected medical and scientific publications. Although, in the COVID era, fraud in high-level journals is now well documented. They both have very high impact factors, with NEJM topping the list. Nature published a landmark paper on the relationship between the total cholesterol value and the risk of dying young. It was a mammoth study of 12.8 million people. Drug approval trials seldom include more than 3000 subjects in the studies. The title is "Total cholesterol and all-cause mortality by sex and age: a prospective cohort study among 12.8 million adults."<sup>167</sup> There is a clear denial by the medical community of the results of this study because it has only been cited 50 times in three years. This is an astonishingly low number for a paper on the most studied of all biological substances.

One figure from the paper tells the entire story, Figure 5.11.

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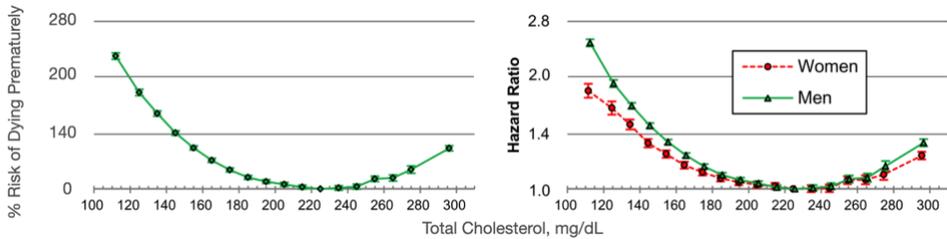


Figure 5.11 Percent risk of dying prematurely (all-cause mortality) versus total cholesterol values expressed in mg/dL. The left graph is the composite for all adults regardless of age. The right graph is for both men and women.

Interpretation: You do not want your total cholesterol value to be below 200 or above 260, in general. There are exceptions to this, of course. For example, if your HDL is high, you can err on the side of a higher total cholesterol. Based on a massive number of studies, not just this one, you do NOT want the total cholesterol below 200 in most cases.

Since the study included such a large number of people, the authors were able to break down risk by age group and sex. The summary of the article explains where you want your total cholesterol (TC) to be.

"TC had U-curve associations with mortality in each age-sex group. TC levels associated with the lowest mortality were 210–249 mg/dL, except for men aged 18–34 years (180–219 mg/dL) and women aged 18–34 years (160–199 mg/dL) and 35–44 years (180–219 mg/dL). The inverse associations for TC < 200 mg/dL were stronger than the positive associations in the upper range."

The last sentence of their summary is 180 degrees opposite to what we are being told about TC.

- The risk of dying young becomes MORE dramatic below 200 mg/dL.
- The risk of dying young becomes LESS dramatic above 200 mg/dL.

The article concludes with the following statement:

"Inverse associations in the range <200 mg/dL were more than 3-fold stronger than positive associations for cholesterol levels  $\geq 200$  mg/dL, except for the youngest adults. Positive associations in the upper TC range were strongest for youngest adults and weakened with advancing age. TC levels <200 mg/dL may not necessarily indicate good health. Identifying and properly managing diseases associated with lower TC levels might improve survival."

Summary: The risk of dying young if your total cholesterol is <200 mg/dL is 300 percent greater than if your total cholesterol is  $\geq 200$  mg/dL.

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The root-cause reason younger people have better survival at slightly lower than 200 mg/dL TC less is due to the strength of their innate immunity. TC goes up with inflammation and infection. Their stronger immunity controls these factors. An important finding is that, in older people, higher TC indicates lower early mortality rates when compared to younger people. This is consistent with the fact that older people have a less robust innate immune system and need other forms of immunity - like the cholesterol molecule - to elevate as innate immunity declines.

A group of Japanese scientists explains the value of elevated LDL with increasing age. They do so in a paper that challenges the standard of care. The paper is titled, "A Critical Review of the Consensus Statement from the European Atherosclerosis Society Consensus Panel 2017." Their key messages are included here.

"Apart from the European Atherosclerosis Society hypothesis that LDL causes atherosclerotic cardiovascular disease, recent pharmacological and biochemical studies, as summarized in this review and elsewhere, have revealed that atherosclerosis is caused by:

- "Statins, when taken to lower LDL as well as by,
- warfarin; and
- some vegetable fats and oils, without significantly elevated LDL levels."

Thus, the promotion of statin treatment by the statement is rather risky, and we do not feel that the conclusions are justified for the prevention of atherosclerotic cardiovascular disease."

The risk of dying prematurely decreases with aging in all of the studies included in their analysis. At the same time, most guidelines for cardiovascular disease prevention set lower targets for cholesterol values in older people. This is contrary to the data. The important fact is that while the incidence of cardiovascular disease increases with age, the impact of high TC on ischemic heart disease decreases.

Out of apparent frustration about the TC and LDL standards being opposite of the data, the authors state, "So far, we have found no rational explanations given by other scientists" for the current upside-down standards. Figure 5.12 shows their analysis's relationship between early mortality risk and LDL levels.

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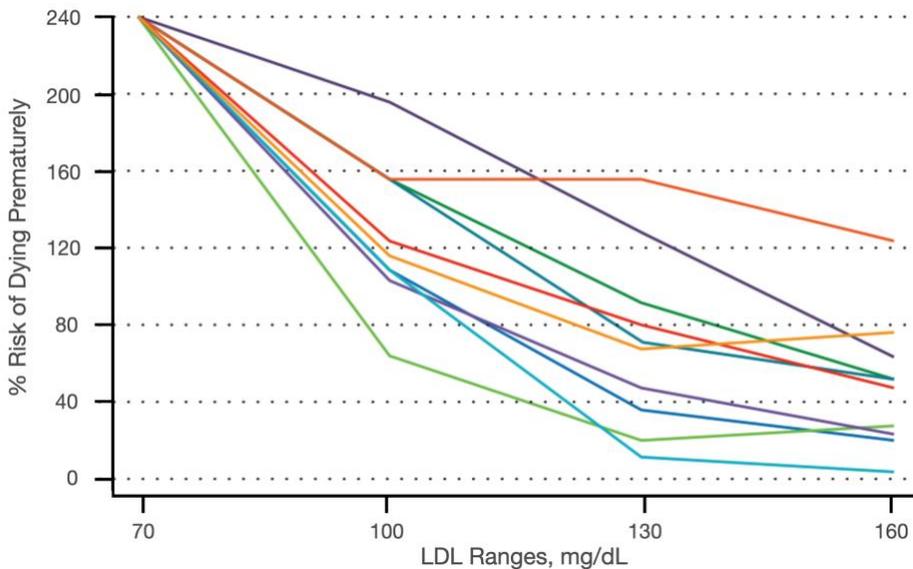


Figure 5.12. The percentage increase in the risk of dying young versus LDL ranges from 10 independent studies on individuals over 60.

Another large study of Japanese people shows a similar trend found in these two studies. The paper explaining this trend is titled "Towards a Paradigm Shift in Cholesterol Treatment. A Re-examination of the Cholesterol Issue in Japan."<sup>168</sup> Over 90,000 people were included in this evaluation. The authors explain their conclusion succinctly.

"All-cause mortality is the most appropriate outcome to use when investigating risk factors for life-threatening disease. Overall, an inverse trend is found between all-cause mortality and total (or low-density lipoprotein [LDL]) cholesterol levels: mortality is highest in the lowest cholesterol group without exception. If limited to elderly people, this trend is universal. Elderly people with the highest cholesterol levels have the highest survival rates irrespective of where they live worldwide."

The Japanese understand the value of using early mortality as a criterion for measuring health. In Volume 2 we explain the rationale for using early mortality as an evidence-based standard for determining true normal values for biomarkers.

Figure 5.13 shows that as the LDL value decreases, deaths from all types of diseases increases. This includes cancer, as explained in the Japanese study.

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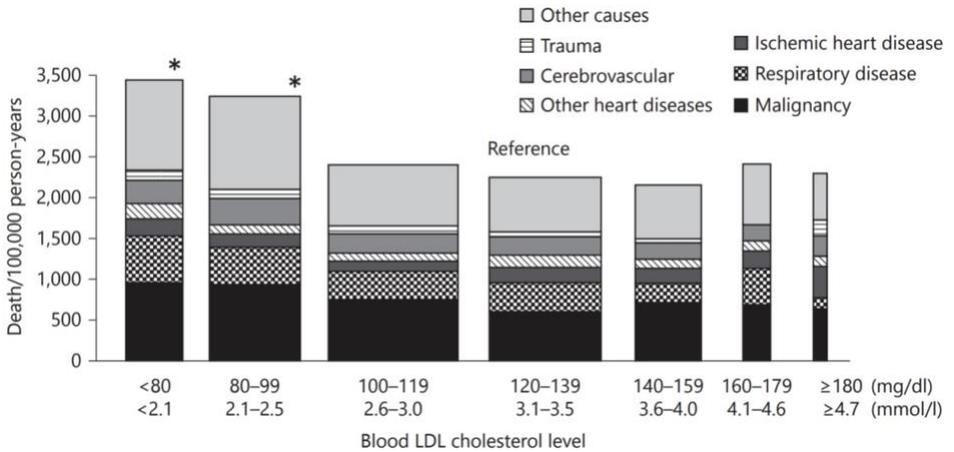


Figure 5.13: Low-density lipoprotein (LDL) cholesterol and mortality in men. The trends are similar in women.

What is the ideal LDL value to optimize longevity?

Japanese (and many other studies): **140 - 159 mg/dL**

What is the worse LDL value with respect to longevity?

Japanese (and many other studies): **<80 mg/dL**

What LDL level is recommended by the America College of Cardiology (ACC)?

ACC target for LDL: **<70 mg/dL**

How much money does the ACC obtain from the drug companies by direct and indirect means?

?

Some ones are getting away with murder, and your doctor prescribing statins is an accomplice.

One more major study cements the concept that low total cholesterol leads to early death. This is the Honolulu Heart Study. This analysis examined the incidence of coronary heart disease (CHD) and cerebrovascular accidents in 165,000 men. The purpose of the study was to determine whether there was a difference in CHD incidence and mortality between Japanese living in Japan and individuals of Japanese ancestry living in Hawaii. There was a drastically lower mortality rate in Japan compared to Japanese men living in Hawaii.<sup>169</sup>

The Honolulu investigation highlights the difference between data and dogma. The people analyzing the results came in with the belief that high cholesterol levels are problematic, leading to higher mortality. Their strong bias toward this belief is expressed in their conclusion where they cannot deny the actual results from the study. They state,

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"We have been unable to explain our results. These data cast doubt on the scientific justification for lowering cholesterol to low concentrations (< 180 mg/dL or <4.65 mmol/L) in elderly people," Figure 5.14.

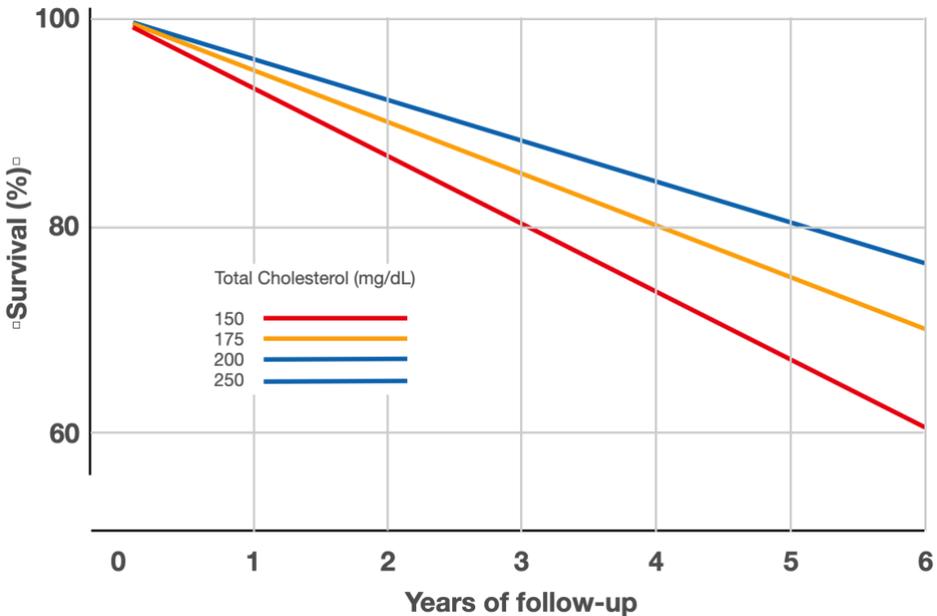


Figure 5.14: Survival (early mortality) risk with total cholesterol levels in the elderly. Early mortality goes up as total cholesterol goes down. There is essentially no difference in survival (mortality) in the 200 and 250 mg/dL cholesterol levels consistent with the Korean study of 12.8 million people.

The authors of the Honolulu study conclude,

"Clinically, two issues emerge.

- First, is there a difference in biological effect from a permanent, untreated, intrinsically low cholesterol concentration compared with the effect in those with a dietary or pharmacologically induced reduction of cholesterol? As far as we know, this issue has not been addressed scientifically.
- Second, given our data and those of others, is there scientific justification for attempts to lower cholesterol to concentrations below 180 mg/dL (4.65 mmol/L) in elderly people?

We believe that until more information about these complex relations is available, prudence dictates a more conservative approach in this age group."

Prudence actually means to stop prescribing statins.

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Major organizations came out against statins around 2011. There is a darn good reason for this, these drugs were coming off patent, meaning the profitability of these drugs was to be significantly reduced. The short period around 2011 revealed a lot about the true understanding of the harm and benefit of these drugs not previously told, for financial reasons. But something went terribly wrong. The drugs to replace statins were so harmful that they have not seen widespread use. Thus, we are still stuck with the statins. Here is one story about 2011 expose of statins truths.

According to Harvard Medical School, treatment with statin drugs does NOT improve outcomes. Proto Magazine is an internal publication for healthcare professionals that are part of the Harvard Medical School healthcare network. In 2011, a feature article was published titled, "Questioning Statins."<sup>170</sup> The byline was "WHAT STATINS MIGHT DO FOR YOU: Lower cholesterol // Reduce risk of cardiovascular disease // Cause muscle pain and fatigue; Fail to significantly prolong your life." Figure 5.15 is the cover to that article.



Figure 5.15. Cover of Protomag article titled, "Questioning Statins." Proto is a national science magazine and website produced by Massachusetts General Hospital. This article was published on January 15, 2011.

Other gems in this publication include "Statins don't seem to confer the ultimate health benefit – longer life. So, is lowering cholesterol as important as everyone has been led to believe?"

Harvard dropped the bombshell in their internal publication, but it remains ignored even at Harvard hospitals. Also stated in Harvard magazine, "Why did statins appear to protect the hearts of people who didn't have high cholesterol? It could be that they lower cholesterol and reduce inflammation." If you read between the lines, it appears that Harvard Medical School is saying that

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cholesterol is not the cause of cardiovascular disease, but inflammation is. We can also infer that statins are anti-inflammatory, but based on their results against cardiovascular disease, they are very poor at the job and have too many side effects.

This Harvard article is not a coincidence. It was published in 2011, when most statin drugs were coming off patent. So, they were going generic, and profits were about to tumble. Harvard was setting up a treatment transition from statins to the new and very expensive on-patent biological drugs. As you will see later in this chapter, they are miserable failures because lowering LDL is harmful. Harvard could not feasibly retract the Proto article, and statins are still heavily prescribed because the new alternative class of drug failed.

What happens if you naturally have either low or high LDL without any treatment? Studies are few and far between. However, one substantial report reveals that an LDL level that is low or very high has close to the same impact on early mortality regardless of treatment. And, having a low LDL is much more hazardous compared to a high LDL. Again, this is regardless of treatment versus no treatment.

The evaluation included 108,243 individuals aged 20-100, of whom 11,376 (10.5 percent) died during the study, at a median age of 81. The association between LDL levels and the risk of all-cause mortality exhibits a U-shaped curve, as usual. Low levels of LDL show a dramatic increase in mortality risk, whereas, at high levels, the increase in mortality is much less dramatic, Figure 5.16. These results were consistent in men and women, across age groups, and for cancer and other causes of early death.

The lowest risk of all-cause mortality is at a concentration for LDL of 140 mg/dL (3.6 mmol/L). The American College of Cardiology sets the standards for LDL normal values and asserts that an LDL below 70 mg/dL is optimal.

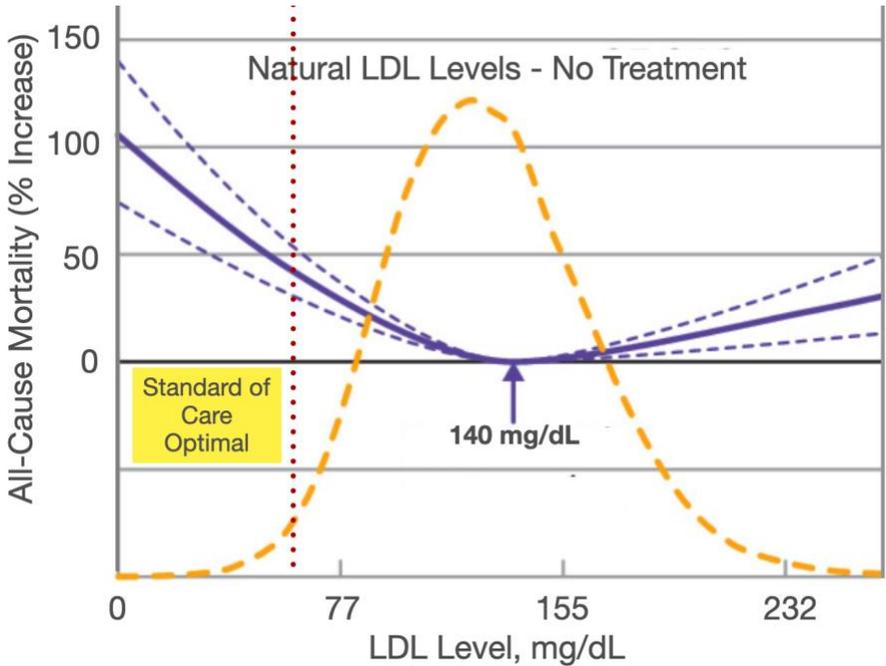


Figure 5.16. Early mortality risk with LDL values in people not on LDL-Lowering therapy. The optimal LDL level is 140 mg/dL.

As of April 2022, over 100 peer-reviewed publications link low total cholesterol and early death. Searching on the term "LDL" as opposed to "cholesterol" adds another dozen.

### Other Cholesterol Lowering Drugs

Many statin drugs are now “off-patent.” That means these drugs can be manufactured by generic drug companies and offered at a lower cost than when they were protected under patent laws. Subsequently, the pharmaceutical industry developed a whole new set of drugs to lower cholesterol that are "on patent" to garner higher profits.

Scientific American weighed in on the value of new versus old drugs in an article titled "When Older Drugs are Better Drugs."<sup>171</sup>

"The trend toward using newer medications often develops during doctor residency training. Pharmaceutical firms market their products to young doctors in all specialties. Whether with free meals, medical tools, or travel scholarships, pharmaceutical companies find ways to influence doctors' prescribing practices. Because most physicians continue recommending the medications they learned in residency, these companies strategically expose residents to newer medications that are still under patent and thus far more profitable for the manufacturers."

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Importantly, both new and old cholesterol-lowering drugs provide strong evidence that lowering LDL is not beneficial to your heart. According to the CDC, the following drugs lower LDL or cholesterol.

- Statins. These drugs lower LDL cholesterol by slowing down the liver's production of cholesterol. They also increase the liver's ability to remove LDL cholesterol that is already in the blood.
- Bile acid sequestrants. Bile acid sequestrants help remove cholesterol from the bloodstream by removing bile acids. The body needs bile acids and makes them by breaking down LDL cholesterol.
- Niacin, or nicotinic acid. Niacin is a B vitamin that can "improve" (should say "change") all lipoprotein levels. Nicotinic acid raises high-density lipoprotein (HDL) cholesterol levels while lowering total cholesterol, LDL cholesterol, and triglyceride levels.
- Fibrates. They mainly lower triglycerides.
- Injectable medicine. A newer type of drug called PCSK9 inhibitors lowers cholesterol (wrong, they lower LDL exclusively). These medicines are primarily used in people who have familial hypercholesterolemia, a genetic condition that causes very high levels of LDL cholesterol. (Note, that was not their original intent).

### Bile acid sequestrants

The United States Federal Government, through the website MedlinePlus, defines bile acid sequestrants. "Bile acid sequestrants are medicines that help lower your LDL (bad) cholesterol. Too much cholesterol in your blood can stick to the walls of your arteries and narrow or block them. These medicines work by blocking bile acid in your stomach from being absorbed in your blood."

The Feds, in just 2 sentences, are able to provide an astounding level of misinformation. The term "bad" associated with something your body naturally produces is incongruent. If our bodies truly produced "bad" things, we would not survive as a species - pure and simple. And "stick to the walls of your arteries" shows a complete lack of understanding of physiology.

Dr. Kilmer S. McCully is the former Chief of Pathology and Laboratory Medicine Services for the United States Department of Veterans Affairs Medical Center. McCully was the first to propose the homocysteine theory of cardiovascular disease and is the author of the book, *"The Homocysteine Revolution."* He is a thoughtful man and historian. His path to brilliant discoveries and conclusions was not an easy one as highlighted in *The New York Times* article titled *"The Fall and Rise of Kilmer McCully."*<sup>172</sup>

You see, McCully knew that cholesterol was not at the root of cardiovascular disease way back in the early 1960s, but Harvard did not want this "convenient"

## Chapter 5. Cholesterol is Essential to the Function of ALL Cells

theory uprooted. Not only did they fire Dr. McCully, but they blacklisted him. Dr. McCully had to travel far from his home to obtain employment.

In 2009, along with his co-author, Uffe Ravnskov, he authored a “Review and Hypothesis” on how infection contributes to heart disease.<sup>173</sup> Here, he explains that vulnerable plaques, the type that kills or debilitates us by way of heart attack or stroke, do NOT form from inside a blood vessel as stated by the U.S. Federal Government, as depicted on TV and, in your doctor’s office. Instead, they start on the outside of the vessel and work their way inside. Dr. McCully does not get full credit for this discovery as he was scooped by at least 140 years by a German doctor by the name of Koester.<sup>174</sup>

Dr. Trempe explains this correct description of heart disease this way:

“Heart disease is a disease of the small vessels of the large vessel.”

Say this fast three times and then give it some deep thought! This means that large vessel walls are big enough to require their own blood supply. The smaller vessels that support the structure of large vessels become diseased first and lead to the disease of the larger vessels - and eventually to heart attacks and stroke. Figure 5.16 shows the incorrect and correct depiction of the heart and vascular disease process.

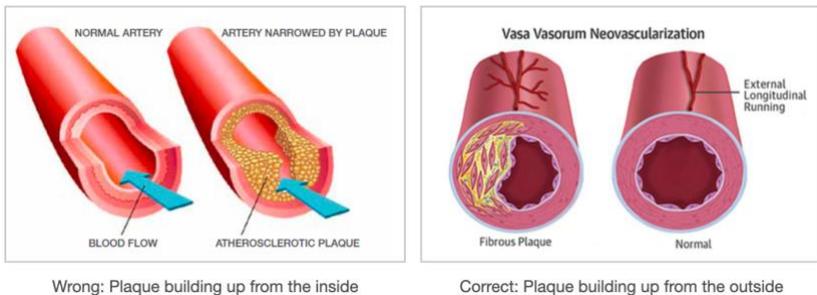


Figure 5.16. Wrong (left image) versus correct (right image) depiction of the heart disease process.

This may seem like nitpicking but since heart disease is the number one killer, how the disease develops should be properly understood and represented. More importantly, most of the vessels in the body are capillaries. The "correct" image above shows how the large vessel disease is really a small vessel (capillary) disease. Many ailments beyond the heart are vascular diseases. Alzheimer's is an example.<sup>175</sup> In the brain, tissue is nourished, and the waste is removed by capillaries. The image on the right explains a disease like Alzheimer's more clearly. The small vessels become diseased, impacting the tissue they supply leading to the loss of neurons, thus neurodegeneration.

Now back to the topic of bile acid sequestrants. Granted, bile acid sequestrants lower LDL, but not directly. Bile acids make any fat bioavailable. That is, bile

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acids are soaps of the gut that digest fats. If fats are not available because of the lack of bile acids, then LDL production will go down. LDL goes up when there are fats to transport through your water-based bloodstream. Remember, your brain is 60 percent fat. A common phrase is "you are what you eat." However, this is actually false. You are what you absorb. Optimal digestion is at the top of the list of the most important physiological processes. When you inhibit the digestion of fats, your brain and eyes are first in line to suffer because they are composed of the highest levels of fats.

Some of the most common adverse effects of bile acid sequestrants are gastrointestinal, including constipation, stomach pain, bloating, vomiting, heartburn, loss of appetite, indigestion, and upset stomach.<sup>176</sup> Interestingly, these are considered "limited systemic side effects." Every one of these symptoms is indicative of poor absorption. Since you are what you absorb, poor absorption equals poor health. The impact of these drugs may not be experienced immediately but will eventually manifest in serious diseases of aging. It is actually a simple process. Our bodies are constantly being torn down and rebuilt. Diseases may be expressed as wear and tear exceeding repair and recovery. Nutrient absorption is critical to the repair and recovery process.

Bile acid sequestrants put you at a repair and recovery deficit.

### Niacin

Niacin has a fantastic therapeutic profile as opposed to a fantastic therapeutic effect. That is, all the lipid levels change for the presumed better on high-dose niacin. Surely heart disease must go down under these circumstances. However, such is not the case. The NEJM published a paper with an interesting title. "Niacin at 56 Years of Age - Time for an Early Retirement?"<sup>177</sup> This is another paper the medical community is fearful to acknowledge because it goes against the cholesterol-lowering doctrine. Published in 2011, it has been cited just 36 times, whereas articles touting the benefits of statins often are quoted thousands of times. The "Early Retirement" paper is written by Robert P Giugliano, MD, Associate Professor of Cardiovascular Medicine at Harvard Medical School. He is a man with a sense of humor. He wrote,

"Despite the achievement of the expected favorable changes in the levels of HDL (an increase of 25 percent), LDL (a decrease of 12 percent), and triglycerides (a decrease of 29 percent) with niacin, the clinical results were chillingly null; niacin did not reduce the incidence of the primary composite endpoint (reducing heart disease), nor did it show any clinical benefit overall or in a major subgroup. The trial was stopped early by the independent data and safety monitoring board because the boundary for futility had been crossed, and an unexpectedly higher number of ischemic strokes was observed in patients assigned to niacin."

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The moral of this story is do not mess with your lipids, even with a seemingly natural substance. The dose makes the poison.

### Injectable Medicine - Biologics

These newer drugs, led by Amgen's Repatha, were supposed to replace statins. They are very effective at lowering LDL and are also very expensive and profitable. However, they hit a serious snag. The side effects of these drugs are considerable. The CDC soft pedals on these drugs saying they are for familial elevated cholesterol, but that was not their initial intent.

As a reminder, statins do NOT directly lower the total cholesterol value. Instead, they impact the activity of a liver enzyme responsible for producing LDL. In doing so, the total cholesterol value is usually lowered, too, because LDL is part of the total cholesterol number. Repatha is even more effective, when compared to statins, at lowering LDL production. This drug, made by Amgen, was approved by the FDA for its LDL-lowering capability.

It is very important to understand that the criteria for approval, when you read the fine print, was not for a health benefit. LDL (soap) is presumed so harmful that an endpoint like reducing deaths was not needed to approve this drug. This is not a scientific approach. Every drug must only be approved by showing an actual health benefit.

Here is a press release from Amgen on the authorization of Repatha and a translation of their language.<sup>178</sup>

"Despite treatment with the current best therapy, many patients are still at high risk for cardiovascular events. Physicians now have a new FDA-approved treatment option to prevent cardiovascular events by dramatically lowering LDL cholesterol with Repatha, especially for patients already on maximally-tolerated statin therapy who need further LDL cholesterol lowering."

Translation: Statin drugs do not work very well, if at all. Repatha lowers LDL even further, going against all new knowledge on the value of higher LDL levels.

"Consistent with recent trials of more intensive LDL lowering, there was no observed effect on cardiovascular mortality. Similarly, there was no observed effect on hospitalization for unstable angina."

Translation: Take Repatha, and your risk of dying from heart disease does NOT change. Surely this is true for the studies they decided to share.

The FDA does not require drug companies to submit all their data. It is important to read Dr. Demasi's paper at the end of this chapter to understand the limitations of clinical trials and the benefits they report.

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The reported side effects from lowering LDL with Repatha, or any drug for that matter, are extensive. For Repatha, in particular, side effects that require an immediate call to your doctor include:

- difficulty with breathing or swallowing;
- fever;
- hives, itching, or rash;
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals;
- nausea;
- reddening of the skin, especially around the ears;
- swelling of the eyes, face, or inside of the nose;
- unusual tiredness or weakness.

Our observations of people on Repatha include very common and severe memory issues.

Memory loss is not found anywhere on the entire list of side effects, but this is not a reflection of the real effects experienced by people on this drug. A paper in the prestigious New England Journal of Medicine concluded the following with regard to Repatha and memory loss.<sup>179</sup>

"In a randomized trial involving patients who received either Evolocumab (Repatha) or placebo in addition to statin therapy, no significant between-group difference in cognitive function was observed over a median of 19 months. (Funded by Amgen; EBBINGHAUS ClinicalTrials.gov number, NCT02207634.)"

Interestingly, the manufacturer also conducted the study. Also, note that a placebo in addition to statin therapy is NOT a placebo. Statins are well known to impact cognition even though this information is hard to find because of the marketing power of the statin industry.<sup>180</sup> Do not be concerned, however, because Amgen has an Alzheimer's drug in case Repatha destroys your memory.

The media was quick to report on the meager benefits of Repatha.

The New York Times led with, "this new class of drug has the potential to improve the health and longevity of millions of Americans with heart disease, the nation's leading killer, accounting for one in four deaths." However, buried in the ninth paragraph, the article revealed that the drug "did not show a benefit in overall death rates from cardiovascular causes."

Am I dense, or are there conflicting statements in this article?

- "Improve the health and longevity of millions of Americans with heart disease."
- "Did not show a benefit in overall death rates from cardiovascular causes."

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NPR's piece, written by Yale cardiologist Harlan Krumholz, displayed a bit more caution: "Pricey New Cholesterol Drug's Effect on Heart Disease Is More Modest Than Hoped." The relatively small reduction in cardiovascular events received prominent emphasis in NPR's story. "Repatha, over about two years of study, reduced the risk of cardiovascular events, including heart attacks and stroke, by about 15 percent. For about every 66 people treated, one person avoided one of these events. There was no reduction, however, in the risk of death."

Here are the absolute statistics on that data - although the data itself is questionable at best because LDL is a critically important lipoprotein.

- Reported benefit: 15 percent;
- Absolute benefit:  $(1/66) \times 100 = 1.5$  percent.

Even the Yale faculty will do well to repeat 4th-grade math.

Kaiser Permanente took a more pragmatic view of the data because their system is both the provider (prescriber) and payer, so cost matters. In their Health News piece in USA Today headlined, "Cholesterol drug prevents heart attacks - but costs \$14K a year." Journalist Larry Husten, writing on the Cardiobrief blog, wondered if "the modest efficacy of the drugs is worth their immodest cost."

Patient advocate Dave deBronkart, also known as e-Patient Dave, explains what we all need to understand. Relative statistics do NOT explain risk relevant to you, but absolute statistics do. DeBronkart states, "avoid relative risk reduction (headlines about percentages) and look instead for actual (absolute) numbers of patients helped." The problem is essential all statistics for drug benefits are published in relative statistics. To find the absolute statistics, the actual data must be found and the absolute statistical value calculated. This is nearly impossible to calculate the way the data is reported.

Amgen's own data on Repatha looks like this:

- Major heart problems or strokes happened to 11.3 percent of patients WITHOUT the new drug and 9.8 percent of patients WITH the new drug. In other words, 1.5 percent of patients avoided a problem event, but 9.8 percent still experienced a problem event despite taking the drug.
- 1.5 percent means, on average, 1 patient in 67 benefits from the drug.
- Note the drug did not save lives. The same percent died whether or not they got the drug.
- The drug costs \$14,000/year, and the patients studied were monitored for an average of 2.2 years, making the cost \$30,800 per patient.
- To prevent one heart attack, the cost is 67 (the number needed to be treated to avoid one heart attack) x \$30,800 (the cost for each patient) = \$2.06 million.

**Repatha: \$2 million per patient to avoid one heart attack, yet not one death avoided!**

Now you know another reason why the United States spends 2.5 times more per person for healthcare, yet our citizens live 2.5 fewer years.

No new side effects were reported in the study, but this is not believable based on its mode of action - inhibiting repair and recovery by lowering LDL. But considering that Stanford University Medical School indicates that a single drug has over 300 side effects, on average, this is not necessarily good news because Repatha is usually compared to statins that have an exhaustive list of adverse side effects.<sup>181</sup>

The results reported by the manufacturer were only for very high-risk patients. If your risk is lower, the benefits of the drug will not be comparable, but the side effects will be the same. If no lives are saved in the high-risk group, how many will be saved in a low or moderate-risk group? How many will be harmed?

Claims of “landmarks” and “breakthroughs” should be viewed skeptically in the absence of data. The evidence-based reality is almost always substantially less than initial reports would have you believe.

The website <https://www.ehealthme.com/> allows individuals and doctors to conduct phase IV clinical trials.<sup>182</sup> This is a fancy phrase that means evaluating the effect of drugs after they have been approved for human use. According to ehealthme, "After a drug is approved, phase IV trials are conducted by the FDA and pharmaceutical companies to monitor its safety and effectiveness in the real world. Using big data and innovative AI/ML algorithms, eHealthme provides a platform for everyone to run their personal phase IV trials. What's more, we work with your doctors to ensure serious effects are checked out promptly."

The ehealthme database reports over 100,000 side effects from people taking Repatha as of April 3, 2022. It certainly is interesting that Amgen indicates no new side effects are noted. However, the side effects that are recorded occur at very high rates based on the ehealthme data. One of the more disturbing ones is a large reduction in white blood cell counts. The reports are rare, but it does not mean the actual incidence is rare.

Our team has had just one person on Repatha in 2021. That person was very diligent at mapping out his labs on a spreadsheet, including his white blood cell counts. In 2016 his white blood cell count plummeted from 5,400 cells/mL to 1,500 cells/mL. He also noted any drugs or other changes he made on the spreadsheet. His wife saw the coincidence between starting Repatha in 2016 and a precipitous decline in his WBC counts. Low white blood cells are strongly associated with cancer.

The Canadian Cancer Society explains low white blood cell counts.<sup>183</sup> They state,

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"Leukopenia refers to lowered numbers of white blood cells (WBCs) in the blood. WBCs help the body fight infection and disease. When WBC counts are low, there is a higher risk of infection."

"Leukopenia is a decrease in the total number of white blood cells. Leukocyte is another name for white blood cells. They are made in the bone marrow and are found in the blood and lymphatic tissues. Leukocytes play a key part in defending the body against viruses and bacteria, which can cause infection. Normal levels of WBCs are  $4.5\text{--}11.0 \times 10^9/\text{L}$  (we know these ranges are not correct). A person has leukopenia when the total WBC count is less than  $3.0 \times 10^9/\text{L}$ ."

Our individual had a WBC of  $1.5 \times 10^9/\text{L}$ , which is very dangerously low.

Note: if this person dies from cancer, it will NOT be reported as a Repatha-induced death.

The Canadian Cancer group says, "It is important to do everything possible to lower the chances of infection and to seek immediate treatment even if you think you have an infection." This statement is intended for those with low white blood cell counts. I have not spoken to this person since the onset of COVID. God forbid he caught the virus with that low WBC count.

Another injectable drug is evacetrapib. It acts by siphoning cholesterol out of HDL so the cholesterol can be discarded in bile. Statins, in contrast, lower the production of LDL that carry fats, including cholesterol, through the circulatory system. It seemed logical that evacetrapib, by ridding the body of cholesterol in HDL and lowering the number of LDL proteins, would work to protect against heart disease.

Although this drug increased the so-called good and lowered the so-called bad cholesterol, treatment with evacetrapib did not result in a lower rate of cardiovascular events than placebo among patients with high-risk vascular disease.<sup>184</sup> Here is an excerpt from the New York Times titled, "Dashing Hopes, Study Shows a Cholesterol Drug Had No Effect on Heart Health."<sup>185</sup>

"Evacetrapib is a drug that reduces levels of LDL cholesterol, the dangerous kind, as much as statins do. And it more than doubles levels of HDL cholesterol, the good kind, which is linked to protection from heart disease. As a result, heart experts had high hopes for it as an alternative for the many patients who cannot or will not take statins."

"But these specialists were stunned by the results of a study of 12,000 patients,"<sup>5</sup> announced on Sunday at the American College of Cardiology's annual meeting: There was no benefit from taking the drug evacetrapib. The drug's maker, Eli Lilly, stopped the study in October, citing futility, but it

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<sup>5</sup> Do we laugh or cry at how easily the brains of doctor are manipulated to ignore facts.

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was not until Sunday's meeting that cardiologists first saw the data behind that decision."

"Participants taking the drug saw their LDL levels fall to an average of 55 milligrams per deciliter from 84. Their HDL levels rose to an average of 104 milligrams per deciliter from 46. Yet 256 participants had heart attacks, compared with 255 patients in the group who were taking a placebo. Ninety-two patients taking the drug had a stroke, compared with 95 in the placebo group. And 434 people taking the drug died from cardiovascular disease, such as a heart attack or a stroke, compared with 444 participants who were taking a placebo."

"We had an agent that seemed to do all the right things," said Dr. Stephen J. Nicholls, the study's principal investigator and the deputy director of the South Australian Health and Medical Research Institute in Adelaide. **"It's the most mind-boggling question. How can a drug that lowers something that is associated with benefit not show any benefit?"** he said, referring to the 37 percent drop in LDL levels with the drug."

Dr. Nicholls needs to go back to his science training in college and not his medical school training. The answer to his "mind-boggling" question is straightforward. Wipe out preconceived notions and just evaluate the data. When doing this, it is very clear that lowering LDL with drugs does NOT show a benefit. Now Dr. Nicholls, freed from the slavery of a false narrative, can properly work up and treat his patients.

### **The First Cholesterol-Lowering Drug**

Triparanol was the first cholesterol-lowering drug introduced for human use. It was introduced around 1960 with much fanfare. According to the Journal of the American Medical Association,<sup>186</sup>

"Triparanol, an inhibitor of cholesterol biosynthesis, significantly reduced the serum cholesterol in 71 of 89 subjects with and without hypercholesterolemia. The compound in a maximally effective dose of 250 mg. per day was well tolerated and caused no serious side effects. The decrease in serum cholesterol (Abell) averaged 45 mg and ranged from 20 to 110 mg. The ratio of serum cholesterol to serum phospholipid also was favorably influenced by therapy."

Oops - so much for good objective "safe and effective" drug trials even back in 1960. Note that it was reported to be well tolerated and caused no serious side effects. But a scant 2 years later, in 1962, it was withdrawn from use due to severe adverse effects such as nausea and vomiting, vision loss due to irreversible cataracts, alopecia (hair loss), skin disorders including dryness, itching, peeling, and "fish-scale" texture, and accelerated atherosclerosis. Indeed, it increased heart

disease. Not surprising now that you are aware of the importance of cholesterol in repairing tissue.

Triparanol cost the manufacturer, Merrell, \$50,000,000 to settle the civil lawsuits for the harm the drug caused. Consequently, many pharmaceutical companies moved away from this type of treatment. However, some drug companies did not shut down their research programs on inhibitors of cholesterol biosynthesis. Most of them decided to steer clear of inhibitors that blocked the synthesis of cholesterol at the later stages, hoping that inhibitors working at earlier steps would not share the disastrous effects on eye and hair growth. For almost 30 years, they came up with nothing usable.

Between 1959, when Triparanol was introduced, and 1987, when the statin drugs reached the clinic, there were many patent applications for inhibitors of cholesterol synthesis. All of them produced more harm than good, and none of them were ever approved for human use.

Why did this data not direct medicine away from LDL?

### **Side Effects of Cholesterol-Lowering**

Dying young is clearly something to avoid. As, too, is living in a state of poor health. Artificially lowering LDL leads to an increase in early death and also contributes to poor health.

The Massachusetts Institute of Technology (MIT) is considered the most prestigious science institute in the world. Researchers there developed a system to evaluate patient complaints about the side effects of pharmaceuticals. In an article titled "Automatic Drug Side Effect Discovery from Online Patient-Submitted Reviews: Focus on Statin Drugs," Drs. Seneff, Lui, and Le present data on statins.<sup>187</sup> This paper was published in 2011, so is an incomplete review of side effects.

"In recent years, consumers have become empowered to share personal experiences regarding prescription drugs via Web page discussion groups. This paper describes our recent research involving automatically identifying adverse reactions from patient-provided drug reviews on health-related websites. We focus on the statin class of cholesterol-lowering drugs. We extract a complete set of side effect expressions from patient-submitted drug reviews and construct a hierarchical ontology of side effects."

"We use log-likely ratio estimation to detect biases in word distributions when comparing reviews of statin drugs with age-matched reviews of a broad spectrum of other drugs. We find a highly significant correlation between statins and a wide range of disorders and conditions, including

- diabetes;
- amyotrophic lateral sclerosis (ALS);

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- rhabdomyolysis;
- neuropathy, Parkinson's disease;
- arthritis;
- memory loss; and
- heart failure.

A review of the research literature on statin side effects corroborates many of our findings."

### **Statins and Heart Failure**

Statins are off-patent, reducing profitability. However, side effects of this class of drug are usually treated with another, often expensive, on-patent drug. The formula is logical. The researchers know the harm the drugs promote so develop drugs associated with these new emerging classes of harm. Heart failure is on the rise, and the increases correspond to statin use. The list price for the heart failure drug Entresto is ~\$6,000 annually. Insulin, to treat diabetes, costs about the same, and its use is also elevated by statin prescriptions. The total mean direct medical care costs for patients with established cardiovascular disease is around \$20,000 per patient per year.

As you can see, even though statins drugs are no longer expensive, the downstream costs associated with their use if very substantial.

The Weston A. Price Foundation provides a wealth of valuable health information. Dr. Price's initial work revolved around assessing health by examining jaw structure. The correlation is straightforward and logical. Bone is composed of dense minerals similar to rock. If a person is micronutrient deficient from a poor diet or absorbs poorly due to gut issues, their bone structure will be compromised.

The Price Foundation weighs in on statins and heart failure. Their treatise on the connection is provided here.<sup>188</sup>

"We are currently in the midst of a congestive heart failure epidemic in the United States. While the incidence of heart attack has declined slightly, an increase in the number of heart failure cases has outpaced these gains. Deaths attributed to heart failure more than doubled from 1989 to 1997. (Statins were first given pre-market approval in 1987.) Interference with the production of Co-Q10 by statin drugs is the most likely explanation. The heart is a muscle, and it cannot work when deprived of Co-Q10.

Cardiologist Peter Langsjoen studied 20 patients with completely normal heart function. After six months on a low dose of 20 mg of Lipitor a day, two-thirds of the patients had abnormalities in the heart's filling phase, when the muscle filled with blood. According to Langsjoen, this malfunction is due to Co-Q10 depletion. Without Co-Q10, the cell's

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mitochondria are inhibited from producing energy, leading to muscle pain and weakness. The heart is especially susceptible because it uses so much energy.

Co-Q10 depletion becomes more and more of a problem as the pharmaceutical industry encourages doctors to lower cholesterol levels in their patients by greater and greater amounts. Fifteen animal studies in six different animal species have documented statin-induced Co-Q10 depletion leading to decreased ATP production, increased injury from heart failure, skeletal muscle injury, and increased mortality. Of the nine controlled trials on statin-induced Co-Q10 depletion in humans, eight showed significant Co-Q10 depletion leading to a decline in left ventricular function and biochemical imbalances.

Yet virtually all patients with heart failure are put on statin drugs, even if their cholesterol is already low. Of interest is a recent study indicating that patients with chronic heart failure benefit from having high levels of cholesterol rather than low. Researchers in Hull, UK, followed 114 heart failure patients for at least 12 months. Survival was 78 percent at 12 months and 56 percent at 36 months. They found that for every point of decrease in serum cholesterol, there was a 36 percent increase in the risk of death within three years."

They found that for every point of decrease in serum cholesterol, there was a **36 percent increase in the risk of death within three years.**

### **Statins and Type 2 Diabetes (T2D)**

Statin drugs contribute to diabetes. The mechanism here is straightforward too. Reducing LDL reduces fat transport, including triglycerides. If cells cannot get and burn fats, then burning sugar is the only option. This leads directly to insulin resistance. Statins may also impair the ability of the pancreas to secrete insulin leading to the buildup of glucose in the blood.

Many studies support the causal link between statin intake and diabetes.

"Increased risk of diabetes with statin treatment is associated with impaired insulin sensitivity and insulin secretion: a 6-year follow-up study of the METSIM cohort."<sup>189</sup>

Finding: 46 percent increase in diabetes.

"Diabetes Secondary to Treatment with Statins"<sup>190</sup>

Findings: Statin therapy increases the risk of diabetes by 9%–12% in the two meta-analyses of statin trials and by 18%–99% in five population-based studies.

"Statin Use and Risk of Diabetes Mellitus in Postmenopausal Women in the Women's Health Initiative."<sup>191</sup>

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Findings: Statin medication use in postmenopausal women is associated with an increased risk for diabetes by 71%. This may be a medication class effect.

"Duration and Types of Statin Use and Long-Term Risk of Type 2 Diabetes Among Men and Women with Hypercholesterolemia: Findings From 3 Prospective Cohorts."<sup>192</sup>

Findings: Statin medication use in postmenopausal women is associated with an increased risk for diabetes by 38% in a group of 4555 women. The positive association between statin use and T2D was more pronounced with a longer duration of use, and the association varied with different types of statins.

### **Women and Statin Drugs**

Far too many healthy people are coerced into taking statins, and women top the list. A significant amount of research indicates that the drugs will do them no good and may be more likely to cause serious side effects in women.

"If you're going to tell a healthy person to take a medicine every day for the rest of their life, you should have really good data that it's going to make them better off," said Dr. Rita Redberg, a cardiologist at the University of California, San Francisco, and the former editor of JAMA Internal Medicine. Lowering cholesterol should not be an end in itself, she stated,

"You can have high cholesterol and still be really healthy and have a low risk of heart disease," she said.

Although women represent slightly more than half of the population, they have been vastly underrepresented in clinical trials on statins. As a result, evidence of the benefits and risks for women is limited. Women develop heart disease about 10 years later in life on average compared to men.

Studies have found that healthy women who took statins to prevent cardiovascular disease did experience fewer minor episodes of chest pain and had fewer treatments like stents and bypass surgery, arguably due to the antibiotic effect of the drugs. But statins did NOT prevent healthy women from having their first heart attacks and did NOT save lives. The Jupiter trial, which included 6,801 women age 60 and older, found a lower risk of hospitalization for unstable angina, but that was the only real benefit.<sup>193</sup>

The absolute number of these adverse health issues was tiny, and there was no reduction in heart attacks, strokes, and deaths in women.

"The data are underwhelming, to say the least,"

said Dr. Barbara Roberts, author of "The Truth About Statins: Risks and Alternatives to Cholesterol-Lowering Drugs" and an associate professor of medicine at Brown University. "Women who are healthy derive no benefit from statins. I have women come to me who were put on statins in their 30s by their

physician because their cholesterol was a point or two above what's said to be normal," Dr. Roberts said.

"This is insane."

But Dr. Roberts advises women that they can reduce their heart risk by watching their weight, exercising, and following a diet rich in fish, fruits and vegetables, nuts, and olive oil and, if they've never had heart trouble, forgetting statins. "We know you can get the benefit and relative risk reduction from adhering to a Mediterranean-style diet," she said.

Medscape produced an article titled "Statins, Cholesterol, Women, and Primary Prevention: Evidence-Based Medicine or Wishful Thinking?"<sup>194</sup> Their summary is provided here.

"A basic tenet of modern cardiology is that elevated cholesterol increases the risk of myocardial infarction (MI is a heart attack). Significantly lowering cholesterol should, therefore, reduce MI risk. Statins reduce cholesterol and, in some contexts, minor adverse heart outcomes, but meta-analyses of primary prevention clinical statin trials have found no statistically significant cardioprotective effect for women. These meta-analyses reasonably reflect the individual primary prevention trials."

Of these studies, none showed statistically significant cardioprotection for women, and some yielded hazard ratios exceeding one, meaning they had worse outcomes compared to no treatment. The meta-analyses are consistent with the absence of effect for women in the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), atorvastatin's (Lipitor®) primary prevention clinical trial, and are also consistent with the unpublished Carotid Atorvastatin Study in Hyperlipidemic Postmenopausal Women (CASHMERE) atorvastatin clinical trial, which demonstrated no improvement in carotid intima-media thickening (IMT) in a study limited to postmenopausal women.

The cholesterol-heart attack link and the achievement of lowered cholesterol without protective effect is an important scientific puzzle."

There is really no puzzle. Lowering LDL, thus total cholesterol is not the proper target to prevent heart disease.

### **Statins and Myopathy**

Cleveland Clinic is widely regarded as the top cardiovascular clinic in the world. It is a non-profit academic medical center that provides clinical and hospital care and is a leader in research, education, and health information. The clinic is a heavy prescriber of statin drugs. Therefore, the clinic must be classified as a leader in health MISinformation. In their own journal, they published a paper titled "Statin myopathy: A common dilemma not reflected in clinical trials."<sup>195</sup>

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Myopathy is a disorder of the skeletal muscles. Muscle disorders arise from abnormalities that affect the muscle's structure or metabolism. The intent of the paper is to provide guidance on the use of statins in such a way as to reduce myopathy. However, they do admit that statins induce myopathy as a significant side effect. In the article, they state,

"There is little consensus on the definition of statin-induced myopathy, and it is underdiagnosed. The incidence of statin-induced muscle toxicity in randomized controlled trials is lower than in clinical practice."

There is a "smoking gun" moment when the Cleveland Clinic admits that side effects are underreported in the most important studies, those used for drug approval.

The types of pain and muscle problems statin drugs induce include:

**Myalgia:** This type of muscle pain usually feels like mild soreness in the shoulders, arms, hips, or thighs. Myalgia also often comes with mild feelings of weakness.

**Myositis:** Myositis, a type of myopathy, causes muscle pain and inflammation, as well as an elevation in CK (creatine kinase, a muscle enzyme) levels in the blood. The presence of CK in the blood is an indicator of muscle damage. Our practice had a patient with CK levels in the high hundreds when they should be around 50. Her doctor determined it was from the use of statins.

**Rhabdomyolysis:** This severe type of myopathy is a life-threatening condition characterized by the breakdown of muscle tissue that causes muscle fiber contents to be released into the blood, potentially causing kidney damage.

Statin creating muscle pain is well appreciated. PubMed has over 32,000 publications on the topic. That is an extraordinarily high number of reports of adverse reactions. One of the reported elevated biomarkers associated with myopathy of the myositis kind is creatine kinase. Creatine kinase (CK) is an enzyme found in the heart, brain, skeletal muscle, and other tissues. Increased amounts of CK are released into the blood when there is muscle or tissue damage.

Note the locations in the body where CK is found: heart, brain, and skeletal muscle. This explains many of the side effects of statin drugs. So even though myopathy is defined as a disorder of the skeletal muscles, statin drugs also create myopathy of the heart and brain. Myopathy of the brain is medically defined as a neuromuscular disease. However, many people experience brain fog on statin drugs. Therefore, the impact of statin drugs on the brain - myopathy - goes well beyond muscular issues.

Figure 5.17 shows the relationship between statins prescriptions and Alzheimer's disease. The trends are undeniable. Diseases like Alzheimer's are multifactorial,

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and this figure illustrates a strong association. However, association and causation are different. Here is a look at the basic facts.

- Statins cause myopathy at high rates.
- The brain is impacted by myopathy.
- The lack of detectable myopathy in terms of muscle pain does not mean some level of myopathy is not occurring.
- The upward trend in Alzheimer's corresponds with the upward trend in statin prescriptions.

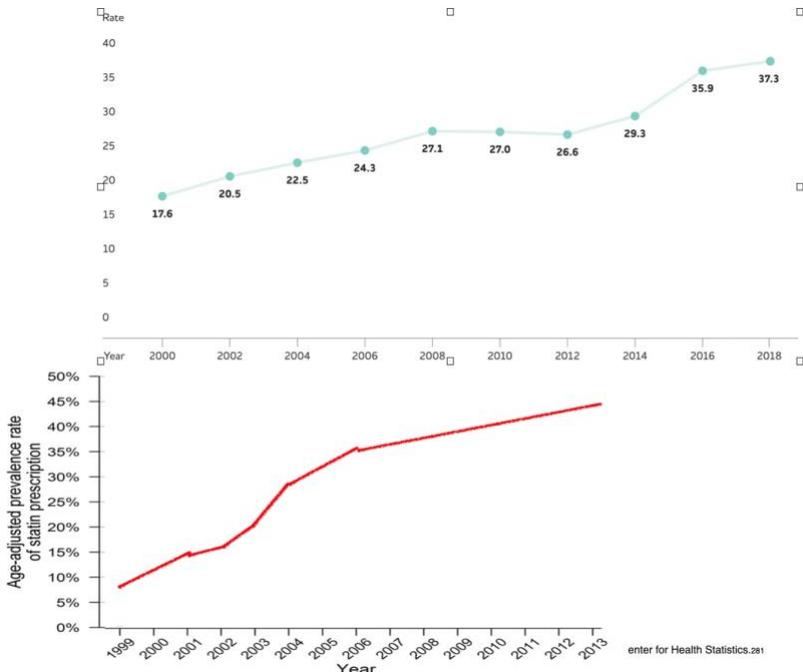


Figure 5.17: Trends in Alzheimer's and trends in statin prescriptions.

Medical experts claim that the incidence of muscle pain is quite low, occurring in roughly 5 percent of people taking statins. However, in the real world, people report pain at much higher rates. The substantial disconnect is likely driven by the \$1 trillion in financial gains by the statin industry and their ability to control the narrative. Samuel Clemens (Mark Twain) is famous for his quote,

"It's Easier to Fool People Than to Convince Them That They've Been Fooled"

People, AND DOCTORS, know that these drugs induce pain. What they do not know is the severity of the impact of these drugs on their physiology beyond just the annoying pain. How often has a doctor ordered a creatine kinase test on statin users? Everyone on these drugs should have a creatine kinase test, at a minimum, to truly determine the depth and breadth of the people impacted by these drugs. Without testing, you are guessing. And, without testing, the powers that be can

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say anything they want because it cannot be refuted by data. Could this be part of the reason why your doctor can order a cholesterol test but has a hard time justifying a CK test?

According to a review article, COVID-19 induces acute respiratory distress syndrome and respiratory failure, sepsis, acute cardiac injury, and heart failure.<sup>196</sup> Increased levels of creatine kinase were detected in many of those that died from the disease when the CK test was actually obtained. In 11 of 12 studies, CK levels were higher in the more severe group of COVID-19 patients. Could statin usage have been the "straw that broke the camel's back," causing death in some of these cases? Time and honest statistical analysis will tell.

### Statins and Memory Loss

Repatha, the biological drug that dramatically lowers LDL, impacts the brain, particularly short-term memory. Statin prescription trends coincide with Alzheimer's incidence. The mechanism is clear. The brain needs fats, and LDL transports fats. However, scientific reports on the association between LDL lowering and memory loss appear to be controversial. Our clinical evidence shows it is not controversial. It is simply a fact that those in control of the narrative try to ignore.

Surprisingly, one study on the topic of brain health and statins was published in the Journal of the American Medical Society (JAMA).<sup>197</sup> The study was substantial, covering 16 years and over half a million people. Most studies on statins, LDL lowering, and memory in this and other prestigious journals contradict these findings. Maybe this article got through the review process because it only delved into "acute" memory loss that occurs within the first 30 days of being on a statin. The data presented in the JAMA paper are profound. What follows is the results summary and interpretation of those results. The abbreviation LLD stands for lipid-lowering drugs or LDL-lowering drugs.

Study results:

"When compared with matched nonusers of any LLDs, a strong association was present between first exposure to statins and incident acute memory loss diagnosed within 30 days immediately following exposure (fully adjusted, 4.40; 3.01-6.41). This association was not reproduced in the comparison of statins vs non-statin LLDs (fully adjusted, 1.03; 0.63-1.66) but was also present when comparing non-statin LLDs with matched nonuser controls (adjusted, 3.60; 1.34-9.70)."

Interpretation:

- There is a **STRONG** association between first using any LDL-lowering drug and immediate memory loss.

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- The 4.40 number means a 440 percent increase in memory loss risk with a range of 301 - 641 percent.
- The profound memory loss occurs with statin and any other LDL-lowering drug. Thus, it is not the statins but the mechanism of lower LDL that causes memory loss.
- Drugs that lower LDL but are not statins showed a memory loss range of 134 to 970 percent, probably due to their varying ability to lower LDL, at least in part.

The authors conclude, "Both statin and non-statin LLDs were strongly associated with acute memory loss in the first 30 days following exposure in users compared with nonusers but not when compared with each other. Thus, either all LLDs cause acute memory loss regardless of drug class or the association is the result of detection bias rather than a causal association."

The last statement about detection bias is probably the language that allowed the paper to be published. Statins were approved because of their approximate 25 percent reduction in heart disease. We now know that is a relative statistic and the actual benefit of reducing a heart attack in high-risk individuals only is around 0.3 percent. The substantially higher relative statistics for memory loss - 440 percent, on average - is hardly a statistical error or due to detection bias. If anything, the alleged 20 percent benefit is the bias.

The paper does go on to say, "long-term use of statins has found either improved memory or no effect." Who is kidding whom? Do you really think that taking a drug that harms your short-term memory will improve your long-term memory? If so, please start banging your head against the wall for the next year so you can recite *War and Peace* from memory. Again, the mechanism is clear. These LDL-lowering drugs reduce the number and amount of critical nutrients that can reach the brain. This sort of incongruity is not possible based on how human physiology works. But it clearly serves someone's agenda.

In a study of 60 patients who had memory loss associated with statins, 36 patients received simvastatin, 23 atorvastatin, and 1 pravastatin.<sup>198</sup> About 50 percent of patients showed cognitive adverse effects within two months of therapy. In a randomized trial with healthy adults, simvastatin was associated with decreased performance on some neuropsychological tests compared with the placebo. A survey conducted on 171 patients on statins reported that cognitive problems associated with statins have variable onset and recovery courses, that is, the time for some reversal in memory loss after stopping the drug. And there is a clear relationship with potency. The higher the dose, the greater the impact on memory resulting in a significant negative impact on quality of life.

In 2012, the United States Food and Drug Administration (FDA) changed the labeling for statins, advising of the possibility of cognitive impairment and further adding to the concerns regarding cognitive decline. Does your doctor tell you

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about this warning, or just write a script? This is where I have a problem with doctors. Those who are not brave enough to stick up for the patients, at least behind closed doors, are one simple thing - COWARDS.

Canadians beware! The Canadian Consensus Working Group has updated its evaluation of the literature pertaining to statin intolerance and adverse effects.<sup>199</sup> They concluded, "Cognitive considerations should not alter the decision to prescribe statins if indicated for the management of lipids or cardiovascular risk."

Translation: Canadians: although these drugs do not prolong life, you will not notice this because your memory will be shot.

Cholesterol, the actual molecule, as opposed to "total cholesterol," is a critical component of any organism that contains cells with a membrane and nucleus. This includes all animals, plants, fungi, and single-cell organisms, as well as most algae. Pigs are no exception, and an article explains the importance of cholesterol in early brain development in these animals.<sup>200</sup> The authors conclude, "dietary cholesterol deprivation during the first 4 to 8 weeks of life in piglets is associated with lower cholesterol concentration, and total content in the young adult cerebrum than in pigs supplemented with cholesterol in early life. These data support previous observations and suggest the possibility of a metabolic need for neonatal dietary cholesterol in normal brain development."

Optimal (regarded as high in the standard of care) levels of cholesterol are important in human infants, not just pigs. Quotes from different peer-reviewed references include:

- Higher early cholesterol is associated with improved cerebellar volumes.<sup>201</sup>
- High rates of de novo (in the brain) cholesterol synthesis in the glia and neurons provide the sterols necessary for early brain development. Once a stable brain size is achieved in the adult, cholesterol synthesis continues, albeit at a much lower rate.<sup>202</sup>
- Fat, including cholesterol, is necessary for the diets of infants and young children because of their extraordinary energy needs and limited dietary capacity. Deficiencies in the amounts of these long-chain fatty acids in the diet during infancy may affect the maturation of the central nervous system, including visual development and intelligence.<sup>203</sup>
- Researchers found those on the autism spectrum with low levels of high-density lipoprotein cholesterol had lower adaptive functioning than others with autism.<sup>204</sup>

The next market for statin use may well be the veterinary discipline. Statins and LDL-lowering drugs, during the development phase, are first studied in animals before being introduced to humans. Statins lower the total cholesterol across all species, although with large differences in the effect size: -30% in rabbits, -20%

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in mice, and -10% in rats. The reduction was larger in animals fed on a high-cholesterol diet. Lipitor does, in fact, work on dogs too. Studies indicate they also get a cholesterol reduction from Atorvastatin.

The point of this discussion about animals is that cholesterol is ubiquitous. And the brains of animals, like humans, have the highest concentration of the actual cholesterol molecule, as 20-25 percent of all the cholesterol in the body is in the brain. Apparently, all animals and any species with cells were born to self-destruct. Could this be the key to the biological clock and aging? You know this is not the case because no one lives longer when their cholesterol is lowered with the drugs.

Dr. Jonny Bowden holds a Ph.D. in holistic nutrition, earning the certification of Certified Nutrition Specialist from the American College of Nutrition. He wrote the book, "The Great Cholesterol Myth." According to Bowden, "Your brain without cholesterol? You're dead, it's one of the most important compounds in the body, and it's involved in memory and thinking and much more." Shockingly, some labs list the reference range for acceptable total cholesterol levels of 0 - 199 mg/dL while the ranges vary. Other lab normal values are reported to be 100 - 199 mg/dL, 0 - 169 mg/dL, and 100 - 169 mg/dL.

I do wonder if there is any record of a living human with a "total cholesterol" of zero. Oh, to be given the opportunity to hand-select a cohort upon which to do this study! After all, it would just be for the greater good!

Cholesterol in the brain is involved in the communication process for neurotransmitters, such as dopamine and serotonin. It makes up the majority of myelin, the white fatty sheath that provides a protective coating on neurons to increase the brain's processing speed. And they play a role in the development of "lipid rafts," membranes that are involved in brain cell signaling. When this coating breaks down, the disease is called multiple sclerosis.

### **Other side effects of statins and LDL-lowering drugs**

Books have been written on the dangers of statins and LDL-lowering drugs, so covering all harmful aspects of this class of drugs is beyond the scope of this chapter. What follows are references to other harms created by taking these drugs.

- Statins and exercise: Exercise worsens muscle injury with statins, and statins worsen the pain and injury induced by exercise.<sup>205</sup>
- Low cholesterol and kidney cancer: Low cholesterol before kidney surgery is associated with more advanced cancer and greater cancer spread after surgery. High cholesterol is associated with a 43 percent reduction in death after surgery.<sup>206</sup>
- Low cholesterol in cancers: In some malignant diseases, it has been demonstrated that blood cholesterol levels are significantly altered. It has

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been proposed that low or high levels of cholesterol in the proliferating tissues and in the blood have a role in carcinogenesis.<sup>207</sup>

- Low cholesterol predisposes to cancer: Nine studies involving more than 140,000 people found that cancer was inversely associated with cholesterol measured 10 - 30 years earlier. That is, low cholesterol levels are associated with increased incidences of cancer. An increase in non-melanoma skin cancer in two early statin trials is statistically significant. A study showed increasing prostate cancer risk with increasing statin dose.<sup>208</sup>
- Statins and breast cancer risk: Twelve out of 286 women in the statin group but only one out of 290 in the placebo group had breast at follow-up for a relative risk increase of 1,200 percent. After this result, most statin investigators took care not to include high-risk women in their trials.<sup>209</sup>
- Statins and memory: It is not crazy to connect cholesterol-modifying drugs with cognition; after all, one-quarter of the body's cholesterol is found in the brain.<sup>210</sup>
- Statins and suicide: According to Psychology Today,<sup>211</sup> "many studies over decades have (for the most part) consistently linked low total serum cholesterol with suicide, violence, and depression. Total cholesterol levels below 160 mg/dL, and especially below 130mg/dL, correlate with a higher risk of mental problems. There are other curious findings as well. Cholesterol tends to be lower in Alzheimer's Disease, and cholesterol has been found to be lower during a manic episode in bipolar disorder, and tends to pop up again when the episode gets better."

As promised, here is the full paper by Dr. Demasi, who did an excellent job covering some of the more political aspects of the cholesterol conundrum.

Since their introduction in the late 1980s, statins have been an immensely lucrative drug class, with Pfizer's Lipitor being the most profitable drug in the history of medicine. Despite the expiration of their patents, revenue for statins is expected to rise, with total sales on track to reach an estimated US \$ 1 trillion by 2020. Statins have now cemented their place in cardiovascular medicine. They are effective at lowering cholesterol and therefore perceived to be the most valuable tool in the prevention of heart disease. But the scientific data have not convinced everyone.

Proponents have described them as one of 'the most important advances in medical history and have prevented untold heart attacks and strokes. Yet other cardiologists say statins 'serve no purpose in lowering cholesterol to prevent cardiac problems and even label them 'unnecessary and toxic,' pointing out the methodological flaws contained within the early statin trials.

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Now, a chasm has formed between doctors who prescribe statins with unbridled enthusiasm and those who remain unconvinced by the science. Have doctors and patients been misled about the benefits and risks of statins?

Statins (HMG-CoA reductase inhibitors) were initially recommended for people with existing heart disease (secondary prevention), but manufacturers quickly sought to increase the indications of the drug and capture a larger piece of the market share. The next target population was healthy people (primary prevention).

An effective way to mandate wider drug prescribing is to exert influence on the committees in charge of formulating the medical guidelines. In the early 2000s, the US National Cholesterol Education Program (NCEP) revised the definition of 'high cholesterol' by dramatically lowering the threshold. Virtually overnight, it meant that millions more people would be eligible for statins. It was not based on any new scientific data but rather on the increasingly popular notion that 'less is best' when it came to cholesterol.

The decisive move sparked a furor when it was revealed that eight out of nine members of the 2004 NCEP guideline committee had direct financial ties to statin manufacturers. But it was too late. The ink had already dried, and the new guidelines were being widely enforced.

Meanwhile, prominent researchers at Oxford University formed an alliance called the Cholesterol Treatment Trialists' (CTT) Collaboration. Spearheaded by Sir Professor Rory Collins, this group of researchers began periodically publishing their own reviews of the statin data from clinical trials. The reviews were dogmatic about advocating the wider use of statins in healthy people (primary prevention). An accompanying editorial argued that 'everyone over 50' should be taking a statin, regardless of their cholesterol levels, and if implemented in the USA, it would lead to 64 million people, more than half of the population over the age of 35, starting statin therapy.

One prominent cardiologist even published an article in the American Journal of Cardiology stating that statins should be offered as condiments at burger outlets, with the suggestion that statins could 'cancel out' the unhealthy effects of the meal.

Soon, doctors began to recommend screening children and infants for high cholesterol to identify potential statin recipients, as well as marketing to kids with 'grape-flavored chewable' statins. There was even a debate in the USA about putting statins in the water supply.

In 2013, the American College of Cardiologists (ACC) and the American Heart Association (AHA) updated their guidelines to recommend that statins be prescribed to patients based on their cardiovascular risk (7.5% over ten years). Again, serious concerns were raised about the financial conflicts of committee members and the fact that millions more adults would be eligible for statin

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therapy, most of whom were older people without cardiovascular disease. It was referred to as the ‘statinisation’ of the population.

Shortly after, the UK’s National Institute for Health and Care Excellence (NICE) announced it planned to halve the risk threshold for prescribing statins (from 20% to 10% over ten years). Doctors vigorously objected to the changes. A UK survey revealed that two-thirds of general practitioners would disregard the advice to offer statins to people at the newly proposed threshold of 10% on the grounds that it was ‘not evidence-based’ and could lead to the ‘medicalization of healthy people at the cost of more needy, unwell patients. Skepticism was inevitable once it was revealed that 8 out of the 12-panel members at NICE had financial ties to manufacturers of cholesterol-lowering drugs.

Then, evidence emerged that the ‘calculators’ used to assess atherosclerotic cardiovascular risk were inaccurate. One study examined five risk calculators and demonstrated that four, including the new AHA-ACC risk calculator, showed the overestimation of risk could be as high as 115%, leading to legitimate concerns about the undisciplined over-prescription of statins.

Doctors are now seeing the effects of a phenomenon called ‘diagnosis creep,’ whereby simply changing the definition of a disease or lowering the threshold of a surrogate marker turns healthy people into patients and leads to overdiagnosis and unnecessary treatments.

If the data are hidden, can we even have a debate?

Science prides itself on the informed debate, but is that even possible if the data are hidden?

Much has been made about the fact that the raw data from statin trials are only available to a single group of researchers—the CTT Collaboration—and they have agreed to keep the data in confidence and will not share anonymized data with independent researchers. This is one of the most contemptible breaches of transparency. Neither the doctors prescribing statins nor the millions of people taking these medications have had access to independent analysis of the efficacy data. In addition, the side effect data were simply not collected in the vast majority of trials.

When asked in 2013, the CTT confirmed that it would not allow other scientists to access the raw statin data to conduct an independent analysis. They wrote:

The CTT secretariat has an agreement with the principal investigators of the trials and, in those instances where trial data were provided directly by the drug manufacturers, with the companies themselves, that individual trial data will not be released to third parties. Such an agreement was necessary in order that analyses of the totality of the available trial data could be conducted by the CTT Collaboration: without such an agreement, the trial data could not have been brought together for systematic analysis.

Alarming, the widely influential analyses of the CTT Collaboration cannot be verified by independent researchers because most, if not all, of the principal investigators of the individual studies have not agreed to make their data available. Hence, the rest of us are supposed to have faith in the interpretation of science by this select group of scientists without seeing it for ourselves.

Not even the Cochrane Collaboration had access to the patient-level data when conducting its review of statins in low-risk people, and its conclusions ultimately influenced the prescribing guidelines.

Dr. Fiona Godlee, Editor in Chief of the BMJ, has called for the release of the raw data on the side effects of statins and has described the discourse as ‘a bitter and increasingly unproductive dispute’ because the data for harms have not yet been given the same level of scrutiny as the data for benefits. As in the case of the hidden data on Tamiflu, independent scrutiny of individual patient data uncovered new and revealing facts about the benefits and harms of the medications.

### **Erosion of public confidence**

The discernible lack of scrutiny surrounding statin side effects has eroded the public’s confidence.

In 2015, Professor Collins made a public admission to the media that he had not seen the full data set on statin side effects, despite repeatedly protesting that statins had just a few troubling side effects like muscle weakness in 1 in 10000 people. Several studies have now linked statins to a small but significant increase in type 2 diabetes, leading to a safety label change on statins by the Food and Drug Administration and has sparked multimillion-dollar class actions against the statin manufacturers.

It is now a matter of urgency that the CTT Collaboration, a branch of the Clinical Trial Service Unit (CTSU) at Oxford, demands that the principal investigators of the statin trials release the raw data on efficacy and side effects. There is growing unease that the CTSU has received over £ 260 million in research funding from the pharmaceutical industry, the vast majority of it from manufacturers of cholesterol-lowering drugs.

There has been an over-reliance on the results of studies, which have been funded by industry. A recent Cochrane review showed that sponsorship of drug trials by the manufacturing company leads to more favorable results and conclusions than sponsorship by other sources. In the case of statins, the vast majority of trials are sponsored by industry. Only one major non-industry-funded study on statins has been done (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)), which showed pravastatin had no significant benefit in reducing either all-cause mortality or coronary heart disease in primary prevention.

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The problem of industry bias has become so serious that Britain's Chief Medical Officer expressed her concerns to the Academy of Medical Sciences. In the letter, Dame Sally Davies wrote:

There seems to be a view that doctors over-medicate, so it is difficult to trust them, and clinical scientists are all beset by conflicts of interest from industry funding and are therefore untrustworthy too. I have, therefore, reluctantly come to the conclusion that we do need an authoritative, independent report looking at how society should judge the safety and efficacy of drugs as an intervention.

If the public demands that scientists declare their conflicts of interest in order to restore confidence, then so should medical journals.

Former Editor in Chief of The New England Journal of Medicine, Dr. Marcia Angell, famously said,

“It is simply no longer possible to believe much of the clinical research that is published or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine.”

In a recent US interview, Dr. Angell explained that she began working for the journal in 1979.

Starting about then was when you began to see the drug companies assert more power. Over the next couple of decades, they began to treat the researchers as hired hands. They would design the research themselves - you can make a lot of mischief in how you design a trial. Or [they'd say] we'll test this drug, and we'll tell you whether it can be published or not, and so if it's a positive study, it's published, and if it's a negative study, it's not.

In a welcome step toward financial transparency of medical journals, BMJ's Executive Committee has recently approved a proposal to publicly disclose revenues received from industry sources, including the pharmaceutical and devices industries.

### **Scare campaigns and censorship**

Those who publicly challenge the over-prescription or side effects of statins in the media are castigated and blamed for undermining public health initiatives. They are compared with reviled groups like 'anti-vaxxers'. In a public statement to the press, Professor Collins said those who spoke out about statin side effects were “far worse” and had probably “killed more people” than “the paper on the MMR vaccine.”

A recent article published in The Lancet by Professor Rory Collins and colleagues boldly claimed to ‘end’ the statin debate, once and for all, ostensibly to silence dissenting views. The authors blamed ‘media hype’ for people allegedly dumping

their statin therapy. However, prior to the widespread media coverage, the largest known statin usage survey conducted in the USA found that 75% of new statin users discontinued their therapy by the end of the first year, with 62% of them saying it was because of the side effects.

BMJ's Editor in Chief, Dr. Fiona Godlee, was critical of The Lancet review, accusing the authors of trying to 'shut down the discussion and award themselves the final word'. Instead, she rightly drew attention to legitimate questions about the benefit of statins in people at low risk of heart disease, especially given the discrepancy over side effects documented in the clinical trials (reported to be negligible) compared with real-world data.

I have also been criticized for questioning the over-prescription of statins for healthy people. A documentary I produced was labeled 'biased' because it gave prominence to the views of University of California San Francisco Cardiologist Professor Rita Redberg and Harvard University's Dr. John Abramson, who disagree with prescribing statins to healthy people at low risk of heart disease. Even though the programs were factually accurate, a small but vocal group of doctors, many of whom received funding from statin manufacturers, launched an orchestrated attack. One cardiologist stated, "the ABC has blood on its hands" for broadcasting the documentary, while another medical commentator claimed "people will die" as a result of the program.

Later, a report co-authored by the same doctor who tried to have the program censored speculated on the potential number of deaths that may have resulted after the program aired. Several months later, the television network capitulated to pressure and removed the program from its website, despite government data showing that statin prescriptions had not fallen in the months following the program's broadcast. Recently, a British cardiologist reflected on the controversy regarding the program, describing the reaction of critics as 'complete nonsense designed to smear' those with dissenting views.

In 2013, a similar situation occurred in France after there was intense controversy about statins in the media. An alarmist report claimed the 'controversy' had the effect of causing a ~50% increase in statin discontinuation that year compared with previous years.<sup>38</sup> Extrapolations predicted that it would cause 10000 people to die unnecessarily from statin cessation. Fortunately, these claims were refuted when a subsequent report of the 'actual' death rate from national statistics showed a significant decrease in the number of deaths that year. The authors concluded that it was 'not evidence-based to claim that statin discontinuation increases mortality' and that in the future, scientists should assess 'real effects of statin discontinuation rather than making dubious extrapolations and calculations.

### **Statistical deception**

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It may not always be intentional, but non-transparency is often a tactic used to manipulate or persuade people into taking statins.

For example, when patients are told about the benefits of statins, they will be quoted ‘relative risk reduction’ (e.g., 30%) rather than ‘absolute risk reduction’ (e.g., 2%), because it sounds more impressive and is more likely to persuade the patient. In contrast, when patients are told about statin side effects, they are often quoted ‘absolute risk’ figures. This kind of ‘mismatched’ statistics is mischievous. A 2007 analysis of three major journals between 2004 and 2006 found that one in three articles contained ‘mismatched’ statistics, where the benefits were expressed as relative risk, and the harms were reported as absolute numbers.

According to Professor Gerd Gigerenzer, director of the Harding Center for Risk Literacy, “It is an ethical imperative that doctors and patients understand the difference between relative and absolute risks to protect patients from unnecessary anxiety and manipulation.” In fact, failure to do so would be “unethical.”

Another example of statistical trickery has arisen from a change in the expression of statin benefits. The CTT collaborators report statin benefits with each drop of ‘1mmol/L in Low-Density Lipoprotein-cholesterol (LDL-c)’. Rather than observing the rates of cardiovascular disease in a randomized population of people (as was performed in the original clinical trials), the CTT Collaboration recalculates the results as if everyone experienced a 1mmol/L drop in LDL-c. However, the cardiovascular effect of statins can be unrelated to the degree of LDL-c drop, and it says nothing about the broader primary prevention population, some of whom will not respond to LDL-c lowering on statins. Therefore, it has raised concerns that the CTT collaborators simply revisit old data, and perform statistical ‘acrobatics and restructure questions to arrive at different conclusions. This may explain why the CTT Collaboration found a mortality benefit in low-risk people taking statins and is at odds with three other independent analyses.

Unless doctors understand and relay to their patients the number needed to treat (NNT) for people to benefit from a drug and the number needed to harm (NNH), people will continue to be oversold on the benefits of statins. TheNNT.com is a valuable resource that can assist in shared decision-making.

### **Underplaying the risks**

There are simple ways to design a clinical trial in order to minimize the harm of the drug. One example is the use of a run-in period, such as in the Heart Protection Study, which assessed the efficacy of simvastatin therapy and vitamin supplementation in reducing the risk of cardiovascular disease. During the run-in period, all participants took a placebo for 4 weeks, then a statin for a further 6 weeks prior to randomization. At the completion of the run-in period, 36 % of the

participants were excluded from the trial, the vast majority of these choosing not to participate or were not compliant. It is plausible that they declined to participate because the statins caused unacceptable side effects. The authors said the run-in period was to assess ‘the LDL-lowering responsiveness of each individual’.

Many have questioned whether it is scientifically valid to remove those participants whose cholesterol levels did not ‘respond’ to statin therapy or who did not tolerate statin therapy. The act of excluding a large group of people from clinical trials after they have taken the drug for several weeks is not only legal, but it is an accepted practice. The explanation for designing trials with run-in periods is that it allows the assessment of people who are compliant. But if people are not taking the medication because of unacceptable side effects and are removed from the study, then surely it results in a study that grossly underestimates the actual rate of side effects associated with statins.

Furthermore, when recording side effects during a trial, questions may not be ‘designed’ to enquire about complaints that are not spontaneously reported. This may additionally explain why the rate of side effects in statin trials is wildly different from the rate of side effects seen in real-world observations.

Also, women are under-represented in clinical trials. For example, the Scandinavian Simvastatin Survival Study (4S) trial showed benefits for statins in secondary prevention, but when women were analyzed separately, there was a non-statistical increase in mortality. This result was obfuscated when male and female groups were combined, but doctors still impute the benefits of statins to women based on these results.

Another way of underplaying the risks of a drug is by excluding trials from meta-analyses. For example, the CTT Collaboration performed a meta-analysis of 18686 people with diabetes from 14 randomized trials of statin therapy. However, there was a glaring omission of two significant trials, namely, the Atorvastatin Study for Prevention of Coronary Heart Disease (ASPEN) and the Deutsche Diabetes Dialyse Studie (4D) trials.

Both ASPEN and 4D trials, which had been specifically designed and powered to assess the effect of statins in diabetes, failed to demonstrate a mortality benefit. Interestingly, the CTT collaborators did consider including them in their meta-analysis. The CTT collaborators wrote:

Since both [ASPEN & 4D trials] reported apparently unpromising results, we considered whether their inclusion would have been likely to change our conclusions.

Their rationale for excluding these trials was that the group on statins did not respond with a significant reduction in LDL-c. The CTT wrote:

Our main conclusions, therefore, are not materially affected by the results of ASPEN and 4D trials.

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This is problematic for two reasons. First, if the exclusion of a trial is based solely on the fact that the intervention arm did not demonstrate a reduction in LDL-c, then a trial like the Lyon Diet Heart Study would have also been ruled a failure since it showed a dramatic reduction in cardiovascular disease associated with the adoption of a Mediterranean-style diet, despite no change in cholesterol levels. Second, if ASPEN and 4D trials would not have altered the CTT's conclusions, why wouldn't they have just included the trials for the sake of scientific integrity?

A recent study showed that people who took a daily statin for 5 years only increased their life expectancy by 4.1 days (in secondary prevention) or 3.2 days (in primary prevention). Statin proponents claim that the benefits would have accumulated if the statins were taken beyond 5 years. However, it is disingenuous to claim that the benefits accumulate in the absence of accumulating side effects. In fact, the longer the trial, the more likely it is that other diseases (which take longer to develop) would emerge, such as cancer and neurocognitive dysfunction.

### **Conclusions**

In conclusion, the egregious lack of transparency surrounding the raw data on statins has meant that doctors have been misled about the evidence and it has divided medical opinion. While there is more agreement on statins for secondary prevention, the debate about primary prevention remains divisive.

Few argue that statins are very effective at lowering cholesterol, but the ultimate goal is to improve quality of life and longevity. Dr. Rita Redberg explains:

The marketing [of statins] concentrates on the fact that you can lower your cholesterol as if that were the end in itself, which it is not. Cholesterol is just a lab number. Who cares about lowering cholesterol unless it actually translates into a benefit to patients?

LDL-cholesterol is merely a surrogate marker, and its causative role in the development of cardiovascular disease is increasingly being questioned by prominent cardiologists. Clinicians speculate that the benefits of statins are independent of lowering cholesterol and that it is more likely to be their anti-inflammatory (pleiotropic) effects. More recently, the distrust in statins comes from those who assert that the early trials are flawed and that since more stringent reporting regulations were introduced in 2005, the subsequent trials have been inconsistent and underwhelming.

There must be shared decision-making between patients and doctors about statins. Patients often report being 'fired' by their doctors when they complain about the side effects of statins and feel threatened by claims that 'they will die' if they do not continue with their medication. Often, the side effects can be vague; for example, patients might complain of mind fog and fatigue. Doctors won't connect these symptoms to statins and blame it on 'normal ageing'. It only becomes

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apparent when the patient stops the medication, and the symptoms resolve. Doctors can then re-challenge with a statin to verify the drugs' side effects.

All medications come with risks, which is why doctors need to be extra vigilant about prescribing them to healthy people. If we accept that clinical trials use run-in periods to exclude participants who cannot tolerate statins, exclude people with comorbidities, they exclude people taking other medications, and the vast majority of trials are industry-funded and lack transparency, lending to biased results, then we must also accept that perhaps we have been too quick to label statins as the safest and effective way to reduce the risk of heart disease.

The acrimonious debate about the risks and benefits of statins will continue, but until the raw data on statin efficacy and side effects are released, we are deluding ourselves if we think that we are even having a reasonably informed debate.

Meanwhile, doctors prescribing statins should remain inherently skeptical because the majority of those taking statins are 'healthy' people at low risk, where the benefits are vanishingly small and the raw data on side effects are kept hidden."

Finally, this overview of the statin debate provided in the journal "Health Policy" sums up the problem with these drugs in a subtle but important way.<sup>212</sup>

- The 2013 U.S. cholesterol guideline recommends the use of statins for the primary prevention of CVD in low-risk individuals.
- This expands the number of patients for whom the use of statins is recommended.
- The recommendation has been controversial due to disagreement about the robustness of the evidence base.
- Pharma is involved in the development of clinical guidelines – from trial design to data analysis to meta-analysis of studies.
- Policies could reduce the influence of Pharma on the research process and prevent pharmaceuticalization.

These drugs are being pushed on us by big pharma and almost every doctor. Should you take a statin or other LDL-lowering drug. If you want to live longer and healthier, the answer is a simple -

NO.

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A disease usually represents the inconclusive negotiations for symbiosis, a biological misinterpretation of borders."

- Lewis Thomas

### **The Stealth of Chronic Infections Ignored**

Summary: Many people who are unhealthy, when treated, get better. However, many people have lingering nagging symptoms that interfere with their quality of life. When this is the case, they most likely have a hidden infection. In health, we all recognize acute (immediate) and chronic (lingering) disease syndromes. However, only acute infections are recognized in standard medicine. This chapter explains the "stealth of chronic" infections and how to measure and treat them to reverse the most severe diseases our populations face.

The concept of infection-causing disease is historic. Chronic diseases are rampant because there are two different responses to infection - acute and chronic- but only acute infections are recognized in the standard of care. The standard of care completely ignores or dismisses chronic infection as a causal agent of chronic disease. However, the concept of chronic infection and chronic disease is extremely clear based on the work of eminent thought leaders in medicine.

It is difficult and expensive to demonstrate causation. For example, someone bitten by a tick in their youth may experience no or only mild immediate or acute symptoms. However, later in life, that person may develop unexplained joint pain and general malaise, including a few signs of chronic Lyme disease. This concept is called "crypticity." The term means it is hard to associate the exposure - the tick bite 40 years ago - and symptoms today.

Some of the historical leaders in the field of chronic infection in disease are:

- Hippocrates;
- Louis Pasteur and Claude Bernard;
- Robert Koch;
- Alois Alzheimer;
- Charles Mayo.

In more recent times, these individuals have made great contributions to the understanding of cryptic infections.

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- Judith Miklossy;
- Paul Ewald;
- Warren and Marshall;
- Charles Stratton;
- David Wheldon;
- J. Thomas Grayston;
- Clement L. Trempe and Kilmer S. McCully.

Dr. Ewald has written the most comprehensive and thoughtful pieces on chronic infections, their history, and their current contribution to modern disease. His book, "Plague Time - How Stealth Infections Cause Cancers, Heart Disease and Other Deadly Ailments," is a detailed dive into the root causes of many seemingly intractable and unexplainable diseases. In the introduction to this book, Ewald frames the concept quite succinctly.

"This book is not about the infectious diseases on which popular media have focused. It is not about the infectious threats to rich countries from the world's poor countries. The Ebola and West Nile viruses that captured headlines during the 1990s are, in fact, minor threats. The balance of evidence indicates that the major infectious plagues are not emerging from an African jungle.

Infections are already here, embedded in every society, in rich and poor countries alike.

They have been here for centuries, even millennia. They are as deadly and painful as the sensationalized plagues, but they have spread more insidiously and imperceptibly. They are slow-motion plagues that are difficult to recognize and difficult to control. The flash-fire outbreaks (COVID-19, for example) that make the headlines usually burn out on their own. The serious infectious plagues are not so easy to escape."

As you read Ewald's introductory statement, do you know what he is referring to? It should be very clear, but it is not because of the prevailing medical dogma focused on symptoms or surrogate markers.

Another quote from Dr. Ewald may provide the hints necessary to decipher his remarks.

"The (medical) textbooks say, in 1900, most people died of infectious diseases, and today most people don't die of infectious disease; they die of cancer and heart disease, and Alzheimer's and all these things. Well, in the future, I think the textbooks will have to be rewritten to say, "Throughout history, most people have died of infectious disease, and most people continue to die of infectious disease."

Chronic diseases are infectious diseases.

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The translation of Dr. Ewald's statement is that modern medicine says that the major chronic diseases are statin, blood pressure medication, chemotherapy, metformin, SSRI, and Aricept deficiencies. That is why these drugs are so widely prescribed.

### **Hippocrates**

The father of modern medicine was the first scientist noted to separate the science of medicine from superstition. Several infectious diseases were first described by Hippocrates or a Hippocratic doctor, who no longer believed in "miasma" or "bad air" that could contaminate whole populations. Instead, they forwarded the concept of contagion. He was the first to regard disease as a natural rather than a supernatural phenomenon, encouraging doctors to look at illness's physical causes and use objective observation and critical deductive reasoning. Hippocrates believed that the causes of disease could be understood only through empirical study.

Do doctors practice these basic root-cause concepts 2,500 years after  
Hippocrates?

In "Insights into infectious disease in the era of Hippocrates,"<sup>213</sup> the authors state,

"Although infectious agents have existed since long before humanity, and despite the rapid advances characterizing the previous century in terms of the recognition and treatment of the diseases induced by these agents, infection remains a major cause of human morbidity and mortality, and an ever-present threat. In looking into the past for options for the future, the heritage of Hippocrates is of great significance."

### **Claude Bernard and Louis Pasteur**

These two giants of medicine are included together because they discovered the yin and yang of health and disease. Claude Bernard was a doctor and the first modern-day medical scientist. He was responsible for a major breakthrough in understanding the fundamental principles of organic life, which is still profoundly valid today. His concept of "homeostasis," or controlled stability of the internal milieu, that is, our internal environment of cells and tissues, defines good health. Simply put, Dr. Bernard asserted that our internal terrain is more important than any other health consideration. He lived in the 19th century when highly intellectual people used poetic language. He famously stated,

"It is the fixity of the internal environment that is the condition for free and independent life. All vital mechanisms, however, varied they may be, have only one objective, that of preserving constant conditions of life in the internal environment. The living body, though it needs the surrounding environment, is nevertheless relatively independent of it. This independence that the organism has of its external environment derives from the fact that in the living being, the tissues are withdrawn from direct

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external influences and are protected by a veritable internal environment which is constituted, in particular, by the fluids circulating in the body."

He was a champion of the rigorous experimental approach, based on a strict marriage between physiology and the underlying laws of physics and chemistry that were just being discovered and advancing at an impressive rate at that time. He was considered an excellent methodologist and a great inventor of physiological techniques. He famously said that "the laboratory is the temple of the science of medicine." His most important book, "Introduction to the Study of Experimental Medicine," published in 1865, was enormously influential.

Claude Bernard also helps us understand how little we know and how preconceived notions and bias holds back our intellectual evolution. He did this through a variety of illustrative quotes.

"It is what we think we know that keeps us from learning."

"When we meet a fact which contradicts a prevailing theory, we must accept the fact and abandon the theory, even when the theory is supported by great names and generally accepted."

Low fat and cholesterol come to mind, as do vaccines.

"Art is I; Science is We."

"Man can learn nothing except by going from the known to the unknown."

"The true worth of a researcher lies in pursuing what he did not seek in his experiment as well as what he sought."

"Science increases our understanding in proportion as it lowers our pride."

Dr. Fauci, are you listening? Dr. Bernard was apparently not influenced by greed.

"A theory is a verified hypothesis after it has been submitted to the control of reason and experimental criticism. The soundest theory is one that the greatest number of facts has verified. But to remain valid, a theory must be continually altered to keep pace with the progress of science. As new facts appear, it must be constantly resubmitted for verification and criticism."

And my favorite quote from Dr. Barnard is:

"The experimenter who does not know what he is looking for will not understand what he finds."

Does Dr. Bernard belong in a chapter on chronic stealth infections? Absolutely! He is the most important figure among all the other contributors to our knowledge about infection and disease. The initial narrative on COVID-19 was all about immune health, which provides every individual with the potential of freedom and independence. However, it made a tragic shift to vaccines, reflecting perceived weakness and dependence upon others for a solution. Bernard espoused

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the concept that we can be healthy and resilient if we take better care of ourselves and remain free from most diseases.

We could learn so much from our forebears if we would only listen. Did you listen to your parent's advice? Do your children listen to your advice? The answer is likely "no," until you or they achieve a higher level of "enlightenment." Modern medicine is no different. In some respects, like a teenager, modern medicine seems to chide, "How can scientists from the 19<sup>th</sup> century know more than us? After all, we continue to progress in the breadth and depth of our knowledge. And we have sophisticated tools that our ancestors could not even imagine." Yet, Bernard, a proper medical scientist, provides us with requisite lessons on homeostasis (balance) for which we lack appreciation or understanding. The proof is rampant chronic diseases that did not exist during his time. But infectious diseases did.

Louis Pasteur is another giant who remains highly respected, but his most significant contribution to health is ignored. Pasteur, like Bernard, hailed from France and was at the pinnacle of fame during the mid-to-late 1800s. His laboratory, at one time, commandeered 10 percent of the research budget of France. Pasteur is credited with developing the "Germ Theory" of disease. His name is undoubtedly attached to this theory, but less significant names in history developed that postulate. Regardless, there is much we can learn from the Germ Theory in the modern context of chronic disease.

Germ theory states that many diseases are caused by the presence and actions of specific microorganisms within the body. The theory was developed and gradually accepted in Europe and the United States in the mid-1800s. It eventually superseded existing miasma (bad air from rotting organisms) and contagion, where one disease could change into another or manifest itself differently in different people. In so doing, Pasteur radically changed the practice of medicine. Germ theory remains a guiding theory that underlies aspects of acute disease management in contemporary medicine but is not considered in chronic conditions.

Awareness of the physical existence of germs preceded the germ theory by more than two centuries. Discoveries made by several historical figures pointed the way to germ theory. On constructing his first simple microscope in 1677, Antoni van Leeuwenhoek was surprised to see tiny organisms, which he called 'animalcules,' in the droplets of water he was examining. He made no connection with disease, and although later scientists observed germs in the blood of people suffering from disease, they suggested that the germs were an effect of the disease rather than the cause. This fit with a popular theory of spontaneous generation of disease.

The observations and actions of Ignaz Semmelweis (hand sanitizing before surgery), Joseph Lister (antiseptic surgery), and John Snow (Cholera spread from a single water supply) would retrospectively be acknowledged as contributing to

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the acceptance of germ theory. But the laboratory research of Louis Pasteur in the 1860s and then Robert Koch in the following decades provided scientific proof for germ theory. Their work opened the door to research into the identification of disease-causing germs and potentially life-saving treatments.

Today we suffer from a myriad of diseases that may have a “germ” cause, but medicine often chooses to address symptoms rather than explore germs as a possible cause. A classic modern example is a story about a bug that causes stomach ulcers. It is an initially sad tale with a happy ending, a Nobel Prize in Medicine, and is explained later in this chapter.

### **Robert Koch**

Robert Koch brought the science of medicine to a new level. Microbes are everywhere. What Koch did was develop criteria to determine if a microbe created disease. He demanded, through his process, high standards of evidence never before required in medical history and, in some respects, modern medicine. The four constructs of Koch's Postulates are:

1. The microorganism must be abundant in all organisms suffering from the disease but should not be found in healthy organisms.
2. The microorganism must be isolated from a diseased organism and grown in pure culture.
3. The cultured microorganism should cause disease when introduced into a healthy organism.
4. The microorganism must be isolated from the inoculated, diseased experimental host and identified as identical to the original specific causative agent.

These postulates are highly effective at pinpointing causal pathogens in many cases. They are most impressive, considering the original publication date of this work was 1890. This approach is still used today to verify a pathogen-disease relationship. However, his postulates have seen diminished usage not because of the value of the tests but rather due to a shift away from the concept that infections cause disease. This happened for various reasons, some good and others more driven by agendas other than health.

### **Crypticity**

The concept of crypticity may be a reason for part of the shift away from infection. In infection, crypticity is when a pathogen does not initially noticeable illicit symptoms. In these cases, that turns out to be the true majority of instances, symptoms may not emerge for days, weeks, years, or decades making the association between the microbe and disease "cryptic." Additionally, the pathogens that cause chronic smoldering disease are not particularly virulent, so symptoms are subtle, and changes in blood biomarker values are unremarkable,

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especially when using the standard of care outrageously unpredictable reference ranges.

I have a personal story about crypticity. I was bitten by ticks many times in my youth when I lived in Massachusetts. In my forties, I developed atrial fibrillation (Afib) and uncovered the connection between chronic Lyme disease and Afib. A tick had not bitten me in decades. I self-treated for 18 months, underwent a procedure, and stayed out of Afib for over a decade. Usually, people with Afib revert out of sinus rhythm regardless of the medical intervention because they are never treated for the underlying cause. I am fortunate I am in sinus rhythm and confident I will stay in it as well.

As it turns out, pathogenicity is a continuum. Here is how this works.

- Most organisms create no harm.
- Some cause very little harm but doing so over long periods leads to understated but nagging conditions. Autoimmune disease, chronic pain, and lack of energy are manifestations of these bugs, as are rampant brain maladies.
- Others are slightly more virulent, but the asymptomatic period can be quite long. Again, slight harm multiplied by a long period leads to disease. These somewhat more virulent pathogens are responsible for the more well-known chronic diseases of modern society, including heart disease, cancer, Alzheimer's disease, and diabetes.
- Others are more fast-acting, like the viruses behind the common cold.
- Still, others are more harmful, like the influenza bacteria and SARS viruses.
- Others are downright lethal, like MRSA, E-Coli, and Ebola.

Figure 6.1 shows a relationship between pathogen virulence, crypticity, and lethality.

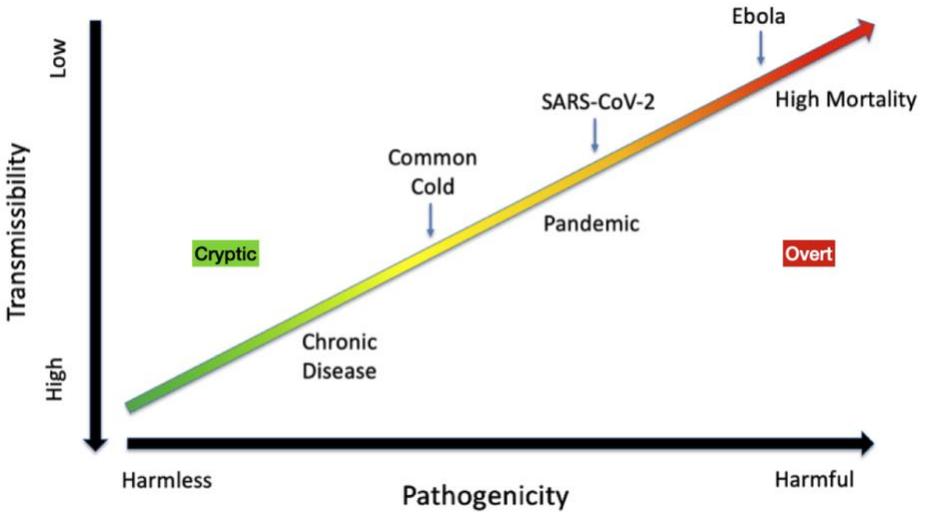


Figure 6.1. Relationship between an organism's harmfulness (pathogenicity) and its transmission likelihood. Those less harmful are often capable of initiating cryptic diseases in the future.

Interestingly, even though Penicillin was introduced in the late 1940s to treat infection, medicine steered away from pathogens as a cause of disease around the same time. This occurred despite the emerging understanding that infection was at the root of peptic ulcers, cancers, and cardiovascular diseases. In some cases, seemingly unrelated conditions were rectified by applying antibiotics for an acute infection. A combination of scientific and medical developments and the difficulty of associating diseases with infection allowed the medical leaders to allow biases to interfere with directing medicine down this path altogether.

The rigor of Koch's postulates also sidelined infectious causation studies in modern times. Were Koch's postulates rock solid? When the criteria were met, they were. The rub came when one or more were not met. Many experts assumed that infectious causation could not be substantiated if one of them was not met. As it turns out, that was a naive assumption. Instead of abandoning the relationship, modifications and exceptions that still included strong scientific rigor should have been added. This is no different from amendments to the United States Constitution. We evolve. Science is a progressing discipline that should adapt to new knowledge rather than abandon something proven but that only fit some scenarios.

Koch is not to blame, as he was well ahead of his time. He anticipated exceptions to the postulates and cautioned that scientists should not use the guidelines as the only basis for asserting a cause-and-effect relationship between infection and disease. Unfortunately, it is easier to follow guidelines than to apply critical thinking to every situation. That describes our modern doctors all too well. The

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consequence was that even when compelling evidence of infectious causation was available, it was often dismissed if any of the four postulates were not rigorously fulfilled. This dismissal had significant consequences for future study of chronic infectious disease because, for some species, fulfilling all of Koch's postulates is impossible.

Cancers with infectious causation are a prominent example of Koch's postulate not being fulfilled. T-cell leukemia is a lethal disease that results from the cancerous growth of white blood cells promoted by the HTLV-1 virus. This cancer has been exceptionally well studied in Japan, where people who die from it are infected as babies from their mother's milk. Though infected during the first year of life, they first develop leukemia decades later. About half the people who eventually develop cancer do so after their sixtieth birthday. That is crypticity!

Imagine applying Koch's postulates to evaluate whether suspected viruses cause this cancer. Human subjects cannot be used for ethical reasons. Even if they could, who would conduct a study that might take sixty years to complete? And who would fund it? An agent of such a disease might cause cancer only in humans, precluding the use of laboratory animals required in the Koch evaluation. If an agent does cause such a disease in laboratory animals, the disease would have to be different because test animals do not live sixty years. In this case, asserting it is the same disease would not be possible.

The point is that over the past century, medical investigators have consistently established a cause-and-effect relationship between many chronic diseases and infections that are much more cryptic compared to historic infections like tuberculosis. Koch's postulates may not have held, but modern analytics have been able to substantiate the findings through rigorous forensic analysis. More recently, there have been compelling cases of infection associated with diseases considered genetic or caused by unspecified environmental toxins.

Type 1 diabetes is a genetic disease, right? Well, actual genetic diseases are observed at birth. These include sickle cell anemia, cystic fibrosis, and Down's syndrome as well-known examples. The average onset of type 1 diabetes is 12 - 14 years. However, babies and people over 40 also develop type 1 diabetes for the first time. In its infinite wisdom, the CDC states, "It isn't obvious what causes type 1 diabetes, but we know that diet and lifestyle habits don't. Type 1 diabetes is thought to result from an autoimmune response, where your body attacks the cells in your pancreas that make insulin. Insulin is a key hormone to let blood sugar into your body's cells for use as energy. Sometimes infection with a virus seems to trigger the autoimmune response. Many people with type 1 diabetes have family members with type 1, but most don't."

All that handwaving language makes it quite clear that the CDC does NOT understand the mechanism or mechanisms that drive the disease. If autoimmune diseases were real, how would our species survive? Think about it: your body

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suddenly attacks itself, making you weak and vulnerable. That is not a formula for the survival of the fittest. In actuality, there is always a cause if investigated thoroughly. Autoimmune disease is really a mea culpa - also known as "we do not know" (yet).

The CDC needs to read more of the published literature, and they would find compelling information and scientific consensus that their public statements ignore. For example, in the Journal "Diabetes," a group published a paper with a straightforward name, "Viral Trigger for Type 1 Diabetes."<sup>214</sup> "The most popular hypothesis circulating within and beyond the scientific community is that viral infections enhance or elicit autoimmune disorders such as type 1 diabetes. Indeed, viruses can injure  $\beta$ -cells and have been isolated in pancreatic tissues from diabetic patients."

Several viruses have been associated with Type 1 diabetes, but one type of virus, Human Enteroviruses (HEVs), has the most substantial body of evidence. HEVs are a large family of viruses that enter the gut and are spread through poor hygiene or sanitation. This is not the only reason they may spread, however. Poor hygiene is a major cause of transmission, as shown by Dr. Snow with Cholera. However, blaming hygiene has led to the "hygiene hypothesis" of many neurological diseases caused by being too clean.

National Geographic Magazine<sup>6</sup> helps us understand the challenge of determining the causation between infections and diseases. In this case, it is just with regard to viruses, not other types of pathogens like parasites, bacteria, and fungi. In the article, NatGeo explains that quantifying viruses is next to impossible. They inform us about the following:<sup>215</sup>

- "An estimated 10 nonillion (10 to the 31st power) individual viruses exist on our planet, enough to assign one to every star in the universe 100 million times over.
- Viruses infiltrate every aspect of our natural world, seething in seawater, drifting through the atmosphere, and lurking in minuscule motes of soil. Generally considered non-living entities, these pathogens can only replicate with the help of a host, and they are capable of hijacking organisms from every branch of the tree of life, including a multitude of human cells.
- Yet, most of the time, our species manages to live in this virus-filled world relatively free of illness. The reason has less to do with the human body's resilience to disease than the biological quirks of viruses themselves, says Sara Sawyer, a virologist and disease ecologist at the University of Colorado Boulder. These pathogens are extraordinarily picky about the cells they infect, and only an infinitesimally small

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<sup>6</sup> National Geographic assumes that all viruses cause harm by classifying them all as pathogens.

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fraction of the viruses that surround us actually pose any threat to humans. (I am not sure this statement gives due respect to our immune system.)

- Still, as the ongoing COVID-19 pandemic clearly demonstrates, outbreaks of new human viruses do happen, and they aren't as unexpected as they might seem."

Few new examples of infectious causation were noted from 1950 to the present day, with HIV and COVID-19 being notable exceptions. And they are true exceptions. The work of Dr. Ewald makes it unmistakably clear that we have already been exposed to everything natural, some of which is harmful, on earth. The world is completely connected. Anything new is either from outer space or synthetic.

The standard of care is an acute care system that seldom delves into the causes of chronic diseases. In 1967, the U.S. surgeon general, William Stewart, made a statement that directed medicine away from infectious causation of disease. Of course, if an infection is a major contributor to disease, then this leads medicine down a blind path. Focusing on cholesterol rather than innate immune response biomarkers like white blood cells is an obvious misguided manifestation of this approach.

Notably, the progress made on preventing or reversing chronic diseases has increased dramatically under dictated policies to where over 60 percent of adult Americans have at least one chronic condition. Despite this trend, the NIH did and continues to increase its budget on disease research, but little is funneled into chronic infectious studies. There is a big difference between studying the subtlety of infections with mild virulence that slowly cause chronic conditions and expanding research initiated to explore biowarfare.

Cancer research is divided into two silos, and neither side seemed willing to accept any contribution from the other. There were infection and non-infection groups but rarely did either party accept a combination of factors. It was "all or none." Researchers fighting for a fixed allocation of funds developed more and more specific expertise and argued, through grant proposals, that their single-minded approach was the right approach. Generalist-type proposals are not as fundable because study designs are, by necessity, too complex. Most research papers, regardless of how compelling the data, often conclude with the statement, "more research is needed." This is just a ploy to gain more funding in their area of expertise. After all, most researchers are not practicing clinicians. They are researchers, and their salaries are paid through grant funding. If they claim absolute victory of proof, there is no need to further fund their research.

In cancer, there is a lack of practical success. However, marketing of cancer results provides a hopeful but false message that perpetuates a high level of funding and marketing campaigns that garner large donations from citizens. Cancer instills universal fear, which is easily leveraged into cash by the

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unscrupulous. We see television ads of children providing testimonies about fabulous outcomes or, on the other extreme, parents beseeching us to provide money for the cause.

The greatest advancement in cancer is early detection. But has it led to an improvement in outcomes or a great marketing opportunity? An irrelevant benchmark of cancer treatment is survival up to 5 years. If the cancer is discovered 2 years early today compared to 20 years ago, then the 5-year survival is only 3-year survival - but it is still advertised as 5-year survival. Substantially more cancer sufferers survive 3 years compared to 5 years. This is statistical trickery, not an improvement in cancer outcomes. The point here is that medicine continues to pursue the wrong causal factors. Cancer is the #2 killer of Americans and is on the rise, not the decline.

Quietly, the infectious connection to cancer is being managed. For example, most women are aware they can avoid cervical cancer by improving hygiene and having fewer sexual partners, thereby reducing their risk of exposure to papillomaviruses. Anyone who receives a blood transfusion has a reduced risk of liver cancer because the blood supply is protected against hepatitis B and C viruses. A lesser-known preventative approach is the detection and treatment of *Helicobacter pylori*. This pathogen is associated with a variety of gut cancers: colon, rectal, gastric, anal, and esophageal. Warren and Marshall were awarded the 2005 Nobel Prize and Physiology and Medicine for their research that showed definitive proof that the pathogen causes stomach ulcers. Today you get a colonoscopy. However, few are tested for *helicobacter pylori*.

Pink ribbons are everywhere. How many pink ribbon wearers have root canals? There is a strong causal relationship between periodontal bacteria and breast cancer. Note that this is not just an association. Periodontal bacteria cause breast and other cancer, including pancreatic cancers. See the oral health chapter for more details.

Genetics are often blamed for diseases. In a previous chapter, we quoted the CDC, who states humans are genetically 99.9 percent the same, and it is the 0.1 percent difference that causes most diseases. We dispelled that idea in that chapter. Still, a genetic revolution is in full swing. There are a couple of key problems with this approach.

1. What is the treatment of a truly genetic disease? If it is genetic, what is your hope for prevention, remission, and recovery?
2. Can a 0.1 percent genetic variation really cause 60 percent of the U.S. population to have a chronic disease? There is a crucial unrecognized problem with the genetic causation of harmful diseases, whether they are cancers or other chronic diseases. How do the harmful genes maintain their representation over time? The harm caused by a gene reduces its representation in the next generation in proportion to the negative effects

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of the gene on the survival or reproduction of the people who carry it. Over generations, a harmful gene will become so rare that it will slip away into ignominy. That is, the gene and its disease will disappear, not proliferate. Chronic diseases are proliferating.

3. Mostly, "genetic" diseases are epigenetic and impacted by environmental factors. A highly overlooked cause of epigenetic changes is infection.

Rare but important peer-reviewed papers explain that microorganisms are capable of altering genetics. They do so for a simple reason - the same reason people slapped on masks and took the shot during COVID-19 - for survival. But the microorganisms are not motivated by fear and misinformation. Instead, they use bona fide physiological mechanisms to change the DNA of host (your) cells.

One key paper on this topic is titled "Microbe-Induced Epigenetic Alterations in Host Cells: The Coming Era of Patho-Epigenetics of Microbial Infections."<sup>216</sup> This paper is seeing some acknowledgment as it was cited 74 times as of 2022. Dr. Minarovits, who wrote this paper, states,

"I suggest that in addition to viruses and bacteria, other microparasites (protozoa), as well as macroparasites (helminths, arthropods, fungi), may induce pathological changes by epigenetic reprogramming of host cells they are interacting with. Elucidation of the epigenetic consequences of microbe-host interactions (the emerging new field of patho-epigenetics) may have important therapeutic implications because epigenetic processes can be reverted, and elimination of microbes inducing patho-epigenetic changes may prevent disease development."

Dr. Minarovits calls the general topic "Patho-Epigenetics." However, a team from the U.K. coined the term "Infectogenomics." They wrote a paper with the title, "Infectogenomics: Insights from the Host Genome into Infectious Diseases."<sup>217</sup> The summary is reproduced here.

"As with most biological phenomena, disease is the outcome of both nature and nurture. In the case of infectious disease, however, the interaction of two natures, that is, two genomes (host and pathogen), is at play. Environmental and social factors, or nurture, may affect the risk of acquiring infection and also the risk of becoming ill. How we behave and what environment we live in will determine the number of exposure events. The dose of infection and the fitness of the host and pathogen will determine sickness. After all, unfit pathogens can make excellent live attenuated vaccines."

This last statement is quite important. It basically means that when we are exposed to pathogens, especially weaker ones that do not kill us, we develop natural immunity. Interestingly, people who got COVID without the vaccine have

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superior sustainable natural immunity when compared to the deadly and engineered pseudo-vaccine.

Microorganisms are everywhere and unavoidable, often for good reasons. There are at least three (3) classifications for microorganisms:

1. Beneficial or symbiotic;
2. Commensal; and
3. Pathogenic.

The national geographic report on the ubiquitousness of microorganisms implies that most are not pathogenic. Otherwise, we would surely not be able to survive the onslaught.

### **Beneficial or symbiotic organisms**

The NIH published a credible article on "Your Microbes and You."<sup>218</sup> Some informative excerpts are included here.

"Microscopic creatures - including bacteria, fungi, and viruses - can make you ill. But what you may not realize is that trillions of microbes are living in and on your body right now. Most don't harm you at all. In fact, they help you digest food, protect against infection, and even maintain your reproductive health. We tend to focus on destroying bad microbes. But taking care of good ones maybe even more important.

You might be surprised to learn that your microbes actually outnumber your own cells by 10 to 1. "The current estimate is that humans have 10 trillion human cells and about 100 trillion bacterial cells," says Dr. Martin J. Blaser at the New York University School of Medicine. Researchers from almost 80 institutions published a landmark series of reports. They found that more than 10,000 different species occupy the human body. The microbiome actually provides more genes that contribute to human survival than the human genome itself (8 million vs. 22,000). Humans need bacteria and their genes more than most of us thought.

One of the most important things microbes do for us is to help with digestion. The mix of microbes in your gut can affect how well you use and store energy from food. In laboratory experiments, transferring bacteria from certain obese mice to normal ones led to increased fat in the normal mice. Blaser and his colleagues are concerned that changes in our microbiome early in life may contribute to weight problems later. "We're in the middle of an epidemic of obesity that is very severe," Blaser says. "It's relatively recent, it's widespread across the United States and across the world, and increased calories and decreased exercise seem insufficient to explain this."

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We might be changing our microbiome for the worse, he says, by using antibiotics too often. In a recent NIH-funded study, Blaser's team found that low-dose antibiotic therapy affected the gut microbiomes of young mice. Antibiotics also altered how the mice used sugars and fats. After 7 weeks, treated mice had up to 15 percent more fat than untreated mice. This and other studies suggest that gut bacteria can affect both appetites and how you use energy in food.

Microbes are also important for your skin, one of the body's first lines of defense against illness and injury. Skin health depends on the delicate balance between your own cells and the microbes that live on its surface. "Basically, the healthy bacteria are filling all those little niches so that the more dangerous bacteria can't get a foothold onto the skin," says Dr. Julie Segre of NIH.

Segre and other NIH researchers looked at skin microbes collected from different body regions in healthy volunteers. They found that body location has a huge effect on which types of bacteria live. For example, bacteria living under your arms likely are more similar to those under another person's arm than to the bacteria on your own forearm.

Microbes are also important to the body's infection-fighting immune system. In one recent study, NIH scientists examined special mice that were born and raised to be germ-free. These mice seemed to have a weak immune function. In contrast, normal mice have vibrant bacterial communities and a rich variety of immune cells and molecules on their skin. The germ-free mice were exposed to *Staphylococcus epidermidis*, one of the most common bacteria on human skin. Adding this one species of bacteria boosted the immune function in the mouse skin. The mice with *S. epidermidis* were able to defend against a parasite, whereas the bacteria-free mice weren't.

We often have a sense that the bacteria that live on our skin are harmful," Segre says. "But in this study, we show that these bacteria can play an important role in promoting health by preventing skin infections from becoming more prolonged, pronounced, and serious.

There's strong evidence that the microbes in the female reproductive tract affect reproductive health and help protect against disease. A recent study also found a diverse community of microbes in the male urinary tract and on the penis. NIH-funded researchers are investigating other positive roles for microbes. One major area of research concerns allergy-related conditions, including childhood asthma, skin allergies, hay fever, and eczema.

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Many researchers worry that some people are trying to get too clean. Blaser thinks that people are using sanitizers and antibiotic products too often these days. “Obviously, there are many bad germs, but I think we’ve gone overboard, and it looks like trying to get rid of the bad guys has had a collateral effect on the good guys.

### **Commensal organisms**

Commensalism is an association between two organisms in which one benefits and the other derives neither benefit nor harm. The image that comes to mind, although not of the microscopic type, is the remora fish and sharks. Remora is a two-foot-long fish that has a suction cup on the top of its head that allows attachment to a shark's belly. It is along for a ride to collect the food debris from the feeding shark.

In many ways, commensal organisms may really be better classified as beneficial organisms. However, our knowledge of the true depth and breadth of the microbial world is still limited. The microbiome of the gut, for example, is highly complex and is not understood entirely. Seventy percent of the bacteria present inside our body cannot be cultivated by the present microbial technique so many mysteries are yet to be uncovered.

### **Pathogenic organisms**

Hopefully and likely, this group of microorganisms constitutes a small percentage of the total population. However, like a rotten apple, they get the most notoriety leading many to assume they are the majority. Various labs test for organisms with the main focus on the pathogenic type. The more advanced ones advertise they have "robust & efficient next-generation sequencing data, and their proprietary service combines next-generation sequencing & advanced bioinformatic data analysis to detect pathogens of public and animal health importance." Unfortunately, despite these sophisticated advances, many microbes and pathogens go undetected based on our clinical experience.

Consider the case of Robert. He was a long-time smoker and also had advanced periodontal disease and gingivitis. Late in life, he developed the cardiopulmonary disease (COPD). Robert underwent extensive blood testing, including for a broad array of "usual suspect" pathogens. The results were unremarkable, which is a medical term for "nothing of significance showed up." However, his COPD raged on, and a constant productive cough yielded mucous that could only be explained by an infectious process.

Robert elected to participate in an antibiotic treatment program. He was first administered an extremely low dose of the drug at about 1/8th of the normal recommended dose. He immediately experienced a severe Jarisch–Herxheimer reaction (herx) associated with the "die-off" of some organisms presumed to be pathogenic. Healthy people on the same treatment seldom, if ever, experience this

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response. If you have had the flu or other acute infectious disease, you have experienced the Herxheimer's (herx) reaction that was induced by your immune system and not by an antibiotic.

Narrow definitions associate the herx reaction with spirochetal infections like those connected with Lyme disease, but the die-off reaction is common across a broad array of pathogens properly treated by enhancing immunity or more aggressive treatments. One of our participants put on high-dose cod liver oil experienced a herx reaction. Importantly, the herx reaction may occur generally or may only occur in regions of infected tissue. People with a chronic eye infection may only feel the effect in the eye, whereas in Robert's case, the reaction was in his lungs, the site of the obvious infection.

The treatment of Robert revealed some important things about him. Here are a couple of takeaways.

- No specific pathogens were detected using traditional serology techniques.
- His WBC count was slightly low. The expectation was a higher-than-normal count because there was a presumption of bacterial infection. The antibiotics treat bacteria, and there was a clear response to them.
- His percent neutrophils were elevated modestly.
- His lymphocytes were low, implying some type of viral process.

These results indicate that the best of lab testing and interpretation may yield nothing while the patient suffers from a chronic condition. In these instances, medical doctors should consider treating the patient "clinically." However, that is a challenge in a medical system that relies on a diagnosis before delivering treatment. In the standard of care, it is downright impossible to treat people like Robert, as chronic infections are not considered disease-causing.

Robert's story is ongoing but also has a happy side. He fastidiously measured his lung volume and peak flow daily. He took a variety of supplements marginalized by the standard of care, including cod liver oil, known historically to reduce mortality from lung infections, including TB. In a study from the 19th century during the TB epidemic, Tuberculosis was arrested in 18 percent of the patients given cod liver oil, compared with 6 percent of those in the control group.<sup>219</sup> Deterioration or death was reduced from 33 percent to 19 percent. These are remarkable statistics and are superior compared to the presumed value of the most prescribed drugs used in modern medicine, including statins.

Robert's lung volume increased over six months from 1800ml to 2800ml. His energy improved greatly. He attributed the improvement to supplements, breathing exercises, and some treatment. He resumed the antibiotic treatment about 6 months after experiencing the herx reaction but started at a dose 1/32nd of the normal dose. He continues treatment.

## Warren and Marshall

Pathogens can change our genome (Infectogenomics), and they can outcompete commensal and beneficial organisms. The Lewis Thomas quote at the beginning of this chapter explains this. *Helicobacter pylori* (*H. pylori*), a bacterial infection that often starts in the mouth and migrates to the gut, illustrates an example of the struggle for survival. *H. pylori* has strong urease activity and hydrolyzes urea in gastric juices to produce ammonia. Ammonia is classified as a base in chemistry, and a base is at the opposite end of the pH scale from an acid. The medical term for a base in the body is an antacid. People with *H. pylori* have a living antacid in their guts. When infected with this organism, a person is taking the equivalent of tums daily.

Beneficial microbiome organisms adapted to thrive in a strong acid environment.<sup>220</sup> *H. pylori* disrupts that environment making it less hospitable to the organisms that help with digestion. *H. pylori* creates a microenvironment in which the pH is nearly neutral, and it neutralizes the surrounding area of the gut as well.

The *H. pylori* story, which ultimately led to the Nobel Prize in Physiology and Medicine, is one that illuminates the hesitancy of modern medicine to accept infectious causes of chronic diseases. The evidence that *H. pylori* trigger ulcers had been accumulating since the early 1900s, with renewed interest developing in the 1970s. America's medical establishment (the National Institutes of Health) officially accepted the idea in 1994. This encouraged others who were looking for hitherto unsuspected connections between infections and disease.

Dr. Warren, a pathologist from Australia, made a revolutionary discovery during a routine diagnosis of diseased tissue.<sup>221,222,223,224,225</sup> He applied extra efforts in his diagnosis due to his nascent curiosity. Through his advanced diagnosis, he eventually was able to prove a cause/effect relationship that has profoundly impacted treatments of stomach ulcers. Warren, along with his colleague, Dr. Marshall, hypothesized that a specific bacteria known today as H-Pylori caused stomach ulcers. At that time (and inexplicably still by some medical professionals today), the belief was that these ulcers were caused mainly by stress and other causes of excess stomach acid. This is not intended to underplay the impact of negative stressors on human health.

There was an assertion of excess stomach acid, which was made without testing, but rather by assumption. Acid reflux referred to as Gastroesophageal reflux disease, or GERD for short, occurs when gas is produced in the gut - or, more specifically - the stomach. The pressure then pushes stomach fluids through the lower esophageal sphincter (LES). The lining of the stomach is very tough and can tolerate strong acids. The esophageal tissue is much more delicate and is subject to irritation with even mild acid. For proof, drink some apple cider vinegar. Another test is to pour apple cider vinegar on a finger. The skin on your

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finger is tough, like the inner "skin" of your stomach. However, if you have a little cut or abrasion, it will be painful.

In actuality, it is low stomach acid that leads to a slow digestion process known as fermentation. Carbon dioxide gas is produced. When a liquid is converted to a gas, it expands 1000-fold. The muscles surrounding the stomach hold it in place, so the gas has to go somewhere - and that somewhere is the esophagus. With strong stomach acid and a diverse microbiome, carbon dioxide production is much less likely, as is GERD. GERD is not the only symptom of low stomach acid. Some people experience teeth erosion from a slight mist of acid from the stomach that is not ample enough to cause GERD. Others experience an esophageal stricture which is an abnormal tightening or narrowing of the esophagus. People with this often get a surgical procedure to widen their esophagus. Nice money-making scheme. However, do they get a test for stomach acid, *H. pylori*, and treatment to expand their microbiome? Doubtful.

Small intestinal bacterial overload (SIBO) is another consequence of low stomach acid created by antacids, drugs, and poor diet. Strong stomach acid is an essential part of your barrier immunity. In the morning, when sunlight brightly shines into your window, close the shade or curtain so that just a beam of light makes it into your room. Do you see the dust particles? Do you think they are sterile, or are organisms riding on them? Do your gums bleed a little when you floss? Do you swallow saliva? Are you seeing the sequence? We swallow roughly 1.5L of saliva each day. It carries organisms of all ilk, good and bad. Good ones have evolved to bathe in strong stomach acid, whereas bad ones have not (yet). Those that are not destroyed by stomach acid migrate through the gut and have the potential to cause SIBO, the manifestation of which is diarrhea, constipation, or both.

We had a corporate wellness participant who, upon the first interview, admitted that he vomited at least four times each week in the morning. His Indiana University doctor told him the following,

"That is normal, but stop eating so close to bedtime."

This is actually a reasonable representation of the acumen traditional doctors have with respect to gut health. Is there such a thing as a negative zero? A proper diagnosis, made by my team, based on labs and a full history, was presumed low stomach acid leading to ANY pathogen that was swallowed the day before festering in his stomach overnight and creating low-grade food poisoning. We solved his issue by stopping his antacid prescription, adding fiber and probiotics to his diet, and temporarily supplementing with betaine hydrochloride.

Actually, getting your stomach acid measured is an unpleasant experience. So, if you have had your stomach acid measured, you would clearly recall the experience. Jonathan Wright, M.D. is a world expert on stomach acid and the need for it to be strongly acidic. Stomach acid is measured by gastric analysis using

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radio telemetry. The technique was developed in Heidelberg, Germany, so it is sometimes called the “Heidelberg capsule.” If you have not had this test, then your doctor is guessing about the pH of your stomach acid, and they are usually wrong. If you are not testing, you are guessing. We often guess too, but when we are told the person is on an acid blocker or antacid, you might assume it is at least an educated guess.

Marshall and Warren's suggestion that ulcers may be caused by bacteria was initially viewed by some researchers as absurd and outrageous. Martin Blaser of the Division of Infectious Diseases at the Vanderbilt University School of Medicine thought a 1983 talk by Marshall was “the most preposterous thing I'd ever heard; I thought, ‘This guy is a madman.’” In fact, these two Australians, Warren and Marshall were not even invited to present their data at gastroenterology society meetings for many years. Blaser has since become one of the leading researchers on *Helicobacter pylori*, having changed his belief 180 degrees in the face of overwhelming evidence. There is equivalently overwhelming evidence against lowering LDL, but few doctors are brave enough to go against the narrative like Dr. Blaser, so most still prescribe statins.

Dr. David Forman of the Imperial Cancer Research Fund thought that Marshall's claim that bacteria are responsible for various stomach diseases, including cancer, was a “totally crazy hypothesis.” But he thought it worth demolishing and since has concluded that *Helicobacter pylori* infection is a major factor in gastric cancer as well as ulcers. Through the course of their trials, Warren and Marshall even infected themselves with H-pylori and then successfully treated themselves with appropriate and known medications. In 2005, the two were awarded the Nobel Prize in Medicine for their discovery and the work they did to prove their thesis.

Paul Thagard is a Professor of Philosophy and Director of the Cognitive Science Program at the University of Waterloo. He has written extensively on the philosophy of acceptance of new discoveries. His paper, aptly titled “*Ulcers and Bacteria I: Discovery and Acceptance*,” is certainly worth reading to fully understand the complexities and pitfalls of the acceptance of new scientific discovery.<sup>226</sup> One of the snags to any new idea is “Not Invented Here.” According to Princeton University, “‘Not Invented Here’ is a term used to describe persistent social, corporate, or institutional culture and preconceived notions that avoids using or buying already existing products, new research, or knowledge because of their external origins. It is normally used in a pejorative sense and may be considered an antipattern.” Antipatterns are considered ineffective and/or counterproductive in practice. Are there scientists, researchers, and physicians out there who, like Warren and Marshall regarding ulcers, have similarly ignored chronic disease discoveries?

Sadly, COVID has illuminated the fact that Thagard's work is important but insignificant compared to the real reason new discoveries often languish - greed.

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The impact of H-pylori on the body was first thought confined to the stomach, but it is now emerging that H-Pylori may migrate into the brain and be involved in dementia and Alzheimer's disease. A number of other bacterial suspects, including *C. pneumoniae*, are known to have broad effects. Interestingly, similar wide-ranging symptoms can be produced by a variety of organisms, as they all appear to stimulate the same immune response. The diseases appear to be a manifestation of that response connected to the tissue in which the bacterial infection proliferates.

### **Alois Alzheimer**

Dr. Alzheimer, for whom the brain disease is named, was a German psychiatrist and neuropathologist. Alzheimer is credited with identifying the first published case of "presenile dementia", which his colleague, Emil Kraepelin, would later classify as Alzheimer's disease. This disease was not the first degenerative brain disease. General paresis, also known as general paralysis of the insane, paralytic dementia, or syphilitic paresis, was well appreciated long before Alzheimer's time and is known to be caused by syphilis and chronic meningoencephalitis, both having infectious origins. Alzheimer's was apparently aware of the causes of brain maladies. The infection hypothesis for Alzheimer's disease was presented as a causative explanation even by Alois Alzheimer himself.<sup>227</sup>

Syphilis is a sexually transmitted disease caused by *Treponema Pallidum*, a bacterium classified as a spirochete. This is the same class of bug that is associated with Lyme disease. Syphilis loomed as a major cause of disease for hundreds of years. In the 19th century, asylums and clinics overflowed with patients who had multiple neurologic and psychiatric disorders associated with Syphilis infection. Few physicians today take note of the possibility that the epidemic of mood disorders, dementias, and even stress and traumatic brain injury disorders are exacerbated by Syphilis, spirochetal infections, or related bugs that can cross the blood-brain barrier and elicit an inflammatory response.

The outstanding work of Dr. Judith Miklossy presented later in this chapter, demonstrated the commonalities between neurosyphilis and Alzheimer's disease.

### **Charles Mayo**

Charles Horace Mayo, born in Rochester, MN, in 1865, was an American medical practitioner and was one of the founders of the Mayo Clinic along with his brother William James Mayo. Dr. Mayo attempted to educate the medical community on the concept of focal infection, an important advancement in the germ theory of disease.

An article published by the Samaritan Ministry summarizes the efforts of Dr. Mayo to explain and promote an understanding of focal infection.<sup>228</sup> Samaritan Ministries is a Biblical solution to health care. Their review of his work is reproduced here.

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"Dr. Charles Mayo, the founder of the famous Mayo Clinic, believed in the "focal infection" theory of disease, something so archaic that today almost no one has heard of it. The theory basically states that oral infection can influence the health of the entire body. Addressing the Chicago Dental Society in 1913, Mayo said, "The next great step in preventative medicine must come from the dentists."

Mayo appointed Dr. Edward C. Rosenhow to head a team of researchers dedicated to focal infection theory. From 1902 to 1958, Rosenhow conducted experiments and published more than 300 papers, 38 of which appeared in the *Journal of the American Medical Association*. During the same period, Weston A. Price, founder of the research institute of the National Dental Association, published his findings indicating that dental and oral infections were often the primary cause of disease.

These two medical pioneers established a simple but profound fact. If you pull an infected tooth, the patient will often recover from disease—serious disease, from chronic fatigue to cancer, from dermatitis to diabetes, from hemorrhoids to heart disease. Drs. Rosenhow and Price theorized that disease often originated from infections in the mouth that entered the bloodstream and eventually caused major problems in some parts of the body. The evidence they amassed and published is staggering, yet the next great step Dr. Mayo hoped for did not come, and their work is largely forgotten today.

The experiments performed by Price and Rosenhow are impressive. Not only did Price pull any infected tooth, but after many years of experience, he came to believe that all root-canal teeth harbor infection and so they also should be pulled. He took root-canal teeth that he extracted and sewed them under the skin of a rabbit. The rabbit invariably died from the same disease that had plagued the person. If the patients had kidney trouble, the rabbits developed kidney problems; if eye trouble, the rabbits' eyes became affected; heart trouble, rheumatism, stomach ulcers, bladder infections, ovarian diseases, phlebitis, osteomyelitis, whatever the disease, rabbits promptly became similarly affected. Dr. Price claimed he never found an exception to this rule.

Dr. Rosenhow was a bacteriologist whose experiments demonstrated elective localization and transmutation. That is, bacteria taken from an infected liver, for example, when injected into another animal, would preferentially infect the second animal's liver. Similarly, bacteria from the mouths of patients with specific health conditions would produce similar conditions when injected into laboratory animals."

The Mayo Clinic, arguably one of the most famous in the world, does not appear to honor the legacy of its founder. They have standard and unhelpful information

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on oral care and dental health. Here is what they say regarding adult health and dental care.<sup>229</sup>

"Regular dental care is an important part of oral health. Having healthy teeth and gums isn't a given, though. Brush up on daily dental care tips, and know which signs and symptoms deserve a dentist's attention.

Also, consider common dental care questions. Should you use an electric toothbrush or a regular toothbrush? Does whitening toothpaste really work? Should your dental care include fluoride treatments or dental sealants? How often should you visit the dentist for professional dental cleanings? What can you do about bad breath?

Dental care counts. Take charge of your dental care today!"

What the Mayo Clinic should add to the blurb on dental care is this, based on what they recommend, or more importantly, what they do NOT recommend.

"Count out being exposed to any teachings by our founder. Our Mayo physicians will not ask you about the health of your mouth, gums, and teeth even if you have chronic diseases our founder showed are caused by your sub-optimal oral health status."

Upon searching for the terms, "Mayo Clinic" and "focal infection," zero links to Mayo Clinic are obtained. Interestingly, very few sites have this search term. The top hit is for our organization, Health Revival Partners.

Mayo clinic should be the leader in diagnosing and addressing focal infection. However, since even they must follow the standard of care, they do not invoke protocols to detect focal infection. This is explained in Volume 2.

Here is an example of the problems encountered in standard-of-care medicine when trying to elucidate the possibility of focal infection. A medical doctor colleague, Michael, has glaucoma that has been matriculating for 30 years. He was introduced to Dr. Clement Trempe of Harvard Medical School, the most brilliant of all Ophthalmologists, who explained focal infection of the eye. Michael obtained blood testing for chronic infections and discovered he had several pathogenic critters in his peripheral blood, including *C. pneumoniae* and oral infections. He then treated himself with the anti-inflammatory antibiotic minocycline and experienced a severe Jarisch-Herxheimer reaction just in his retina - the location of his disease. This provided all the evidence he needed to appreciate that his glaucoma was caused by stealth focal infections and the localized inflammation they induce.

The retina, the tissue involved in glaucoma, is a circular disc between 30- and 40 mm in diameter. In other words, it is tiny. Even if the retina is experiencing raging infection and inflammation, the cytokines and immune cells activated in the retina are highly diluted in the total volume of blood circulating in the body. And, since

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blood is drawn from the arm, not the retina, the blood sample reflects a substantial dilution of those cytokines compared to their concentration in the retina. The results are that important biomarkers like white blood cell counts and C reactive protein are barely elevated, if at all. This was the case for doctor Michael with glaucoma. Thus, a standard-of-care doctor would not have a clue that an infection is raging in the retina.

The point of this example is that focal infection is challenging to detect. One of Dr. Claude Bernard's quotes, "The experimenter who does not know what he is looking for will not understand what he finds," is highly apropos in the instance of our glaucoma sufferers and many other people with nagging health issues in specific tissues. Focal infection is at the root of:

- joint pain;
- fatigue;
- poor healing;
- sleeplessness;
- mood disorders; and
- many other common afflictions.

Dr. Trempe surveyed fifty (50) seniors with glaucoma over a period of one month and asked each one a simple question, "Did your primary care doctor or cardiologist ask you about your oral health or if you had root canals?" Most of his patients had doctors within the Partners healthcare system of Harvard Medical School. Zero out of the fifty indicated that their doctors asked that question.

Glaucoma continues to be a leading cause of blindness worldwide. It is now well-established that glaucoma and Alzheimer's disease have many common features, including focal infection. Glaucoma usually precedes Alzheimer's by a decade, but few people with glaucoma are apprised of this information. Eye doctors assume the fetal position when it comes to informing their patients about connections outside of their narrow swim lane.

Sorry, Dr. Mayo. Your fifty years of dedication to real medical science goes unnoticed, at least through the year 2022.

### **Judith Miklossy**

Dr. Mayo is not alone in being ignored. Dr. Miklossy has performed some of the most definitive work on causal factors in Alzheimer's, and medicine is deliberately not listening.

Judith Miklossy has contributed greatly to our understanding of the infectious origins of severe disease. Her fabled career extends over 40 years and has focused on providing a strong scientific foundation for infectious causes of Alzheimer's disease. She was the first to really make the association between a class of

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intracellular organisms called spirochetes and Alzheimer's with her landmark paper titled, "Alzheimer's, a Spirochetosis?"<sup>230</sup>

Dr. Miklossy is an M.D. with a Ph.D. She is the founder of the Prevention Alzheimer International Foundation and director of the International Alzheimer Research Center in Switzerland (CH) also practices memory and Lyme disease consultation at Vigimed Medical Center, CH. She is board certified in neurology, psychiatry, and psychotherapy (Faculty of Medicine, University of Debrecen, Hungary) and in neuropathology (Swiss Society of Neuropathology and Swiss Medical Federation).

Medicine is intended to be an evidence-based discipline. Dr. Miklossy has provided robust evidence supporting the spirochete - Alzheimer's connection, except no one is listening. Instead, Alzheimer's is considered an Aricept deficiency or a disease of amyloid plaques or neurofibrillary tangles. Granted, these formations are present in Alzheimer's disease. However, decades of drug development to stop or eliminate these formations have been and continue to be abject failures. Thus, any indication that they are evidence-based causal factors in Alzheimer's is completely wrong.<sup>231</sup> In 2022, it was revealed that some research implicating amyloid as a cause was falsified.<sup>232</sup> Who or what can we trust anymore? Volume 2 provides you with answers.

Dr. Craig Atwood was the first to publicly predict the failure of any treatment that reduced the amyloid plaques in Alzheimer's. He did so in a publication in 2004. He was right. We were the first to publicly predict the failure of any treatment that reduced neurofibrillary tangles in Alzheimer's. We did so in our book, "The End of Alzheimer's - The Brain and Beyond," in 2017. We were right. Were we brilliant or clairvoyant? Not necessarily, but we understand the mechanisms of disease and how the body responds to focal infection. With that knowledge, making predictions is NOT risky business.

Here is an abstract from a paper Dr. Miklossy published 20 years after her initial one on Alzheimer's. It is titled, "Alzheimer's disease - a neurospirochetosis. Analysis of the evidence following Koch's and Hill's criteria."<sup>233</sup> The title indicates she used key evidentiary criteria in her assertion of proof that chronic infections cause Alzheimer's and dementia.

"It is established that chronic spirochetal infection can cause slowly progressive dementia, brain atrophy, and amyloid deposition in late neurosyphilis. Recently it has been suggested that various types of spirochetes, in an analogous way to *Treponema pallidum* (the STD), could cause dementia and may be involved in the pathogenesis of Alzheimer's disease (AD).

Here, we review all data available in the literature on the detection of spirochetes in AD and critically analyze the association and causal

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relationship between spirochetes and AD following the established criteria of Koch and Hill. The results show a statistically significant association between spirochetes and AD.

When neutral techniques recognizing all types of spirochetes were used, or the highly prevalent periodontal pathogen *Treponemas* were analyzed, spirochetes were observed in the brain in more than 90 percent of AD cases. *Borrelia burgdorferi* (the Lyme disease pathogen) was detected in the brain in 25.3 percent of AD cases analyzed and was 13 times more frequent in AD compared to controls.

Periodontal pathogen *Treponemas* (*T. pectinovorum*, *T. amylovorum*, *T. lecithinolyticum*, *T. maltophilum*, *T. medium*, *T. socranskii*) and *Borrelia burgdorferi* were detected using species specific PCR and antibodies. Importantly, co-infection with several spirochetes occurs in AD. The pathological and biological hallmarks of AD were reproduced in vitro by exposure of mammalian cells to spirochetes. The analysis of reviewed data following Koch's and Hill's postulates shows a probable causal relationship between neurospirochetosis and AD.

Persisting inflammation and amyloid deposition initiated and sustained by chronic spirochetal infection form together with the various hypotheses suggested playing a role in the pathogenesis of AD as a comprehensive entity. As suggested by Hill, once the probability of a causal relationship is established, prompt action is needed. Support and attention should be given to this field of AD research.

Spirochetal infection occurs years or decades before the manifestation of dementia. As adequate antibiotic and anti-inflammatory therapies are available, as in syphilis, one might prevent and eradicate dementia."

Dr. Miklossy's work is easily worthy of the Nobel Prize. She is very humble and will tell you that others before her have made the connection between spirochetes, other infectious species, and Alzheimer's, including Dr. Alzheimer's himself. However, she has provided sound scientific evidence. She has dedicated her entire career to creating the requisite proof in an attempt to move medicine towards a better understanding, thus, better prevention and treatment for Alzheimer's. Drs. Warren and Marshall were awarded the Nobel Prize for proving the connection between *H. pylori* infection and stomach ulcers. However, this connection was first suggested more than 50 years before their landmark work. The work of Dr. Miklossy is of equal to or greater importance compared to that of Drs. Warren and Marshall.

### **Trempe and McCully**

Drs. Trempe and McCully are the modern incarnation of Pasteur and Bernard. However, they lack the fame these historic figures garner, but they deserve as

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much. Both were professors of Medicine at Harvard Medical School, so in the Boston vernacular, they are "wicked smaat." McCully, as a pathologist, studied all kinds of disease postmortem. Trempe was a very humble clinician of Ophthalmology. Ophthalmologists are full MDs with a specialty in the eye, and they usually are found in the surgery departments of most hospitals. That, right there, tells you a lot about how medicine is divided into swim lanes, often incorrectly. Surgery's purpose is to repair that specific tissue. But the eye is an important canary for chronic diseases, particularly vascular and neurodegenerative. Surgery does not address these two conditions in the least. Volume 2 delves into the eye as a critical place to evaluate where people are on the chronic health disease continuum.

Dr. Trempe was not a traditional ophthalmologist in any way. To this day, there is no one who practices that discipline the way he did. Arguably, he was the best doctor of the modern era because he was able to literally see disease through the transparent eye in a way that would make other doctors envious. Imagine if a cardiologist had a window to look directly into the heart or a neurologist directly into the brain. Dr. Trempe used the eye to his and his patient's advantage and made an accurate and precise measurement of eye tissue, developed treatment protocols, and then reanalyzed the eye to determine the value of his approaches. In addition, he included extensive blood testing and evaluations for infectious species. Indeed, he understood the concept of focal infection and applied it to his practice. He often found infections in people with major eye diseases, macular degeneration, cataracts, and glaucoma. He executed a true process of continuous improvement that led to much of what is explained in this book that makes medical sense.

Dr. McCully ranks among the top doctors of the modern era as well. He complimented Dr. Trempe perfectly because he performed detailed studies and reviewed the literature extensively. Consequently, he has published hundreds of papers, many of which describe important mechanisms of disease. If the experts involved in developing codes for diagnoses and diseases read the works of Dr. McCully, we would not be burdened with 77,000 diagnostic codes. Instead, we would have a much more precise and impactful system with no more than a manageable set of codes.

Dr. Trempe was my "doctor" with respect to the Latin translation of the word which is "teacher." He read medical journals voraciously. On Fridays, he would review what he learned during that week of study with me. One particular Friday in 2010, he had a single publication on his desk, not his norm. This day was also extraordinary because of the way highlighted specific lines of text in this specific paper. Usually, there would be an underline here and there, but with this 13-page paper, at least half of it was highlighted in four (4) different colors. Here was our dialog.

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Lewis: "My, that paper must be a good one."

Trempe: "It is by McCully."

Lewis: "Who is McCully?"

Trempe: "He is the doctor who pioneered the homocysteine theory of cardiovascular disease."

While Dr. Trempe was toiling over the paper, I looked up Dr. McCully and found out that he was at the Harvard Medical School, New England VA, a scant 15 miles away. I called his number, and the inimitable Dr. McCully himself answered the phone, much to my shock and amazement. I explained that Dr. Trempe and I were reading his most recent paper and were fascinated by it. I also told him that Dr. Trempe regularly tested for homocysteine, which is sadly unusual. I invited him to lunch, which we enjoyed a couple of weeks later. That lunch lasted six hours, and we all became friends and colleagues.

The paper that catalyzed this relationship is titled "Vulnerable Plaque Formation from Obstruction of Vasa Vasorum by Homocysteinylated and Oxidized Lipoprotein Aggregates Complexed with Microbial Remnants and LDL Autoantibodies."<sup>234</sup> The title and the paper are both complex but highly informative about the role of infection in essentially every chronic disease. Fortunately, at a high level, the concept is quite easy to understand. Here is a breakdown of what McCully explains in that paper in great detail.

- Small vessels develop disease from infection.
- These small vessels support larger vessels which also become diseased.
- Specific localized or generalized diseases result from the diseased vessels supporting the specific tissue.

There is really nothing more to it than that. This process explains so many chronic diseases.

Here are some key excerpts from Dr. McCully's paper:

"A century ago, bacteria and viruses were considered as the main cause of atherosclerosis, a view that was based mainly on post-mortem observations. Thus, Thayer reported a high frequency of arterial lesions in patients who died from typhoid fever and a high prevalence of hardened radial arteries in those who survived."<sup>235</sup> Wiesel found an association between the degree of atherosclerosis in people who had died from an infectious disease and the length of the preceding infection."<sup>236</sup>

"Ott et al identified fragments from >50 different microbial species within atherosclerotic plaques (heart disease), but not a single one in normal arterial tissue."<sup>237</sup> On average, each patient had microbial remnants from 12

different species; some patients had more, some had fewer, and other investigators have found various virus species as well."<sup>238,239,240</sup>

**On average, 12 different infectious species are found in diseased tissue.**

“It is highly unlikely that a single antibiotic could eliminate >50 different microbial species. It is not even likely that antibiotics could eliminate *Chlamydia pneumoniae* (a common infection attributed to vessel disease), because this species is able to survive inside living cells, where they are resistant to the effects of antibiotics.<sup>241</sup> Furthermore, antibiotics are generally ineffective against viral infections. Whether the total burden of multiple microbial invasions or the effect of a single pathogen is the key to progression remains to be determined.”<sup>242</sup>

McCully makes his assertions about the causal impact of infection on heart disease while also explaining why the cholesterol theory is not a workable model. He explains six "disturbing facts" that illustrate why elevated cholesterol is not the cause of heart disease.

1. The concept that high LDL cholesterol causes endothelial dysfunction is unlikely because there is no association between the concentration of LDL cholesterol in the blood and the degree of endothelial dysfunction.
2. The concept that endothelial damage leads to an influx of LDL cholesterol is unlikely as well because the atherosclerotic plaques seen in extreme hyperhomocysteinemia (elevated homocysteine) caused by inborn errors of methionine metabolism do not contain any lipids in spite of pronounced endothelial damage.
3. No study of unselected individuals has found an association between the concentration of LDL or total cholesterol in the blood and the degree of atherosclerosis at autopsy.
4. In studies of women and the elderly, hypercholesterolemia (high total cholesterol) is a weak risk factor for cardiovascular disease, or, in most cases, not a risk factor at all, although the large majority of cardiovascular deaths occur in people above 65 years of age.
5. Among individuals with familial hypercholesterolemia (FH), there is no association between LDL-cholesterol and the prevalence or the progress of the cardiovascular disease. The higher coronary mortality in young people with FH may instead be due to inherited abnormalities of the coagulation system, often seen in FH, and a strong risk factor for coronary heart disease in this population. (Note, this is true in COVID also)
6. With one exception, an occluding coronary thrombus has never been produced experimentally in rodents by hypercholesterolemia alone, indicating that the pathological process in these models may differ from that in human beings.

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Indeed, this language may be quite technical to the uninitiated. However, chapter 5 provides a simplified explanation as to why the cholesterol theory of cardiovascular disease is invalid. Facts did not prevent Harvard Medical School from firing Dr. McCully for not complying with the cholesterol dogma. He lost his job and was blacklisted in 1969. For some reason, as explained in an article in a New York Times article titled, "The Fall and Rise of Kilmer McCully,"<sup>243</sup> he was reinstated at Harvard in 1997.

McCully remains a medical giant, and his work will live on long after he passes because it is based on sound scientific principles. Most importantly, his work helps explain that there is much more to heart disease than a statin deficiency. Infection is clearly part of the degenerative process in heart disease and all the diseases that rely on blood to nourish tissues. What diseases are not included in this list?

### **Charles Stratton**

Dr. Stratton was an Associate Professor of Pathology and Medicine and Director of a Clinical Microbiology Laboratory. He was Board Certified in Internal Medicine, Infectious Diseases, and Medical Microbiology. He has authored or co-authored over 200 papers on this subject and is recognized as an international authority in this area. Dr. Stratton has served on several editorial boards. Dr. Stratton is a retired Colonel in the U.S. Army Reserves. He received the Bronze Star for service in the Persian Gulf War.

Dr. Stratton contributed greatly to the knowledge base necessary to understand chronic diseases. He put much of his attention on the organism *C. pneumoniae*. His most important contribution in this area is an appreciation for the stealth and cryptic nature of this and likely other pathogens. His work provides important information on the detection and treatment of chronic disease-causing organisms that are substantially different compared to commonly accepted pathogens that cause acute disease. The following is a summation of some of Dr. Stratton's findings concerning *C. pneumoniae*.

"Chlamydiae are obligate intracellular microorganisms which parasitize eukaryotic cells and are ubiquitous throughout the animal kingdom. Eukaryotes include all living organisms other than eubacteria and archaeobacteria. Members of the chlamydial genus are considered bacteria with a unique developmental cycle, including several forms, each having different properties. This developmental growth cycle alternates between

1. Intracellular life forms, of which two are currently recognized,
  - a. a metabolically active, replicating organism known as the reticulate body (RB); and
  - b. a persistent, non-replicating organism known as the cryptic phase; and

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2. an extracellular life form that is an infectious, metabolically-inactive form known as the elementary body (EB).

EBs are small infectious, spore-like forms that are metabolically inactive, non-replicating, and often found outside of cells. EBs are physically stable. Under oxidizing conditions, the outer membrane of EBs is relatively impermeable as well as resistant to inactivation. EBs are thus well suited to survive long enough outside their hosts to be transmitted to a new host in the form of a droplet.

Infection by Chlamydiae induces a significant inflammatory response at the cellular level. For example, genital lesions produced by *Chlamydia trachomatis* frequently elicit a vigorous influx of lymphocytes, macrophages, and plasma cells. Yet, clinically, the initial infection is often varied in symptomatology and may even be asymptomatic. Once fully established, Chlamydia is challenging to eradicate, with frequent relapse following antibiotic therapy. Evidence also indicates that the Chlamydia may become dormant and are then shed in quantities too few to detect by culture reliably.

*Chlamydia pneumoniae* (from now on, “*C. pneumoniae*”) is the most recent addition to the Chlamydiae family and is recognized as causing approximately 10 percent of community-acquired cases of pneumonia. It commonly infects the upper and lower respiratory tract and is now recognized as ubiquitous in humans. *C. pneumoniae* is well-accepted as a human pathogen that may be difficult to eradicate by standard antibiotic therapy. *C. pneumoniae* is known to persist as a silent or mildly symptomatic pathogen, resulting in persistent infection.

The current therapy for suspected or confirmed *C. pneumoniae* infection involves a short course (e.g., 2-3 weeks) of a single antibiotic. However, *C. pneumoniae* infections may relapse following antibiotic therapy with short-course antibiotics. In vitro studies on the persistence of Chlamydiae despite specific and appropriate antibiotic therapy have suggested that the presence of antibiotics promotes the formation of an intracellular, non-replicative state typically referred to as the latent or cryptic phase. Stopping treatment allows the organism to resume replication. Thus, in this way, the organism can escape the current antibiotic therapy used in clinical practice.

Given the chronic and persistent nature of chlamydial infections, there is a need for reliable, accurate methods for the diagnosis of pathogenic infection as well as therapeutic approaches to manage the infection. Due to the highly infective nature of Chlamydia EBs and their ability to reinfect cells, there is also a need for anti-chlamydial therapy which eradicates this pathogen, thereby preventing the long-term impact of such chronic infections."

### **David Wheldon**

David Wheldon was an author, poet, and pathologist. He was born in 1950 in Moira, Leicestershire, England. He practiced medicine throughout England and Wales. He wrote four novels, *The Viaduct* (1983), which won the 1982 Triple First Award; *the Course of Instruction* (1984), *A Vocation* (1986); and *At the Quay* (1990). He wrote five collections of short stories and numerous poems and essays. He put his literary work on hold to work on a treatment for multiple sclerosis.

Dr. Wheldon's wife, Sarah, began to suffer from multiple sclerosis in 1989. Dr. Wheldon posted Sarah's story upon her request to inform others about the possibility of reversing this disease. Her story, as written by Dr. Wheldon, is reproduced here by permission.

"Sarah, an artist of considerable ability, was diagnosed with MS in July 2003. Her illness stretched back to 1989 when she experienced a sudden weakness in the right arm. After a fortnight, she recovered its function completely. A few years later, she experienced a slight greying of vision in one eye; this resolved over a few weeks. Occasional relapses followed, all with a complete recovery.

In 1999 the remissions started to become less complete. Right foot drop began insidiously and did not resolve. Then, in 2001, shortly after a prolonged upper respiratory infection that led to mild new-onset asthma, Sarah entered a new, rapidly progressive stage of the illness. Within two years, she could not stand unaided, had to hold furniture, could not hold or use a pencil or paintbrush with her right hand, and felt giddy. She said that she seemed to live in a mental fog: indeed, in the evenings, she would fall into a half-sleep from which she obtained no rest. Her speech was becoming slurred. There was a continual sense of flickering and worsening neurological deficit. She suffered tinnitus, hearing the continual sound of distant machinery. She developed L'hermitte's sign, manifested as an electric-shock-like pain down the back on bending the head forward and signifying damage to the cervical spinal cord.

An MRI scan showed many typical active lesions, visible as variably-sized bead-like hyperintensities in the brain's white matter.

The neurologist told Sarah she had Multiple Sclerosis; the disease had entered an aggressive secondary progressive phase for which there was no treatment, and the illness must be expected to take its course without abatement. He took me (Dr. Wheldon) to one side and told me that her days of creativity were finished. (He said this with a despairing pass of his hands.) He advised me to make preparations and find a nursing home.

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I'm much more interventional than he- this goes with the territory of my being a consultant medical microbiologist - and I quickly found the Vanderbilt paper which first described the association of *C. pneumoniae* infection and MS.<sup>244</sup>

Then the problem of treating a chronic infection with *C. pneumoniae* had to be solved. Many medical microbiologists in the field believe this infection cannot be adequately treated. Using the Internet, I quickly found a US patent was taken out by two Vanderbilt doctors, Mitchell WM and Stratton, CW, to record the intellectual priority of their discovery. Using the information in this patent as a basis for treatment, I recommended the following oral anti-chlamydial regimen:

- doxycycline 200mg once daily;
- roxithromycin 300mg once daily (azithromycin 250mg three days a week is an alternative.);
- Short courses of metronidazole will later be added to this regimen.

We started the doxycycline first, as it was immediately available. The results were astonishing. For five days, Sarah suffered worsening symptoms, accompanied by a flu-like illness, a headache around the eyes, pains in the large joints (hips and shoulders), and night sweats. This is a typical Herxheimer-like reaction. It is caused when antibiotics or other agents expose a sizeable bacterial load. After five days, she lost the mental fog: indeed, she said she felt mentally clearer than for two years. The roxithromycin was added three weeks later when it became available.

This information has been made available at Sarah's request. It has to be said that, despite all the research published in the scientific literature, the existence - let alone the therapeutics - of chronic infection with *C. pneumoniae* is barely understood by the medical community."

I had the pleasure of communicating with Dr. Wheldon about Sarah's case and chlamydia pneumoniae in general. Here is what Dr. Wheldon told me.

"After Sarah began to improve, I saw numerous patients with MS and other illnesses, and I encountered nothing but unconstrained hostility from the neurologists. Generally speaking, the earlier the disease is treated, the better the outcome. Unfortunately, patients with early relapsing-remitting MS are caught up in the neurological machinery, so they never get to see people like me. (Cambridge, not far from Bedford, is the British epicenter of the useless biologic Alemtuzumab treatment.)

Testing for antibodies to *C. pneumoniae* is problematic in the UK. Few laboratories do it; the reference laboratories use the MIF test, which I found from personal experience was insensitive and highly subjective. At Bedford, we used an Elisa system to detect specific IgA. Savyon

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Diagnostics, Ashdod, Israel, made the kit we used. It proved to be reliable, well-controlled, and repeatable. I can recommend it.

Because the organism is rarely thought of diagnostically, requests for serology were vanishingly few. We set up an algorithm to select sera (from blood) we thought might be likely positive. The results proved astonishing. The range of subacute and chronic illnesses with elevated specific IgA was huge. Many of them were vasculitis or neurological.

A brief (and incomplete) list of ailments caused by *C. pneumoniae* include,

- Cardiac conduction defects;
- Effusive pericarditis with tamponade;
- Chronic obstructive airways disease;
- Multiple Sclerosis;
- Chronic fatigue syndrome;
- Encephalitis;
- Retinal vasculitis;
- Macular degeneration;
- Progressive presbyopia;
- Crohn's disease;
- New onset adult asthma; and
- Schizophrenia (hebephrenia).

Sometimes when treating a patient with one condition, an apparently unrelated condition would unexpectedly improve. The most dramatic case I have encountered was a woman in her 40s with chronic fatigue syndrome and a high specific IgA. She also had achalasia of the cardia (which is thought to be due to loss of neurological control of esophageal peristalsis.) This had been worsening for a decade, and she could only swallow liquids. I saw her six months later. The fatigue was much improved. I asked about the achalasia. 'What achalasia?' she said, beaming. 'Now I can eat well-chewed pizza.'

Chuck Stratton and I wrote a letter to the *Lancet* a few years ago. They declined to publish it. I hope I don't have cause to say I told you so."

That paper is titled, "Personality changes in persons with chronic brain infection with *C. pneumoniae* (including Multiple Sclerosis)."

### **Paul Ewald and J. Thomas Grayston**

Paul W. Ewald, Ph.D., is an evolutionary biologist specializing in the evolutionary ecology of parasitism, evolutionary medicine, agonistic behavior, and pollination biology. He is the author of *Evolution of Infectious Disease* (1994) and *Plague Time: The New Germ Theory of Disease* (2002) and is currently

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director of the program in Evolutionary Medicine at the Biology Department of the University of Louisville.

Ewald is known for his "theory of virulence," suggesting that "the deadlier the germ, the less likely it is to spread,"<sup>245</sup> Figure 6.1, above. He also champions the concept that many common diseases of unknown origin are likely the result of chronic low-level infections from viruses, bacteria, or protozoa.

Stealth pathogenic infections of lower virulence cause chronic diseases - the true pandemic - are highly transmissible because of crypticity and are thus not associated with widespread chronic diseases.

Dr. Ewald, in his book "Plague Time," explains the roadblocks Dr. Wheldon experienced from his medical colleagues. Ewald writes:

"Chronos, from the Greek, means "time." Chronic diseases are distinguished from acute diseases because they are drawn out over time. Sexually transmitted diseases (STDs) often have acute phases, but almost all of them have a chronic phase. Their acute phase often involves a lesion, pain, and inflammation near the site of entry a few days or a few weeks after the onset of infection. But STDs cause worse damage at more distant sites due to their chronic presence.

This continuum between acute and chronic disease among STDs reveals a surprising inconsistency in generalizations about disease causation. STDs, and a few other diseases, such as tuberculosis, that demonstrate this continuum have led to the recognition that infectious diseases can be chronic. But when it comes to chronic illnesses that do not have a distinct acute phase, infectious causation is often either dismissed or not even considered. Peptic ulcers, for example, do not have a distinct acute phase, and the infectious causation of ulcers was dismissed for a century despite supportive evidence.

**Infectious causation is often either dismissed or not even considered when it comes to chronic diseases that do not have a distinct acute phase.**

A shocking realization arrives when we notice the general trend of which peptic ulcers are merely a specific example. All the diseases accepted as infectious during the last quarter of the nineteenth century were either entirely or largely acute. The diseases were prominent because sufferers had obvious symptoms just after being infected. But all the human diseases that have NOT been accepted as infectious during the past quarter century have been entirely or largely chronic. Stealth infections cause them."

Dr. Ewald goes on to explain how *Chlamydia pneumoniae* was discovered and how this organism may explain a substantial portion of the human misery currently endured by way of chronic diseases.

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"In 1965, about fifteen years before Marshall and his Australian colleagues were piecing together the role of *H. pylori* in ulcers, a much smaller bacterium was isolated from a child's eye in Taiwan. This bacterium would incite investigations into the infectious causation of chronic diseases far more deadly than peptic ulcers. In the 1980s, while Marshall and his colleagues were wondering why medicine was not paying attention to their evidence for infectious causation of ulcers, this other line of inquiry traveled a circuitous route, passing through critical junctures in Seattle, South Africa, and Finland. This route, which is continuing in unforeseeable directions, may lead to one of the greatest medical advancements since the development of antibiotics.

Dr. J. Thomas Grayston, Professor Emeritus of Epidemiology at the University of Washington School of Public Health, led the research in Taiwan. Grayston's group initially thought that the organism in the eye of the child was *Chlamydia trachomatis*, the same *Chlamydia* featured on pamphlets in STD clinics. *Chlamydia trachomatis* has been seen in tissue samples since the first decade of the twentieth century, but a much longer history in humans, as evidenced by some ancient medical paraphernalia. Special spoons made about two thousand years ago in the Middle East were made for people with trachoma, a disease characterized by a puffy swelling of the eyelids that rotates the eyelashes, pushing them onto the eyeball. With every blink, the lashes brush the eye. The continual brushing eventually abrades the eye, causing scarring and invasion of the cornea by blood vessels, often leading to blindness.

Grayston's group initially thought that their organism was *C. trachomatis* because trachoma was widespread in developing countries. Worldwide, about 400 million people have the disease, and the infection is quite common. But their isolate did not grow well in cell cultures that supported a florid growth of *C. trachomatis*. In 1986, they published their findings in the *New England Journal of Medicine*, proposing that they had discovered a new variant of the bird parasite *Chlamydia psittaci*.

Having taken the problem back to their laboratory at the University of Washington, Grayston's group attempted to figure it out when they were visited by a young Finnish researcher named Pekka Saikku. Together they began testing different populations of people for antibodies to the unusual *C. psittaci*-like organism. They found antibodies in Seattle, Helsinki, and everywhere else they tested. By the time people reached middle age, over half showed signs of infection. That seemed strange because *C. psittaci* was thought to be transmitted only from birds to humans and not from person to person. In the past, it had been found in people who owned pet birds and in poultry farmers, but rarely in the general public. This new variant was far more widespread than the standard version of *C. psittaci*. Moreover, the

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pathogen was not just a benign freeloader. It was responsible for about one of every five cases of pneumonia.

The Grayston lab found that the DNA of the *C. psittaci*-like bacterium was just as distinct from the known strains of *C. psittaci* as it was from the known strains of *C. trachomatis*. In 1989 the Seattle researchers named the bacterium that they had first isolated from the Taiwanese child's eye *Chlamydia pneumoniae*. A combination of epidemiological and microbiological studies revealed that *C. pneumoniae*, like *C. trachomatis*, used humans as its primary host. But unlike *C. trachomatis*, it was a respiratory tract pathogen; it infected the lungs and was transmitted to other people's lungs via droplets expelled into the air by coughing.

As Grayston's group was moving toward this conclusion, Pekka Saikku and Maia Leinonen analyzed Finnish patients in a direction that still has experts in the health sciences vehemently arguing. With one of the world's highest rates of heart disease, Finland has many labs working cooperatively on the problem. To assess the presence of infections after heart attacks, a large sample of blood serums was collected by researchers at Helsinki University Central Hospital and distributed to several labs in the area.

Working at the National Public Health Institute of Helsinki, Maia Leinonen analyzed the samples for *Chlamydia*. She found that 70 percent of the samples from heart attack patients had antibodies against a compound common to *Chlamydia*. This percentage was significantly higher than the control serums from people who had not had heart attacks. Only one *Chlamydia* species could produce rates so high: *C. pneumoniae*.

There was no evidence, however, of recent infections - (as measured with IgM antibody titers), and heart attack rates in Finland did not follow the six-to-seven-year cycles of acute *C. pneumoniae* outbreaks. This evidence led Leinonen and Saikku to hypothesize that heart attacks and underlying atherosclerosis that caused them were caused by chronic *C. pneumoniae* infections - (noted by the presence of elevated IgG antibody titers).

Responses from the medical community ranged from fascination (from the very few who were curious) to ridicule (by those happy with the prevailing unsuccessful dogma). Assertive responses are appropriate to any suggested explanation of a disease that eventually kills about half of the people living in wealthy countries, usually leading to a heart attack or stroke. Atherosclerosis is that lethal. The jarring implication of Saikku and Leinonen hypothesizes that humans have never escaped plagues of infectious disease. Even the bubonic plague did not claim such a toll. If their hypothesis is correct, the primary differences between the notorious plague of the present are the slow, insidious pace of cardiovascular disease and the mature age at which it strikes - in short, the plague's timing."

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Figure 6.2 illustrates the difference between acute and chronic infection and the diseases that result from these processes. It also shows the concept of a health-disease continuum.

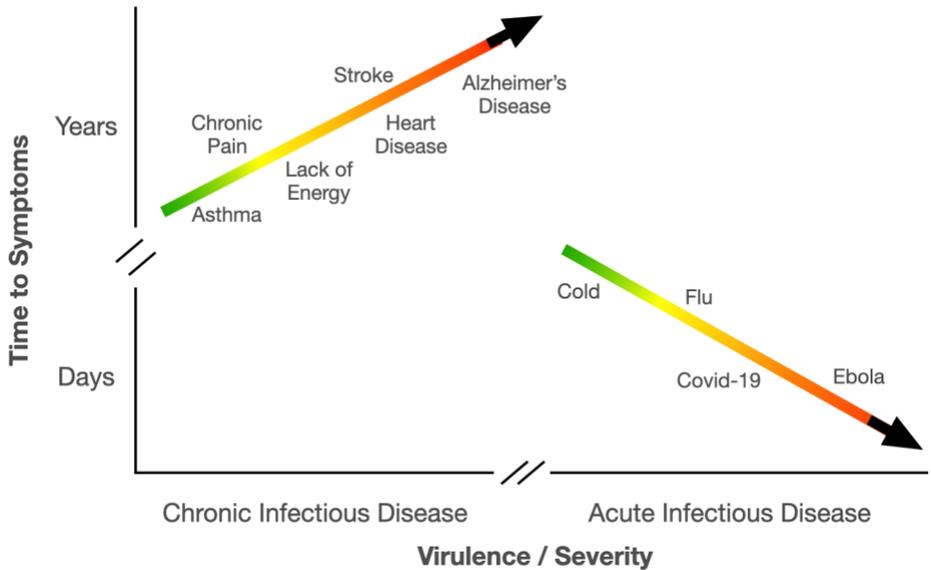


Figure 6.2: Comparison of the timing of onset of acute versus chronic diseases after exposure to a causal infectious agent. In the case of acute illness, the virulence of the infection determines the time to symptoms and severity of the disease. In chronic disease, the time the chronic infection is active plays a more chief role in the disease severity. Both acute and chronic infections express differences in virulence, but it is more evident in acute diseases.

People with nagging health problems often have causal infectious agents. Over time, if the immune system does not resolve the situation, the underlying infection may replicate, causing worsening symptoms. In this state of infection, other opportunistic infections opportunistically replicate, leading to the expression of new symptoms. On the other hand, in acute infection, symptoms are seemingly immediate and may have a short incubation period where the organism(s) multiply to a toxic and harmful level. Your innate immune system is ready for this and, in most cases, keeps you alive. Your adaptive immune system also kicks in but is slower to respond because specific antibodies must be designed and made.

Here is a simple example of the difference between chronic and acute diseases. Imagine stabbing the back of your hand with the sharp side of a pencil. It is suddenly painful, bloody, and will bruise. Now flip the pencil and gently rub the back of the other hand with the eraser. Continue to irritate the skin for two months, non-stop, taking no breaks. Now, at the two-month mark, compare the backs of both hands. Which one looks worse? Remember, you stabbed one of your hands

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two months ago. If you are healthy, that skin should be perfectly healed. However, the skin you just stopped rubbing after two months is probably rubbed raw. This is what is silently happening to the tissue inside your body. With Chlamydia pneumoniae, it is happening inside your vessels.

Every one of the chronic diseases indicated in Figure 6.2 may be caused, at least in part, by C. pneumoniae infection. A wealth of published literature supports this statement. And, in those cases where C. pneumoniae is not found, another similar organism is probably causal. Here are some examples of the relationship between C. pneumoniae and the diseases listed in Figure 6.2.

Asthma: NLM has 260 publications with "Chlamydia" and "Asthma" in the article titles. One paper titled "Chlamydia pneumoniae and asthma" indicates a strong statistical correlation of 400 percent. The authors conclude, "titers suggesting a previous infection were found in 34.8 percent of patients with severe chronic asthma: the difference between this group and the control group was statistically significant with an adjusted odds ratio of 3.99." Other infectious agents were undoubtedly involved in the cases not accounted for by C. pneumoniae infection.

Chronic pain: NLM has 320 publications with "Chlamydia" and "Arthritis" in the article titles. "New insights into Chlamydia and arthritis. The promise of a cure?"<sup>246</sup> concludes: In this viewpoint, we provide an overview of recent key findings in the epidemiology, pathophysiology, clinical manifestations, diagnosis, and treatment of Chlamydia-induced arthritis. Our intention is for these insights to be translated rapidly into clinical practice to overcome misdiagnosis and underdiagnosis of the disease and for them to stimulate the continued development of a cure.

Hmm... "translated rapidly." They did not understand the powers of greed at work to suppress this type of life- and health-saving information.

Fatigue: This only shows up in five National Library of Medicine publications. One is titled "Chronic Chlamydia pneumoniae Infection: A Treatable Cause of Chronic Fatigue Syndrome."<sup>247</sup> The conclusion states, "Collectively, these results suggest that C. pneumoniae is an uncommon yet treatable cause of chronic fatigue. The DNA test's sensitivity, specificity, and interlaboratory variability will need to be better defined." The authors imply that C pneumoniae is quite prevalent, but better testing must be performed. Do you have chronic pain? Have you been tested for the presence of C. pneumoniae? Obligate intracellular organisms, as a class that includes D. pneumoniae, are cellular energy robbers. Thus, the association between these organisms and chronic fatigue is substantially underreported and underappreciated.

Stroke: This condition gets 110 hits. Dr. Grayston, the doctor who first characterized C. pneumoniae, weighs in by saying, "Serological evidence of chronic infection with C pneumoniae is associated with risk of ischemic stroke in

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an urban, multi-ethnic population. This association is independent of other vascular disease risk factors."<sup>248</sup>

Heart attack: Over 400 publications show up with Chlamydia and heart attack in the title of scientific reports on NLM. Dr. Saikku, who first showed the association between heart disease deaths and *C. pneumoniae* infection, states, "The presence of elevated antibody titers and immune complexes containing chlamydial LPS was a significant independent risk factor (up to 260 percent), for acute myocardial infarction 3-6 months before cardiac incidents in the Helsinki Heart Study. The odds ratio was especially significant (720 percent) if the cohort on the cholesterol-lowering drug was followed."<sup>249</sup>

These data are critically important for your future health. Lowering LDL ("cholesterol") is well known to increase the risk of infection. This was first definitively shown during the early phases of the AIDS epidemic. The journal article from 1998 titled "Association Between Serum Total Cholesterol and HIV Infection in a High-Risk Cohort of Young Men" discusses the dangers of statin prescriptions.<sup>250</sup> The authors state, "Low serum total cholesterol (TC) is associated with a variety of nonatherosclerotic (heart) diseases, but the association of TC with the infectious disease has been little studied. In this study, we examined the relationship between serum TC and HIV infection in members of a large health maintenance organization in Northern California." They found that the men in the study under 50 had a significantly higher infection rate if their total cholesterol was <160. They also found a similar excess risk of AIDS and AIDS-related death. These findings suggest that low serum total cholesterol levels should be considered a marker of increased risk of HIV infection in men already at heightened risk of HIV infection. Thus, cholesterol protects our bodies against viruses and other infectious species.

People on presumed statin therapy (what else would they be on) experienced an additional 460 percent increase in heart attacks compared to those who were not on statin when *C. pneumoniae* was present. This data supports the HIV data. The 460 percent increase is  $720\% - 260\% = 460\%$  percent increase by being on statins. Wow, that is an enormous increase in adverse outcomes.

### **Statins therapy increases the risk of heart attack by 460 percent when *C. pneumoniae* infection is present!**

Are you on a statin?

Do you have a *C. pneumoniae* infection?

Are you sure?

Alzheimer's: Dr. Brain Balin is the world's expert on *C. pneumoniae* infection and Alzheimer's. His key paper is titled "Proof of Concept Studies of Chlamydia Pneumoniae Infection as a Trigger for Late-onset Alzheimer Disease."<sup>251</sup> Dr. Balin concludes:

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"Our data suggest that *Chlamydia pneumoniae* introduced intranasally to normal BALB/c mice triggers the accumulation of A $\beta$  1-42 in the brain. Further, upon infection of THP-1 monocytes, significant changes occur in the regulation of gene transcripts and protein expression that correlates to the inflammatory signature observed in late-onset Alzheimer's disease. Thus, our data suggest that infection can trigger specific protein and gene changes that correlate to Alzheimer's disease pathogenesis."

This is a crucially important paper, and infectious causes of Alzheimer's are a crucially important consideration. Alzheimer's is fast becoming the #1 cause of early mortality. In some countries like Thailand and the U.K., it is close to the #1 killer. Yet this paper, published 20 years after Dr. Balin's initial assertion of the connection between *C. pneumoniae* and Alzheimer's, was cited only one (1) time! This is an outrageous indication of the narrow-mindedness of modern medicine that enjoys vast profits from drugs like Aricept which do nothing to slow the Alzheimer's disease process. Also, guess who is the only one who cited Dr. Balin's work in a newer publication? If you guessed, Drs. Lewis and Trempe, you are correct.

NIH does understand the connection between vascular disease and Alzheimer's. Dr. Roderick Corriveau of NIH appreciates the possibility that chronic infections may cause vascular diseases. Dr. Corriveau joined the National Institute of Neurological Disorders and Stroke (NINDS) as a Program Director in 2010 and is responsible for the NINDS vascular contributions to cognitive impairment and dementia (VCID) portfolio. He is the NIH Lead for the Alzheimer's Disease-Related Dementias (ADRD) Summits and planning efforts, including in 2013, 2016, and 2019. He encouraged me to apply for a grant to study *C. pneumoniae* and other infections as part of the vascular component of Alzheimer's. I thought about it but decided to do something that had a better chance to see the "light of day" in my lifetime.

### **Trempe-Lewis Criteria for chronic infections**

Hopefully, by now, you have an appreciation that chronic (stealth, cryptic, occult, focal) infections must be considered a factor that causes various chronic diseases. Importantly, how do you know if you have one? The obvious way is through testing. However, in the case of Robert, and many others, the specific pathogen or pathogens may go under-detected with even the best analytical techniques available today.

Here are methods we have developed to determine the presence of chronic infections. Not all the criteria need to be met to indicate the possibility of a chronic pathogen being present. The Hill and Koch parameters are not definitive but informative. Symptoms, how you feel, and the lack of an impact by standard treatment also provide sufficient evidence that chronic infections may be involved in symptoms or diseases.

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### Innate immune response

- White blood cells: <4000, >5000 cells per mL
- Neutrophils: <2000, >3000 cells per mL;
- Lymphocytes: <1400, >2000 cells per mL;
- Neutrophil-to-Lymphocyte ratio: < 1.1, >1.5;
- Neutrophil percent: >58%, <52%;
- Lymphocyte percent: <38%, >48%;
- C reactive protein: >0.6 mg/dL;
- Fibrinogen activity: <180 mg/dL, >280 mg/dL;
- Erythrocyte sedimentation rate >10mm/hr.; and
- Red blood cell distribution width >13%.

Note: the WBC count may be in the optimal range. However, if the differentials (neutrophil and lymphocyte values) are abnormal, chronic infection may be present. For example, a high absolute neutrophil count and a low absolute lymphocyte count may yield a "normal" total WBC count. However, in this instance, infection is clearly suspected. Also, the NLR value will be elevated under these circumstances.

### General infections

- Lyme line blot: Any band positive, IgG, IgM, IgA;
- Periodontal DNA testing: Positive for high and medium-risk pathogens;
- Any level of bleeding gums;
- Any oral pain;
- Sinus inflammation;
- Jarisch-Herxheimer's response to antibiotics or anti-infective nutraceuticals; and
- Unexplained or unresolved health conditions.

Here is a partial list of specific infections for which blood testing is available.

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Anaplasma phagocytophilum	Chlamydia pneumoniae
Babesia duncani	Chlamydia trachomatis
Babesia microti	Chlamydia psittaci
Bartonella elizabethae	Coxiella burnetii.
Bartonella henselae	Coxsackie Virus
Bartonella quintana	Cytomegalovirus
Bartonella vinsonii	Epstein Barr Virus
Borrelia afzelii	HGA Anaplasma
Borrelia andersonii	phagocytophilum
Borrelia bavariensis	HHV-6
Borrelia bissettiae	HHV-7
Borrelia burgdorferi	HME Ehrlichia chaffeensis
Borrelia californiensis	HSV-1
Borrelia garinii	HSV-2
Borrelia hermsii	Mycoplasma pneumoniae
Borrelia lonestari	Parvovirus B19
Borrelia lusitaniae	Capsid
Borrelia maritima	Powassan Virus
Borrelia mayonii	Rickettsia rickettsii
Borrelia miyamotoi	Rickettsia typhi
Borrelia spielmanii	Rickettsia conorii
Borrelia turcica	Streptococcal A
Borrelia turicatae	Tickborne Encephalitis Virus
Borrelia valaisiana	Toxoplasma gondii
Borrelia yangtzensis	West Nile Virus

### Pan-Bacterial DNA Sequencing:

This test is designed to screen for the presence of any bacterial species in a patient-provided sample. It identifies it or the nearest known relative by DNA sequencing analysis using a proprietary next-generation sequencing method and bioinformatics analysis. This test requires that the organisms be present in the sample provided and does not discriminate between viable or dead bacterial cells. Potential novel organisms are flagged, and the nearest known relative is identified.

### Pan-Eukaryotic DNA Sequencing:

This test is designed to screen for the most medically relevant protozoa and eukaryotic microbial species in a patient-provided sample. It identifies it or the nearest known relative by DNA sequencing analysis using a proprietary next-generation sequencing method and bioinformatics analysis. This test requires that the organisms be present in the sample provided and does not discriminate between viable or dead microbial cells. Potential novel organisms are flagged, and the nearest known relative is identified.

### Shotgun Metagenomics:

Shotgun metagenomic sequencing allows researchers to comprehensively sample all genes in all organisms present in a given complex sample. The method enables microbiologists to evaluate bacterial diversity and detect the abundance of microbes in various environments. Shotgun metagenomics also provides a means to study unculturable microorganisms that are otherwise difficult or impossible to analyze.

### Final Thoughts

Organisms are everywhere. Most of them are beneficial or not harmful. And diseases caused by them are often preventable. We fear sharks, but very few are killed or harmed by shark attacks. Why? Because we take precautions to avoid sharks, and more times than not, they do not attack. Claude Bernard articulated the solution to diseases caused by infection - take better care of yourself, and you will probably avoid having a chronic disease caused by infection until late in life when it is time to pass the torch. If you have a nagging chronic issue, get appropriately tested. Treatments, both natural and synthetic, are available to reduce the burden of these infections and ameliorate disease symptoms. Enhancing your microbiome may be one of the best methods you can implement.

You may not be able to avoid chronic infectious diseases. Dr. Ewald forwarded the concept that chronic infectious disease "is not pathogen-specific, it is vulnerability specific." I am a perfect example. In my youth, I was bitten by ticks many times. In my 40s, I developed atrial fibrillation. How did this happen? A constellation of vulnerabilities enabled latent Lyme pathogens to "come out and play." I was going through a stressful period, was overtraining for an iron man, and had an acute infection that Dr. Trempe diagnosed as bacteremia (just by looking at me). These three vulnerabilities set me up for disease. I got tested for Lyme disease, underwent a long-term treatment, and today I am free of Lyme and atrial fibrillation.

### Deep Dive

There continues to be controversy and misunderstanding about chronic infections as causal in chronic diseases. However, this assumes that there is a dialog between camps when in fact, there is not. Infectious disease doctors just abjectly do not recognize the "stealth of the chronic." I have written a detailed research paper on this topic. The introduction explains the evidence in favor of chronic infections - not "past infections."

To me, the best evidence of chronic infections is the undertaker. Hopefully, you find this statement curious. How could an undertaker be proof? When you die, your immune system drops to zero. And you are no longer interacting with the environment. That is, you are no longer breathing and circulating blood and lymph. However, you immediately start decomposing, and that is where the

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undertaker comes in. They are already in their stealth form, waiting for an opportunity. Sickness and other vulnerabilities offer opportunities for stealth organisms to replicate. Death is the ultimate vulnerability. You start decomposing immediately, like a cut of meat, and need the undertaker to "preserve" you.

What follows is a detailed review of the stealth of chronic infections. Feel free to proceed to Chapter 7 if you feel fluent on this topic.

### **Introduction to "The Stealth of the Chronic"**

Developed nations, particularly the United States, continue to confront a chronic disease crisis.<sup>252</sup> The WHO reported that in 2010, non-communicable chronic diseases, including cardiovascular diseases, diabetes, cancers, and chronic respiratory diseases, accounted for 2/3rds of deaths worldwide.<sup>253</sup> The Institute of Medicine reported that America is less healthy than other high-income nations in obesity, diabetes, heart disease, chronic lung disease, and disability.<sup>254</sup> The Organization of Economic Cooperation and Development tracks the health of 36 developed nations.<sup>255</sup> The U.S. scores in the lower half compared to 36 nations on all significant indicators of health and longevity. When considering that the per person per year cost of healthcare in the U.S. is more than two and a half times higher compared to the OECD nation average, a health paradox exists in America. This American Paradox is the worst cost-to-value benefit for chronic disease outcomes compared to the 35 other nations by far.

The chronic disease management system is failing in both disease prevention and disease management, disease reversal, or stopping the progression of the underlying conditions. Health and prevention recommendations currently supported by the major medical societies thus are proving ineffective. Laboratory tests are of limited scope and don't address the root causes of chronic diseases. Pharmaceuticals indicated based on test results have meager statistical success at preventing or reversing disease as eighty-six percent of the nation's nearly 4 trillion annual health care expenditures is for people with chronic conditions.<sup>256</sup> In America, if treatments were solving rather than managing chronic conditions, our healthcare spending would be more in line with the OECD average. Based on exorbitant spending, our outcomes should be superior, but they are not.

On average, Americans with five or more chronic conditions spend 14 times more on health services than those without chronic conditions.<sup>257</sup> As of 2014, 60 percent of American adults had at least one chronic disease, and 42 percent had more than one chronic condition. Five percent of the population accounts for an estimated 49-53 percent of total healthcare expenses.<sup>258</sup> The 15 most expensive health conditions account for 44 percent of total health care expenses.<sup>259</sup> The financial and productivity costs impact our corporations, which fund over half of the national healthcare at a price of roughly 4 percent of gross corporate revenues. And much of this cost is segmented into high-cost beneficiaries where, for example, the top 1 percent of claimants cost \$150,000/y compared to the

population mean of \$4800/y.<sup>260</sup> The United States' total population average cost is well more than double the corporate average cost because most employees are under age 65.

In a report compiled by the Health Care Cost Institute, there is a surprisingly large turnover among the highest-cost healthcare spenders from year to year. Three of the five top spenders in any given year were not top spenders in the prior year. In 2015, only 39 percent of the top 5 percent of spenders were in the top 5 percent of spenders in 2014. Moreover, this trend was consistent in each year from 2009 to 2015. These new top spenders came from all portions of the spending distribution. For example, in each year studied, almost 15 percent of top spenders were in the bottom 50 percent of spenders or had no spending in the previous year.<sup>261</sup> Thus, there is a need for better predictive analytics and patient workup to determine causal factors of chronic disease to identify better and manage risk to finally start reversing the escalating chronic disease and cost trend facing America and, to a lesser degree, other nations globally.

Obligate intracellular bacterial pathogens and other infectious species, including viruses, fungi, and parasites, are an understudied but significant group of human disease agents.<sup>262</sup> Despite dramatically reduced genomes relative to most free-living bacterial pathogens, obligate intracellular bacterial pathogens retain potent pathogenetic potential that can manifest in infections ranging from asymptomatic to fulminating and deadly.<sup>263, 264</sup> It is now widely recognized that microscopic species, including bacteria, play a crucial role, both beneficial and adversarial, in human physiology. For example, complete sequences of numerous mitochondrial, many prokaryotic, and several nuclear genomes confirm that the mitochondrial genome originated from a eubacterial ancestor.<sup>265</sup> Pathogenic bacteria are slowly regaining notoriety as relevant in human disease as indicated by the Nobel Prize and Medicine or Physiology in 2005 for the evidence that H-pylori infection is a causal agent in stomach ulcers.<sup>266</sup> Now, it is widely understood that this pathogen causes a broad spectrum of chronic gut issues, including cancers.

Ewald states, “Over the past two centuries, diseases have been separated into three categories: infectious, genetic, and diseases caused by too much or too little of some noninfectious environmental constituent. At the end of the 19th century, the most rapid development was in the first of these categories; within three decades after the first cause-effect linkage of a bacterium to disease, most of the bacterial causes of common acute infectious diseases had been identified. This rapid progress can be mainly attributed to Koch’s postulates, a rigorous systematic approach to identifying microbes as disease causes. Koch’s postulates were helpful because they could generate conclusive evidence of infectious causation, particularly when (1) the causative organisms could be isolated and experimentally transmitted and (2) symptoms occurred soon after the onset of infection in a high proportion of infected individuals.

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Koch's postulates, while guiding researchers down one path, directed them away from alternative routes. Researchers attempting to document infectious causation were steered away from diseases that had little chance of fulfilling the postulates, even though they might have been infectious. Fulfillment of Koch's postulates confirms infectious causation, but doing so has become less feasible over the past century.<sup>267</sup> It is likely to become even less achievable in the future because many of the characteristics that make infectious causation cryptic also hinder the fulfillment of the postulates.<sup>268</sup>

Fields et al. state, "Obligate intracellular bacteria represent consummate parasites, often covertly co-opting host resources to enable development and ultimately transmission to a new host. The overall success of this survival strategy is doubtless derived from co-evolution with respective eukaryotic hosts over hundreds of millions of years. Indeed, many species of obligate intracellular bacteria represent pathogens capable of significant negative impacts on worldwide human health. This link to human disease and the fascinating infection biology exhibited by these parasites renders them exquisite subjects for investigation. Despite the absolute overarching requirement for growth within eukaryotic cells, this class of bacteria has evolved distinct strategies that enable colonization of diverse tissues, cell types, and even subcellular niches."<sup>269</sup> Ewald's work substantially rationalizes the infection-chronic disease connection for known and common chronic conditions such as cancer and cardiovascular diseases. Fields help us understand that pathogens are a logical place to look in ill-defined and refractory chronic conditions.

*Chlamydia pneumoniae* (*C. pneumoniae*) is an obligate intracellular pathogen known to infect a large percentage of the human population. According to Crother and Porritt, "The majority of individuals are exposed to *C. pneumoniae* throughout their lifetimes with an antibody prevalence of 50 percent by age 20 and 80 percent by 60–70 years old."<sup>270</sup> Although *C. pneumoniae* infection is predominantly asymptomatic or mild; it can result in the development of acute upper and lower respiratory illness, including bronchitis, pharyngitis, sinusitis, and pneumonia.<sup>271</sup> *C. pneumoniae* infection and its relationship to chronic inflammatory diseases remain controversial. A mounting body of evidence shows that not only is *C. pneumoniae* involved in respiratory infection, but it also contributes to the pathogenesis of a range of inflammatory diseases including, but not limited to, atherosclerosis, arthritis, asthma, lung cancer, and chronic obstructive pulmonary disease as well as neurological disorders, namely, Alzheimer's disease, multiple sclerosis, and schizophrenia."<sup>272</sup>

Epithelial cells infected with *C. pneumoniae* are resistant to apoptosis induced by treatment with drugs or by death receptor ligation.<sup>273</sup> "The induction of protection from apoptosis depended on the infection conditions since only cells containing large inclusions were protected. The underlying mechanism of infection-induced apoptosis resistance probably involves mitochondria, the major integrators of

apoptotic signaling. In the infected cells, mitochondria did not respond to apoptotic stimuli by releasing apoptogenic factors required for activating caspases.” This data suggests a direct modulation of apoptotic pathways in epithelial cells by the organism, the purpose of which is organism survival and proliferation.

Infectious agents are known to reprogram host cell gene expression to the benefit of their life cycle, and these changes can be long-lasting, global, or transient and of limited breadth.<sup>274</sup> A landmark review of 32 studies involving 77 different host-pathogen interactions demonstrated that pathogens impact the host cell genetic program. And a large percentage of the studies reported examples of pathogens that down-regulate innate immunity. Interestingly, the 2018 Nobel Prize for Physiology or Medicine was awarded for “Cancer therapy by inhibition of negative immune regulation.” Cancer impacts innate immunity, or more probably, infectious species like h-pylori, HPV, chlamydia pneumoniae, and other organisms that are part of the complex cancer cascade and are likely the basis for this effect.<sup>275</sup>

Kellam et al. were the first to publish the concept of “Infectogenomics.”<sup>276</sup> Some key teachings manifest from this original paper. They explain how “the dose of infection and the fitness of the host and pathogen will determine sickness,” as demonstrated by van Opijnen,<sup>277</sup> who states, “After all, unfit pathogens can make excellent live attenuated vaccines.” They conclude: “The host's functional genomics is crucial in analyzing host-pathogen interactions. Host genetic variation plays a key role in determining the outcome of many potentially pathogenic infections, and the prevalent pathogens have influenced the genetic makeup of human populations. Infectogenomics can be harnessed to identify infectious states, to understand the host response, to predict disease outcomes, to monitor responses to antimicrobial therapies, and to indicate promising new types of treatment.”

Stratton et al. explain that intracellular organisms can exist in lifecycle phases cleverly crafted to avoid detection by the host immune system.<sup>278</sup> “Chlamydiae organisms growth cycle alternates between 1. intracellular life forms, of which two are currently recognized, a metabolically-active, replicating organism known as the reticulate body (RB) and a persistent, non-replicating organism known as the cryptic phase; and 2. an extracellular life form that is an infectious, metabolically-inactive form known as the elementary body (EB).” Stratton indicates that patients infected with C. Pneumoniae have high IgM and IgG titers as characterized by elevation above reference ranges. The IgM titers fall over time upon specific antibiotic therapy, and IgG titers rise, as expected based on organism life cycles. However, with detoxification, the IgG titers fall, indicating partial or complete elimination from the perspective of clinical significance.

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There continues to be controversy and confusion over IgG-positive antibody tests and the presence of an organism. The usual view is that IgM must be positive to indicate a potential infection.<sup>279</sup> IgM antibodies are the first produced in the body in response to an infection. IgM antibodies are larger than IgG antibodies and may indicate a recent or new active infection when present in high numbers. The IgG antibodies are produced once an infection has been going on for a while and may even be present after the infection has apparently been resolved. The presence of IgG antibodies for an organism, when accompanied by a negative IgM test for the same organism, classically means that the person was exposed to that organism at one time and developed antibodies to it but does not have a current active infection of that organism. However, it does not indicate the eradication of the organism. It often implies that the organism is dormant or hiding in a life cycle phase that is purposefully invisible to the immune system.<sup>280</sup>

*Toxoplasma gondii* is an intracellular parasite known to cause brain-altering manifestations in humans and animals. It is classified as one of five “neglected parasitic infections of the United States” by the Centers for Disease Control.<sup>281</sup> One of the characteristic manifestations of toxoplasmosis is retinal eye scarring. It is presumed this is a sign of past infection, and people with these scars often test positive for *Toxoplasma gondii* serologically with IgG antibodies. However, a recent study showed that tissue cysts containing *Toxoplasma gondii* are not dormant but relatively quite active.<sup>282</sup> Sinai et al. state,

“Despite over a third of the world’s population being chronically infected with *Toxoplasma gondii*, little is known about this largely asymptomatic phase of infection. This stage is mediated in vivo by bradyzoites within tissue cysts. The absence of overt symptoms has been attributed to the dormancy of bradyzoites. In this review, we reexamine the conventional view of chronic toxoplasmosis in light of emerging evidence challenging both the nature of dormancy and the consequences of infection in the CNS.

New and emerging data reveal a previously unrecognized level of physiological and replicative capacity of bradyzoites within tissue cysts. These findings have emerged in the context of a reexamination of the chronic infection in the brain that correlates with changes in neuronal architecture, neurochemistry, and behavior that suggest that the chronic infection is not without consequence.”

Thus, the immune system never clears the parasite. Immunity causes it to morph into the “dormant” tissue cyst form, leading to a life-long chronic infection that can reactivate in a compromised host, similar to chicken pox.<sup>283</sup>

Fagerberg et al. showed that any positive titers, including just elevated levels of IgG for *C. pneumoniae*, were associated with an increased risk for future stroke, with a relative risk of 8.58, and for any cardiovascular event, with a relative risk of 2.69.<sup>284</sup> They concluded that seropositivity for *C. pneumoniae*, including when

only IgG was elevated, was associated with an increased risk for CVD, independent of all other usual risk factors.

In the Northern Manhattan Stroke Study,<sup>285</sup> “titers for IgG, IgA, and IgM antibodies specific for *C. pneumoniae* were measured and  $\geq 1:16$  were considered positive.” “Elevated *C. pneumoniae* IgA titers were significantly associated with risk of ischemic stroke after adjusting for other stroke risk factors (adjusted OR 4.51, 95% CI 1.44 to 14.06). IgG titers were less strongly associated with stroke risk but still substantial (adjusted OR 2.59, 95% CI 0.87 to 7.75). The association of IgA with stroke risk was detected in both younger and older groups, in men and women, and whites, blacks, and Hispanics. There was also a significant continuous increase in risk associated with the log-transformation of the titer for IgA (adjusted OR 1.32, 95% CI 1.05 to 1.66).”

Importantly, even though IgA antibodies were more strongly related to poor outcomes, the elevation in stroke risk with just elevated IgG antibodies was 260 percent.

Amyloid formations in humans are referred to as the disease state “amyloidosis.” Most authorities consider these formations a serious health problem that can lead to life-threatening organ failure. Beta-amyloid, a type of amyloid formation, is regarded as the hallmark of Alzheimer’s disease and an important treatment target. After dozens of clinical trials that successfully reduced the level of beta-amyloid and nearly 1 trillion dollars spent, not one study participant with Alzheimer’s showed any improvement.<sup>286</sup> These Alzheimer’s amyloid plaques may actually be part of the immune system, a Harvard study has revealed. The research indicates that amyloid-beta may be the first line of defense against infection in the brain and other tissues.<sup>287,288</sup>

The Harvard team reports, “Members of this evolutionarily ancient family of proteins, collectively known as antimicrobial peptides (AMPs), share many of the amyloids’ purportedly abnormal activities.”<sup>289</sup> This connection should not have been met with surprise in the medical community as many researchers and clinicians have reported infection as a contributor to Alzheimer’s since the 1990s. Judith Miklossy, in particular, has published over 20 papers explaining the evidentiary link between spirochetes and Alzheimer’s, beginning with a landmark paper published in 1993 titled “Alzheimer’s - A Spirochetosis?”<sup>290</sup>

Many examples of infection-causing chronic disease are focal in nature. Frank Billings was the first to promote the profound impact on health by infection residing in localized tissue.<sup>291</sup> Charles Mayo presented the concept of dental focal infection in 1913 and subsequently was involved in over 50 publications addressing the crypticity of disease caused by focal dental infections.<sup>292</sup> Gorzó reviewed the history of focal infection in 2003.<sup>293</sup> A scant three papers have cited this work indicating that the focal infection theory of disease is considered an archaic concept among medical community members. Tissue tropism is a cause

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of inflammation and secondary diseases beyond the foci. Párkányi et al. demonstrate how odontogenic focus, particularly periodontitis and periapical periodontitis, causes disease in distant areas of the body in general, leading to the development of specific conditions, such as cardiovascular diseases, pneumonia, diabetes mellitus, metabolic syndrome, rheumatoid arthritis, and adverse pregnancy outcomes.<sup>294</sup>

Focal infection raises white blood cell counts concomitant with the extent a severity of the infection. However, the elevated leukocyte levels seldom elevate beyond normal reference ranges. Al-Rasheed demonstrated that periodontitis patients have significantly higher WBC count than control patients,  $7.22 \pm 1.42 \times 10^9$  cells/L as opposed to  $5.64 \pm 1.09$  cells per liter. At  $7.22 \times 10^9$  cells per liter, few medical practitioners indicate that future health risk is inferred. The Women's Health Initiative clearly demonstrates that WBC counts consistent with those in the periodontal cohort warn of a significant increase in fatal heart attacks.

Harvard University, by way of The Harvard Gazette, in a 2005 article titled, "Simple test predicts heart attack. White blood cells sound a new alarm,"<sup>295</sup> explains: "As part of the federally supported Women's Health Initiative, investigators at medical centers all over the United States collected information on 72,242 postmenopausal women 50 to 79 years old. All were free of heart and blood vessel disease at the start of the study. During six years of follow-up, 1,626 heart disease deaths, heart attacks, and strokes occurred. Women with more than 6.7 billion white cells per liter of blood had more than double the risk of fatal heart disease than women with 4.7 billion cells per liter or lower. A count of 6.7 billion white cells per liter of blood is considered normal, so what is "normal" may have to be redefined."

In their original investigation, Margolis et al. conclude: "The WBC count, a stable, well- standardized, widely available and inexpensive measure of systemic inflammation, is an independent predictor of CVD events and all-cause mortality in postmenopausal women. A WBC count greater than 6.7 billion white cells per liter of blood may identify high-risk individuals not currently identified by traditional CVD risk factors."<sup>296</sup> Neither infection nor the concept of focal infection was considered in that article, but inflammation as causal was.

Focal infection caused by periodontal disease results in the elevation of other markers of inflammation, signaling to immune cells, and tissue repair. Fibrinogen and CRP serve as important biomarkers for determining the presence and extent of focal infection.<sup>297</sup> Fibrinogen has been used as a biomarker for detecting periprosthetic joint infection.<sup>298</sup> Iqbal et al. show an increase in WBC, neutrophil, lymphocyte, and platelet count and a decrease in total protein, albumin, and globulin in aggressive periodontitis patients compared to healthy individuals.<sup>299</sup>

The eye is a profound marker of inflammation and infection. Ebola survivors describe significant limitations in vision due to cataract formation, even at ages

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as young as 5.<sup>300</sup> Elevation in WBC is frequently noted in people with Age-related Macular Degeneration. According to the Blue Mountain Study, individuals with a WBC >6.7 billion cells/liter are twice as likely to have ARMD compared to people with counts of  $5.5 \times$  billion cells/liter). The Age-Related Eye Disease Study (AREDS) demonstrates the strong connection between prolific eye diseases and early mortality.<sup>301</sup> For cataracts, the increase in mortality is particularly significant at 11 percent in 6.5 years compared to <1 percent in the general age-matched population.

Cataracts and macular degeneration reflect systemic rather than only local processes. Viral infections are known to contribute to cataracts. Hepatitis virus infections are associated with cataract formation and age-related macular degeneration.<sup>302,303</sup> Glaucoma, a neurodegenerative eye condition similar to Alzheimer's disease,<sup>304</sup> is potentially caused or exacerbated by infection. C. pneumonia, long ago implicated in Alzheimer's disease,<sup>305</sup> is also shown to be a potential cause of optic nerve head ischemia.<sup>306</sup> The eye, then, may find important use as a screening tool for focal and general low-grade chronic infection and inflammation.

Cholesterol-lowering drugs, led by statins, have been the dominant approach to cardiovascular disease primary and secondary prevention. However, leading authorities indicate that even the most efficacious of these agents do not improve mortality. According to an article in Protomag from the Massachusetts General Hospital, "What statins might do for you: Lower cholesterol // Reduce the risk of cardiovascular disease // Cause muscle pain and fatigue // Fail to prolong your life significantly."<sup>307</sup> Objective data seriously question the effectiveness of statins in prevention. In an observational study of 136,905 people hospitalized for a heart attack, 72.1 percent had admission LDL levels less than 130 mg/dL.<sup>308</sup>

Diabetics are much more susceptible to dying from heart disease, with published rates around 250 percent higher mortality compared to non-diabetics. Statin therapy increases the risk of diabetes by 9 - 12 percent in two meta-analyses of statin trials and by 18 - 99 percent in five population-based studies.<sup>309</sup> Feingold et al. note, "The changes in lipids and lipoproteins that occur during inflammation and infection are part of the innate immune response and therefore are likely to play an important role in protecting the host."<sup>310</sup>

Obligate intracellular bacteria manipulate the cholesterol levels of the host.<sup>311</sup> The outcomes are increased host levels of total cholesterol, LDL, and oxidized low-density lipoprotein. Infection may well explain the source of elevated cholesterol in many chronic diseases while also explaining why statin and other cholesterol-lowering approaches have failed to provide morbidity and mortality benefits based on LDL and the cholesterol molecule being disease-causal agents.

In "Infectious Causes of Chronic Inflammatory Diseases and Cancer,"<sup>312</sup> Dr. Gail Cassell leads with, "Powerful diagnostic technology, plus the realization that

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organisms of otherwise unimpressive virulence can produce slowly progressive chronic disease with a wide spectrum of clinical manifestations and disease outcomes, has resulted in the discovery of new infectious agents and new concepts of infectious diseases. The demonstration that final outcomes of infection are as much determined by the genetic background of the patient as by the genetic makeup of the infecting agent indicates that one or more infectious agents cause many chronic diseases of unknown etiology.”

Immune system vitality may be the most important risk factor in any chronic disease, including those with contributions from infection. The World Health Organization in “Risk Factors of Communicable Diseases” states, “Apart from symbiotic coexistence of humans with micro-organisms, disease-causing organisms breed in man-made unhygienic conditions of air, water, and soil. People with low immunity, weak, and living in unhygienic conditions are at greater risk for contracting infections from surroundings.”<sup>313</sup>

Chronic inflammation is an accepted cause of chronic disease.<sup>314,315</sup> As defined by Opie, “Inflammation may be defined as the process by which cells and serum accumulate about an injurious agent and tend to remove or destroy it.”<sup>316</sup> Chronic inflammation continues to be blamed for tissue damage. Still, this complex cascade, stimulated by internal and external mediators, releases danger signals that promote immune responses to antigens.<sup>317</sup>

Chronic occult infection is a potent stimulator of chronic inflammation that often is overlooked as a cause of chronic inflammation due to its enigmatic nature. Associations between IgG titers for intracellular pathogens, when elevated, typically considered a sign of past infection and disease, have yielded mixed results. Yet sufficient evidence for a causal relationship between bugs and illness exists, based on the preponderance of existing evidence, the magnitude of ill-defined conditions, and continued unacceptably high morbidity and mortality in common chronic diseases.<sup>318-333</sup>

The occult nature of specific pathogens, especially those thriving intracellularly, necessitates more robust and comprehensive risk and disease causation assessments. For example, heart disease continues to be the #1 cause of morbidity and mortality in the U.S. and globally, in developed nations, despite the broad use of cardiovascular disease medications for both prevention and intervention.<sup>334</sup> The LDL study in 136,905 hospitalized patients referenced above implies there is room for more robust testing to augment the evaluation of cardiovascular risk and cause. Infection with species like *Helicobacter pylori*, Lyme disease, and *C. pneumoniae* may explain a lack of association between disease and lipid-lowering approaches.<sup>335, 336,337</sup>

In older populations, “concentrations of homocysteine alone can accurately identify those at high risk of cardiovascular mortality, whereas classic risk factors included in the Framingham risk score do not,”<sup>338</sup> potentially reflecting the ability

of homocysteine to measure infectious antigen load.<sup>339</sup> In healthy men, adding C-reactive protein levels to traditional risk factors, the Reynolds Risk Score, improved cardiovascular risk prediction.<sup>340</sup> The Intermountain Risk Score uses standard blood measures and assesses risk from the group of markers to develop a risk score. Although limited in application, this scoring system has been reported to be more predictive of increased mortality risk than that used in the standard of care.<sup>341</sup> C-reactive protein, used in both these scoring systems, provides insight into an infectious burden.<sup>342, 343,344</sup>

Approaches designed to augment usual care diagnostics are emerging, including the “Allostatic Load” and “InflammAging” measurements. Each concept considers a broader molecular view of disease rather than an organ system view. According to McEwen, “When these (our body’s) adaptive systems are turned on and turned off again efficiently and not too frequently, the body can cope effectively with challenges that it might not otherwise survive. However, there are several circumstances in which allostatic systems may either be overstimulated or not perform normally. This condition has been termed “allostatic load” or the price of adaptation.”<sup>345</sup>

Claudio Franceschi coined the term “inflammaging” in 2000 to describe the concept of low-grade chronic inflammation and its impact on health.<sup>346</sup> Inflammaging was described as an extension of the “network theory of aging.”<sup>347</sup> Similar to the allostatic load, a global reduction in the capacity to cope with a variety of stressors, including stealth infection, and a concomitant progressive increase in proinflammatory status are considered the major characteristics of the inflammation aging process and susceptibility to premature disease and mortality.

According to Salinas et al., the allostatic load leads to dysregulation of the neuroendocrine system and subsequent elevation in inflammatory markers, leading to metabolic syndrome and chronic diseases such as cardiovascular disease.<sup>348</sup> Thus, the allostatic load and inflammaging are measured, at least partly, through inflammatory markers like C-reactive protein, cortisol levels, glycosylated hemoglobin, white blood cell counts, and fibrinogen as examples. Inflammaging is associated with cumulative lifetime exposure to antigenic load caused by clinical and subclinical infections.<sup>349, 350</sup> Non-infective antigens are also implicated in this process and may be the first step to proliferating or activating existing infection or lowering resistance to future exposures.

Measuring inflammatory biomarkers can better assess both infective and non-infective antigen burden. Multiple biomarkers, in general, improve the predictive power of a panel. In a study of 3209 people assessed with ten biomarkers, persons with multi-marker scores in the highest quintile compared with those in the lowest two quintiles had elevated risks of death and major cardiovascular events of 4.08 and 1.84 (adjusted hazard ratios), respectively.<sup>351</sup> This far exceeds the predictive

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hazard ratio for cholesterol alone, for example, which varies from 0.89 to 1.25 depending on the study.<sup>352, 353, 354</sup>

Numerous studies and reviews consistently show the value of multiple markers in predicting disease events and premature mortality.<sup>355,356,357,358,359,360</sup> Thus, expansion of the depth and breadth of diagnostics and risk assessment beyond lipids, A1C, blood pressure, and basic chemistry testing is required to better access risk, future outcomes and get to the root causes of diseases and offer solution beyond disease management.

The Chronic Disease Temperature™ (CDT) risk scale used in our studies combines emerging concepts for improving disease risk evaluation and measuring active disease. The significant attributes of the CDT scale are:

1. Consideration of multiple biomarkers;
1. Selection of markers based on traditional and new predictive markers based on inflammaging and the allostatic load;
2. Harmonizing each marker to a standard endpoint – statistically significant increase in early all-cause mortality risk;
3. Consideration of risk contribution to early mortality based on log-linear scales appropriate to each biomarker fitted to individual biomarker hazard ratios for mortality; and
4. Mathematical modeling of the risk values from each marker to generate a single, highly predictive score value for current or future risk of chronic illness.

The aggregate CDT score indicates early mortality, and it is well established that those who die early statistically suffer from more prolonged and frequent morbidity.<sup>361</sup> The markers' values reflect mortality and disease risk based on the association of a given marker to disease indication. This single number may be an essential bridge to a better appreciation of antigen burden and health literacy, as most patients need help understanding the meaning of their current lab values.<sup>362</sup> The CDT does not constitute a medical diagnosis of disease any more than any individual marker, like homocysteine, but does afford better statistical predictive capability and measurement of disease progression or regression compared to any single biomarker.

Accurately measuring disease burden is vital in establishing objective health risks and evaluating interventions. Lifestyle, however, is the fundamental root cause of many common chronic diseases. Lifestyle diseases, including well-recognized chronic diseases, account for up to 86 percent of the total disease burden in developed nations.<sup>363, 364, 365, 366, 367</sup> Meng et al.<sup>368</sup> developed and evaluated a semi-quantitative composite chronic risk index (CDRI) and investigated its relationship with chronic disease. In a group of over 30,000 individuals over five years, they showed that positive health behavior they measured was associated with a lower risk of cancer and greater longevity.

## Chapter 6: The Stealth of Chronic Infections Ignored

In our studies as a companion to the CDT, we implemented an expanded version of a CDRI that assesses risks beyond smoking, alcohol use, body mass index, fat intake, and fruit and vegetable consumption. The risk evaluation tool used in our studies, the Chronic Disease Assessment™ (CDA), is an online health risk assessment and mitigation tool and involves answering  $120 \pm$  questions that probe deeply into the lifestyle and environmental sources of risks, along with behaviors, health attitudes, readiness to change, current and past complaints, problems, and diagnoses. The output of the CDA is a raw subjective but comparable risk score based on numerical risk values assigned to question-and-answer combinations. A letter “grade” associated with risk score ranges reflects the extent of an individual's risk and health “portfolio.”

The letter grade is provided to participants as an easily understood value for the extent of their risks. The tool overcomes poor health literacy that especially impacts high-risk populations. Everyone understands a letter grade (A - F).<sup>369</sup> In addition, the Chronic Disease Assessment output generates a series of actions, including personalized education and actionable solutions specific to each risk in a participant's risk portfolio. Finally, a Health Revival Care Plan™ is generated from the risk portfolio and adjusted by health providers and participants to create a comprehensive yet manageable personalized roadmap to overcome risks and improve health.

Expansion of the depth and breadth of risk assessment and linked prevention and mitigation programs is important because the limited set of measures in usual care provides marginal and often negative results. A well-studied disease prevention arena is corporate wellness programs. Most of these programs rely on “usual care” that includes: basic dietary recommendations, weight loss, smoking, alcohol consumption, and metabolic and lipid index targets.<sup>370</sup> A broad-based team of wellness professionals and academics evaluated workplace wellness programs.<sup>371</sup> They unanimously concluded that few wellness programs meet expectations, and most are abysmal failures. What separates bad, good, and great programs are “a combination of good design built on behavior change theory, effective implementation using evidence-based practices, and credible measurement and evaluation.”

To further support the need for a more thorough risk assessment, in a global study of 84 risks, the authors concluded, “Increasingly detailed understanding of the trends in risk exposure and the relative risks for each risk-outcome pair provide insights into both the magnitude of health loss attributable to risks and how modification of risk exposure has contributed to health trends.”<sup>372</sup> These types of data clearly illuminate a path to improved health outcomes and the urgent need for more robust root-cause assessments of disease risks.

Health coaching is an important component of a health renewal program seldom included in the standard of care. Health coaches interacted face-to-face and

## Chapter 6: The Stealth of Chronic Infections Ignored

electronically with participants and implemented care plans developed by licensed health providers based on the CDA and CDT findings. Coaching activates patients to change through collaborative learning and social support.<sup>373</sup> Recall that "doctor" means "teacher" in the Latin translation. Adding health coaches creates what is known as a P4 environment which is defined as predictive, preventative, personalized, and participatory. Patient engagement and P4 medicine are increasingly essential components of strategies to prevent and reverse chronic disease.<sup>374</sup> The doctor's main charge is to evaluate patients, review records, order and interpret labs, remove participants from pharmaceuticals, and prescribe treatments based on new findings when necessary.

The goal of the Health Revival approach is to establish a new, genuinely evidence-based program for the measurement and remediation of disease. The standard of care has failed. Diseases and costs are on the rise. Accurate measurement and risk assessment at the primary care level, along with tools and resources to mitigate what is found, both naturally and pharmaceutically, has the potential to improve health and reduce healthcare costs by at least 1 trillion USD per year in the United States.

"We have already been exposed to the microbes of the world. They are already within us."

- Paul Ewald, Ph.D., Evolutionary Biologist

### **Modern Pandemics Are Planned**

Dr. Ewald, in his book "Plague Time," published in 2000, explains that modern humans have traveled to all parts of the globe and returned home. In this respect, we have been exposed to everything beneficial and harmful nature offers. What is inferred is that any new pandemic is highly unlikely to be from a natural source.

The globalists are shockingly forthcoming with their plans if we pay attention. Concerns about overpopulation have been discussed for a century or more. Can you think of another reason our government and healthcare system would inject babies and children with untested biological and synthetic substances? Thankfully, a few brave doctors put their careers at risk to bring us proper and early treatments. These treatment protocols are a treasure and model for current and future "outbreaks."

Individuals have lost their health freedom. The erosion of health freedom increased exponentially during the COVID-19 pandemic, and doctors and their patients were not spared. Arguably, for the first time in history, doctors were blatantly admonished, threatened, and demonized from practicing within their scope of medicine and for providing the best care for their patients.

Drs. Peter McCullough, Paul Marik, Zev Zelenko, and Pierre Kory are specific and notable examples of how standing up for patient care cost them dearly. All have been outspoken about the rights of patients to receive treatment during the early stages of the disease when it is most controllable. Notably, many other doctors working in the trenches and providing great and compassionate care also found that this put their careers at risk. Dr. McCullough refers to this as Pillar 2 in a 4 Pillar approach for battling the COVID pandemic. The "pillars," subject to appropriate modifications, apply to any new pandemic that will inevitably be thrown our way.

Dr. McCullough is exceptionally qualified to treat those suffering from SARS diseases, especially those experiencing vascular complications. He is a renowned cardiologist, epidemiologist, and clinical trial expert. Many of Dr. McCullough's

## Chapter 7: Pandemics Are Planned

>600 peer-reviewed publications have appeared in top-tier journals such as the New England Journal of Medicine, the American Medical Association, and The Lancet. He testified before the United States Senate in November 2020 regarding what he described as the federal government's politicization of health care during the pandemic, curbing or blocking the availability of inexpensive and effective treatments.

Baylor University Medical Center fired him, and Texas A&M College of Medicine, Texas Christian University, and University of North Texas Health Science Center School of Medicine all cut ties with McCullough, accusing him of spreading misinformation, a charge that, as new information became available, was proven ludicrous. Dr. McCullough's medical license to practice is under fire.

"Satan wants to steal our joy, kill the good thing God is doing in us, and ultimately destroy us. How does he do that? He tries to confuse our identity."

- God

"I have been stripped of every title I have ever had in that institution. I have received a threat letter from the American College of Physicians and the American Board," Dr. McCullough said. All because of his lawful participation "in a topic of public importance." He said, "powerful forces at work, far more powerful than we can possibly think of, that are influencing anybody in a position of authority regarding anything that threatened the vaccine-only narrative." He is now the chief medical adviser for the Truth for Health Foundation. This physician-founded charity is "dedicated to following the Oath of Hippocrates to serve individual patients to the best of our ability and judgment and to uphold the highest standards of medical ethics."

Dr. Pierre Kory is an American critical care physician who advocated the widespread off-label use of certain drugs as treatments for COVID-19. He is the Front Line COVID-19 Critical Care Alliance (FLCCC) president and co-founder. He testified before the United States Senate Committee on Homeland Security and Governmental Affairs, explaining the vital need for early outpatient COVID-19 treatment. On December 8, 2020, during that testimony, he stated, "It will all be needless deaths from here on out, given that there is a readily available scientific solution to the pandemic." He resigned from his hospital, Aurora St. Luke's Medical Center of Wisconsin, in 2021 over his stance on early treatment.

Dr. Kory's co-founder at the FLCCC, Dr. Paul Marik, resigned from his position as professor of medicine and chief of pulmonary and critical care medicine at Eastern Virginia Medical School in Norfolk, VA, for his promotion of early home and outpatient treatment of COVID. Ivermectin promotion was at the center of the pressures that led him to leave that post, even though he stated that he was never prescribed the medication. Sentara Healthcare, another employer of Dr. Marik's, suspended his duties in the ICU, stating he "has no plans to return to

Sentara Norfolk General Hospital as the Director of the ICU due to their continued prohibition of safe and effective treatments for COVID-19."

Countless doctors, without the notoriety of Drs. McCullough, Kory, or Marik suffered similar consequences or stayed silent and did not perform interventions they knew could be life-saving for fear of retribution. Censorship makes it nearly impossible to determine the breadth of doctors affected and untold lives lost because early, safe, effective, and legal treatments were denied.

Dr. Mollie James, D.O, an ICU physician practicing in St. Louis and New York, who fought the COVID-19 pandemic on the front lines for 18 months, was fired for refusing to take the experimental vaccine. "When the pandemic hit," Dr. James said, "I just felt a calling to go to New York when they called for volunteers. So, I went there in April 2020 and liked being in the midst of it. My purpose for going was to help them see what they were doing in real-time and what was the most effective for patients so I could bring that back to my community."

During her time treating patients at the height of the pandemic, Dr. James said one of the first significant improvements in treatment that she witnessed was the addition of steroids and blood thinners to treatment protocols. In December 2020, Dr. James said the United States Senate committee testimony of Dr. Pierre Kory, a fellow ICU physician, caught her eye. "There's an entire protocol, and ivermectin is a key part of it," James said. "We use blood thinners, different vitamins, and stronger steroids than most doctors use called methylprednisolone. We combine that with ivermectin, and that combination seems to be extremely effective."

"I had two patient successes at the hospital that was offering Ivermectin, and they pulled it off the shelf a week later," James said. "I was told the COVID committee did not approve it, so doctors who were not involved in the patient's care, my patient's care, were making decisions about what I could use." "When I was able to dose and use Ivermectin in an ICU patient properly, I saw the fastest turnaround of any patient out of probably a couple thousand that I have treated," James said. "When administrators tell physicians what medications they can prescribe, or how to counsel patients regarding interventions or tell doctors not to do something they believe is in the patient's best interest, doctors must leave those situations."

Dr. James is in private practice now, seeing patients virtually from across the country. She said she would prescribe several medications, including ivermectin, to patients who have tested positive or are worried about contracting COVID-19. She adds she has run into roadblocks at pharmacies, with pharmacists unwilling to fill prescriptions for ivermectin. Insurance companies do not cover it either, leaving patients to pay out-of-pocket. "Everyone is a candidate for early treatment," she said. "I believe it is 85 percent effective at keeping people out of the hospital." Conservatively, 20 percent of people hospitalized with COVID die in the hospital.<sup>375</sup> A reasonable estimate is that millions lost their lives due to

## Chapter 7: Pandemics Are Planned

policies against early treatment. The current conservative estimate of COVID-19 deaths globally is ~ 6.6 million people.

Dr. Scott Jensen was voted family physician of the year in 2016 and is a former Minnesota senator. Dr. Jensen publicized letters he received from the Centers for Disease Control (CDC) that instructed physicians to report as many COVID-19 deaths as possible. This type of reporting has the potential to influence policy with inaccurate data – yet another example of health freedom lost. Specifically, doctors were encouraged to report COVID-19 on death certificates in cases where such reporting was not usual. Specifically, the letter advised that if a doctor thought that COVID-19 was a contributing condition, they should put it down as a cause of death in Part 1 of the death certificate, not as a contributing condition in Part 2. Dr. Jensen indicated that we had been putting contributing conditions in Part 2 for nearly 30 years.

Dr. Jensen searched the CDC website and noted that COVID-19 might be included as a cause of death even if a test for the virus had not been performed. He reached out to officials at the CDC, expressing concern that this type of reporting would corrupt the value and quality of the Federal Registrar data. This data is used to inform our healthcare system in many areas, including pharmaceutical efficacy, mortality trends, containment controls, and resource allocation. Dr. Jensen expected some action to correct this obvious error in policy. However, his medical license was investigated for the first time in his storied career, not just once, but five times.

Interestingly, Dr. Jensen asks the question relatively few doctors and officials are asking. That question is, "how is it that deaths from influenza have dropped dramatically?" He posits that these flu deaths are now put in the COVID-19 category.

As dissected by Rochester Regional Health using CDC data, the official report on flu deaths shows a startling improvement in America's apparent resilience to the flu. The CDC releases the final national data on the flu season annually in April.

Between October 1, 2019, and April 4, 2020, the flu resulted in the following:

- 39 to 56 million illnesses;
- 410,000 to 740,000 hospitalizations
- 24,000 to 62,000 deaths;
- 195 pediatric deaths.

Between October 1, 2020, and April 1, 2021, the flu resulted in (percent reduction from 2019/20 and 2020/21 noted in parenthesis):

- 1,675 illnesses (330,000 percent decline);
- 224 hospitalizations (330,000 percent decline);
- An unknown number of deaths;

- One pediatric death (19,500 percent decline).

Figure 8.1 shows the trends in flu cases over the past ten years. Either medicine has quietly found a cure for the flu, or there is something very wrong with reporting flu cases and deaths since the onset of COVID-19. This is the kind of corrupted data that allows for the justification of emergency use authorization of untested pseudo vaccines.

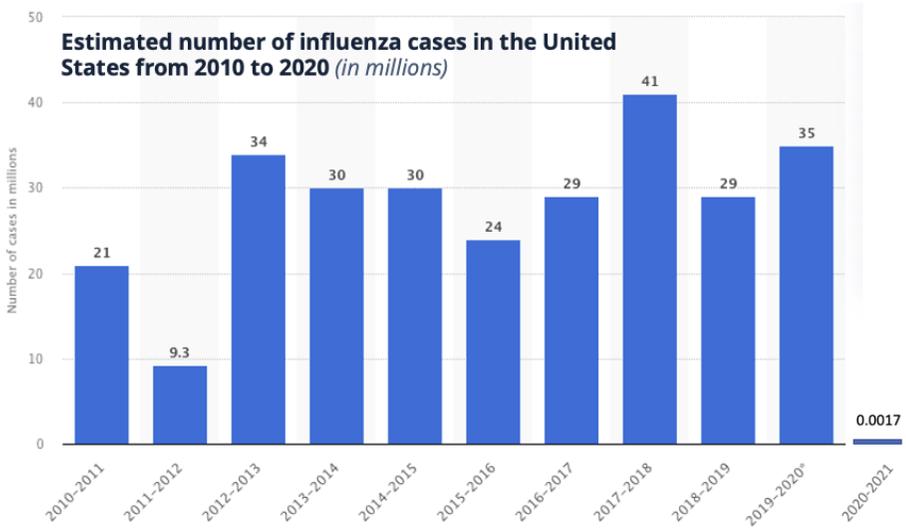


Figure 8.1 Estimated influenza cases in the United States from 2010 to 2020.

Dr. Jensen considers himself a huge advocate of health freedom. His approach has always been to provide objective information to his patients and let them decide what to do with their bodies. He, for example, explains to elderly patients with much higher mortality risks in COVID-19 compared to the seasonal flu that the vaccine may be a good option for them. He has changed his mind about these vaccines.

When the COVID-19 pandemic first surfaced, Dr. McCullough immediately focused his attention on this pandemic based on the videos of individuals in Wuhan, China, suddenly falling dead in the streets while going about their daily activities. Dr. McCullough led the narrative on early at-home and out-patient COVID-19 treatments using evidence and science to the extent practical during a crisis driven by a novel virus. With his background and experience as an internist and cardiologist and with a focus on the interface between heart and kidney disease, he was well prepared to meet the new yet unknown challenge head-on. He also has credentials in epidemiology, that is, the study of the incidence, distribution, and control of diseases, adding to his academic foundation appropriate for dealing with a rapidly spreading viral pandemic.

## Chapter 7: Pandemics Are Planned

As anticipated, COVID-19 reached America, unavoidable with our Global connectedness, with the first case being reported in Washington State on January 20th, 2020. "There had to be the first case somewhere," Washington State epidemiologist Dr. Scott Lindquist told reporters crowded into a room the next day. The very first COVID-19 patient survived. High anxiety and fear were rampaging among people around the world, and this first patient's fear was piqued as he saw the videos from Wuhan, from where he had just returned.

The earliest videos from Wuhan gave the impression that anybody infected with SARS-CoV-2 could spontaneously die. Has this happened elsewhere since? In 2021, some extremely elite athletes spontaneously died while participating in their sport or vigorously training. However, we now know that these individuals have an elevation in cytokines, heart, and tissue damage markers induced by the extreme exertion on their heart and muscles. Average citizens have not been reported to die from COVID-19 spontaneously. Now, it is well documented that spontaneous deaths are occurring at alarming rates, but for those who got the jab and not those who developed natural immunity from the infection. Were those early videos from Wuhan staged or real? Regardless, those images created global panic and fear, and this first United States victim set the stage for what was to come.

Fear is contagious and crippling. The Wuhan videos inferred that the virus was as fatal as Ebola, with the potential to wipe out nearly everyone. After all, Ebola is known to be quickly lethal, and the new virus, at the time, was unknown in this regard. In previous outbreaks, Ebola killed as many as 90 percent of the infected people. There is a significant problem with this fear. Ebola did enter the United States in 2014, and less than ten people died. Governmental health officials and the media did nothing to assuage this fear of either Ebola or the SARS-CoV-2 outbreak. There was a rush to judgment and, more importantly, a rush to vaccinations.

The extent of contagiousness is a vital determinant in developing a pandemic response. Ebola, although potentially very contagious, shows clear and immediate symptoms affording adequate warning for containment by isolating infected victims. Chronic diseases must be considered a pandemic and are prolific because they come on slowly, without warning provided by the virulent Ebola virus. The SARS-CoV-2 virus is somewhere in between these two, exhibiting a long latency period with confounding early symptoms that look like the common cold or flu. With attributes like these, to isolate or not to isolate becomes a conundrum. This SARS-CoV-2 has the perfect combination of latency and pathogenicity to create a pandemic. One could infer that the virus was designed and synthesized rather than derived from natural sources. Figure 8.2 shows a relationship between harm caused by infectious organisms and transmissibility based on the way symptoms manifest.

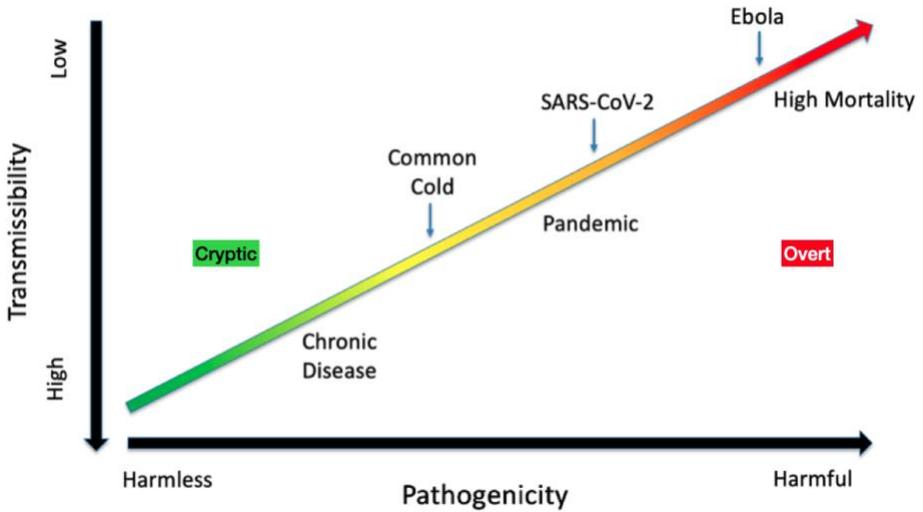


Figure 8.2: Practical relationship between pathogenicity and transmissibility of infectious agents.

What this graph clearly shows is the following:

- Highly lethal infectious agents cause immediate symptoms enabling infected people to be quickly isolated before the infection can spread widely.
- The people infected with virulent agents die quickly, ending the chain of transmission.
- Less virulent infections often do not cause immediate symptoms allowing infected people to come in contact with uninfected people, thereby spreading the infection.
- Very weak infections may not even impact health, at least not immediately, and may be cause of many chronic conditions.

Is it coincidental that the SARS-CoV-2 virus has just the "right" blend of pathogenicity and lethality while having the "right" level of transmissibility to cause a pandemic?

Fear overrides rational thought. For example, people fear shark attacks but do not fear driving in a car. Shark attacks claim very few lives yearly, while deaths on our highways kill tens of thousands annually. Air travel elicits anxiety in many, yet it is safer than driving to your local grocery store. Globally, Ebola is responsible for substantially fewer deaths compared to the true pandemic of chronic diseases. One reason some experience irrational, sometimes crippling unease is an inability to process these risks.

Unfamiliar things tend to make us feel more afraid, as do things that have been mythologized as "scary." People tend to share what is on their minds, especially

## Chapter 7: Pandemics Are Planned

troubling things. The pandemic created a dramatic shift in what people fear most in a scant year or two. The contrast between 2018 and 2021 is telling - Table 1. Table 1. What Americans found most troubling in 2018 (first column) and 2021 (second column)

The greatest source of angst over COVID-19 has been the perpetual tuning into social media and the major news outlets famous for accentuating or cherry-picking bad news. This is not a new phenomenon. News embellishment was highlighted in the celebrated movie about William Randolph Hearst and his media empire, “Citizen Kane.” The movie bookend to Citizen Kane about synthesized news was the James Bond movie “Tomorrow Never Dies.” Today, social media and video platforms are significant sources of news and information. Seven viral videos shaped how fear surrounding COVID-19 spread significantly faster than the virus.

- Several Wuhan citizens showed dying spontaneously as they walked down the street (video removed);
- Residences of Wuhan locked inside the high-rise apartment, screaming for help.
- Trucks disinfect residential areas by spraying chemicals in the air, flashing emergency lights, and streams of mist filling what appear to be otherwise deserted streets.
- Police officers drag a woman out of a car and pin her to the ground, after which she loses consciousness with the claim that these cops publicly killed this woman who was apparently infected by the coronavirus.
- Doctors with guns kill patients. The implication appeared that doctors were killing patients instead of treating them.
- Infected chicks and birds were buried alive.
- Burning pigs alive to control the outbreak.

These Wuhan videos sparked what is called an “infodemic” that set off a mass panic. Was it a setup to promote a hidden agenda? Regardless, these events and the ensuing apprehension set the stage for global citizens to become glued to media and to abide by the instructions being constantly delivered by governmental health officials. The combination of the first United States COVID-19 patient and the Wuhan videos set the tone for a single source of messaging for how to respond to the virus without scientific debate or objective information. After all, the world was suddenly in crisis mode, where governmental authorities had the responsibility to take control of the public rather than the individual good.

The early narrative, even in traditional media, was about the strength of our immune system. The Chinese published information illustrating the connection between co-morbidities and mortality rates from COVID-19. However, this narrative never translated into protocols. In fact, it soon became quite the opposite as the only action promoted was containment, isolation, and a vaccine as our only

hope for survival. Proof positive that immune strength was a topic early into the pandemic is based on Figure 8.3, which shows the relationship between comorbidities and death rates from COVID-19. This graphic was published very early into the pandemic, around March 2020. Few, if any, subsequent such data have since been published, and the death rates shown in the graphic are substantial overestimates of actual mortality rates.

The concept of vulnerability and what to do about it to save lives was never implemented and quickly disappeared from the global conversation. This was a regrettable opportunity lost because America, in particular, is an unhealthy nation, and leveraging the pandemic to focus on our poor health could have been a bright spot in an otherwise bleak time in our history. We intuitively know why this did not happen. Medicine is no longer a pursuit; it is a business. A cured patient is a lost customer.

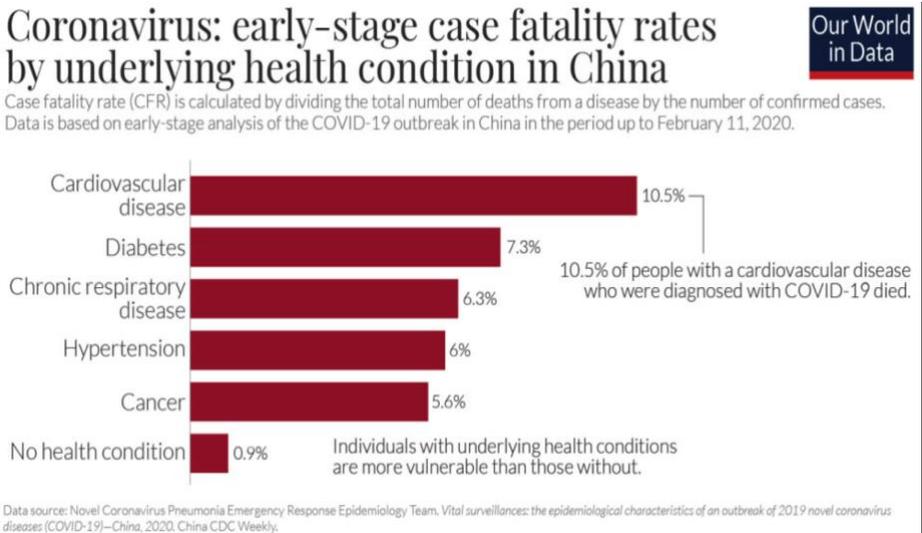


Figure 8.3: 2020 case fatality rates from COVID-19 by underlying health condition in China.

The single approach of containment and isolation makes sense in an emergency such as the 2019 pandemic. However, that discounts the vast medical resources we have at hand globally. A governmental call to action to help people improve their resilience could have led to a nationwide movement by practitioners who wanted to contribute to the crisis rather than desert their patients or route them into hospitals after the virus incubated and proliferated for weeks. Thus, the only response was completely reactive rather than proactive and treated every human as a potential victim whose only recourse was to:

- stay home and isolate;
- go to the hospital if very sick, and

- wait for a vaccine to become available.

It is time to distrust the medical industrial empire completely.

Early data indicated that the SARS-CoV-2 virus did not cause immediate death, as was portrayed through global media. Instead, the virus incubates for weeks before inflicting severe symptoms. Data from New York nursing homes provided some of the first clues about the slow development of the disease, COVID-19 appeared in a peer-reviewed publication titled, “Estimates of the severity of coronavirus disease 2019: a model-based estimate.”<sup>376</sup> The critical finding about the latency of the disease is captured in the following statement:

“The New York State Department of Health further analyzed the timing of the COVID-positive employee infections and nursing home deaths. Based on published data, the average time between COVID-19 infections and death is 18-25 days. Therefore, the link between the timing of staff infection and nursing home mortality is supported by the fact that the peak number of nursing home staff reported COVID-19 symptoms on March 16, 2020 - 23 days before the date of the peak nursing home fatalities, which occurred on April 8, 2020. Thousands of employees infected in mid-March likely transmitted the virus unknowingly - through no fault of their own - while working, leading to resident infection.”<sup>377</sup>

This information explains that the disease develops slowly, and there is time to treat people before they are in jeopardy of dying.

Dr. McCullough was one of the very first doctors who helped patients in the two-week window before hospitalization. When COVID-19 first struck, Dr. McCullough saw the potential human toll confronting society and knew it was a medical problem of potentially catastrophic proportions. He stopped his research and turned his full attention to understanding the disease. His unique multifactorial background gave him the tools to get to the root of the clinical matter. He saw that the public and governmental narrative were not addressing substantial gaps and what he was seeing being implemented clinically.

Unfortunately, the disease soon struck his family with the death of a young woman on his wife's side of the family. His father, who was in a senior home, contracted COVID-19 and had a prolonged battle with the disease. Ultimately, he and his wife became infected also. These personal experiences were strong motivations to dig deep into the disease as his duty as a physician. As part of a task force, he utilized his past collaboration and investigated what was happening in Milan, Italy, where there were high disease incidences. Italy has above-average national longevity; thus, it is interesting that it displayed high levels of SARS-CoV-2 infection, morbidity, and mortality. He dug deep into the science around past respiratory viruses.

A network of doctors treating COVID-19 immediately started a sizeable multi-center prospective (forward-looking) study to begin to understand the disease. This group published a series of peer-reviewed papers intended to create a global medical dialog on how best to approach the pandemic. These papers looked at mortality according to levels of respiratory care needed, the protective effect of chronic use of ace inhibitors, and the observation of thrombosis, and they developed a risk score. This scoring system was previously created to risk-stratify patients with atrial fibrillation and thrombosis. This scoring system, CHA<sub>2</sub>DS<sub>2</sub>-VASc, provided important early risk prediction information for COVID-19, demonstrating that the disease-creating mechanism was reasonably well understood based on knowledge about thrombosis. Importantly, this data clearly showed opportunities for individualized early treatment rather than waiting for the illness to progress and applying an ineffective "one size fits all" approach.

The first published treatment algorithm for early ambulatory COVID-19 was submitted early in the summer of 2020, just six months into the pandemic. It was accepted in the American Journal of Medicine with a publication date of August 7th, 2020. Dr. McCullough was one of many authors of this published report. It was based on known anti-infective agents that, based on pre-clinical and clinical studies, had demonstrable successes at reducing viral replication and had acceptable safety profiles. The drugs included in the report, although not approved for COVID-19, could be used off-label clinically and had a history of successful use against viruses.

Viruses replicate and cause disease by different and often overlapping mechanisms. Additionally, not all drugs have just one mode of action. For example, popular cholesterol-lowering drugs modulate human physiology in at least three ways. Antibiotics are known to treat a range of infectious species. The same is valid for anti-viral agents. Viruses are classified as obligate intracellular pathogens and cannot replicate without the machinery and metabolism of a living cell. The replicative life cycle of viruses differs between species and categories of viruses. However, six typical stages are essential for viral replication: attachment, penetration, uncoating, replication, assembly, and virion release. Thus, any drug that has a generalized action against any of these pathways has a chance to slow or stop viral replication and the resulting disease caused by a tremendous untreated viral burden.

Other groups were studying medication for prophylaxis to be given to prevent the initial clinical infection. Dr. McCullough's team focused on acute treatment in early symptomatic individuals. The average patient, they learned, was typically sick from COVID-19 for about two weeks before symptoms became critical, leading to hospitalization. Thus, there was a two-week opportunity to do something to help these patients and prevent hospitalization. This, of course, is a superior option compared to doing nothing, which was and continues to be the global narrative on treatment. Early treatment was most important for older

individuals and seniors with medical problems. Initial data from Washington State and New York nursing homes indicated that older people, especially those with comorbidities, were dying at very high rates compared to young, healthy people, as was the case in Italy.

Widespread fear propagated by officials and media created high anxiety, which contributed to poor outcomes. The emerging guidelines did not advise home or outpatient treatment, which left people wondering what to do. Most people just waited at home until many either became sufficiently ill to be admitted to a hospital or died. In addition, there was a general public misconception about off-label drug use, which is imperative during a sudden, rapidly spreading, severe disease. Off-label drugs are immediately available, as opposed to new medicines in development for COVID-19 that could take years to be approved. How many unnecessary deaths occurred because people were not afforded access to safe, proven drugs for early treatment?

Off-label drug use is common and well-known among physicians and is allowed under medical laws. The Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938 gave the Food and Drug Administration (FDA) the authority to regulate drug promotion by pharmaceutical companies. FDA regulations have attempted to balance giving physicians the freedom to use their best clinical judgment and preventing drug manufacturers from inappropriately influencing prescribing practices. Therefore, according to FDA regulations, physicians may prescribe drugs for off-label use, but drug manufacturers may not promote such benefits. The FDA and the Federal Trade Commission (FTC) share responsibility for regulating drug medical device advertising. The FTC substantially defers to FDA regulatory practices, especially when therapeutic claims are involved.

What does all this government speech mean? Since 1938, doctors have possessed the coding right to prescribe a drug beyond its originally intended and approved use. Doctors take advantage of this provision and prescribe off-label drugs at a rate constituting 20 percent of all prescriptions in the United States. Drug manufacturers cannot directly promote off-label use, but they can provide information on its use when they intend to obtain a supplemental new drug application. They are inclined to do this if the market for this further use meets potential financial objectives. It seldom happens with generic drugs for profit reasons but does occur for "on-patent" higher-priced drugs.

Common examples of off-label drug use involve the treatment of cancer and heart failure. These are high-risk indications, and the body of evidence supports drugs not officially intended for these uses. According to the American Cancer Society, cancer treatment often involves using certain chemotherapy drugs off-label because a chemotherapy drug approved for one type of cancer may actually target many different types of tumors. SARS-CoV-2 is a virus, and many approved medications for treating various viruses are available and widely used. Off-label

use of a drug or combination of drugs often is included in the standard of care. Beta-blockers are another example of beneficial off-label prescribing. Such medications are FDA-approved for treating high blood pressure but are widely recognized by cardiologists as a standard of care for patients with heart failure. Some beta-blockers are now formally approved to treat heart failure. It is common for off-label uses to get approved by the FDA eventually.

Why did this not happen for the SARS-CoV-2 virus?

According to G. Caleb Alexander, MD, MS, medical ethics advocate and assistant professor of medicine at the University of Chicago Medical Center, "Off-label use is so common that virtually every drug is used off-label in some circumstances." He also states, "Name the drug, and one can come up with off-label uses." He did not note that if the drug works for COVID-19 and it may interfere with emergency use authorization status leading to the development of a vaccine, it is not allowed to be used. The declaration of an emergency use authorization became a critical move by governmental health officials to launch the development of vaccines outside of the usual safety and efficacy requirements.

As Dr. McCullough reflected on COVID-19, he realized that, like any disease, one size does not fit all. The data he was analyzing showed the following trends that could be leveraged to create an intelligent response to the crisis that was not being discussed by authorities:

- Young and healthy people were quite resilient toward the disease.
- Home and outpatient treatment being used by brave doctors bucking the narrative during the early phases of the disease were demonstrating positive outcomes with desirable safety.
- Hospitalization was required for those without access to early care or otherwise who were highly vulnerable to the disease and thus was a necessary component of treatment. Or at least this was the belief early on.
- Vaccines and vaccinations had a place in the overall therapeutic scheme for the disease. Still, many did not have a need, including the young and healthy and those with natural immunity.

Dr. McCullough developed the "Four Pillars" approach for properly treating COVID-19 sufferers based on emerging objective, peer-reviewed published data, and his clinical experience, Figure 8.4. For COVID-19, the Four Pillars approach includes treatments that have some specificity. However, each pillar generally applies to managing any grave disease and past, present, or future pandemics.



Figure 8.4: The Four Pillars of Health for pandemics or any severe infectious disease.

The Four Pillars evolved from the desire to care for people in the two-week timeframe leading to potential hospitalization. This was a vitally important approach missing because the reports from hospitals, initially in New York, showed mortality was high for those entering the hospital using what was allowed and recommended, specifically ventilators and drugs approved by the FDA, including Remdesivir.

The Four Pillars are:

- Pillar 1: Control contagion;
- Pillar 2: Early home and out-patient treatments;
- Pillar 3: In-hospital treatment;
- Pillar 4: Vaccination or other forms of immunity enhancement.

Dr. McCullough posited that vaccination would be of the traditional type used for infectious disease and not some experiment form with no history of safety and efficacy. We now know that the vaccine we got caused more deaths compared to NOT using the vaccine.<sup>378</sup>

### **Pillar 1: Control contagion**

SARS-CoV-2 is a contagious virus, and methods like wearing protection, socially distancing, and quarantine at home can be impactful if appropriately implemented. Importantly, this method is most important for very virulent infections like Ebola. SARA-CoV-2 is NOT such a virus. Though, it became evident that it did not snuff out the infection because of the virus's contagiousness and how long the pandemic had been going on. With such a massive public health

effort on contagion control, other approaches were ignored or shot down but were arguably of critical importance.

### **Pillar 2: Early home and out-patient treatment**

This is the key pillar of the McCullough protocol. The goal of early treatment is to reduce the rates of hospitalization and death in that two-week window. This is accomplished by lessening the intensity and severity of symptoms. It involves the use of a combination of off-label drugs to treat respiratory disease, clotting, and vascular complications. It also includes supplemental support of the immune response.

Pillar 2 is absolutely critical to saving lives because the virus and all infectious species have the potential to replicate exponentially. Time matters. In the early stages, people often have mild symptoms such as nasal congestion, injected conjunctiva, mild fever, sore throat, loss of taste and smell, and mild shortness of breath that is typically not prominent early on. They have a general viral malaise that would be typical during the first three days and mimics the common cold. But, by day five, pulmonary symptoms might set in in some people, who then are likely to have more severe manifestations. These symptoms are not unusual when compared to other respiratory infections and present as a cough and malaise. SARS-CoV-2 also presented with unusual stress on oxygenation, that is, to get a satisfactory breath. However, this symptom did NOT discount the potential proven value in early treatment. In fact, it made this treatment a necessity.

### **Pillar 3: In-hospital treatments**

The very sick require hospitalization, assuming that protocols used in hospitals are effective. We are well into the 21<sup>st</sup> century, and we have great technologies and treatments at our disposal. Unfortunately, there has been a great deal of confusion and disagreement on almost all the in-hospital treatments, including Remdesivir, convalescent plasma, various forms of antibodies, and when and how to initiate mechanical ventilation. In-hospital mortality rates during the height of the pandemic remained high at about five to seven percent in United States hospitals. In those who required oxygen at the highest level of respiratory care had a mortality rate of 12 percent or higher, and those who needed mechanical ventilation experienced a 25 percent mortality, at least. Unmistakably the interventions used in the hospitals were not working.

The United States has had hundreds of thousands of deaths due to COVID-19, and the rate of dying on a per-person basis is among the highest in the developed world, which is more United States citizens lost than from any or all wars in history. The hospital is obviously not an adequate safety net. With this data in hand, it is irresponsible and immoral to forego additional medical interventions inside and outside of the hospital, as provided by Pillar 2. As with any disease,

early treatment is always the most effective, thus treatment before hospitalization is crucial.

### **Pillar 4: Vaccination and Immunity Enhancement**

Vaccination or herd immunity has the potential to close out the infection whereby everybody becomes sufficiently immune that if someone has the infection, they cannot give it to somebody else regardless of contagion or shedding. This stops the spread. Historically, few pandemics of the respiratory type have extended more than two to three years through herd immunity prior to vaccination technology. But vaccination plays a role, especially when targeted toward the most vulnerable. A few vaccines, introduced early in our medical history, have proven effective, but more recent ones have not provided the same value.

With all the efforts on contagion control, hospital treatment, and vaccines, the narrative about comorbidities, prolific in the pre-vaccine period of COVID-19, was silenced. Essentially no one was talking about or implementing early home treatment and early ambulatory treatment. Not only were there no discussions or policies other than those that impeded early treatment, but not a single government-initiated conclusive randomized trial has also been conducted in these areas, and that includes governments worldwide. Billions of dollars were spent on testing, but testing is not treatment. With all the resources available to the governments, at least one could have funded a convincing prospective randomized clinical trial on outpatient treatment protocols or one on comorbidities and what increases resilience against the infection. Why?

Clinical trials, even gold-standard ones, are not always adequate because they seldom represent the broader population, but they are still essential to moving medicine forward. Clinical trials most often focus on one drug. However, the medical community – doctors, in particular, know that single agents do not provide full benefits for serious viral infections. Multiple medications are usually needed in acute viral infections. For example, HIV is best treated with a cocktail of up to five drugs. Herpes Zoster, the chicken pox virus that can reactivate as Shingles, requires the use of valacyclovir and prednisone early on. Thus, viruses are never treated effectively with a single agent. Randomized trials, the gold standard for what patients receive in the standard of care that involves testing one drug, is not the right approach. Governments basically gave up on trials early in the pandemic without any clear rationale.

We became stuck with reactive, relatively ineffective hospital treatments and the vaccine, in rapid development, as the only "so-called" evidence-based approach being considered. This is sadly consistent with the delivery of "sick care" medicine we all endure in this modern era. The medical community, pre-pandemic, was already highly reticent to go outside the standard of care for liability reasons. Medical liability is a considerable risk for physicians. A single black mark can ruin a career that requires 20+ years of schooling and hundreds of

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thousands of dollars of medical school investment. Medical societies and the standard of care are purportedly there to protect doctors. But what about the patient? For example, suppose a doctor sees a patient who just acquired labs, and the labs are normal. In that case, even if the patient dies just after leaving the clinical visit, the risk of liability to the doctor is diminished. This is one explanation as to why standard-of-care lab ranges are often utterly inadequate at measuring your health.

"What about the patient?"

Dr. Peter McCullough

My teacher,<sup>7</sup> Dr. Clement L. Trempe, a Harvard ophthalmologist, never encumbered his patients just with the standard of care. The clinical director at his last place of employment reviewed Dr. Trempe's chart to prove what he already knew. That is, Dr. Trempe was achieving admirable outcomes not seen by other doctors in that profession. However, the clinical director told me he was reticent to refer patients to Dr. Trempe because he did not practice the standard of care. Thus, there was a liability risk to himself and the clinic if something went wrong with a patient or if a patient decided to file a complaint, even if unfounded. This attitude is pervasive and discourages doctors from going beyond the limited bounds of the standard of care. It simply means medicine does NOT evolve from within. It also means the only treatments available to doctors; thus, patients come from authorities that seldom, if ever, experience or solve "real world" medical challenges. Medicine, under these circumstances, de-evolves rather than evolves.

Substantially increased pressures arose to control what doctors did during the pandemic. Hospital administrators and governmental officials, who usually are not involved in the clinical delivery process, began dictating what a doctor could or could not do, regardless of what their medical license allowed. The ramifications were profound as doctors were fired, lost their licenses, or became blacklisted, and not just became subject to a liability suit. In other words, they could forfeit their career if they veered from the universal narrative regardless of their clinical observations and judgment. Those doctors who chose to take on the Pillar 2 initiative were in the unfortunate position of risking their careers while filling a vital treatment gap that unquestionably saved lives.

COVID-19 is not like a heart attack that often comes on without any or little warning. Yet, at no time during the pandemic did any medical organizations, regulatory or governmental bodies promote the principle of early treatment to reduce the intensity and severity of a disease. This is despite recognizing that COVID-19 is a fatal infection. When they look back on this behavior, historians will view this inaction and wonder why there was such a dramatic shift in policy. After all, community-acquired pneumonia includes pre-hospitalization treatment

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<sup>7</sup> The definition of "doctor" in Latin is "teacher."

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with antibiotic administration, as are urinary tract infections or staphylococcal infections, yet not those infected with the SARS-CoV-2 virus got nothing of this sort. This lack of action permeated through infectious disease guidelines of the National Institutes of Health (NIH), the FDA, and the World Health Organization (WHO) regarding this specific illness.

The concerted global effort against early treatment strongly indicates that the pandemic actually was a PLANDEMIC.

All the early treatment trials were stopped early. The NIH started an introductory trial in May and June of 2020, a prospective randomized trial on 2000 patients, and they aborted it after 20 cases. The WHO did the same thing. Some trials in the United States were not fast-tracked, as should be the case in a crisis. This was done to ensure any data, and the introduction of the jab preceded subsequent recommendations.

Favipiravir, an anti-viral, is one of the drugs in a study. Colchicine, which brave clinicians reported was providing unquestionable help, was studied at the Montreal Heart Institute but was also on a slow track. This was no urgency attached to these trials. These COVID-19 trials were on a two to four-year schedule, and there was no behavior consistent with being in the middle of an emergency. If significant resources were dedicated to an outpatient sequence multi-drug approach, evidence for adding pillar 2 to patient protocols would have been available before the jab.

Countries other than the United States implemented some level of Pillar 2, but they were the exception, and this approach did not spread globally. Canada, the UK, some countries in South America, and Australia installed absolutely no early treatments. In the United States, a minority of doctors instituted treatment based on doctors' judgment but without support from the broader medical community. In 30 countries, doctors were distributing sequence multi-drug kits, including hydroxychloroquine, ivermectin, antibiotics, and steroids. Japan used Favipiravir, which was fully approved for influenza but worked on the same RNA-dependent polymerase that is the target of Remdesivir, without the gross toxicity.

Japan, Russia, Bangladesh, Greece, and India all used drugs not even considered for use in the United States except by the rare, brave doctor willing to go against the system. Many drugs used routinely overseas were and still are, for the most part, prohibited for COVID-19 in the United States yet have proven track records for safety. The Hippocratic Oath includes helping patients while doing no harm, and these substances meet that criterion. Yet safe substances like n-acetyl cysteine and ivermectin became banned in the United States. In a truly unprecedented move, a pharmacist routinely overruled a doctor's prescription by not filling the order for these beneficial drugs in the U.S. This is an incredible, unethical, and illegal activity for which there have been no consequences. They followed orders issued by those normally prosecuting this unlawful action.

The immediate pandemic response for acute care of the ill, an urgent and potentially fatal problem, could not have been more different globally, at least initially. Anytime there is variation in practice, it is always something to investigate because it implies policy differences, not necessarily the science of care. Variation in approaches presents an opportunity to learn, study outcomes, and make adjustments to any current tactic to move towards the implementation of best practices globally. This is what we all (hopefully) do in our lives – engage in the process of continuous improvement. This concept, introduced in post-world war to Japan by W. Edwards Deming,<sup>379</sup> became the standard methodology for all businesses and industries, leading to substantial process advancements.

Why did this not happen in medicine during the pandemic?

### **SARS-CoV-2 mode of action**

ACE inhibitors are somewhat protective against SARS-CoV-2. This virus is an RNA virus that enters the upper respiratory tract cells through the ACE-2 receptor. It is markedly upregulated chronically by ACE inhibitors which is one of the reasons why ACE inhibitors offer a protective response. Once the virus gains access to the body, it invades all the different lines of white blood cells, the liver, the heart, and the kidneys. It has been found in urine, stool, and the myocardium, which is clearly a systemic infection impacting multiple organs and tissues.

A virus signature is an immune dysregulation characterized by a depressed white blood cell count, with absolute lymphocyte values being the most suppressed. Initially, high concentrations of inflammatory markers are the hallmark of the disease sequelae. C reactive protein (CRP) elevates 10 to over 100 times the baseline values. Fibrinogen, a signal molecule for tissue repair, goes up markedly, as does ferritin, an iron storage molecule. Concomitantly, free iron levels go down, giving the classic profile referred to as anemia of chronic inflammation, also called anemia of chronic disease or ACD. It is a type of anemia that affects people with conditions that cause inflammation, such as infections, autoimmune diseases, cancer, and chronic kidney disease (CKD). Viruses depend on iron to replicate efficiently within living host cells. In response to an infection, including a virus, our bodies shuttle iron away from pathogens and into the iron storage molecule, ferritin, as a protective measure.

Endothelial damage occurs as revealed by the elevated CRP, fibrinogen, and other cytokines. In severe disease, a cytokine storm trips off the coagulation system. The Italians first described micro-thrombosis (clotting) in COVID-19, explaining why the chest X-ray pattern showed characteristic covert pneumonia. This observation was incongruent with typical desaturation points to micro thrombosis in the lungs. Elevated d-dimer is now recognized as a biomarker signature for this micro clotting process in COVID. Since then, there have been multiple cases of very large thrombi throughout the body. This is one of the critical reasons for

severe symptoms, including fever, weakness, shortness of breath, and low oxygen saturation. Some viruses cause hemolysis (rupturing of red blood cells), but this virus causes thrombosis that is somewhat unique to this virus. This is arguably the most feared clinical complication of this virus. In cases of fatalities, thrombosis has played a role in most of them by creating massive organ damage.

The COVID-19-induced thrombosis likely exacerbates pre-existing conditions. That is why people with cardiovascular disease, cancers, diabetes, and other chronic conditions fair so poorly compared to healthy individuals. In one of his recent papers, Dr. McCullough discussed clinical cases of acute myocardial infarction treated with stenting where the rates of acute thrombosis are typically less than one percent.<sup>380</sup> In that analysis of patients with this syndrome and COVID-19, the rate of stent thrombosis in COVID-19 patients was 20-fold higher than typical. It is stunning, but not unexpected, how this thrombotic component worsens many conditions significantly. That is why Pillar 2 is so important. Patients cannot afford the risk of waiting two or three weeks and then developing severe thrombosis with the myriad of complications it drives. It is so much easier to prevent than to treat thrombosis. Therefore, the treatment principles must include reducing viral replication as early as possible and addressing the cytokine storm and thrombosis.

### **Seniors denied needed care**

Pillar 2 treatment protocols that Dr. McCullough developed are risk-based. People under the age of 50 with no apparent medical problems, who have been exposed to the virus, yet express no severe symptoms, need not have the pharmaceutical treatment applied in most cases. They may supplement with zinc, quercetin, vitamin D, and other substances known to be safe and anti-viral. This population is a large segment of the population. Concerns grow exponentially over the age of 50, especially in those with pre-existing conditions. Mortality for this group is in the range of 2-3 percent, which is higher than for the flu in the same age range. Someone of a similar risk profile but age 80 or older could be in a 40-50 percent mortality zone. Again, this is higher than flu mortality rates in the age category. The mathematical relationship between mortality and age is very well understood. The older the person, the higher the mortality risk. Thus, applying the same treatment principles to younger people, the jab, in particular, is nonsensical.

Considering the high mortality in the older population, it is astonishing the advice this age group receives when they test positive and have symptoms of COVID-19. They are just sent home to isolate with no treatment advice other than to go to the hospital if it gets worse. This is the policy advice from the lowest to the highest level of healthcare. Not only do they not receive any advice, but there was also no clear resource center available, for example, no hotline to call to get help or to become enrolled in research studies. They just went home and tried to figure out

what their next steps were, often with little or no support, and, in many cases, their condition worsened. This is not a justifiable medical practice.

The American Association of Physicians and Surgeons (AAPS) and the Front-Line Critical Care Alliance (FLCCC) were among the very few that took a proactive approach. They published very useful resources for patients with positive COVID tests and symptoms or those wanting to become more resilient to the virus. Our government health officials provided no such guidance other than masks, social distancing, and quarantining if infected. These non-governmental groups provided actions to be taken based on evidence of what could be done reasonably, in the home or at outpatient centers. These doctors provided much-needed hope in what became a crisis of emotions as much as illness. These suggestions showed promise and adequate safety based on publications and personal stories available on non-censored channels. If these measures saved one life and caused little to no harm, they fulfilled the Hippocratic Oath, and this is what doctors have sworn to do.

### **Nutrients as a COVID treatment**

Supplements that are the introduction of supplemental micronutrients have a long history of providing benefits against infectious diseases. In the 1840s, for example, high doses of cod liver oil were used as a treatment for “consumption,” which is a late-stage Tuberculosis lung infection. High-dose treatments reduced mortality in hospitalized patients by 6 percent on an absolute basis.<sup>381,382</sup> Compare that to Statin drugs that, on an absolute basis, reduce cardiovascular mortality in high-risk males by <1 percent and do not reduce total mortality overall. The mortality benefit of these ubiquitously prescribed drugs is zero, yet they are prescribed and recommended for a large percentage of patients based on an erroneous interpretation of lipid biomarker values.

The absolute value of statin drugs is meager, and this statement is probably surprising to many who have been told by their doctor that statins will protect their hearts. Dwelling on this point is important because many supplements may provide meager but important improvements in outcomes. T. Grant Phillips, MD, wrote an editorial in the *American Family Physician Journal* explaining the true benefit of statins drugs using absolute statistics. The article is titled, “Looking at the Benefits of Statins from a Different Perspective.”<sup>383</sup> Dr. Phillips wrote:

“Dr. Crawford-Faucher reviewed the meta-analysis by Brugts and colleagues that concluded that statins are beneficial for the primary prevention of cardiac disease. I agree with this conclusion, but with some reservations. The review stated that the relative risk reduction for all-cause mortality was 12 percent, which sounds very good; however, I think it is important to look at the absolute risk reduction. All-cause mortality after a mean follow-up of 4.1 years was 5.1 percent in the group treated with statins and 5.7 percent in the control group. That translates into an absolute risk

reduction of 0.6 percent and a number needed to treat (NNT) of 167. This means that 167 patients would need to be treated with a statin for 4.1 years to prevent one death. Additionally, based on the study data, the NNT to prevent one major coronary event is 77, and the NNT to prevent one major cerebrovascular event is 250.”

All medical benefits should be published based on absolute statistics and numbers to treat. Relative statistics are meaningless to your health.

Over-the-counter vitamins and mineral nutrients are part of in-home treatment protocols included in Pillar 2. The ample evidence behind natural substances that are in supplements supports their use. Both randomized and prospective trials confirm their benefits. Historic use of these types of substances, predating pharmaceuticals for thousands of years, corroborates their benefit. The main defense our bodies mount through innate immunity is against infection. Anything that boosts cellular health is a candidate treatment against infection, including SARS-CoV-2.

The reason there are few studies on natural substances compared to pharmaceuticals is money. United States patent law does not allow a patent to be issued for a natural substance. Most pharmaceutical profits are realized during the 20-year window of patent protection afforded synthetic drugs. Evidence-building trials are extraordinarily expensive and time-consuming regardless of the nature of the substance being investigated, natural or synthetic. Thus, what entity is willing to invest millions or even billions of dollars in building an evidence-based safety and efficacy portfolio for vitamin D? Not one penny of that expenditure would be recoverable by the trial sponsor because vitamin D may be sourced through any entity not just from the trial sponsor.

Clinical trials cost a median of \$41,117 per patient and \$3,562 per patient visit. A 6000-person trial, as was done in one instance for a COVID-19 vaccine, cost one-quarter of a billion dollars. The standard of care only adopts substances that go through the rigor of the so-called “gold standard” randomized clinical trial process. Thus, the system is financially rigged against natural substances. The standard of care system will not adopt the use of these substances because of a “lack of evidence” regardless of how much is known about their efficacy. If they are not proven through the “gold standard,” they are disparaged as lacking evidence.

Certain supplements are proven to exhibit efficacy against coronaviruses and have minimal to no toxicity when taken at the recommended dosages.

- Zinc sulfate used against other coronaviruses reduces the duration of symptoms, proven even in randomized trials. Zinc plays a beneficial pathophysiologic role once it is intracellular by inhibiting viral replication.

It is believed to be synergistic with hydroxychloroquine and the natural substance quercetin that is found in apples, onions, and other foods.

- Vitamin D is another supplement backed by significant evidence. Vitamin D is not a vitamin. It is a pro-hormone which means it is a precursor to a hormone or hormones. Hormones are physiological regulators. Epidemiologic data shows that patients who are vitamin D deficient have much higher rates of hospitalization and death from COVID. A randomized trial from Israel unequivocally demonstrated reduced mortality from vitamin D supplementation versus placebo. The trial was small because trial participant recruitment and participation are costly. However, Israel became the most "vaccinated" of all the countries on the planet. Governmental officials did not trust their own scientists.
- Vitamin C is known to reduce the length and severity of colds. A type of coronavirus is present in at least 20 percent of common cold cases. The Linus Pauling Institute is a valuable resource for compiling objective literature on certain nutrients. An excerpt from its website on vitamin C data is included here. Note that the dose of vitamin C in the studies cited was between 0.25 and 2g/day. The recommendations for vitamin C to prevent viral infections varies but are generally higher compared to the levels used in most studies, including those used by the Linus Pauling Institute to draw conclusions about the value of this substance.

“The work of Linus Pauling stimulated public interest in the use of doses greater than 1 g/day of vitamin C to prevent the common cold. In the past 40 years, numerous placebo-controlled trials have examined the effect of vitamin C supplementation on the prevention and treatment of colds. A 2013 meta-analysis of 53 placebo-controlled trials evaluated the effect of vitamin C supplementation on the incidence, duration, or severity of the common cold when taken as a continuous daily supplement (43 trials) or as therapy upon the onset of cold symptoms (10 trials). Regarding the incidence of colds, a difference was observed between the two groups of participants. Regular supplementation with vitamin C (0.25 to 2 g/day) did not reduce the incidence of colds in the general population (23 trials); however, in participants undergoing heavy physical stress (e.g., marathon runners, skiers, or soldiers in subarctic conditions), vitamin C supplementation halved the incidence of colds (5 trials).

A benefit of regular vitamin C supplementation was also seen in the duration of colds, with a greater benefit in children than in adults. The pooled effect of vitamin C supplementation was a 14 percent reduction in cold duration in children and an 8 percent reduction in adults. Finally, no significant effect of vitamin C supplementation (1-8 g/day) was observed in therapeutic trials in which vitamin C was administered after cold symptoms occurred.”

Three (3) key takeaways from these findings are:

1. Even low doses of vitamin C have some benefits against the various pathogens that manifest in the common cold, including coronaviruses.
2. Vitamin C is not a treatment, rather it is a preventative agent and must be taken prior to infection to be effective or at least early into the disease (Pillar 2).
3. The results may seem meager but are presented as absolute values, not the deceptive relative statistics used to justify most pharmaceuticals. In the case of a deadly infectious disease, no one therapy may be adequate to save lives. Therefore, any substances with an admirable safety profile and evidence-based benefits must be considered as part of a treatment protocol.

Quercetin is a beneficial substance, as reported in the *Journal of Agriculture and Food Chemistry*.<sup>384</sup> It is a water-insoluble flavonoid present in onions, nuts, apples, and many other vegetables. The health benefits of flavonoids have historically been ascribed to their antioxidant activity, which they exert directly by scavenging reactive oxygen species, some of which are produced during infection by the action of our immune system. According to a study by O'Sullivan cited above, "quercetin rapidly increases intracellular labile (active) zinc and is an ionophore for zinc. Thus, natural flavonoids can be added to an arsenal of substances that may be used to modulate zinc homeostasis and regulate zinc-dependent biological pathways, including intracellular destruction of viruses."

Many other supplements have proven efficacy against viruses and bacteria. Thus, they are candidates for COVID-19 prevention and treatment. Supplemental vitamins and minerals do play a role in Pillar 2. They fall in the category of helpful but certainly not harmful against viruses supported by evidence-based data. These substances are not curative in any way but contribute, in important ways, to improve basic immune response or directly work against viruses. That is enough to include them in Pillar 2, considering the path of no treatment too many people wound up following.

In COVID-19, as with any viral or infectious disease and chronic diseases, outcomes become worse with age. In COVID-19, in particular, there is a marked increase in hospitalization and death starting with people aged 50 or older. The Pillar 2 treatment guidance for this age group, especially for those with developing symptoms, is to start a combination treatment of anti-infectives. These drugs serve three (3) purposes, as demonstrated in pre-clinical and clinical studies. They reduce viral replication, inhibit the duration of viral shedding and improve the clinical outcomes of hospitalization and death. These drugs include hydroxychloroquine (HCQ) and ivermectin, preferably used in combination with azithromycin or doxycycline. Hydroxychloroquine is not specific to COVID-19, and the key experience with this drug is as an anti-malarial agent. It impairs the

endosomal (part of the endocytic membrane transport pathway) transfer of the virus and is also anti-inflammatory.

Hundreds of peer-reviewed published studies, both randomized trials and observational studies, when aggregated, indicate a 64 percent risk reduction for death and hospitalization when the administration of HCQ is started early in an outpatient setting. The calculated odds that HCQ does not work are 1 in 17 billion, as the number of studies is adequately great to statistically substantiate this conclusion. Detractors say that only randomized trials with a single drug should be counted. However, a meta-analysis of randomized trials published in the *British Medical Journal* with just hydroxychloroquine alone is associated with a 24 percent relative risk reduction for new COVID-19 infection when used prophylactically or to prevent death and hospitalization.<sup>385</sup> Thus, hydroxychloroquine has clear clinical benefit in this indication, and there is absolutely no reason not to include it in Pillar 2.

Early reports on antibiotic treatment, especially azithromycin, showed apparent benefit as a COVID-19 treatment. Why would bacterial antibiotics afford this effect? Azithromycin and doxycycline have a mild intracellular effect in impairing viral replication. However, those at the highest risk, those over 50, and those with co-morbidities frequently have superimposed bacterial infections that these drugs treat. When attacking a severe infection like COVID-19, a multi-factorial approach is necessary. For example, it is well known that just treating the virus is often inadequate as the developing cytokine storm must also be addressed to reduce mortality and hospitalization. Peer-reviewed studies, looking beyond the virus for co-infections, show an overlap with organisms such as mycoplasma and chlamydia pneumoniae at a level of at least 2-3 percent. However, these numbers are probably low estimates because these organisms are not usually part of diagnostic testing protocols.

Chlamydial and mycoplasma infections are common but not recognized as such because few doctors understand or test for these chronic infectious species. *Chlamydia pneumoniae* (CP) is among the most common etiologic agents of community-acquired pneumonia, with an incidence ranging from 6 percent to 25 percent, again a likely underestimate based on testing frequency. More than 60 percent of subjects with chronic bronchitis have specific CP antibody titers.<sup>386</sup> More than 60 percent of the adult population worldwide was infected at least once with CP.<sup>387</sup> Importantly, in immune-compromised individuals, CP infection is strongly associated with coronary artery disease and atherosclerosis of the carotid artery, aorta, and peripheral arteries. Since COVID-19 attacks the vascular system, it is reasonable to assume that co-infection with CP may worsen vascular outcomes, including thrombosis. These stealth and cryptic co-infections may explain why the vaccine, which contains the spike protein of the virus, frequently leads to the heightening of pre-existing vascular conditions.<sup>388</sup>

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*Chlamydia pneumoniae* and other obligate intracellular pathogens, including Lyme disease and periodontal infections, can impact many systems manifesting in a variety of diseases. Dr. David Wheldon, a retired physician from England, intensely studied CP after his wife contracted Multiple Sclerosis and tested positive for the pathogen. The testing showed she was positive for the chronic phase of the infection using IgG, not IgM antibodies. IgG is widely regarded as an indication of a historic infection, not a current one. However, she improved remarkably on a long-term antibiotic and anti-inflammatory regiment. Dr. Wheldon reported many diseases and syndromes that were associated with *chlamydia pneumoniae* elevated IgG titers during his 45-year clinical career, including:

- Cardiac conduction defects,
- Effusive pericarditis with tamponade,
- Chronic obstructive airways disease,
- Multiple Sclerosis,
- Chronic fatigue syndrome,
- Encephalitis,
- Retinal vasculitis,
- Macular degeneration,
- Progressive presbyopia,
- Crohn's disease,
- New onset adult asthma, and
- Schizophrenia (hebephrenia).

According to Dr. Wheldon, “this is a brief and incomplete list based on my clinical observations.”

Besides hydroxychloroquine and the antibiotic options, the next anti-infective option is ivermectin. With an impressive safety profile, this drug is a broad-based antiparasitic delivered at a dose of 200 mcg per kg. This translates to about 12 mg as a single dose for a 132-lb person. The dosing rule of thumb is to divide your body weight, in pounds, by 11. The number you get is the dose in milligrams. A growing number of observational studies and randomized trials supports ivermectin. Dosing is not standardized for preventative and home care. The recommendations for prophylaxis vary from one dose every other day for six days – or one to three doses per week indefinitely, as long as the threat of infection exists.

Home treatment recommendations for ivermectin are generally a daily dose as long as symptoms persist. One organization recommended doubling the dose if symptoms are severe, oxygen saturation levels are declining, and fever persists. These recommendations will change based on new data and new coronavirus variants. Since the safety profile of ivermectin is so favorable, continued administration for weeks after symptoms abate is advisable. Abatement of

symptoms does not infer complete elimination of the virus and the spike protein component. Therefore, it should be recognized that any treatment that disrupts the interaction between the disease and tissue should be continued as advised by a healthcare professional based on emerging evidence.

Favipiravir is used in 30 countries, including Japan and Russia. It is an oral RNA-dependent polymerase inhibitor with the same action mechanism as the toxic but approved drug, Remdesivir. When compared to Remdesivir, favipiravir has fewer and less severe side effects. The United States has been very slow at providing alternatives to Remdesivir, including Favipiravir. The first known treatment with this drug in the United States occurred in a major hospital for a patient who invoked the “right-to-try” law, where legally, a patient cannot be denied therapy.

Right-to-try laws are United States state and federal laws that were created to allow terminally ill patients access to experimental therapies (drugs, biologics, devices) that have completed Phase I testing but have not been approved by the Food and Drug Administration (FDA). Implementation of right-to-try law varies by state; not all provide this authorization.

Right-to-Try laws are in place in 41 states as of 2022, including Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

We now know that the SARS-CoV-2 virus has a long period of latency. Exposure to the virus is through the air, and it first adheres to mucosal membranes. The initial concentration of the virus on these surfaces is low. It then starts replicating and spreading throughout bodily systems. However, the concentration is presumed highest on the mucosa. At some point, as the virus multiplies, there are sufficient amounts to start causing symptoms. As with any toxin, the dose determines the effect. Initially, a person has no idea they have been infected. Most people may have mild cold-like symptoms that abate in a few days because of their robust immune systems and prophylactic measures to fight the potential viral invasion. But this often is not enough to prevent symptoms. After all, the virus was designed to create a pandemic.

Breathlessness is a strong indicator of the virus replicating efficiently and portends a cytokine storm. In published studies, it is associated with rampant inflammation, measurable with C reactive protein (CRP), fibrinogen activity, elevated ferritin, and interleukin-6 (IL-6). Interestingly a thrombotic marker, D-dimer, is ectopically high and is a measure of micro clotting or microthrombi leading to endothelial injury. The spike protein, common to the virus and the jab, is alleged to cause this clotting process. This cytokine storm phase can be treated with

steroids. Inflammation is the response of the body to the infection and is protective. However, as the infectious “fire” rages and spreads, the immune “water” poured on the fire may cause substantial damage. Thus, while initially protective, the cytokine storm of inflammation is known to contribute to accentuated symptoms and even death.<sup>389</sup>

Data from the UK “Recovery” trial generated helpful data from which clinicians learned about treatment.<sup>390</sup> An unusually low dose of dexamethasone, 6 mg, was used and demonstrated a statistically significant reduction in mortality of 23 percent. The overall mortality reported from this trial was still unacceptably high. Still, it provided evidence that steroids could move the mortality needle and should be included in a multi-drug clinical protocol for severe viral invasion.

A Brazil study showed that the common steroid prednisone, administered early and at a moderate dose, quelled the cytokine storm.<sup>391</sup> The dose reported was approximately one milligram per kilogram, translating to 40 mg for an average person, delivered for five days with or without a taper. That dose is commonly used clinically in inflammatory diseases like arthritis.

To manage the cytokine storm, colchicine provides an option, too. Colchicine inhibits microtubule formation in granulocytes (specific white blood cells). In the Montreal Heart Institute trial, also known as the COLCORONA trial, colchicine was delivered to homes.<sup>392</sup> It was a trial, not a therapeutic program because some people got colchicine while others got a placebo. The Montreal study results were presented on January 22, 2021. Their summary text is shown here:

“The Montreal Heart Institute (MHI) announced today that the COLCORONA clinical trial has provided clinically persuasive results of colchicine’s efficacy in treating COVID-19. The study results have shown that colchicine has reduced the risk of death or hospitalizations in patients with COVID-19 compared to a placebo. This result for the global study population of 4488 patients approached statistical significance.

The analysis of the 4159 patients in whom a nasopharyngeal PCR test proved the diagnosis of COVID-19 has shown that the use of colchicine was associated with statistically significant reductions in the risk of death or hospitalization compared to placebo. In these patients with a proven diagnosis of COVID-19, colchicine reduced hospitalizations by 25 percent, the need for mechanical ventilation by 50 percent, and deaths by 44 percent. This significant scientific discovery makes colchicine the world’s first oral drug that could be used to treat non-hospitalized patients with COVID-19.”

Despite these impressive results, colchicine saw limited application against COVID-19 in the United States.

Thrombosis and its treatment must be considered as symptoms of COVID-19 manifest and escalate. Thrombotic events are ubiquitous in those where

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symptoms worsen, and antithrombotic agents must be utilized in these cases. These agents lead to a massive 50 percent reduction in mortality, as reported in very large observational studies. Coincidentally, the randomized trials were not initiated promptly to generate evidence for incorporation into the standard of care. One might ask why there is a time constraint. Also, why is the standard of care not incorporating the best emerging information?

Clayton Christensen is famous for his book, *The Innovators Dilemma*.<sup>393</sup> He followed this work with an essay published in the *Harvard Business Review*, the title of which is:

"Will Disruptive Innovations Cure Health Care?"<sup>394</sup>

He explained how innovations will not cure healthcare as we are witnessing this today. The article was written in 2000. Eye-catching is the subtitle to the report, reproduced here:

"Health care may be the most entrenched, change-averse industry in the United States. The innovations that will eventually turn it around are ready, in some cases - but they cannot find backers."

No money - no research - no evidence!

The NIH started an anti-thrombosis trial with aspirin and rivaroxaban. However, any doctor observing their patients and reading the most basic literature knows that anticoagulation therapy must be applied in severe cases. When in doubt, any doctor can order inexpensive d-dimer and fibrinogen activity tests and make a clinical decision about the presence of thrombosis and its treatment based on the values obtained for these biomarkers. Nephrologists observed and reported that dialysis tubes were clogging in advanced patients, along with a high incidence of catastrophic strokes and stent thrombosis. Consequently, after too many unnecessary deaths, they applied very aggressive anticoagulation systems.

The thrombosis process and the two-week delay in treating the virus put doctors in a crisis mode, filled hospitals, and made for dramatic headlines, most of which could have been avoided. Thrombosis, from any cause, is a call to action that cannot wait for the completion of clinical trials to prove what doctors already know, as this process quickly becomes deadly. Typical chronic disease-style clinical trials do not have the emergency framework to respond to a rapidly spreading health crisis. Doctors, in emergency situations, are supposed to have the authority to act based on their knowledge and judgment, and that should never be rescinded.

Unprecedented is that many doctors who put together reasonable concepts guided by available clinical data and treatments had a fear of retribution. Hopefully, decision-makers will learn a lesson because this will not be the last pandemic. Let doctors be doctors. We must rely on clear-cut clinical experience to save human lives in these relatively rare circumstances. Regardless, no human should

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be made to wait while their symptoms rage out of control. Pillar 2 applies in any and all circumstances as a mandatory part of proper disease mitigation, especially in new diseases with high mortality rates. Tragically, not one impactful official pushed this approach early on, let alone mention it as an option. In many ways, it was crushed rather than promoted. This is hard to comprehend.

Fortunately, some doctors have organized into treatment networks providing 24-hour hotlines and made themselves unselfishly available, on their own and at their own risk. Desperate and informed patients, who comprised a silent minority and were silenced by censorship, have, and hopefully will continue to drive better care. Individuals going against recommendations were often chided and isolated by family, friends, and the medical community. Medical colleagues providing early treatment reported that not a single person with severe symptoms and heart and lung diseases was satisfied waiting at home and hoping the condition would abate. Who would not choose to take action, especially based on the undercurrent of information about home treatment?

Many people with progressing disease expressed piqued, but reasonable fear about entering a hospital because of documented high mortality once admitted and expressed particular fear of ventilators. And, once in the hospital, people were completely isolated. Imagine being extraordinarily sick and fatigued and having to make life-impacting decisions. You want family members and advocates by your bedside to help you make rational choices. However, once in the hospital, patients lost contact with loved ones and advisers who were completely banned from their bedside. Hospitalized persons were literally put into solitary confinement. In some instances, doctors were reported to be fearful of encountering hospitalized patients adding to their isolation, uncertainty, and fear. It is truly unconscionable to abandon our patients as has been done by the abject denial of any possible treatment outlined in Pillar 2.

"Hospitalized persons were literally put into solitary confinement."

- Dr. Peter McCullough

A home program for those with progressing COVID-19 or any new infectious disease, only used with oversight by a licensed physician, could look like this:

- Supplements. There are various sources for a list of anti-viral supplements provided by organizations, including the Institute for Functional Medicine and The World Council for Health.
- Off-label antivirals, ivermectin, and hydroxychloroquine may be used for a minimum duration of treatment of five days and a maximum of roughly 30 days. Long-haul COVID treatment may extend the use of these treatments significantly.
- Phase in steroids if needed.

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- Layer in anti-thrombotic treatment, including aspirin at 325 mg per day. This is supported by data that the virus markedly elevates thromboxane a<sub>2</sub> and overwhelms a small dose of 81 mg of aspirin.
- If necessary, low molecular weight heparin may be administered under careful monitoring.
- Oral anticoagulants may be applied, specifically apixaban, rivaroxaban, or dabigatran. Aggressive treatment of thrombosis, typically for about 30 days, can be lifesaving when d-dimer is highly elevated.

Another important component of Pillar 2 is barrier immunity. Addressing barrier immunity is critical and easily performed in the home. Mucosal surfaces are the first line of defense, capturing airborne toxins or pathogens. It is on these surfaces that a virus can adhere, multiply, and spread. Treatment at the earliest stages of adhesion is arguably the essential aspect of both prevention and treatment before a “smoldering” virus erupts into a volcano. Five key mucosal surfaces are amenable to early and continuous treatment: nasal passages, mouth, esophagus, GI tract, and lungs. Fortunately, effective treatments are available for all these surfaces.

- **Nasal cavity:** Spray and purging systems are proven safe and effective. Agents include: dilute peroxide, highly diluted bleach, dilute iodine solutions (betadine or povidone), colloidal silver, saline, and hypochlorous acid. These substances are effective against most viruses, bacteria, fungi, and other classes of pathogens. They can be used prophylactically, in case of exposure, or in the face of actual symptoms and progressing disease. The treatment of the nasal cavity and all mucosal areas is critically important during the disease process because this initial site of viral adhesion may be an ongoing source of the virus to the rest of the body.
- **Mouth:** Many types of mouthwash are available, including traditional over-the-counter washes. Many of the treatments for the nasal cavity are safe and effective as mouthwashes.
- **Esophagus:** We swallow up to 1.5 liters of saliva daily. Thus, the throat can harbor pathogens. Throat sprays containing a variety of anti-viral substances are available without a prescription.
- **Lungs:** The SARS-SoV-2 virus is known for its action on the lungs. Nebulizing anti-viral substances may contribute to reducing overall lung infection. Many functional doctors developed and published detailed protocols on nebulization, with Dr. David Brownstein being the most prominent.<sup>395</sup>
- **GI Track:** We are exposed to toxins and pathogens daily. Saliva is a key entry route into the body, and the saliva gathers and moves these substances. Our gut manufactures a strong acid called hydrochloric acid. In the developed world, using antibiotics, OTC antacids, certain drugs,

especially proton pump inhibitors, processed foods with low fiber content, and lack of exposure to nature often leads to a loss of microbiome diversity and acid production. A pathogen named helicobacter pylori (*H. pylori*) disrupts stomach acid by releasing an enzyme that converts urea to ammonia. Ammonia is a chemical base that neutralizes acid, in this case, stomach acid. Small intestinal bacterial overload (SIBO) is an overload of bacteria downstream from the stomach. It gets there readily in people with low stomach acid. Natural strong stomach acid kills most pathogens that enter the gut. SIBO helps us understand the importance of strong stomach acid as a line of defense against the entry and spread of pathogens in our body. Betaine hydrochloride and apple cider vinegar are treatments to improve gut acid. Stomach acid can also be enhanced through the proper use of probiotics, treatments for *H. pylori*, if present, digestive enzymes, and avoiding antacids and certain drugs.

The science behind treating mucosal membranes is strong. Barriers are well-recognized parts of immunity. Chowdhury et al.<sup>396</sup> explain the efficacy of treating the nasopharynx against COVID-19. The abstract from Chowdhury's paper titled "Virucidal effect of povidone-iodine on COVID-19 in the nasopharynx: an open-label randomized clinical trial" is provided here:

"Povidone-iodine (PVP-I) is a time-tested antiseptic agent with excellent virucidal (99.99 percent) properties. Repurposing it against coronavirus disease-19 (COVID-19) is a relatively newer concept and has been sparsely tested in vivo. The nasopharynx is the most common entry route for severe acute respiratory syndrome coronavirus 2 (SARS CoV-2). Averting colonization of the virus could be one of the best options to reduce the incidence of infection. PVP-I gargle and mouthwash were found to be effective in vitro rapid inactivation against SARS-CoV-2 on a smaller scale (Hassandarvish et al. in *BDJ* 1-4, 2020, Pelletier et al. in *ENTJ* 1-5, 2020). However, efficacy in humans is lacking. This parallel armed randomized clinical trial aimed to assess the virucidal effect of PVP-I against SARS-CoV-2 located in the nasopharynx".

"We screened all RT-PCR-confirmed COVID-19 cases aged 18 years and above with symptoms. Written informed consent was obtained before randomization. Nasopharyngeal clearance of SARS-CoV-2 was tested after single-time application of PVP-I nasal irrigation (NI) at diluted concentrations of .4%, .5%, and .6%, and PVP-I nasal spray (NS) at diluted concentrations of .5% and .6%. All groups were compared to the corresponding controls (distilled water). The primary outcome was viral clearance in a repeat RT-PCR (qualitative), and the secondary outcome was the number of adverse events. Final data analysis was performed using the statistical software SPSS (Version 20). A total of 189 confirmed COVID-

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19 cases were randomized into seven groups: 27 patients in each group. Of all, 159 (84.1%) were male, and 30 (15.9%) were female.

“We observed a statistically significant proportion of nasopharyngeal clearance with all strengths of PVP-I NI and PVP-I NS compared to the corresponding controls. Additionally, 0.5% NI was significantly better than 0.5% NS for viral clearance ( $p = 0.018$ ) and had the highest nasopharyngeal clearance among all strengths ( $n = 25, 92.6\%$ ). 0.6% NS is better than CNS and 0.5%NS in viral clearance. The only adverse event was nasal irritation recorded in two patients, each in the 0.4% and 0.6% PVP-I NI groups. PVP-I NI and NS are proven effective virucidal agents against SARS-CoV-2 in the human body. We recommend using PVP-I in the nasopharynx (as well as oropharynx) to prevent COVID-19.”

Povidone-iodine gargles, nasal sprays, and nebulized peroxide diluted with saline, with or without iodine, can be safely used by most people both for prevention and in cases of active infection, provided the substances are appropriately diluted. For instance, while nebulization with 0.1 percent to 3 percent food-grade hydrogen peroxide appears safe, it would be a serious hazard to use hydrogen peroxide of greater concentrations. Food-grade peroxide up to 35 percent concentration can be obtained but should never be used topically or internally. It **MUST** be diluted, or severe injury can occur. The best approach is to use 3 percent food-grade peroxide and dilute it as authorities indicate on this subject, for example, the FLCCC organization. Nasal/oral viricidal washes can be done twice a day prophylactically and up to every four hours during early treatment. The safety of these treatments is now reported by thousands or more who have applied these treatments at all stages of the viral invasion.

Most of the substances listed for barrier immunity are strong oxidants. That is how they destroy the virus and maybe even the spike protein. Indeed, too much oxidation may be harmful to tissue, but humans have mechanisms to repair this damage. We inhale roughly 20.9 percent oxygen with every breath. Oxygen is a strong oxidizer. However, we have repair mechanisms to compensate for this strongly oxidizing environment. We do **NOT** turn brittle like a piece of plastic left out in the sun and the air. The plastic does not have a repair system. White blood cells and antibodies also produce oxidizing reactive oxygen species. That is how they work to kill invaders. Some authorities may say these recommended treatments are not safe and effective; however, there are no reports of anyone dying because of these treatments when administered as recommended. Quite the opposite is true.

The Front Line COVID-19 Critical Care Working Group (FLCCC) also recommends povidone-iodine as part of its I-Mask+ protocol for prevention and early outpatient treatment of COVID-19. Part of that prevention protocol includes twice daily gargling with a 1 percent povidone/iodine solution. Iodine nasal spray

or drops are recommended as one of the first-line agents in its early treatment protocol. Specifically, they recommend:

“Use 1 percent povidone-iodine commercial product as per instructions 2–3 x daily. If 1 percent product is unavailable, dilute the more widely available 10 percent solution and apply 4–5 drops to each nostril every 4 hours. (No more than five days in pregnancy.)”<sup>397</sup>

Povidone-iodine solutions sold as topical skin disinfectants to treat cuts and wounds should not be used for gargling due to potentially harmful ingredients.

Iodine is a vital nutrient that supports thyroid function, among other important physiological pathways. In the United States, iodine deficiency disorders (IDD) such as goiter, cretinism, stillbirth, spontaneous abortion, and retarded physical and intellectual development have been virtually eliminated through the iodization of salt. Salt iodization, the mainstay of global Iodine deficiency disease prevention efforts, has never been mandated in the United States. Many consumers purchase non-iodized salt, including most kosher and sea salt. Iodized salt consumption has declined due to concerns about cardiovascular risk. In addition, the vast majority of salt ingested in the United States is from commercially processed foods, which almost universally contain non-iodized salt. Currently, the major United States source of dietary iodine is dairy foods, the consumption of which is on the decline. Iodine is known to be absorbed sublingually, under the tongue, so treatment with iodine-containing cleanses has the potential to improve physiological iodine status.

Pillar 2 shows highly impressive outcomes and risk reductions.<sup>398</sup> With a complex disease like COVID-19 that attacks many organs and systems, a multi-drug sequence program is imperative for those over 50. Based on published data, the composite of hospitalization death of 7 percent can be reduced to under 1 percent when coupled with early home treatment. This is because those coming to the hospital already have some degree of treatment and aggregate less severe symptoms. That data indicates a relative risk reduction of 700 percent and an absolute risk reduction of 6 percent, which is very impressive. In the elderly group, where death and hospitalization are 40 percent, the Pillar 2 multi-drug treatment can reduce mortality substantially. The statistics are an astonishing 1300 percent relative risk reduction and 37 percent absolute reduction – unheard-of numbers. Also, there is great potential to realize even better outcomes as doctors who practice Pillar 2 refine their protocols.

Of course, early home and outpatient treatment should not be a static approach. Medicine is a branch of science and must advance as new data becomes available. For example, the monoclonal antibody bamlanivimab showed benefits against the virus and must be considered in the multi-drug approach. For home treatment, injectable drugs pose a delivery problem, but many clinics accessible to most COVID-19 sufferers, during the two-week disease incubation period, may

administer an injectable drug like bamlanivimab. Another therapeutic is a Japanese product, ramachaban, which is approved in Japan for allergic rhinitis but uniquely also has an antithrombotic capability. Its safety profile and possible efficacy make it a candidate for the Pillar 2 application.

The Pillar 2 concept is really a trial without error because drugs or supplements are not applied without proven favorable safety profiles. No new, unproven drugs should ever be introduced to a broad population-reaching approach like Pillar 2. Doctors have plenty of options to treat the virus during the incubation period with anything and everything that is proven safe. Adding and subtracting treatments, as necessary, based on clinical experience, is an unavoidable part of treating something new in crisis mode, with the single-minded goal of preventing hospitalizations and death. The principles of sequenced multi-drug treatment, which is supposed to be happening in hospitals anyway, but often when it is too late, must be applied in the home and outpatient setting first to prevent the impending progression of COVID-19 and reduce unnecessary deaths.

### **COVID-19: One Giant Tax**

Little did Dr. McCullough know when he developed the Pillar 2 approach that hospitals stood to lose up to \$500,000 for every patient that avoided hospitalization with this approach. This is not just disinformation distributed by the so-called fringe. The New York Times published, "Covid Killed His Father. Then Came \$1 Million in Medical Bills."<sup>399</sup> The article stated, "Insurers and Congress wrote rules to protect coronavirus patients, but the bills came anyway, leaving some mired in debt." This means that a plan was in place to compensate hospitals handsomely for anything they did as part of COVID treatment.

The COVID-19 plandemic had multiple hidden agendas beyond reducing populations and controlling citizens. Hospitals are in trouble, and closing is mounting, particularly in rural areas. Conspiracy theorists, or those who are taking a good hard look at what governments, private organizations of the super wealthy, and monopolies understand: when populations are contained in urban areas, they are easier to control. Many people make decisions about where to live based on the availability of "good" hospitals or at least the availability of urgent care in their vicinity.

Consolidation of hospitals under the large systems is one reason our rural hospitals are disappearing. Financial strength and stability are also reasons for closures. Are these healthcare-controlling organizations too large and important to fail? This was the excuse used during the real estate financial crisis, so the "government," meaning you and me, bailed out these wealthy organizations. Thus, three (3) massive taxes have been imposed on us over the past 20 years. They are:

1. the mortgage-induced financial system bailout;

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2. the affordable care act (nice bit of marketing as this tax significantly hurt poor and low-income people) and;
3. COVID-19

The Washington Post substantiates the statements made here about the hospital bailout and the tremendous debt and tax burden imposed by the pandemic. The article is titled "The unintended consequences of the \$178 billion bailout to keep hospitals and doctors afloat."<sup>400</sup> A statement in the article is, "Critics say the pandemic-driven Provider Relief Fund widened the gap between haves and have-nots."

In that article, data was presented that some hospitals received \$413,000 per bed in funds from the federal Provider Relief Fund program. A correction later published put the relief number at \$319,557 per bed. Censored information and that presented in the Times article indicate that the actual financial gain from COVID is much higher than these already exorbitant numbers. Regardless, it represented an outrageously high level of compensation for patients who mainly died and could have been made healthy with the McCullough protocol for pennies on the dollar.

Here is proof that hospitals were and continue to need federal bail-out dollars. This information is obtained from Becker's Review. This organization is considered the authoritative source of news and analysis for leaders and decision-makers in ambulatory surgery centers nationwide.<sup>401,402</sup>

January 2, 2020: Hospital acquisitions hurt patient experience; study suggests.

January 6, 2020: 22 hospital bankruptcies in 2019.

January 16, 2020: Advocate Medical Group to close 7 Chicago-area clinics.

January 17, 2020: Aggressive creditor forced hospital chain into bankruptcy.

January - February 2020: LA hospital to close; Washington hospital to close; Missouri hospital abruptly closes; Bon Secours to close Kentucky hospital; New York hospital closes; Texas hospital abruptly closes; West Virginia VA hospital to close; Mayo Clinic to close network hospital; Ohio hospital closes.

February 17, 2020: Healthcare bankruptcies up 125 percent.

March 2, 2020: Texas health system files for bankruptcy.

March 9, 2020: North Carolina health system files for bankruptcy.

March 2020: Taking notice of the high costs related to their informed consent process, a large health system located in the South decided to split with the status quo.

April 13, 2020: Mayo Clinic projected a \$900M shortfall.

This is an extremely abbreviated list from Becker's. As you can see, even though the cost of healthcare in the United States is 250 percent greater than for other similarly developed nations, our healthcare system is, in many cases, in dire financial straits. Where is all that money going? Not in your pockets. We know who is paying for it, however. It is strapping the poor and middle class, ultimately creating more dependency on the government that, ironically, was the cause of their financial dilemma. The payer is...

YOU.

Will you take a future job if the feds threaten to deny you benefits? This is where we are heading if we do not take back our freedom.

### **Humans are Regarded as Sub-Human**

If the humanistic issues arising from a lack of a Pillar 2 implementation were only medical, that would be horrific enough. But the far-reaching consequences of the hospitalization-only approach and the fear associated with the lack of options to avoid what many people have been led to believe is inevitable, that being death or disability, maybe even more damaging across all segments of our societies. Mothers and fathers have had to make great sacrifices and become full-time teachers while caring for young ones, home because of unnecessary school closures, all the while still trying to keep their jobs.

Young people just entering the workforce are losing their jobs with no financial foundation to bridge the unknown gap. The elderly and very old have taken a tremendous mortality hit. People in senior homes who have survived COVID-19 are often placed in individual rooms in what is essentially solitary confinement. It is torture for them as they cannot see their family members, miss birthdays and holidays, and cannot experience the power of the human touch. Poor decisions may impact the emotional health of our children, and the arc of their life may be altered forever. These segments of society will never forget this pandemic, like those impacted by the world wars and holocausts. They will remember this period, and debacle, for as long as they are alive.

Most pandemics fizzle out due to natural immunity, as seen in COVID-19. New data show that more deaths are piling up in those jabbed than those who avoided the experimental treatment. However, that is not to say that natural immunity alone is the approach that should be taken in a pandemic with high mortality. By implementing Pillar 2, lives are saved, and natural immunity is obtained – this is the ultimate win-win. Vaccination may be considered a form of natural immunity, but proper vaccine development always takes time, especially the safety testing phase. Pillar 2 early treatment provides two key benefits:

1. Reduces morbidity and mortality while affording natural immunity;
2. Buys time by reducing mortality while well-designed clinical trials are performed on vaccines and other safe and effective interventions.

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People dying cannot wait for the randomized trials to start, run their course, and lead to a recommended treatment, including vaccines. Vaccine development should not be rushed. When it is, it has the potential to cause as much or more harm compared to the disease itself. Broad-scale vaccination is not out of the question, but mortality statistics should be used to create a more selective targeted approach. Finally, a defensive program like Pillar 2, implemented globally, has the potential to reduce deaths and hospitalization.

If the Pillar 2 process had been authorized and promoted by our health authorities and implemented universally, it would have led to considerable reductions in mortality based on the works of a small number of brave physicians. Thus, the “pandemic” created by the SARS-CoV-2 virus may not have reached mortality magnitudes even to be classified as a crisis requiring emergency use authorizations. In fact, like the seasonal flu, it might not have been categorized as a pandemic at all.

" Early treatment of people with COVID-19 may have prevented the contagion from becoming classified as a pandemic.

- Thomas J Lewis, Ph.D.

Modern Medicine is NOT Safe or Effective

“You cannot pharmacologically intoxicate a person into health.”

- David Baltimore, MD, ND

### **Modern Medicine is NOT Safe or Effective**

Summary: Simple math shows that the cost of medicine is escalating way beyond inflation, and with it is the proliferation of chronic diseases. One can only draw one conclusion. The more we spend on healthcare, the sicker we become. Certainly, repairing a broken leg or removing a tumor, when possible, is essential. However, vastly insufficient medical resources are allocated to understanding, diagnosing, and treating the root cause of costly chronic diseases.

The COVID experience has led to threats to freedoms in a myriad of ways. In chapter 1, I referred to this as "acute" freedom lost. However, decades and even centuries of "chronic" health freedoms were lost, placing us in the unenviable situation we are in today.

- We have chronically and insidiously lost health freedom, engineered by the elite class that has controlled medicine and dictated policy.
- As a result of these policies, medicine and the government have slowly made us sicker.
- Along comes SARS-CoV-2, and because of our poor overall health, these same powers were able to declare a pandemic and need for emergency use authorizations which overrode many laws and freedoms. It created a new normal through the process of "scope creep."
- As a result, 6-month-old babies are injected with an experimental and completely untested drug to prevent what? Nothing? And the fear induced by the sound and picture bites surrounding the pandemic saw intelligent people injecting themselves and their children.
- The loss of health freedom is the "tip of the iceberg" for which each of us has control.

Health freedom did NOT become lost in 2020. Just like a chronic disease, it slowly crept up on us, like Cancer, Alzheimer's, or heart disease does, until it suddenly erupts in an abrupt event.

The core thesis, independent of COVID-19, is that our healthcare system has done nothing to improve our health - overall. If we took the \$4+ trillion annual

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healthcare system and shut it down, would we, as a population in the United States, be more or less healthy than we are currently? Would we be about the same? Would we be healthier? Eliminating and rebuilding the healthcare system will have collateral benefits, including disenfranchising wealthy elites who have turned our government into puppets.

In this chapter, I will attempt to explore this idea. Of course, statistics must be used to prove how low we have sunk. Samuel Clements said, "there are lies, damn lies, and then there are statistics." Arguably the best information is provided in Volume 2, Chapter 1, where Dr. Clayton points out that mid-Victorian British people lived as long as British people today but had 1/10th of the degenerative diseases. If we use this study, modern healthcare is responsible for 90 percent of the misery we currently experience.

Healthcare may be the ultimate paradox. The system designed to make us well is actually making us very sick, and for the substantial price of \$12,500 per person per year. This is not what we bargained for.

### **Heart Disease - Success or Failure?**

Heart disease has been and continues to be the number one killer of Americans. Alzheimer's has passed cardiovascular diseases in some countries as the most prolific cause of death. However, in reality, Alzheimer's is a cardiovascular disease of the microvessels of the brain. Therefore, when considering Alzheimer's as a cardiovascular disease, its impact has hit a new height.

I was listening to a talk presented by the Osher Center of Integrative Medicine at the University of California at San Francisco (UCSF). I have much respect for UCSF Medical School - sometimes. Dr. Robert Baron, UCSF Professor of Medicine, delivered the talk.<sup>403</sup> An excerpt from that presentation is provided here. It is frightening to think this is the mindset of a professor from one of the better medical schools and is from the supposed integrative medicine component of UCSF.

"The impact of treating high blood cholesterol in the United States over the last twenty years between 1980 and 2000 has led to the death rate falling by about half from heart disease and stroke in the last ten."

Comment: Treating "high cholesterol" had no impact on cardiovascular deaths. This remark is somewhat true but hidden because diagnosis codes have exploded, thus changing how diseases are categorized.

"The next ten years, from 2000 to 2010, it fell by about a third. When we try to figure out why this rate has gone down, what we can model and analyze is the following:

Approximately half of it comes from managing acute myocardial infarction, acute coronary syndrome, and acute stroke very differently and much better

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than we did 10, 20, and even 30 years ago. Many lives are saved because of the early use of highly potent medications, stents, heart disease, and stroke procedures."

Oops: You already know, from a previous chapter, that lowering cholesterol offers no mortality benefit. Stents do not save lives either. Here is a link to a NY Times article titled, "Heart Stents Are Useless for Most Stable Patients. They're Still Widely Used."<sup>404</sup> Coenzyme Q10, on the other hand, is noted to be the first "drug" to improve heart failure mortality in over a decade.<sup>405</sup>

"The other half comes from the treatment of risk factors, including all the traditional risk factors including cholesterol; high blood pressure; cigarette smoking; diabetes treatment; and so on, exercise weight, and so on."

Hmmm: How many doctors give good advice on diet and exercise? What statistics do these regular doctors have on compliance with these recommendations? Patients ignoring the perpetual low-fat narrative has saved some lives.

"One-quarter of lives saved comes from the treatment of high blood cholesterol."

Goodnight Irene. Review the chapter on cholesterol and the additional information presented below.

"Now, one would like to say that this is because we changed our diet or that we started to exercise more, but that's not the case, and we'll talk about the role nutrition and exercise play in the prevention of these illnesses but the primary reason why the death rate has gone down for heart disease and stroke in the United States over the last several decades has been the use of medications to treat high blood cholesterol, and this primarily refers to the class of drugs we call statins."

That is enough! I will no longer listen to University of California TV broadcasts any more. This is a completely incorrect message. But what about when I watch lectures on topics that I am not well versed in? How can I trust this source? But Baron cannot help himself. Essentially all medical schools are paid agents of the pharmaceutical industry. He continues to spew misinformation.

"So let me begin with that premise, and so, I know there's much controversy about statins, but I'm going to spend much time talking about statins. I do not own any stock in statin companies. I would rather treat all patients without medication when I don't have to use medications, but statins do work, and they are more powerful than dietary therapy. They have led to very beneficial effects."

In this case, beneficial effects are implied to be reduced mortality. But the data tells a different story. The only beneficial effect of statins is for the drug companies, ensuring healthcare does not lose too many customers to good health.

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"In each study, the patients who are given the cholesterol-lowering medication, in this case, statins versus the sugar pill, had between a 25 percent and, in this case, 38 percent reduction in events."

Let's look at what a 25 percent reduction means to populations on these evil drugs. Assume 250,000,000 U.S. adults and roughly 500,000 die of heart disease. If the reduction is 25 percent, then in 10 years, this is what the death rate from heart disease looks like.

- Year 0: 500,000
- Year 1: 375,000
- Year 2: 281,250
- Year 3: 210,938
- Year 4: 158,203
- Year 5: 118,652
- Year 6: 88,989
- Year 7: 66,742
- Year 8: 50,056
- Year 9: 37,542
- **Year 10: 28,157**

Heart disease is almost eradicated at this rate. This data is just based on a 25 percent reduction in risk. If we use Baron's reported 38 percent, the number of people who die of cardiovascular disease after ten years on the drugs is a mere 4,196 - a dramatic reduction from 28,157. This represents an enormous reduction compared to the initial 500,000 deaths per year. Statins were introduced in 1987, and their use has had over 30 years to have an impact. It turns out that not everyone is on a statin drug, but the "high-risk" people are about 50 percent of people who meet the American College of Cardiology risk criteria are on or were on, the drug.

Here is how the treatment works in the United States, Figure 7.1.

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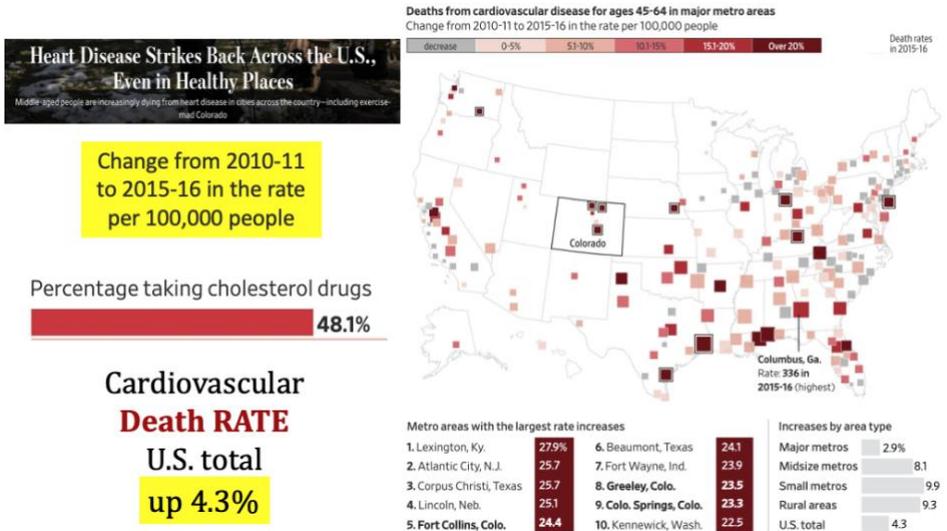


Figure 7.1. The general increase in death due to heart disease from 2010 to 2016 in the United States.

The treatments are increasing deaths from heart disease for the many reasons discussed in chapter 5. Statins are a big part of modern medicine. They may reduce deaths, in rare instances, due to their meager antibiotic properties. However, over time, they cause countless chronic syndromes that eventually lead to higher death rates, including heart disease. Statins and LDL lowering strategies are a complete failure and take away your health freedom in the following ways:

1. Rather than focusing on causes, medicine focuses on a treatment that fails.
2. Not only does it not protect against heart disease, but it also causes a myriad of other problems, including diabetes, vessel calcification, joint pain, cancer, and congestive heart failure.
3. How healthy would Americans be if doctors spent as much time on nutrition as they do threatening patients to take statins drugs?
4. Everyone pays more for medicine because, although statins are no longer very expensive, the drugs used to treat what statins cause are very high.

Dr. Robert Baron, UCSF Professor of Medicine, is apparently unable to perform statistical analysis on his own and relies on what he is told to say or is corrupt. Today, you have to be one or the other to be a full professor. And he has "no conflicts of interest." Imagine what someone with conflicts of interest is telling you. Of course, conflicts are very fluid things. Is a grant to do "more research" a conflict of interest?

### Statin and PCSK9 inhibitor Drugs:

Statin drugs act by lowering LDL. All doctors who prescribe these drugs believe this is the case, including one of my best friends. However, lowering LDL

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increases mortality. So why is there some meager benefit from statin drugs in selected groups? Statin drugs are also antibiotics. In some instances, the insubstantial antibiotic activity of statins offsets the adverse LDL-lowering action.

Would you take an antibiotic for life?

If you are taking a statin drug, you are doing just that. The drug companies know these drugs are antibiotics, as documented in the chapter on cholesterol.

The new class of LDL-lowering drugs is classified as "biologics." One type is called PCSK9 inhibitors. Unlike statins, these drugs only lower LDL and do much more effectively than statins. Credible data on these drugs show a clear increase in mortality risk compared to statin drugs because they lack antibiotic action. Lowering LDL is not an immediate death sentence, however. This leads to the concept of "crypticity," discussed in the last chapter. In this context, a cardiovascular death can be blamed on genetics or other obtuse cause, but never the statin or LDL lowering therapy, God forbid. There is no reasonable doubt that these drugs cause an increase in mortality, Figure 7.2.<sup>406</sup>

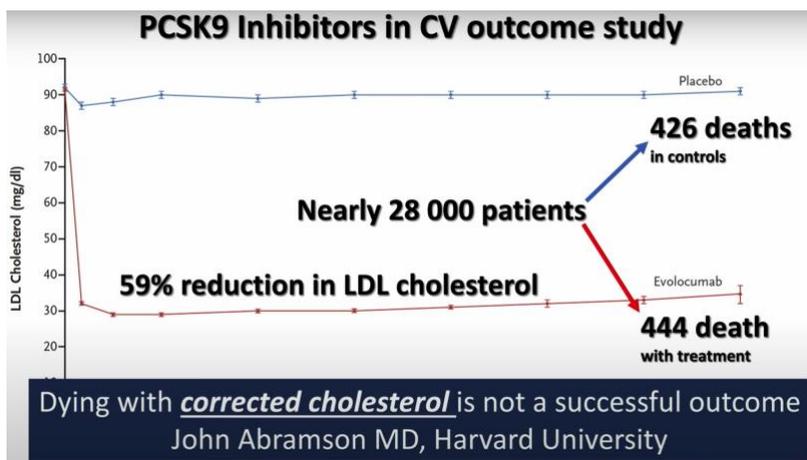


Figure 7.2: Comparative deaths after lowering of LDL with PCSK9 Inhibitors. The timeframe of this study was 3.2 years.

Clinical trials are supposed to run for five years. In some cases, these trials are cut short. For example, the study on PCSK9 Inhibitors presented in Figure 7.2 ran for 3.2 years. In other cases, like in COVID-19, safety and efficacy studies were not run at all. The purpose of the trials is for safety more so than efficacy. Efficacy can be shown quite early on by studying mechanisms. However, safety is another matter. Five years is an entirely arbitrary time. It is designed based on the presumed need to make the drug available timely while properly investigating safety and efficacy. Many drugs, like statins and other LDL-lowering drugs, may be taken for 40 years. Let us examine how nature collides with the 5-year testing

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window. This exercise aims to provide better context to the excess mortality data caused by LDL lowering, not the statistics that make it to CNN, Figure 7.3.

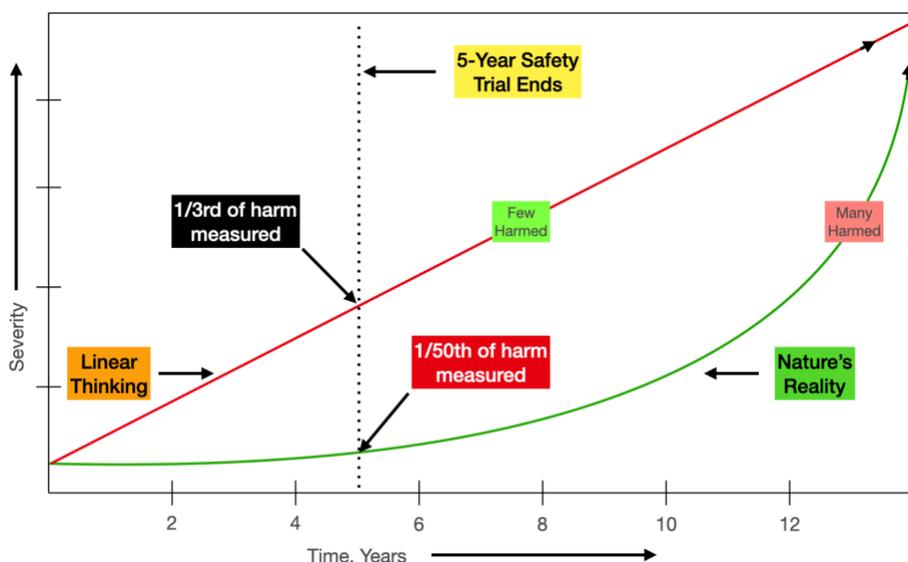


Figure 7.3: Value of clinical trial safety and efficacy studies. Nature and chronic diseases follow a log-linear relationship (green curve), not a linear relationship (red curve). Short safety and efficacy trials may completely miss safety issues that manifest when the drug is taken for periods exceeding a 5-year study.

Consider a couple of examples to put the figure above into context, that is, the fact that we live in a log-linear and not a linear world.

Example 1, running a 100-meter dash: Most of us can walk the distance in 60 seconds. With some training, jogging that distance in 40 seconds is realistic. With much more training, in a couple of months, most of us could travel that distance in 20 seconds. However, how many of us could ever complete 100 meters in 12 seconds or less? Think about the training effort required to get to that point. Which curve better fits the effort required to run a 12-second 100-meter dash, the red or green curve?

Example 2, growing pumpkins: I wanted to grow a 100-pound pumpkin as a child. The closest I got was 84 pounds. Not bad. Every Spring, it was the same process: plant the seed; wait what seemed to be an interminably long time for the seed to germinate; go to the garden daily to observe the growth of the vines; notice that suddenly vine growth was explosive; then the fruit would start forming - slowly at first - and then progressively faster. Each phase followed the green curve, not the red curve.

Example 3, heart disease: The person has some mild risk factors. Over time, biomarkers start edging up slowly. Stressors increase in the person's life, and the

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biomarkers start increasing dramatically, unbeknownst to them. The person develops mild symptoms which are largely ignored. Suddenly the person experiences a tragic adverse health event. Hopefully, the person lives. The rapid upswing much more accurately explains this sudden event in the green curve.

What does this mean regarding 5-year (or less) safety and efficacy trials? If you take the drug beyond these five years, you could be at great risk of an adverse event. In the example presented in Figure 7.3 above, the likelihood of an adverse event in year 14 is 50 times more likely compared to year 5. Fifty times is a 5,000 percent increase in risk.

Here is a look at the PCSK9 Inhibitor data from the 3-year trial when extended out 14 years, as shown in Figure 7.2.

- Study time = 3.2 years;
- Number in study = 28,000;
- The number of deaths in control = 426;
- The number of deaths in the PCSK9 group = 444;
- Total number of excess deaths caused by the PCSK9 treatment: 18;
- Relative increase in deaths = 4 percent;
- The absolute increase in deaths = 0.06 percent;
- Potential increase in deaths over 14 years based on Figure 7.3 above;
  - The relative increase in deaths = 200 percent;
  - Absolute increase in deaths = 3.2 percent;
  - **The total increase in deaths = 900!**

There is no fuzzy math being used here. This demonstrates that short-term safety data may be completely irrelevant when drugs are used long-term. This is indeed an estimate because the study was NOT done. However, it is reasonable based on the way nature works.

Statin drugs fair no better over the long term. Safety and Efficacy tests were run for five years, but many are on statins for life. Also, women and older people are significantly underrepresented in these studies. Concluding the safety of any drug based on young and middle-aged people to older and frail people adds another level of harm underestimation.

Heart failure is a considerable risk for the elderly. Figure 7.4 below shows the risk of heart failure and the use of statin drugs. It is evident that statin drugs, which lower the muscle enzyme CoQ10, impact the heart muscle. There is a substantial increase and cardiovascular harm the longer people are on statins.<sup>407</sup> Interestingly, this is just the type of disease these drugs should prevent. The conclusion is that the 5-year safety studies are inadequate to predict harm if you take the drug beyond year 5.

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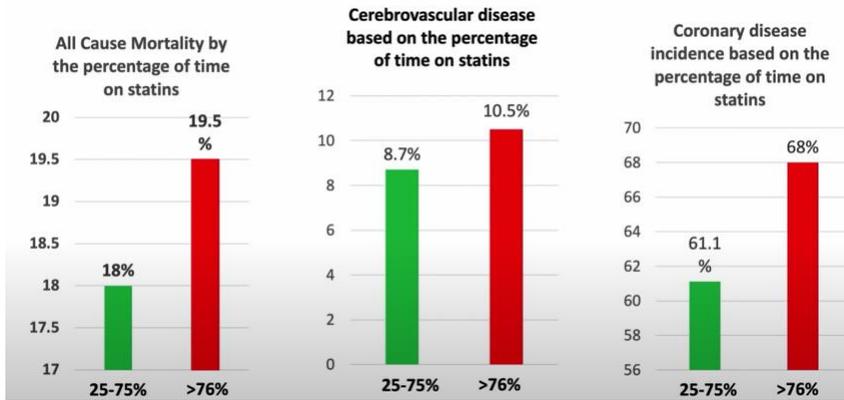


Figure 7.4: Impact of statin use on heart failure (cerebrovascular disease), all-cause mortality, and coronary artery disease based on the percentage of time on statins.

One of my favorite measures of "plausible deniability" in medicine is related to the citation number. The paper on heart failure and statin drugs was published in 2011. Eleven years later, the report has been cited a meager 22 times. However, there are 12,600 peer-reviewed papers published since 2011 with the word "statin" in the article's title. This tells us two things.

1. The authors do not want to tell you about the harm these drugs cause.
2. Doctors do not want to read anything that goes against their "beliefs."

This paper should have been cited thousands of times, so people are informed about risks.

Figure 7.5 should be all you need as proof that statin drugs and the PSCK9 inhibitor drugs do NOT save lives. If they did, cardiovascular disease - based on the drug companies' phony statistics - would be a thing of the past. In the figure, I took data from separate sources with a common time frame, cardiovascular mortality rates, and smoking trends. Can it be any clearer that these drugs do not work? Here are the facts based on Figure 7.5.

1. An increase in cardiovascular deaths follows, but lags slightly behind, smoking trends.
2. The trends are quite uniform, showing a strong correlation.
3. Smoking started trending downward around 1975, and the decline in smoking rates has been relatively consistent year over year.
4. Statins drugs were introduced in 1987, shortly after cardiovascular mortality rates started to show the beginning of a decline. The lag in reducing cardiovascular deaths is NOT related to the introduction of statin drugs - approximately ten years.

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5. After 1990, cardiovascular death rates no longer declined with smoking. This is the first time in 90 years that smoking and cardiovascular deaths did not coincide.
6. The rate of cardiovascular deaths INCREASED, based on previous trends when statins were introduced.
7. Using drug company statistics, the projections for cardiovascular deaths are given. However, the actual death rates are far higher.
8. The PCSK9 inhibitors use began around 2010. Look at the increase in cardiovascular mortality after 2010!
9. Conclusion: These drugs cause cardiovascular HARM and increase deaths - not benefits.

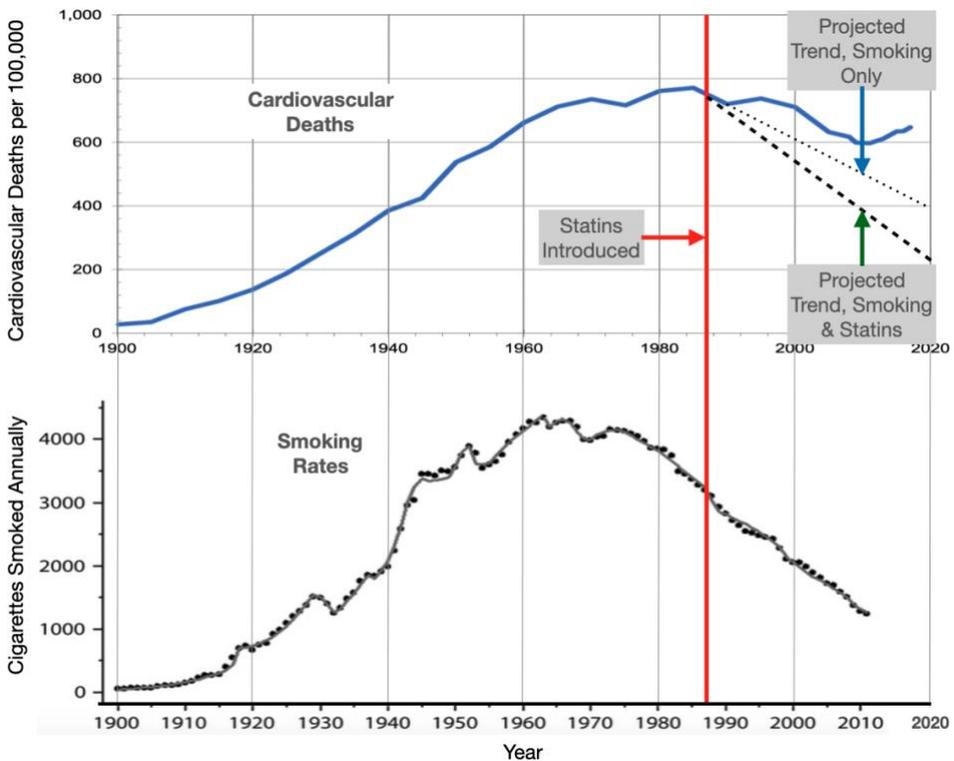


Figure 7.5: Cardiovascular death compared to smoking trends. The red vertical line is when statin drugs were first introduced. The upper curve shows that the trend in cardiovascular disease deaths actually increased as these drugs became highly prescribed.

The mid-Victorians of the 1870s has 10 percent of the heart disease we have today. They did not have statins or other LDL-lowering drugs.

## Stents and Other Surgeries

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Data showing that stents do not save lives is presented in the section on statins above. Simply put, trends in cardiovascular disease deaths are going in the wrong direction despite the heavy application of stents. Stents may improve the quality of life in some people, however. The NY Times published another article on stents titled "Putting Stents to the Test."<sup>408</sup> Some excerpts from that article.

"Researchers tried to get an answer with a big federal study called Courage, published in 2007. But many cardiologists said the study was flawed, and they did not believe its conclusion that stents failed to prevent heart attacks and deaths."

"People believe that if they have a blockage, they have to fix it mechanically," said Dr. Judith S. Hochman, the study chairwoman for the Ischemia trial and a cardiologist at NYU Langone. "It seems logical, but in medicine, many things that seem logical are not true."

Not only do cardiologists find it hard to fight their feelings that stenting makes sense, but they also find it hard to persuade patients to try medical therapy, said Dr. Brahmajee Nallamothu, an interventional cardiologist at the University of Michigan.

The concept that stenting helps, he said, "is a paradigm so deeply set on the part of the public and many doctors that it is tough to overcome."

The NIH-funded studies show that stents and surgery are no better than medication or lifestyle changes at reducing cardiac events.<sup>409</sup> We now know that medication does not save lives. The main medication class referred to in such statements is statin drugs. Therefore, stents do not save lives. Regarding lifestyle changes, we must realize that they are limited ones recommended by your regular doctor and the medical-industrial complex. For example, low-fat is preferred, and saturated fats should be avoided. Of course, when you avoid fat, the replacement macronutrient is either sugar or protein, contributing to diabetes when taken in excess. People with diabetes have much more heart disease.

The New York Times goes on to report the following.

"Invasive procedures such as bypass surgery and stenting - commonly used to treat blocked arteries - are no better at reducing the risk for heart attack and death in patients with stable ischemic heart disease than medication and lifestyle changes alone. However, according to two new milestone studies, such procedures offer better symptom relief and quality of life for some patients with chest pain.

The studies, designed to settle a decades-old controversy in cardiology, appeared online on March 30, 2020, in the New England Journal of Medicine. While researchers released preliminary findings at the American Heart Association annual meeting, the papers published report the official outcomes of the International Study of Comparative Health Effectiveness

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with Medical and Invasive Approaches (ISCHEMIA), the largest and one of the most consequential studies of its kind.

Funded by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, the trial followed more than 5,000 patients with stable heart disease and moderate to severe heart disease for a median of 3.2 years. It compared an initial conservative treatment strategy to an invasive treatment strategy. The conventional treatment strategy involved medications controlling blood pressure, cholesterol, and angina (chest discomfort caused by inadequate blood to the heart) and counseling about diet and exercise. The invasive treatment strategy involved medications, counseling, and coronary procedures performed soon after patients recorded an abnormal stress test. The trial allowed tests that assess coronary blood flow restriction, called ischemia, to determine who could participate in the study.

“Previous studies have reached similar conclusions as ISCHEMIA, but they were criticized for not including patients with severe enough disease to benefit from the procedures. ISCHEMIA studied only patients with the most abnormal stress tests,” said Yves Rosenberg, M.D., study co-author and chief of NHLBI’s Atherothrombosis and Coronary Artery Disease Branch. “These findings should be applied in the context of careful attention to lifestyle behaviors and guideline-based adherence to medical therapy, and will likely change clinical guidelines and influence clinical practice.”

In conclusion, stenting is no better than statin drugs, which increase cardiovascular mortality. Hmmm

Our UCSF full Professor Baron indicates that better procedures and treatments have mainly reduced cardiovascular disease. Do you think this is true?

The mid-Victorians did not have stents but had only 10 percent of the chronic diseases we have today.

### **Blood Pressure Control**

Controlling blood pressure when the systolic number exceeds 140 mmHg is an essential stop-gap intervention. However, blood pressure drugs should only be the second line of defense and should be provided alongside a strategy to find and eliminate causes of elevated blood pressure. Your traditional doctor NEVER does this. Long-term blood pressure medications are a disaster for many who suffer complications associated with reduced blood flow to vital tissue, particularly the brain.

Falls and associated hip fractures are quality-of-life-ending events in the elderly. The elderly are more likely to be put on blood pressure-controlling medications. The Journal of the American Medical Association did publish an important article on this topic titled "The Risk of Hip Fracture After Initiating Antihypertensive

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Drugs in the Elderly"<sup>410</sup> This article, published in 2012, has been cited 200 times, which is inadequate to get the message out to doctors. What is that message?

"Hypertensive elderly persons who began receiving an antihypertensive drug had a 43 percent increased risk of having a hip fracture during the first 45 days following treatment."

A substantial number of lives are ruined, including the lives of a family member who now has to care for these ambulatory people. Our experience with seniors explains the process. Many older people have vessels that have lost some elasticity and integrity. Thus, more pressure is needed for adequate blood flow to highly metabolic tissue like the brain and eyes. A substantial number of these seniors indicate they do not take the meds during the daytime because it makes them feel lousy and often dizzy. Instead, they take them at night time. Inevitably, a person wakes up in the middle of the night to urinate. When their blood pressure is artificially lowered, they tend to be easily disoriented and have a higher propensity to fall.

My father fell when he was on blood pressure-lowering drugs. Instead of turning left to enter the bathroom, he turned right and fell down the stairs. He did not break anything, as he was a tough old bird, but it did take him a month or more to return to normal physically. However, I believe that the fall worsened his already existing cognitive impairment.

The value of 140 mmHg as a target for treatment is well validated, but it may only be necessary for some as an urgent intervention. Laboratory testing can determine the integrity of blood vessels. But to sell more drugs, the standards committee has doctors prescribing blood pressure medications for people with a blood pressure above 120 mmHg. Many studies argue against lowering blood pressure in the 120 - 140 mmHg range, but that does not stop the authorities from pushing drugs.

An example article indicates, "primary preventive BP lowering is associated with reduced risk for death and CVD if baseline systolic blood pressure (SBP) is 140 mmHg or higher. At lower BP levels, treatment is not associated with any benefit in primary prevention. Still, it might offer additional protection in patients with CHD."<sup>411</sup> Drugging people for profit is part of capitalism if there is no harm, but it is still unethical. However, these drugs ALL have side effects. Shame on these consensus developers and the cowardly doctors who follow along with the recommendations they should and probably do know are wrong.

Intermountain Healthcare warned that some blood pressure medications increase the risk of death.<sup>412</sup> They state, "alpha blockers and alpha two agonist show increased variability in blood pressure measurements between doctor visits, which is associated with an increased risk of death, according to new research from the Intermountain Medical Center Heart Institute in Salt Lake City. As a

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result of the study findings, researchers are encouraging physicians to use other classes of blood pressure medications that show a decrease in mortality risk."

How often is there a free lunch when taking a synthetic substance? Pfizer Canada had to recall all lots of the blood pressure drug Accuretic because of the presence of higher-than-allowed levels of a type of nitrosamine called N-nitroso-quinapril. The product pull came just three days after Pfizer Canada said it recalled 15 lots of another blood pressure drug, Inderal, on similar nitrosamine impurity concerns. How many people took the pill before the recall went into full effect?

Many people are on multiple blood pressure medications. In my experience, some of these people never had high blood pressure, as indicated by the individuals. Every drug has side effects. Natural substances have side effects too. That is why my mentor, Dr. Trempe, kept leather-bound volumes of natural herbs on his desk. When his patient indicated they were taking herbs, he investigated them for cross-reactions. Does your doctor review all your drugs and supplements and assess the mix for cross-reactions?

The PARTAGE Study examined the impact of multiple blood pressure medications on side effects.<sup>413</sup> The study showed significant interactions between low SBP and treatment with two or more BP-lowering agents, resulting in a higher mortality risk in patients with low SBP who received multiple BP medicines than the other participants. The findings of this study raise a cautionary note regarding the safety of using combination antihypertensive therapy in frail elderly patients with low SBP (<130 mm Hg).

This is not the only clinical trial data that does not support lowering the blood pressure to less than 130/80 mm Hg in patients at high risk for cardiovascular events.<sup>414</sup> Of course, these high-risk patients are the ones being put on these drugs.

After looking at all these studies on blood pressure lowering, the conclusions are quite clear.

- Some blood pressure medications are dangerous and may increase mortality.
- The drug companies, Pfizer in particular, do not have adequate QA/QC procedures and release contaminated products.
- Lowering BP when it is very high offers a benefit. However, it does not solve the underlying problems, which is why overall mortality is NOT decreased.
- Lowering BP when it is slightly above the American College of Cardiology limits has no benefit but causes harm to many.
- Harm, like feeling woozy or generally lousy, is not often reported.

Why do blood pressure medications work? That is, why in some instances, is there a mortality reduction? In severe cases where the BP meds work, vessels are arguably inflamed and occluded. That is why the BP goes up - the vessels are

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somewhat blocked or otherwise compromised. Dr. McCully of Harvard provided an excellent explanation of this, as presented in Chapter 5.

Think of your vessels like the plumbing in your home. An old and corroded pipe is much more likely to burst than a new one. A way to prevent leakage or pipe bursting is to:

1. Turn down the water pressure;
2. Replace or repair the pipe.

The chapter on oral health, in Volume 2, discusses spirochetal and other infections clogging the pipes. Do BP meds treat the infection? NO!

In the chapter on the longest-lived peoples, also in Volume 2, how "pipes" are repaired is explained. Is that approach better compared to turning down the pressure? Well, women from the United States, who generally use the "pressure" approach, die seven years sooner, on average, compared to the women in Japan who repair the pipes.

BP meds, in certain instances, do lower mortality. However, people from the United States, for example, have very high mortality from cardiovascular disease. The actual benefit of BP meds is NEGATIVE compared to someone who is properly treated. That is, modern medicine relying on BP meds alone, compared to repairing the pipes, leads to higher mortality in our population.

Summary: The net effect of modern medicine using BP meds rather than addressing and fixing root causes is an INCREASE IN MORTALITY.

Blood pressure medications were not available to the mid-Victorians.

### **Cancer**

Cancer is becoming the number one killer in the United States. It is still second to cardiovascular diseases overall. However, on a state basis, in some instances, cancer mortality is higher compared to cardiovascular disease.

Statistics are a convenient way to hide the facts. For instance, since the ICD-10 code book has been in force, doctors have ~70,000 diagnostic codes. The previous version, ICD-9, had <15,000. Have we really contracted a whole new range of diseases over the past few decades? Instead, might this be a convenient way to introduce tens of thousands of unnecessary drugs? It is easy to dilute the actual number of people in a given diagnostic category when you increase the number of codes by 475 percent.

What are the real cancer survival statistics? In most cases, patients who are diagnosed with cancer at earlier stages show improved survival and clinical outcomes. However, screening for earlier cancer detection remains limited. Today, broad-based cancer screenings for asymptomatic patients are recommended in the U.S. for just five cancer types: breast, cervical, colorectal,

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lung for a high-risk subset of the population, and prostate. And 71 percent of all cancer mortality is from cancers that lack broad-based screenings for asymptomatic patients.

There is good and bad news about cancer survival and deaths. The good news is that cancer death rates have appeared to be declining in recent years. The bad news is the way medicine “measures” cancer deaths have changed. It is a confusing subject that we attempt to clarify here. However, the take-home lesson from this exercise is that chemo/radiation/surgery has done little to change cancer mortality rates despite what you have been led to believe. How could they have led to better outcomes? Doing the same thing over and over again and expecting a better outcome is insanity. Do we have better radiation, less toxic chemo drugs, and better surgery? We might have better surgery, but does that really cure cancer?

A paper titled “Measuring cancer survival in populations: relative survival vs. cancer-specific survival” discusses the challenge of measuring cancer mortality.<sup>415</sup> An excerpt from this paper is provided here:

“Two main methods of quantifying cancer patient survival are generally used: cancer-specific survival and relative survival. Both techniques are used to estimate survival in a single population or to estimate differences in survival between populations. Arguments have been made that the relative survival approach is the only valid choice for population-based cancer survival studies because cancer-specific survival estimates may be invalid if there is a misclassification of the cause of death. However, there has been little discussion, or evidence, as to how strong such biases may be, or of the potential biases that may result using relative survival techniques, particularly bias arising from the requirement for an external comparison group.”

That was a confusing paragraph, but the take-home lesson is that researchers and drug companies do not have a standard way to measure the success of their cancer treatments. Thus, we are being bamboozled by “lies, damn lies, and statistics.” To add to the confusion, here is an excerpt from Dr. Malcolm Kendrick’s book, “Doctoring Data.”<sup>416</sup>

“The word survival does NOT mean that you will actually survive (when it comes to cancer). In the world of cancer screening, the term “survival” is taken to mean that you are still alive five years after the cancer was first diagnosed. The five-year cancer survival rate is the measure used for almost all interventions in this area. Or, to turn this around slightly, if you survive for five years after your initial cancer diagnosis, the statisticians will consider that you have been cured.”

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“As a result of this, if a screening test picks up cancer five years earlier than would have happened had it appeared through symptoms, the five-year survival/cure will automatically appear to be astronomically better. Especially with slow-growing cancer (such as prostate).”

Here is a gaussian curve that explains phony cancer statistics, Figure 7.6.

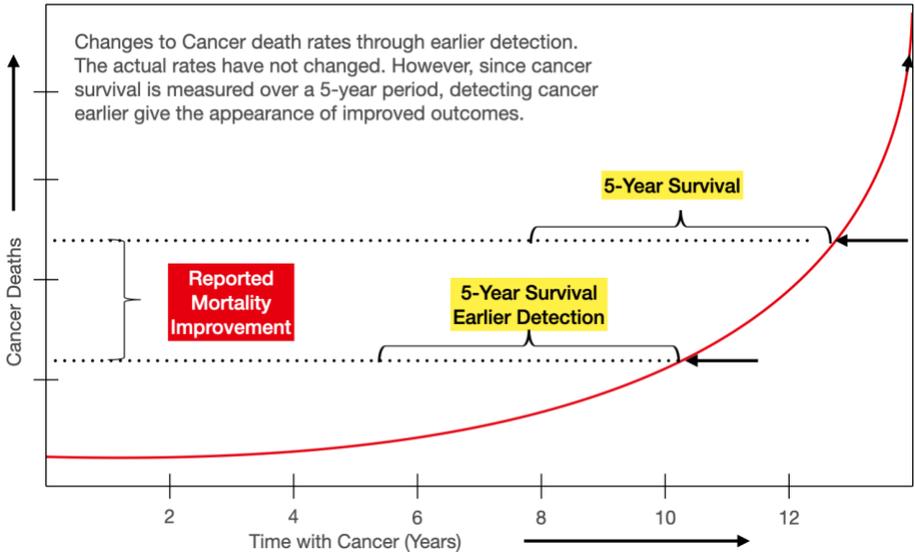


Figure 7.6: How so-called "improved" cancer survival rates are inappropriately interpreted when cancers are detected earlier with the advent of advanced diagnostic techniques.

Statistical mumbo jumbo is a manifestation of the drug company's takeover of medicine. Thus, this trend began around 1980. Figure 7.6 shows, is that when cancer is detected earlier, the mortality rate appears to go down. However, the mortality curve has NOT changed. The place along the curve that is used to represent mortality is altered. This is noted by the difference in values between the horizontal dotted lines. Figure 7.7 reflects true cancer trends. The 5-year survival statistics coupled with earlier detection falsely indicate that treatment of cancer is improving.

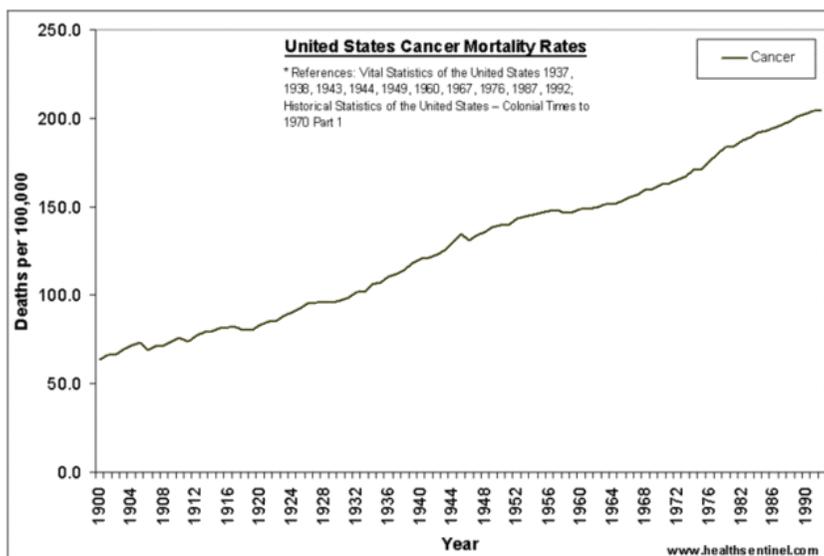


Figure 7.7. Increase in cancer rates since 1900.

### Current Cancer Statistics

Cancer figures among the leading causes of morbidity and mortality worldwide, with approximately 14 million new cases and 8.2 million cancer-related deaths in 2012.<sup>417</sup> The number of new cases is expected to rise by about 70 percent over the next two decades. Among men, the five most common sites of cancer diagnosed in 2012 were lung, prostate, colorectal, stomach, and liver cancer. Among women, the five most common sites diagnosed were breast, colorectal, lung, cervix, and stomach cancer.

Around one-third of cancer deaths are due to the five leading behavioral and dietary risks:<sup>8</sup> high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use, and alcohol use. Tobacco use is the most important risk factor for cancer, causing around 20 percent of global cancer deaths and around 70 percent of global lung cancer deaths. What is glaringly missing is any link to infectious causes of cancer.

Cancer-causing viral infections such as HBV/HCV and HPV are responsible for up to 20 percent of cancer deaths in low- and middle-income countries.<sup>418</sup> However, viral and other infectious causes of cancer are probably severely underdiagnosed and thus underappreciated. The inflammation component of cancer points directly to infectious origins. A prime example is stomach cancers caused by H-pylori infection. World Cancer Report provides clear evidence that

<sup>8</sup> We have a slightly different list. Low fat diets, lack of healthy fats, and other behaviors that lead to low immune system function and manifests inflammation and infection are the major factors in cancer risk. Low vitamin D status is an excellent indicator of high cancer susceptibility.

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actions on smoking, diet, and infections can prevent one-third of cancers, and another third can be cured by properly understanding the cause of cancer and not just treating the tumor.

The mid-Victorians had only 10 percent of the degenerative diseases we suffer from today - including cancer.

### Diabetes

Most drugs to "treat" diabetes are harmful. The term "treat" means to lower glucose levels. This would be wonderful if glucose were the primary causal factor of the disease, but it is NOT. Thus, treating a symptom like high blood glucose levels has the usual negative outcomes provided by our medical establishment.

Metformin is considered to be an anti-aging drug even within certain sectors of the medical establishment. However, we have heard these types of claims before about statins, stents, and blood pressure drugs. Are they true?

In the case of metformin, there appears to be an effect, but there are also consequences. The effect of metformin provides points to a very basic aspect of longevity, that being reduced calorie intake. It is a basic concept. Sugars are important but, in excess, drive inflammation. Also, reducing calories puts less stress on digestion and elimination pathways, providing more bandwidth for repair and recovery. However, the complement to calorie control is to make sure micronutrient intake is high.

The mid-Victorians consumed substantially more micronutrients than we do today. You might be saying, "but the mid-Victorians consumed many more calories compared to people today!" This is true, but their level of physical activity also played an important role in glucose control. They actually needed a high intake of calories and nutrients, whereas today, consuming food in excess, as is the case in the developed world, is, for many, a habit or an act of pleasure rather than necessity.

If diabetes is not about controlling sugar, then what is it? The disease is that of insulin resistance. Having an optimally low fasting insulin value of 1.5 - 3 IU/mL is what contributes to longevity. Metformin may help people lower their fasting insulin by controlling glucose, but this is an artificial approach, and even "good" drugs have side effects.

Many people who are classified as type 2 diabetics are on insulin. Can you predict if this treatment will extend or reduce longevity? Glucose levels on this drug are often lower, but insulin levels are often higher. You need to go no further than a major study titled "ACCORD" to determine if lowering glucose is the appropriate approach to diabetes control. One of the publications from this study is titled "Intensive glycemic control and the prevention of cardiovascular events: implications of the ACCORD, ADVANCE, and VA diabetes trials: a position statement of the American Diabetes Association and a scientific statement of the

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American College of Cardiology Foundation and the American Heart Association."<sup>419</sup> It is quite interesting that the phrase "prevention of cardiovascular events" is in the title because lower glucose does just the opposite. Here is information from the publication.

"Action to Control Cardiovascular Risk in Diabetes (ACCORD), terminated its glycemic control (glucose-lowering) study early due to the finding of increased mortality in participants randomized to a strategy of very intensive glycemic control with a target A1C of <6 percent. The findings of these three major trials led the American Diabetes Association (ADA), with representatives of the American Heart Association (AHA) and the American College of Cardiology (ACC), to reexamine the recommendations for glycemic targets in patients with diabetes, the majority of whom have type 2 diabetes."

Translation: Lower glucose in diabetics (people with high glucose) can be deadly even though conventional medicine thought - and still thinks - just the opposite. An A1C target of <6 percent is not even optimal. Truly healthy people have an A1C of 4.5 - 5 percent. Few U.S. citizens have such a value. However, no one should dwell on the A1C value because it is a trailing indicator. Fasting insulin is the leading indicator and better represents the disease process.

The only thing one can conclude about the American Diabetes Association (ADA) is they are either an incompetent or corrupt organization. In their 82nd year, it is difficult to avoid the myriad of donation buttons on their website, but impossible to find the ACCORD study results. This study should be front-and-center on their website if they cared about people with diabetes. Why is it not? Their message is loud and clear - they care about money.

Figure 7.8 is what you cannot avoid when you visit the ADA website.

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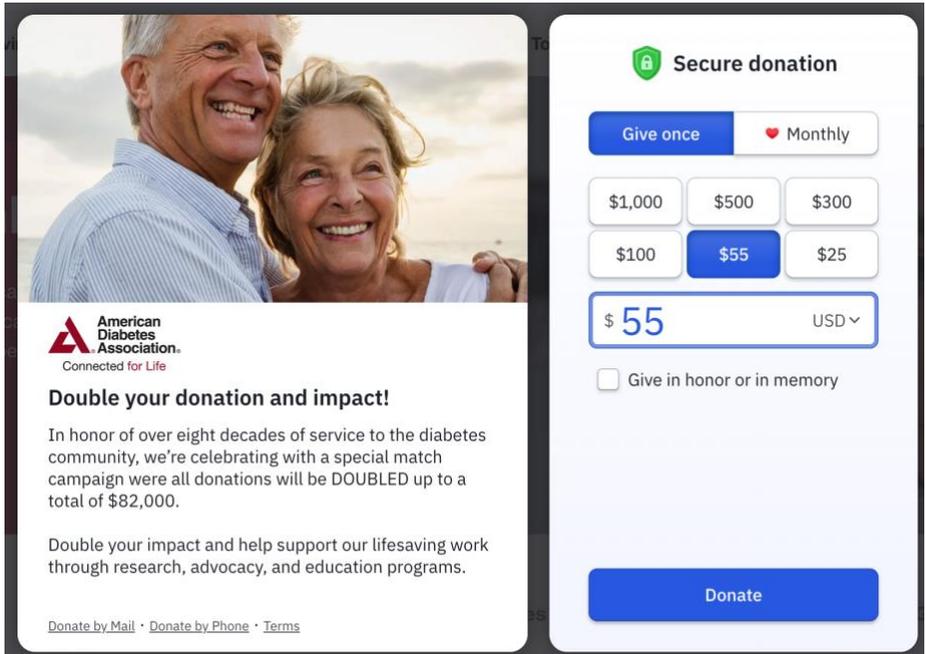


Figure 7.8: Requests for donations are prominent on the home page of the American Diabetes Association.

Figure 7.9 is what you should see when you visit their website.

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Cautionary Note to Site Visitors: It is our duty to inform you that controlling blood glucose in diabetics can have deadly and harmful consequences. The ACCORD Study shows that if you are diabetic, and drugs are used to lower your blood glucose to levels that are normal for a non-diabetic, you may suffer from a range of Serious Adverse Events (SAEs) and death. This is especially true of patients on insulin therapy.

However, there is hope for every type 2 diabetic. This is a reversible disease regardless of the stage of diabetes that you are in. Reach out to our network of functional and integrative doctors who will help you reverse this disease naturally.

<b><u>Lower A1C</u></b>	
<b>Targets (achieved median)</b>	<b>&lt;6% (6.4%) vs 7-7.9% (7.5%)</b>
<b><u>Greater use of medications:</u></b>	
<b>More multiple oral meds</b>	<b>70% vs 45% on 3-5 oral classes</b>
<b>More insulin</b>	<b>77% vs 55% on insulin</b>
<b>More combination orals + insulin</b>	<b>62% vs 18% on 3-5 orals + insulin</b>
<b><u>More consequences of therapy:</u></b>	
<b>Severe hypoglycemia</b>	<b>10.5% vs 3.5% w/ hypoglycemia event requiring medical assistance</b>
<b>Weight gain</b>	<b>28% vs 14% &gt;10 kg gain</b>
<b>More SAEs</b>	<b>2.2% vs 1.6% w non-hypo SAE</b>
<b>Even more consequences of therapy: Dying suddenly and young!</b>	

Figure 7.9: What should be presented on the front page of the American Diabetes Association website? Importantly, this ACCORD study shows that lowering sugar too much by standard-of-care methods is deadly. Sugar is not the root cause of the disease. Thus, the American Diabetes Association is promoting the wrong therapeutic approach for diabetes.

Certainly, you will find papers that support glucose control. And, when you look at those papers, read them completely because Dr. Ioannidis from Stanford indicates that most published scientific research is false. You have to read these studies very carefully to determine how the data is misrepresented. More importantly, the concept of controlling sugars without drugs is always omitted.

To understand a drug and whether or not it will work in diabetes, you simply have to understand the mechanism of this disease. Let us revive the old TV game show to find out the truth about diabetes. The show was called "To Tell the Truth." We have three contestants, Mr. Glucose, Mrs. HbA1C, and Ms. Insulin. We get to ask each contestant a series of questions to determine who the imposters are and who

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is at the root of diabetes. Only one can be the true cause. Let's start the questioning.

Questioner: Mr. Glucose, how do you cause diabetes and early mortality?

Mr. Glucose: I build up in the blood and harm vessels.

Questioner: Mr. Glucose, why do you build up on the blood?

Mr. Glucose: Cells do not want me, and there is a waiting line at the liver to convert me to fat.

Questioner: Mr. Glucose, why, when external insulin is added to the body in which you are, do your levels go down in the blood - a presumed good thing - yet the person dies at extraordinarily high excess rates? I thought the problem with glucose was when there was an excess of you in the blood.

Mr. Glucose: I do not know. I am just a fuel molecule, not a regulatory substance.

Questioner: Mrs. HbA1C, please answer the same questions I asked of Mr. Glucose.

Mrs. HbA1C: My answers are the same as those of Mr. Glucose. I am just an indicator of blood glucose levels. To make matters worse, I reflect past glucose values and not present values. So, I am not a very proactive biomarker.

Questioner: Ms. Insulin, what happens when I add a synthetic version of you into the blood of a diabetic with very high glucose levels?

Ms. Insulin: My job is to keep glucose within a narrow range that is optimal for energy, controlling inflammation, and longevity. When there is a constant oversupply of sugars in the diet that manifest as glucose in the blood, cells resist my action. However, since my job is to keep glucose levels in the blood within an optimal range, I find other outlets for the excess blood glucose. One way for me to lower glucose is through the liver, where glucose is converted to fat storage. However, other things demand energy and help me do my job, so I feed them. These "other things" include; hungry cancer cells and infections. Diabetics, as you know, have higher incidences of cancer and infectious disease. When external insulin is added, there is more of me to divert glucose from important but resistant cells. These cells start to suffer mightily from a lack of energy.

Questioner: Ms. Insulin, does it make sense to help you with exogenous (outside sources of) insulin?

Ms. Insulin: No. When someone is severely insulin resistant, like a long-term diabetic, they need excess glucose outside their cells to create enough glucose "pressure" to get inside the cell to meet the cell's energy needs. Otherwise, the cell does not get enough glucose and lacks energy. I suggest you read the ACCORD Study.

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Well, we have come to the end of the show. Will the real cause of diabetes please step forward?

Of course, Ms. Insulin steps forward.

You can now answer these three questions.

Is type 2 diabetes a disease of excess glucose in the blood?

Is type 2 diabetes a disease of excess HbA1C in the blood?

Is type 2 diabetes a disease of insulin resistance causing a cellular energy crisis?

What this means is that any diabetes drug that lowers glucose in the blood without consideration for the energy needs of your cells will have worse outcomes compared to no treatment, in general. Metformin may be a drug that improves insulin sensitivity and thus provides some health benefits. Beware of drug advertisements that indicate the new drug is better than an old drug or complements insulin.

Traditional medicine largely ignores the concept of a health-disease continuum. What they indicate is if you do not have a diagnosis, you can prevent disease. However, once you have a diagnosis, your only alternative is to manage the condition with drugs. Since health and disease ARE a continuum, and the diagnosis is just an artificial human-defined place along the continuum, what traditional medicine says is nonsense, Figure 7.10. Yes, there is a point of no return for some diseases. Cancer and anorexia are examples. But many people with cancer go into remission long after they have a diagnosis. Maybe drugs were involved, but not in all instances. Very few people should be considered to be hopeless. Importantly, you can probably reverse the disease naturally even if you have a diagnosis. This is especially true of diabetes.

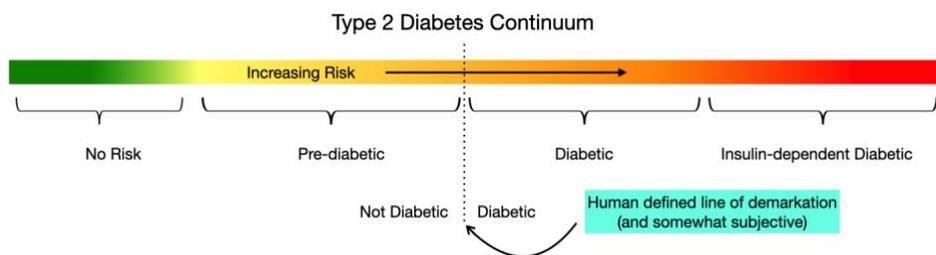


Figure 7.10: The diabetes continuum. The diagnosis of type 2 diabetes is an artificial point along the diabetes continuum. The condition is reversible without drugs regardless of where a person lies on this continuum, despite modern medicine indicating that drugs are the only solution once a person has a diabetes diagnosis.

The only drugs likely to work that improve healthy longevity improve cellular insulin sensitivity. The best "drugs" I know for that are a combination of these:

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1. vigorous exercise;
2. high nutrient-dense foods;
3. low digestible carbohydrate diets;
4. time-restricted eating;
5. adequate digestive health;
6. calorie control to match your physiological needs.

The mid-Victorian used all six of these techniques to avoid degenerative diseases.

Should you take metformin to live longer? No! Do the six abovementioned things, and do not rely on a drug crutch. Metformin has some interesting results for those too lazy to care for themselves properly. However, metformin also has side effects that may counteract its benefits long term. When a study is done on longevity, for how long is it conducted; two years, five years, or ten years? Even at ten years, that is only 15 percent of the average lifespan. This is inadequate to determine if the intervention provides a life-long benefit. Also, what is the makeup of the control group? I can assure you that metformin is never compared to a group that conscientiously practices the six approaches recommended above. "Garbage in, garbage out."

Here is a recent medical review article on Metformin titled "A Critical Review of the Evidence That Metformin Is a Putative Anti-Aging Drug That Enhances Healthspan and Extends Lifespan."<sup>420</sup> The abstract is reproduced here:

"The numerous beneficial health outcomes associated with the use of metformin to treat patients with type 2 diabetes (T2DM), together with data from pre-clinical studies in animals including the nematode, *C. elegans*, and mice, have prompted investigations into whether metformin has therapeutic utility as an anti-aging drug that may also extend lifespan. Indeed, clinical trials, including the MILES (Metformin in Longevity Study) and TAME (Targeting Aging with Metformin), have been designed to assess the potential benefits of metformin as an anti-aging drug. Preliminary analysis of results from MILES indicates that metformin may induce anti-aging transcriptional changes; however, it remains controversial whether metformin is protective in those subjects free of disease.

Furthermore, despite clinical use for over 60 years as an anti-diabetic drug, the cellular mechanisms by which metformin exerts its actions remain unclear. In this review, we have critically evaluated the literature investigating the effects of metformin on aging, health span, and lifespan in humans and other species. In preparing this review, particular attention has been placed on the strength and reproducibility of data and the quality of the study protocols concerning the pharmacokinetic and pharmacodynamic properties of metformin.

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Despite data supporting anti-aging benefits, the evidence that metformin increases lifespan remains controversial. However, via its ability to reduce early mortality associated with various diseases, including diabetes, cardiovascular disease, cognitive decline, and cancer, metformin can improve healthspan, thereby extending the period of life spent in good health.

Based on the available evidence, we conclude that the beneficial effects of metformin on aging and healthspan are primarily indirect via its effects on cellular metabolism and result from its anti-hyperglycemic action, **enhancing insulin sensitivity**, reduction of oxidative stress and protective effects on the endothelium and vascular function."

These authors are smart and realize that enhancing insulin sensitivity is key. Hormones are regulatory, and insulin is a hormone.

Some of the side effects of metformin, not found in the six diabetes-reversing and insulin-regulating suggestions, include:

- feeling sick (nausea);
- being sick (vomiting);
- diarrhea;
- stomach ache;
- loss of appetite;
- a metallic taste in the mouth; and
- vitamin B12 deficiency.

The review article indicates that metformin improves health span. However, feeling sick and vomiting are not exactly improvements in quality of life.

I have found that vitamin B12 deficiency in people who are not vegan or vegetarian is fixed by expanding their microbiome. If metformin disrupts the microbiome, there is no way it will enhance longevity - even if it appears to when compared to unhealthy individuals studied over a relatively short period of time. It is clear it does have its primary adverse impact on the gut based on the commonly noted symptoms. The most common side effects of metformin are nausea, diarrhea, and abdominal discomfort. Many patients (20–30 percent) report experiencing at least one of these side effects.<sup>421</sup>

As a reminder, this chapter aims to explore if modern medicine has improved health and lifespan. Metformin has some interesting anecdotal information, but if compared with good health behaviors, it will certainly come up short. In this respect, metformin is another failure of modern medicine. However, in the context of the health and longevity of diabetics, it is arguably one of the best unnatural treatments. Therefore, it must be the most prescribed type-2 diabetes drug, right?

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Here are some statements comparing metformin to other diabetes drugs. "Metformin reduced the risk of dying from heart attack and stroke by about 30 percent to 40 percent compared with other commonly used drugs called sulfonylureas, such as glibenclamide, glimepiride, glipizide, and tolbutamide, researchers report."<sup>422</sup> Notice the comparison is to other harmful drugs, not the six health behaviors.

From HealthDay News, April 18, 2016, "Pharmaceutical companies continue to make new drugs to reduce blood sugar and improve on safety concerns of the older drugs," said senior study author Dr. Shari Bolen. But, "while adults with diabetes often need more than one medication to control blood sugar, the newer medications do not appear to be safer than the older drugs," added Bolen. "Metformin is still the safest and most effective type 2 diabetes medication," said Bolen. She is an assistant professor of medicine at Case Western Reserve University's Center for Health Care Research and Policy in Cleveland. Does Bolen really think that adults need more than one drug to control blood sugar? She obviously does not understand the diabetes continuum reality.

Here are the top-selling diabetes drugs by sales dollars. I could not find the list by volume or number of prescriptions. Notice that metformin is #15.

- #1. Lantus® (insulin glargine)
- #2. Januvia® (sitagliptin)
- #3. NovoLog® / NovoRapid® (Insulin aspart [rDNA origin] injection)
- #4. Humalog® (insulin lispro injection, USP [rDNA origin])
- #5. Victoza® (liraglutide [rDNA origin] injection)
- #6. Levemir® (insulin detemir [rDNA origin] injection)
- #7. Human insulins<sup>11</sup>
- #8. Janumet® (sitagliptin and metformin)
- #9. NovoMix® / NovoLog® Mix (insulin aspart [rys])
- #10. Humulin® (human insulin [rDNA origin])
- #11. Onglyza® (saxagliptin) + Kombiglyze™ XR/Komboglyze (saxagliptin and metformin HCl extended release)<sup>10</sup>
- #12. Galvus® (vildagliptin)
- #13. Byetta® (exenatide)
- #14. Tradjenta® / Trajenta® (linagliptin) and Jentadueto® (Trajenta [linagliptin] + metformin)
- #15. Glucophage® (metformin)
- #16. Amaryl®
- #17. Bydureon® (exenatide extended-release for injectable suspension)
- #18. Actos® (pioglitazone)

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#19. Nesina® (alogliptin)1

#20. Apidra® (insulin glulisine [rDNA origin] injection)

Hmmm... Metformin is the best - or shall we say - least harmful, and it ranks #15. That means the medical system is doing more harm than is necessary and more harm than good.

The CDC shows the abject failure of conventional medicine to curb diabetes, Figure 7.11.<sup>423</sup>

### Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2015

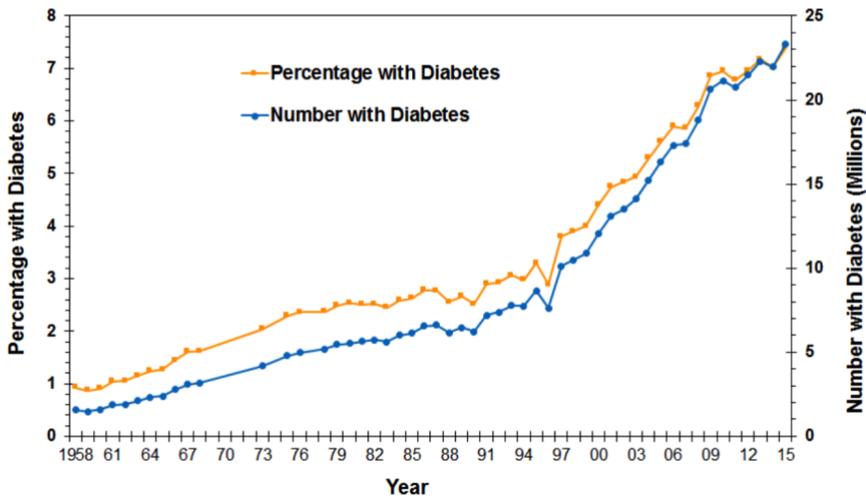


Figure 7.11: Trend in diabetes from 1958 to 2015.

Conclusion - Modern Medicine's contribution to your overall health with respect to diabetes is a NEGATIVE.

The mid-Victorian did not take metformin or insulin.

### Alzheimer's

Alzheimer's is fast becoming the number one cause of early mortality. The medical industrial complex has gone after beta 1-42 amyloid protein as a pharmaceutical target while knowing it is the wrong approach. I have written a detailed book on Alzheimer's, in general, and the failed amyloid approach to treatment specifically, and documented the failures of this approach dating back to the year 2000.<sup>424</sup>

An article published in the Journal Science is titled, "A neuroscience image sleuth finds signs of fabrication in scores of Alzheimer's articles, threatening a reigning theory of the disease."<sup>425</sup> The language "threatening a reigning theory" is an

interesting statement because this theory was discredited in the early 1900s by Dr. Alois Alzheimer's and later by Dr. Judith Miklossy, Dr. Craig Atwood, and Dr. Rudolph Tanzi, to name a few. Dr. Tanzi holds the title of "The Kennedy Chaired Professor of Neurology" at Harvard Medical School.

The introduction to the article is reproduced here. I do recommend you read the whole article. What you need to know is that research will continue in this area, and drugs will be approved. Why? Because the bar for an Alzheimer's drug is so low that anyone that is purported to make a difference, whether or not the data is sound, will be a blockbuster.

"In August 2021, Matthew Schrag, a neuroscientist and physician at Vanderbilt University got a call that would plunge him into a maelstrom of possible scientific misconduct. A colleague wanted to connect him with an attorney investigating an experimental drug for Alzheimer's disease called Simufilam. The drug's developer, Cassava Sciences, claimed it improved cognition partly by repairing a protein that can block sticky brain deposits of the protein amyloid beta (A $\beta$ ), a hallmark of Alzheimer's. The attorney's clients—two prominent neuroscientists who are also short sellers who profit if the company's stock falls—believed some research related to Simufilam may have been "fraudulent," according to a petition later filed on their behalf with the U.S. Food and Drug Administration (FDA)."

One drug that reduces beta-amyloid was approved for human use. Here is the backstory.<sup>426</sup> Three experts have resigned from FDA's advisory committee following the agency's approval of Biogen's Alzheimer's drug, aducanumab, according to multiple reports. FDA approved aducanumab at the beginning of last week. This marked the first Alzheimer's drug approval in nearly 20 years. These FDA advisory committee members resigned after FDA ignored their input during the decision-making process.

This approved drug is the same class of drug subject of the fraudulent data. And it does not end here. There is a wave of such drugs heading for approval. "More Alzheimer's drugs head for FDA review: what scientists are watching Eli Lilly and other pharma firms have begun submitting their anti-amyloid drug hopefuls for approval. But questions linger over the controversial precedent set by Biogen's aducanumab."<sup>427</sup>

Now in the COVID area, you know the side the FDA is on, so anticipate that useless drugs will be approved, and Alzheimer's will NOT be slowed, stopped, or reversed. But the drugs will be prescribed liberally.

Alzheimer's is a disease that, once diagnosed, appears to be beyond the point of no return. But this is just a manifestation of the big pharma approach, the Alzheimer's Association, and others who profit from people with the disease. The data manipulation of the results of the useless biologics cataloged in this chapter

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is just one example of why Alzheimer's appears to be a hopeless disease. However, if proper diagnosis and treatment start with cognitive impairment, or even before, Alzheimer's and other dementias would not be the 1st or 2nd most dreaded disease. Alzheimer's is a continuum and is related to the myriad of diagnoses that imply different brain conditions. Most ultimately lead to Alzheimer's. Figure 7.12.

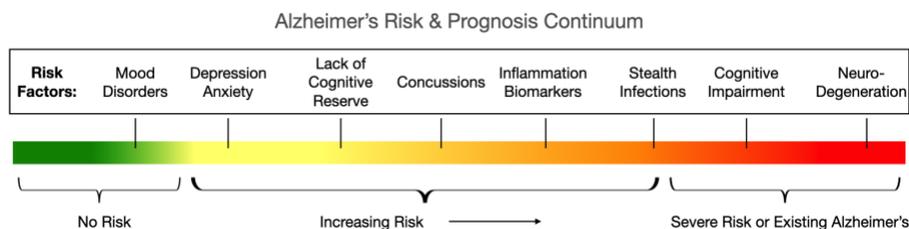


Figure 7.12: The Alzheimer's continuum and risk factors that contribute to neurodegeneration. If treatment begins before cognitive impairment becomes apparent, most cases of Alzheimer's or other dementias are most likely reversible. This is only possible by recognizing that the genesis of the disease is a slow process - a continuum. Many signs and symptoms erupt well in advance of the human-made diagnosis of Alzheimer's disease.

The mid-Victorian era had essentially no Alzheimer's disease.

### Saturated Fats Are Bad

If the world were just the United States, we would have difficulty in determining the positive versus the negative value of specific foods. Fortunately, we live in a world with great diversity. However, modern technology is rapidly homogenizing much of the world. The 36 most developed nations often follow the U.S. lead, including in healthcare. This is quite strange, considering the OECD data clearly shows that the U.S. model is one that no one wants to follow unless you are big pharma. And, since many nations have single-payer systems, the exorbitant cost of this ineffective system is a budget buster for most nations.

Again, COVID has revealed that nations are easily duped into paying huge sums of money for ineffective and unproven medical "treatments."

The French lead the developed world in saturated fat intake. The American Heart Association and other heart-related organizations coined the term the "French Paradox" because of their high intake of saturated fats and low death rates from cardiovascular diseases. This is true in spite of the fact that the French smoke at twice the rate of Americans. The data is clear that smoking is the number one cause of increased heart disease rates. Of course, this is a simplistic view because, on average, smokers tend to exercise less and eat less nutritious foods.

In terms of big lies that have wreaked havoc on the health of the world, and particularly citizens of the United States, the demonization of fats is arguably at

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or near the top of the list. Your brain, after all, is 60 percent fat. Every cell in your body is composed of a phospholipid bilayer. This term translates to a "phospho-fat bilayer" because lipids are fats.

Science writer Nina Teicholz's book, "The Big Fat Surprise: Why Butter, Meat, Cheese Belong in a Healthy Diet (2014)," has extensively documented the history and socio-economic implications of the issue of fats in our foods. The Wire published an excellent article on this topic in 2017.<sup>428</sup> A condensed version of that article is provided here.

"Guidelines from the American Heart Association (AHA), the American College of Cardiology, and even the World Health Organization were clear that fats in general, and saturated fats in particular, were to be strictly avoided to prevent a heart attack. The message was to reduce fats to less than 30 percent of the total calories consumed in a day, with saturated fats to be kept well below 10 percent.

The AHA had declared in 1961 that saturated fats were terrible because they increased blood cholesterol, which they claimed blocked coronary arteries and caused heart attacks. The AHA was surprisingly driven to this conclusion by the hypothesis of one physiologist who selectively reported some, but not all, of the global data available to support his pre-determined thesis.

Ancel Benjamin Keys, a physiologist with a Ph.D. from Cambridge University, stamped his 'diet heart' hypothesis into the consciousness of Paul Dudley White, a founder-member of the AHA. White was attending to Dwight Eisenhower, then the US president, who suffered his first heart attack in September 1955. Many middle-aged Americans were succumbing to heart attacks in the 1950s, and the situation demanded convincing answers from the health community."

Interestingly, there was no consideration that Eisenhower smoked three or four packs of cigarettes a day, picking up the habit while he was a student at West Point and quitting only a few years before becoming President. And, back then, these were the unfiltered type. In the 1950s, almost 60 percent of U.S. adult males smoked. It was not until the 1960s, when the U.S. Surgeon General announced the dangers of smoking, that trends started to decline. It was in 1946 that the Reynolds Tobacco Company launched an ad campaign with the slogan, "More doctors smoke Camels than any other cigarette."

Keys was able to launch his 'diet heart' hypothesis because there was little science available in the 1950s that could explain the near-epidemic of heart attacks among middle-aged Americans. The Tobacco companies were carefully hiding findings on heart disease while using doctors to create confusion. Sound familiar? Why are doctors so gullible to the power of suggestion and, of course, money? I went

to school with several pre-med students at Worcester Polytechnic Institute. I recollect that these students could actually think for themselves. This is a lost art among doctors today.

Keys presented his “seven countries study,” displaying a clear association between eating greater amounts of saturated fats and deaths due to heart disease. The seven countries were the US, Japan, Yugoslavia, Netherlands, Italy, Greece, and Finland. But as Teicholz has shown, the method behind the study was seriously flawed, the biggest of which was that Keys had cherry-picked these countries because they supported his hypothesis. He left out 15 countries that did not reveal any association between saturated-fat consumption and heart mortality. He conveniently ignored Denmark, Sweden, and Norway, each of which had relatively few deaths from heart attacks despite sporting diets with lots of saturated fats. On the other hand, Chile had high cardiac mortality despite eating little saturated fats.

Keys also checked food samples for fats in less than 4 percent of the 12,000 participants he studied. When the food was evaluated, it was checked for a single day among Americans and far less than a week among the European participants. Keys had also been impressed by the large number of long-lived people on the Greek island of Crete. However, as Teicholz writes, he had tested them when they had been fasting for more than a month during a religious festival. In this period, more than 60 percent of the population abstained from meat, butter, and cheese. This led Keys to the wrong conclusion that a low-fat diet was the key to longevity.

Keys cannot be held responsible. Most scientific publications include biased conclusions. That is how the system works. A researcher carves out a niche upon which they can be funded. There is almost no circumstance where a person whose career is supported through grants suddenly changes direction. This is a sure way to lose funding.

Anti-trust rules reduce the potential for monopolies. Today we have cartels so powerful that the first amendment to the American Constitution is extraneous at best. The company formed Bell Labs in the days of the AT&T monopoly. This research center was arguably the best ever. It did not have the time nor funding consideration so scientists could think, test, invent, and even fail! God forbids!

Do you learn more from successes or failures? Failure is NOT an option if you depend on outside funding to support your career. Thus, we wind up with fraudulent science. I am not suggesting we scuttle anti-trust laws. My beliefs are quite the contrary. Microsoft, Facebook, Twitter, and Google should not exist or have the power they have today if anti-trust was actually enforced. However, we do need an objective source for funding advancements in science. The source is supposed to be our government, but Fauci, the FDA, NIH, and CDC illustrate how that system is an abject failure.

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By 1977, more than 220 million Americans were urged by the US government to adhere to a low-fat diet. The British, true to form, officially imposed the same diet guidelines by 1984 on their subjects. This is despite objective diet showing that it is based on flawed data.

The largest randomized trial assessing the effects of a low-fat diet on the heart and cardiovascular diseases was the Women's Health Initiative.<sup>429</sup> It followed over 49,000 postmenopausal women for eight years who had been on a low-fat diet and an increased intake of fruits, vegetables, and grains but had failed to lower their risks of death, heart attack, stroke, or diabetes.

The Minnesota Coronary Experiment, PURE, and FOURIER trials, unnecessarily wasted taxpayers' money while corroborating what we already knew. Saturated fats are not harmful and are more protective than a high carbohydrate diet. There will be more unnecessary trials, thus unnecessary expenditures, and plenty of evidence-biased interpretations or misinterpretations. However, experience with keto, Mediterranean, and paleo diets, rich in healthy fats, shows benefits in metabolic and cardiological outcomes and biomarkers.

The assertion that saturated fats cause heart attacks is junk science.

The mid-Victorians ate plenty of saturated fats.

### COVID Jab for Kids

Dr. Maryanne Demasi explains that the era of clinical trials with safety and efficacy evaluation before approval for human use may be over. Here is her article on the jab for kids. It is titled, "FDA authorized new mRNA formula for kids without a clinical trial."<sup>430</sup>

"In October 2021, Pfizer requested the permission of the US Food and Drug Administration (FDA) to amend the formulation of its covid-19 vaccine for children aged 5-11 yrs. Pfizer wanted to switch the "phosphate-buffered saline" used in previous adult formulations to "tromethamine (Tris) buffer" and to exclude both sodium chloride and potassium chloride, claiming it "improved the stability profile of the vaccine."

A Pfizer spokesperson said, "This allows the mRNA to resist being degraded for a longer period before administration - meaning the pediatric vaccine can be stored [at] 2-8°C in commonly available refrigerators for up to 10 weeks." The FDA granted Pfizer's request stating that Tris buffer was "a commonly used buffer in other FDA-approved vaccines."

But there was a problem. There were no clinical studies of the new formula in children. The FDA only looked at the "analytical comparability" and did not request any safety or efficacy studies of the newly formulated vaccine before it was rolled out to millions of children.

Experts aghast

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“It’s extraordinary,” said Nikolai Petrovsky, Chairman and Research director of Vaxine Pty Ltd, an Adelaide-based biotechnology company focused on vaccine development, including a covid-19 vaccine. “I’ve been doing vaccine development for a long time, and normally regulators say the minute you change something in a formulation that may change its behavior materially, you have to go back to square one and establish safety all over again, to show the change mightn’t have adverse consequences. The FDA apparently did not do this in this case,” he said.

The silence from the medical community is deafening, said Petrovsky. “Why is no one questioning this? It’s the regulator’s job to act cautiously and assume any change could have harmful effects until proven otherwise.” As a vaccinologist, Petrovsky said that altering a vaccine formula, especially for new technology such as mRNA, has too many unknowns.

“Pfizer said they changed the formula for stability - well, does that mean the mRNA in the new stabilized pediatric formulation is more potent or will last longer in the body? If so, you may see big differences in biological outcomes. And what else is the change in buffer doing to those complex lipid nanoparticles in the mRNA formulations?” asks Petrovsky.

The FDA defended its decision by saying that Tris buffer has been used in other vaccines (incl Moderna) and proven safe, but Petrovsky says that misses the point. “No one is questioning the safety of the buffer – it’s about how it might change the properties of this particular mRNA vaccine in its lipid nanoparticles,” he said.

“If you have a biologic that is stable for two weeks, and then you swap the buffer so that it becomes stable for ten weeks, then you don’t have the same biologic because they don’t have the same half-life. You’ve done something that has completely changed the way this biological behaves. How do we know that that biologic isn’t going to behave differently in the body? How do we know it hasn’t changed its safety?” added Petrovsky.

Tom Jefferson, the senior associate tutor at the University of Oxford, agrees. “It’s not acceptable. The manufacturer has taken steps that are not scientifically based and are ethically challenging. If you have a vaccine, it’s made in vats like a big soup. If you change the phosphate buffer, you change your formulation, so you must test it sufficiently. Manufacturing a vaccine is very different from making a drug.”

Most drugs are highly stable, small chemical molecules that can be easily analyzed with a mass spectrometer, but biologics - like vaccines - are on another level.

“Biologics have a trillion times more complexity than small molecule drugs; biologics can exhibit completely different properties depending on how the

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protein, or in this case, mRNA chain, folds up. That's why you need different FDA departments to regulate them because the things that go wrong with biologics are much more complex than those that go wrong with small molecule drugs," said Petrovsky.

FDA was set to green-light more changes to the COVID-19 vaccine without clinical data. On the 28th of June 2022, the FDA's advisory panel voted to recommend that manufacturers update the design of their booster shots to include components tailored to combat the currently dominant omicron BA.4 and BA.5 variants.

Notably, Peter Marks, head of the FDA's Center for Biologics Evaluation and Research, told Reuters that the agency would "not require companies to submit clinical trial data on the modified vaccines." Instead, the agency would rely on the previous data from clinical trials of vaccines designed to combat the BA.1 variant.

Will history repeat?

Jefferson says we are not learning from past mistakes, pointing to the Pandemrix scandal. The Pandemrix vaccine was initially developed as a pandemic "mock-up" vaccine using the H5N1 strain to be ready to tweak in the event of a pandemic.

In 2009, when the swine flu outbreak occurred, the vaccine's formulation was altered to accommodate the circulating H1N1 strain.

There was insufficient testing of the newly formulated vaccine in pediatric populations. By the following year, Scandinavian researchers noticed increased cases of narcolepsy in children. This incurable neurological disease causes an alteration of the sleep-wake cycles and may cause a lack of muscle control.

Despite denials from the European regulator and the vaccine manufacturer, multiple academic and government-led studies subsequently judged that the link between Pandemrix and narcolepsy was likely to be causal.

Another example of how tweaking a vaccine can result in dramatic clinical outcomes is the experience with Merck's MMRV vaccine, which combined the measles/mumps/rubella vaccine with varicella (chicken pox) vaccine.

Authorities noticed that when the two vaccines were combined, it resulted in higher rates of febrile seizures in 1yr old's compared to administering the two vaccines separately.

Despite being based on two existing vaccines, simply mixing the two into a single shot was enough of a change to make a big difference in real-world harm. The MMRV vaccine was soon suspended for that age group and is now administered as two separate shots.

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It's still unclear what impact, if any, there has been on safety since the change in covid-19 vaccine formulation for 5-11yr old's, but since then, Pfizer has swapped the buffers in the adult vaccine (Comirnaty), too.

Conclusion: Dr. Nadir Ali sums it up succinctly in the following quote.<sup>431</sup>

"Consequently, Health Care providers have to accept some responsibility as being the leading cause of death in the U.S. and worldwide."

The mid-Victorians did not have vaccines but lived long, healthy lives.

### **Prescription for Good Health**

Most of us can be healthy and drug-free. We are designed to be healthy, not sick. Yet 60 percent of United States adults have at least one chronic condition. What is suggested here may prevent or solve disease in 80 percent of the people who apply these principles daily. However, my work and my mentor's, Dr. Trempe, and a small group of enlightened practitioners assert that stealth infections must be considered in people who comport themselves well but still have nagging health issues. People with these infections can be healthy too, but the pathogens must be identified and adequately treated as soon as possible.

Recall that there are ~70,000 or so medical diagnoses. However, my team operates based on five disease mechanisms contributing to most of these diseases. These mechanisms are:

1. Poor micronutrient status from poor diets, behaviors, or poor absorption.
2. Thrive vs. survive. In other words, stressors make a person vulnerable to low-grade toxicity or infections.
3. Stealth and chronic infections and toxins, with infections being the greatest offender.
4. Infections, specific sensitivities, and processed foods cause perpetual low-grade inflammation.
5. Lack of autophagy due to a sedentary lifestyle and constant eating.

Dr. Mercola's tagline is "take control of your health." He says that being healthy is actually quite simple. I agree entirely with his thesis. Further, humans are quite resilient to disease if we make an honest effort to be healthy. However, once out of balance, it is often hard, but possible, to reclaim it. The message of the drug industry and even functional medicine practitioners is that you need them to be healthy. The drug industry and your regular doctors say you are unhealthy due to drug deficiencies. The functional world says you are unhealthy due to supplement deficiencies. I believe that you require neither. You can be very healthy without drugs or supplements. Supplements are clearly preferable to pharmaceuticals.

Internal balance is a crucially important concept. The true father of internal balance was Dr. Claude Bernard, who coined this concept using the words "milieu interieur." Consider two people. One person is insulin sensitive, and the other is

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classified as a person with type-2 diabetes. The insulin-sensitive person can eat almost anything: fructose, sucrose, potatoes - that is, all types of digestible carbohydrates while experiencing no significant hyper- or hypoglycemia. The diabetic, on the other hand, will see dramatic swings in blood glucose and suffer the consequences of this behavior. The insulin-sensitive person is in great metabolic balance, and it is hard to perturb that status, at least in the short term. In contrast, the diabetic is dramatically out of balance and easily swings from one extreme (hyperglycemia) to the other (hypoglycemia).

This is no quick fix for the person with diabetes. Drugs provide instantaneous gratification. But gratification does NOT equal health. Clichés like “there is no free lunch” perpetuate for a reason as they are proven true over time. Chronic diseases, which the CDC says are 90 percent of the health problems we face, reverse slowly. Our rule of thumb is simple. If it took you ten years to become a diabetic, it will take you one year to fully reverse the syndrome and regain balance, following the suitable protocols. I know this is NOT instantaneous gratification, but it is 900 percent quicker than it took to get the disease. Be thankful for this relationship.

Dr. Mercola gives five (5) low-cost tips to help you achieve optimal health.

### Health Tip No. 1: Sun Exposure

One of the most basic ones is regular sun exposure, as its benefits include vitamin D production, vitamin A activation, and, most importantly, subcellular melatonin production. Ninety-five percent of your body's melatonin is produced in your mitochondria in response to red and near-infrared light. Mitochondria are responsible for cellular energy production, and mitochondrial dysfunction is the root cause of most chronic diseases.

Melatonin, meanwhile, is a potent antioxidant that reduces oxidative stress. By mopping up free radicals, melatonin reduces damage to the mitochondria and helps them work optimally. Melatonin also helps increase glutathione, a crucial intracellular antioxidant and detoxication agent. Virtually none of the melatonin created in your mitochondria will ever make its way into your blood. Oral melatonin can also help your chronobiology and regulate sleep when taken at the appropriate time (in the evening, shortly before bed).

### Health Tip No. 2: Cut Seed Oils from Your Diet

If you are worried about getting sunburn from all this sun exposure, this next talking point will offer relief because the No. 1 cause of sunburn is the excessive intake of seed oils and other foods high in linoleic acid (LA). This includes oils like canola, safflower, corn oil, and many others. The LA gets incorporated into your cellular membranes, and if you have high levels of LA in your cells, you will be more prone to sunburn and skin cancer. While LA has a half-life of about two years and can take up to seven years to get rid of completely, many will notice a

difference in the amount of sun they can tolerate reasonably rapidly once they cut this fat from their diet.

Your body breaks down LA into harmful subcomponents called advanced lipid oxidation end products (ALEs) and oxidized LA metabolites (OXLAMs), which can cause significant damage at the cellular level. In addition, most seed oils are made from genetically engineered crops, making them a source of toxic glyphosate. Aside from cooking oils, the primary sources of LA are processed foods (any food containing or cooked in seed oil) and conventionally raised chicken and pork.

### Health Tip No. 3: Time-Restricted Eating

A third strategy that will not cost you a dime, and may save you money, is time-restricted eating (TRE), a form of intermittent fasting where you eat all your meals and snacks within a six- to an eight-hour window, and your last meal at least three hours before bedtime. This means that you're fasting for 16 to 18 hours a day.

This schedule will give you virtually all the same benefits as calorie restriction concerning longevity but without any downsides, the primary one being compliance. In the U.S., 90 percent of people eat across 12 hours. Some will even wake up in the middle of the night to eat, a recipe for metabolic issues and chronic ill health. One of the primary benefits of TRE is that it will make you metabolically flexible to burn fat and carbs for energy.

### Tip No. 4: Optimize Your Circadian Rhythm

Circadian rhythm optimization is another frequently overlooked strategy that can have a tremendously beneficial impact on your health. Your body is designed to fall asleep a couple of hours after the sun has gone down and to wake up more or less with the sun. Most adults need around eight hours of solid sleep per night to function optimally. In the evening, avoid blue light from your TV and electronic screens. If you need lighting, you could use red LED bulbs, low-wattage lument bulbs, or salt lamps. Alternatively, you could wear blue-blocking glasses. Various apps will alter the color temperature of your screen at night.

### Tip No. 5: Exercise daily and vigorously

Exercise initiates autophagy that provides general healing and detoxification. When you exercise, nitric oxide is released into your system, and blood vessels expand and dilate, lowering blood pressure while increasing blood flow. Since the "dose makes the cure," elevated blood flow brings healing cytokines, antimicrobial peptides, and a host of healing substances to tissue and rapidly removes waste.

In addition to healing and detoxifying, increasing muscle mass profoundly impacts longevity. Skeletal muscle is your primary site for glucose disposal. Individuals struggling with elevated blood sugar, HbA1C, and triglycerides will

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benefit by increasing muscle mass through weight-bearing exercise. People with higher muscle mass have greater longevity and fair better against prolific diseases, including Alzheimer's, cardiovascular diseases, diabetes, and cancer.

Dr. Mercola is also a strong proponent of life-long learning. Pre-internet learning was a laborious challenge that required physical trips to libraries and bookstores, photocopying, and storing reams of paper. As the internet took off, researching became incredibly easy. For about 20 years, you have had world literature at your fingertips.

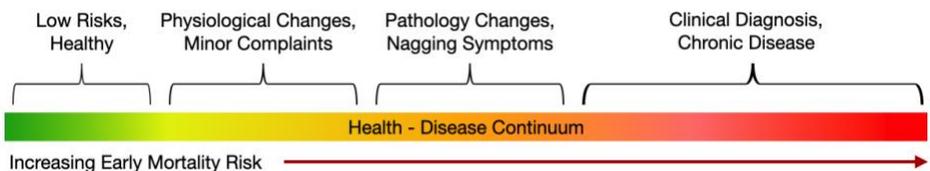
Today, censorship has stifled much of this intellectual freedom, and accessing health information, in particular, is again a challenge. Google, for example, is shadow-banning and hiding valuable sites that contradict the official narrative, so you may need to know where to look to find objective data. At this point, it is imperative to identify trusted sources and follow them regularly.

Where do you start on the quest to take charge of your health? Consider beginning your research with the five mechanisms of diseases rather than chasing any rabbit hole you hear through some sound bite. Stay focused and dive deep. You are smart. All humans are intelligent. Give yourself time, and you will quickly eclipse the knowledge of your traditional doctor. They mostly read pharmaceutical glossy brochures that are advertisements, not peer-reviewed information. You can do much better than that.

### My Health Tips

1. Realize that health and disease are a continuum. Somewhere in the world is the healthiest person, and somewhere else, someone is about to die from multiple diseases. The rest of us lie somewhere in-between these two extremes. There is one high-level health-disease continuum, but you need many measurements to be correctly placed on that continuum. Fundamentally, risks drive everything. If you subscribe to the genetic concept, that leaves you in an unfortunate position of assuming there is no hope. This is not the case. Each of us is at least 99.9 percent genetically the same. Our environments are dramatically different, and our health status is also dramatically different. The connection is clear. Also, since the CDC says that even though we are 99.9 percent genetically the same, the 0.1 percent is what accounts for the vast differences in health. Since our CDC says this, we know it is likely invalid.

You have seen this health-disease continuum image several times, representing it in several ways, Figure 7.13.



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Figure 7.13: The health-disease continuum.

How do you wind up in a less-than-optimal location on this continuum?

Life risks: We all have them. However, are yours significant enough to start harming your health? One way to tell is to measure what I refer to as your "risk portfolio." Seldom does one risk lead to a chronic disease, but a constellation of many, even minor risks may. Risks are the root cause of disease. Adverse risks, over time, may result in physiological changes.

### Chronic Risks Beget Changes to Chronic Biomarkers

Physiological risks: This foundational concept, delved into in Volume 2, is that physiological markers (biomarkers) of health are improperly interpreted in the current medical paradigm. People who suddenly die of a heart attack have early warnings noted through biomarkers long before symptoms, but they are not flagged as consequential in the standard of care. Also, if such a person is evaluated for their "risk portfolio," it can often predict an adverse event like a heart attack. The standard of care does not perform a proper measurement of risks. Importantly, if your physiological biomarkers are abnormal, even slightly, but chronically, you are at risk for chronic disease.

### Chronic Changes to Biomarkers Beget Changes to Tissue (the genesis of disease)

Pathology risks: Changes to pathology may be observed through a biopsy, colonoscopy, ultrasound, MRI, other scanning instruments, and eye testing. These observed changes indicate that risks and physiological changes start leading to diagnosable diseases. Pathology change is the most accurate indication of advancing disease and is often more motivating for people to act. However, pathology changes are late in the game. And, in the standard of care, pathology changes in the eye, for example, are never considered a marker for disease beyond the eye, even though they are. Focusing on risks is the most impactful place to start.

### Changes to Tissue are Early Warning Signs of Imminent Disease

Disease Diagnosis: The ~70,000 codes for diseases are primarily subjective. The great question is, when is the actual start of a disease? Is it when you have enough risks? Is it when your biomarkers indicate something is brewing? Is it when changes in tissue are observed? Or is it only when a symptom associated with any of these changes emerges and impacts your health? The answers to these questions define the health-disease continuum.

In general, earlier detection and action will yield quicker and better health outcomes, Figure 7.14

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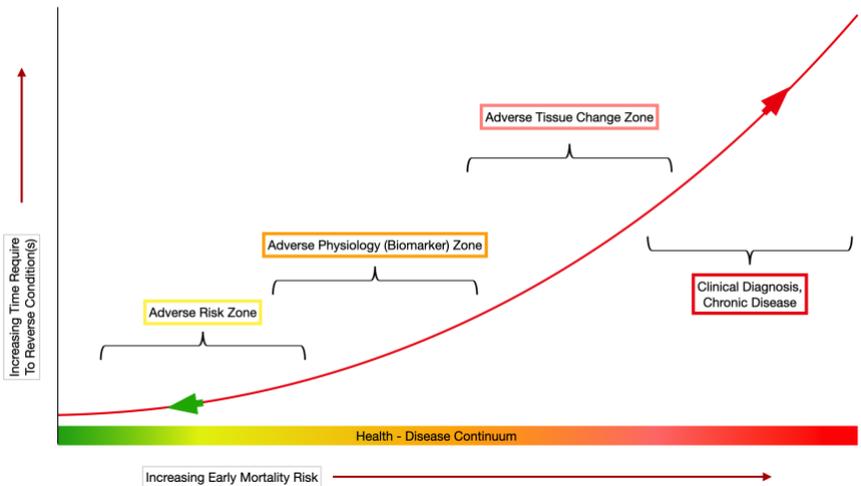


Figure 7.14. Poor health accelerates over time following a log-linear (red) curve. As the disease progresses, the time required to reverse the process and restore optimal health increases substantially.

Intelligent and proactively thinking people want to know when disease is likely present and not when it is obviously there. I have been contacted by many people outside the United States who cannot run our detailed lab panel and have decided to refrain from engaging with our program. I always tell them that we can measure risks as they are more actionable than labs or scans. Dr. Carter and I published a paper that showed we could predict labs by measuring risks. I encourage everyone to run through our risk calculator and get a consult, even if labs are not available. The process is straightforward:

Risks beget physiological changes that generate pathology changes that can turn into disease.

The beginning of this chapter delved into the current healthcare system's failures to prevent and reverse disease. Most of the healthcare narratives on prominent health society websites discuss risks. These group drone on about diet, exercise, smoking, and cholesterol. Of course, we know that these groups are long on words and short on solutions if it is not pharmaceutically related. Otherwise, we, like the mid-Victorians, would have 10 percent of the chronic diseases we have today. Does the phrase "a cured patient is a lost customer" potentially explain the quality of the advice we are getting?

Risks matter.

Here is my advice for optimal health based on the five (5) mechanisms of disease.

Poor micronutrient status from poor diets, behaviors, or poor absorption.

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The Yin and Yang of this mechanism are food quality and digestion efficiency. "You are what you eat" is only part of the equation. We have done various things to harm our digestive tract in modern society. In particular, most people have either started life with insufficient diversity in their microbiome or have been exposed to substances that disrupt this diversity. Thus, the more appropriate cliché is "you are what you absorb." In either or both cases, the solution to improved absorption is reasonably straightforward.

- Eat well, including plenty of fats, modest amounts of protein, and vegetables with no-digestible carbohydrates to support your microbiome. Focus on nutrient density discussed in Volume 2.
- Cook your food. Cooking is a phase of digestion and will improve nutrient absorption.
- Eat more fermented foods. These foods are pre-digested to some degree. Even fermented foods without active cultures are pre-digested and provide more nutrients than the unfermented version of the food.
- Take probiotics regularly or prophylactically. Maintaining a healthy microbiome in our modern and toxic world is a life-long pursuit. It is vital to rotate probiotics because most, if not all, contain inadequate organism diversity. Thus, rotating probiotics is the appropriate way to supplement.
- Consume a warm beverage with meals. Higher temperatures speed up chemical reactions, and your gut is a chemical processing plant.
- Test for and treat gut pathogens like h-pylori, candida, and c. diff. There are specific natural treatments and probiotic substances to control each of these.
- Ensure that you have sufficient stomach acid. This acid kills most harmful organisms in foods that enter through the 1.5 liters of saliva you swallow daily. Infection is a primary underappreciated driver of chronic diseases. Supporting barrier immunity may be the most important thing you can do to prevent identifiable and cryptic infectious diseases. Gut acid is part of barrier immunity.
- Lab testing for gut health is in its infancy, and proper standards for optimal gut health must be refined as we learn more about gut health. However, there are clear indicators of less-than-optimal gut health. If you have any irregularity in your gut, you are far from optimal, and you need to focus on these suggestions long after any symptoms are resolved. Remember, your gut health is best described as a continuum.

Thrive vs. survive. In other words, stressors make a person vulnerable to low-grade inflammation, toxicity, and infections.

This is a complex issue to resolve. Most things that put us in a flight or fight status are related to our personal situations: relationships, finances, health issues, and jobs. Avoiding toxic or negative people is an essential first step. For example, this

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may be challenging if derived from an interdependent relationship. However, there are things we can all do.

- Find a happy place, whether a book, a pet, a song, a location, or a friend, and release your earthly stressors by going there as often as you cannot.
- Do not remain in a state of denial.
- Get more sleep.
- Throw away most of your technology. You really do not need it. This includes all social media. Read books rather than watch TV. Importantly, do NOT listen to any talking heads. They are NOT to be trusted.
- Regaining some control, no matter how slight, relieves stress. Educate yourself. Your brain and what you put into it is your best relief valve.
- Exercise daily. This is a great relief value and will help with sleep.
- Treat any health condition at the root cause. When you are unhealthy, your body will reallocate resources to keep you alive, making it more challenging to cope with stressors.

Stealth and chronic infections and toxins, with infections being the greatest offender.

What do you really think causes cancer, heart disease, and Alzheimer's disease? Is it a deficiency in chemotherapy, statins drugs, or a monoclonal antibody? When your doctor, including your functional doctor, is not sure why you have a disease, it is most likely due to a chronic infection. When your doctor, including your functional doctor, tells you they know why you are sick, and it does not include subtle infestation by a chronic, cryptic infection, they could be wrong. The only way to know for sure is through testing. If your innate immunity is activated in any way, you have a chronic infection.

- Test for usual suspects, including h-pylori, Lyme disease, chlamydia pneumoniae, oral infections, and viruses.
- Evaluate your white blood cell counts for the slightest changes from an optimal count. More tests provide great precision but working towards a white blood cell count, shown in Figure 7.15, is a good start.

WBC Range	4,000 - 5,700
WBC (optimal)	4,400
NLR	1.3
Neut (Abs)	2,400
Neut (%)	55
Lymphs (Abs)	1,800
Lymphs (%)	41

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Figure 7.15: Optimal white blood cell counts, which are a measure of the activity of your innate immune response.

- Optimize your health based on the other four overarching mechanisms of disease.
- Include supplements that improve your anti-infective terrain. These include vitamins C, A, and D, iodine, healthy fats, and oils, including essential oils, zinc, melatonin, and medicinal mushrooms. This is not a comprehensive list, but it is an excellent place to start.
- If your WBC count and lymphocytes are low, get treated with ivermectin and hydroxychloroquine, and thank Dr. Fauci for popularizing this therapy.
- Do not view antibiotics as universally harmful. They have been over-prescribed and misused in many cases. However, they often offer a favorable risk/benefit ratio. There is a presumption that all antibiotics destroy gut flora. This is not entirely true. If every antibiotic did the same thing, we would only need one. Instead, there are hundreds of antibiotics, all with unique properties.

Do not delay an inevitable treatment. Treating sooner is the best approach if you are positive for harmful pathogens and have associated symptoms caused by them. We all have beneficial, commensal, and harmful organisms in our system. That is why when we die, we decompose from within. They are already there. However, controlling their populations may be one of the most important things you can do to "fall off the cliff" at 95 years old rather than slide down the slippery slope starting at 60 years of age.

Perpetual low-grade inflammation caused by infections, specific sensitivities, trauma, and processed foods.

Pathogenic organisms are not the only thing that can lead to persistent inflammation. However, what I recommend for managing chronic infections applies to controlling inflammation. They very often go together. People with elevated CRP who have tried unsuccessfully to lower the value most likely have an undetected or uncharacterized pathogen.

When it comes to inflammation, your eyes and brain are outliers. These fatty tissues have "immune privilege." The upside is that your vision does not blur, and your brain becomes fuzzy with the slightest insult. The downside is that when intense inflammation is triggered, it tends to persist for a long time. In the brain, this can be PTSD, traumatic brain injury, or a neurodegenerative process that is allowed to simmer into symptoms. In these circumstances, you must use every possible approach to quell the inflammatory "fire." Several reported natural anti-inflammatories are known to slow the fire, so start here first. I often recommend the following when this persistent inflammation impacts the quality of life.

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- High doses of cod liver oil are strongly anti-inflammatory, with 15 grams/day being the minimum dose. The cod liver oil fatty acids oxidize so your tissue does not. There are reports of severe concussion victims who made dramatic recoveries on high amounts of fish-type oils.
- Low-dose naltrexone taken as prescribed and monitored by your physician shows anti-inflammatory responses in some tissue.<sup>432</sup>
- Several endogenous peptides identified during inflammatory responses showed anti-inflammatory activities by inhibiting, reducing, and modulating the expression and activity of mediators.<sup>433</sup>
- Photobiomodulation (PBM), or low-level laser/light therapy (LLLT), is a non-invasive light-driven intervention that involves the use of red and near-infrared (NIR) light to stimulate healing processes, reduce pain, protect the aging brain and decrease inflammation in several tissues, including the nervous tissue.<sup>434</sup>
- Other energy medicine modalities provide free electrons. Electrons reduce inflammation. PEMF and microcurrent devices provide free electrons.
- Minocycline is an anti-inflammatory drug capable of reducing the causes of inflammation and the inflammatory response to the causes.

Minocycline is an antibiotic. However, minocycline has multiple modes of action, referred to as pleiotropic. Minocycline can exert an anti-inflammatory effect at doses considered below the antibiotic dosage. Importantly, minocycline is lipophilic. This drug is fat-loving and easily crosses the blood-brain barrier to exert its anti-inflammatory influence. Start with the natural substances; if you are not deriving a benefit, a pharmaceutical approach may be a more potent option.

### Lack of autophagy due to a sedentary lifestyle and constant eating.

The preponderance of chronic diseases occurs in people over the age of 65. This is also the age when your regular doctor tells you to exercise less strenuously, if at all. Walking is an example recommendation. Next time you get this advice, carefully examine the physique of your physician.

Doctors are concerned that aggressive exercise may trigger a heart attack or stroke due to poor vessel integrity caused, presumably, by aging. If this is their concern, should they measure for poor vessel health or lump everyone into a risk category because of age? If you optimize mechanisms 1 - 4, you probably have healthy blood vessels. Here are some recommendations to ensure vessel health.

- Measure and optimize C-reactive protein, fibrinogen, and homocysteine.
- Ensure your white blood cell counts are normal or, preferably, optimal. See Figure 7.15 above.
- Become more Japanese as they likely have the best vessel health. It is not a guess that they have the best longevity. The Japanese eat healthily, including the bounty of the sea and fermented foods.

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If your vessels are healthy, exercise harder and more frequently than you currently do. We evolved into toiling, working, hunting, and gathering. That is now seldom the case. The mid-Victorians toiled at an estimated ten times the level compared to the average British citizen today. My rule of thumb is fundamental. You must pay to play if you want to stay youthful and healthy. That means you have to exercise to the point of fatigue and pain. The term "no pain, no gain" applies to all ages. If you do NOT gain as you age, the only alternative is to decline.

The mid-Victorians may have taught us the most valuable lesson. Eschewing the conveniences of modern society may be the best pill for healthy longevity. Hopefully, you now know modern medicine's most prominent health failures, but the entire system has failed us while taking most of our disposable income. The net impact of this system on our collective health is negative. However, our behaviors play the most relevant role in our overall poor health. Focus on risks, measure your labs, and work hard to bring them into optimal ranges. It is the best you can do.

When someone who does not know me asks what I do, the answer is simple. I have two answers, depending on who they are.

If I know them in some capacity and know they can handle a bit of sarcasm, my response is.

"I work in healthcare, and my approach is simple. I review whatever your regular doctor told you to do and suggest you do just the opposite."

For people who do not know me or if I feel like giving a technically sound evidence-based response, it is:

I help people understand where they lie on the health-disease continuum and then help them move to the healthiest position they can achieve."

## Chapter 8: Modern Medicine is NOT Safe or Effective



## Summary

"The Prince's theme is accepting and justifying the use of immoral means to rule over the subjects."

- Machiavelli

## Summary

Human physiology is a science at its core. It is not an exact science, limited by the ability of humans to understand and piece together enormous amounts of information on a macroscopic, microscopic, and molecular scale. This is indeed a daunting task and makes the science of medicine among the most complex of all scientific endeavors.

Medicine is the delivery of interventions that are intended to enhance human physiology. That is, medicine, in an ideal world, does its best to apply the science of human physiology to individuals and populations to the best of the current state of scientific knowledge.

Most branches of science have advanced dramatically since humans first began making and documenting observations about our physical and quantum worlds. Many aspects of science and resulting technologies had to merge to lead to the types of dramatic advancements we have seen, especially during the industrial revolution. Chief among them has been the advancement in global communication.

Change does not occur linearly. Instead, it follows the "gaussian curve," which is an asymptote, Figure 9.1. This basic concept of nature explains the emergence of the industrial revolution and the dramatic progress we experience today when compared to the time of the founding fathers of the United States. An example I often use is training to run a 100-meter dash in 12 seconds. A person just setting out to achieve this goal can walk 100 meters in one minute, but it gets progressively more difficult as the person's time gets to 20 seconds or below.

## Summary

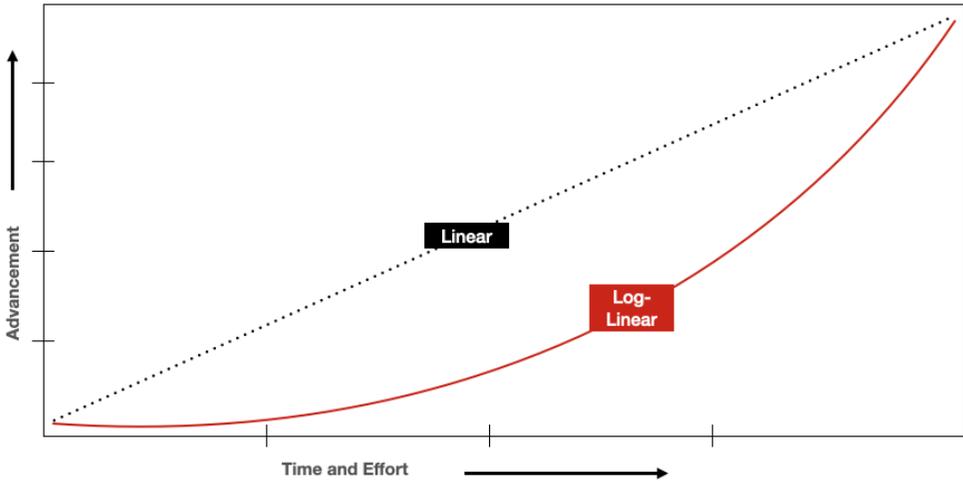


Figure 1. Linear vs. log-linear (asymptotic) advancement.

Essentially all sciences and technologies follow the log-linear curve. We are clearly on the portion of the curve swinging rapidly upward in our modern world. We see significant advancements based on a long history of time and effort spent learning about our world. This is also true for our understanding of human physiology. However, the application of that knowledge is NOT being translated to medicine. In fact, the opposite is true. While other scientific applications have become more efficient, less costly, and amazingly advanced, medicine delivery has become dramatically more expensive and less efficient. Ironically, the populations medicine serves have become considerably less healthy. If we had an alternative, as we do in competitive markets like cell phones, most of us would indeed seek a better product.

The only conclusion one can draw is that the delivery of medicine does not leverage the available best-of-breed and lowest-cost advancements. Medicine is a monopoly, and those who control it ultimately control what we receive. Even though we appear to have choices, we do not. You can choose to go to Mayo Clinic (if they will take you), Harvard, or your country doctor, and they all run the same pathetically unpredictable labs and prescribe the same drugs. Where is the advancement?

If we, the little people, had just to contend with a corrupted medical system, we might have a chance to get better care and be robustly healthy. However, since medicine is the single largest business in the United States, many other industries and special interests have their hand in the medical money pot. Richard Amerling, M.D. expressed what most of us inherently know - the medical system and all the allied industries and governments - are broken. The only solution is to scuttle them entirely and build a new medical system from the ground up.

## Summary

Volume 2 discusses some fundamental ways medicine and healthcare can be saved by being re-engineered. However, suppose those working to the effect that change are successful in the near term. In that case, the monetary savings will have broad economic consequences because the economy of the United States and other developed nations have adapted to depend upon the exorbitant costs. But we must forge forward to make this change.

We must eliminate the so-called "standard of care" and reincarnate it as the "standard of health." Ultimately, our future health, wealth, and freedoms depend upon it.

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