

# THE HEP B CHRONICLES

The Story of a Virus, a Vaccine, and  
Industrial-Sized Vats of Genetically  
Modified Baker's Yeast



Ken McCarthy

Author of the bestseller  
*What the Nurses Saw*

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**- Ken McCarthy**

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# Introduction

## *Vaccines for Newborns, Infants, and Children*

At the time this chapter was being written, the CDC recommended more than 70 vaccine doses for children aged 18 and under. The total reflects the number of individual doses recommended in the CDC childhood immunization schedule from birth through age 18, including booster doses and multi-dose vaccine series.

Before the National Childhood Vaccine Injury Act of 1986, which shielded vaccine manufacturers from civil product-liability claims, the routine childhood immunization schedule in the United States was relatively small and focused primarily on diphtheria, tetanus, pertussis, polio, and measles-mumps-rubella.

In the years that followed, vaccines were gradually added to the childhood schedule for hepatitis B (recommended for infants beginning in 1991), *Haemophilus influenzae* type b (Hib) (late 1980s–early 1990s), varicella (chickenpox) (1995), pneumococcal disease (2000), meningococcal disease (2005), rotavirus (2006), hepatitis A (mid-1990s, expanded nationally in 2006), and human papillomavirus (HPV) (2006).

Each of these additions expanded the number of doses recommended for children and, correspondingly, the size of the pediatric vaccine market. The shielding of the industry from civil product-liability claims not only removed financial liability from these companies for their products but also removed all practical incentives to make them safe and effective.

The number of vaccine doses recommended for children in the United States is substantially higher than in many other developed countries, including nations with child health out-

comes comparable to or better than those of the United States, such as Germany, Denmark, Sweden, and Japan.

In the course of writing this chapter, following a Presidential directive to review international vaccination practices, acting CDC Director Jim O’Neill, under HHS Secretary Robert F. Kennedy Jr., ordered that the U.S. childhood vaccination schedule be brought more closely into line with those of other developed countries. Shortly thereafter, the attorneys general of fourteen states, including California, New Jersey, and Michigan, sued the agency, demanding that the previous schedule be fully restored.

One of the vaccinations removed from the childhood schedule is the hepatitis B injection for infants. However, it remains on the schedule for children and adolescents up to age 18 who have not previously received the vaccine.

The procedure for how vaccines are added to the childhood schedule is covered at some length in Chapter X. Briefly: the FDA approves a vaccine for use; the CDC’s Advisory Committee on Immunization Practices (ACIP) then votes on whether to recommend it; the CDC director formally adopts the recommendation; and individual states, which generally follow the federal recommendation, make accepting the vaccine a condition of enrolling in school. This is the path by which local states made more than 70 vaccine doses for children aged 18 and under, a legal requirement for children to receive an education.

“The safety and effectiveness of vaccines—pediatric and otherwise—has been established beyond any doubt”. This is the often-repeated claim made by the CDC and echoed emphatically by the news media, public health officials, and many—though not all—physicians. Yet an obvious logical question arises. If vaccines have been proven safe and effective, why did vaccine manufacturers seek liability protection in the first place? And why did the U.S. government grant it? No other industry enjoys this kind of government protection for the products it manufactures and distributes. An industry that produces safe and effective products should not require

extraordinary government protection in order to remain in business.

A natural question follows: If vaccines are safe and effective, where is the proof? Simply claiming that something is so does not make it so. One might expect to find an organized and publicly available body of documentation systematically explaining each vaccine on the childhood schedule—how it came to be judged safe and effective, and why it was recommended for routine use in children.

Such a body of documentation would be useful to several groups: pediatricians who oversee the administration of vaccines, media figures who press the public to get vaccinated, state legislators who vote on which vaccines to make mandatory, public school officials who enforce vaccine mandates, and parents and other caregivers who want to make an informed decision regarding an invasive medical procedure required by school authorities. If one sincerely wanted to combat “vaccine hesitancy”, it would be hard to imagine a more useful set of documents.

Instead, if any of the parties listed above wish to obtain a straightforward and comprehensive answer to how a particular vaccine came to be declared safe, effective, and necessary, they must start their quest by piecing together information from a wide array of technical reports, regulatory filings, committee transcripts, and journal articles. The process requires locating documents across multiple government websites and scientific databases and reconstructing the reasoning behind each recommendation from materials that no government agency or medical association has ever assembled into a single, systematic explanation of the schedule as a whole.

In other words, there is no single place where an ordinary citizen—or even a physician—can go to see the complete case for the childhood vaccine schedule laid out in one coherent form. Given the absence of such documentation, it’s reasonable to ask how those who speak with such certainty about the safety and effectiveness of vaccines arrived at their conclusions.

Tracing the science and rationale behind every vaccine on the schedule is beyond the scope of this book. However, in the spirit of helping to “prime the pump”, what follows is the story of how one vaccine—the hepatitis B shot—found its way onto the childhood vaccination schedule, in this case, a vaccine given at birth so far to an estimated 115 million-plus newborns in the US.

# Chapter 1

## *A Child is Born, and the Injections Begin*

A child is born.

In hospitals where it is encouraged, and not all encourage it, the newborn is given to its mother to rest on her chest for skin-on-skin contact and a first attempt at breastfeeding for an “undisturbed first hour”.

Roughly 20% of U.S. hospitals advertise this as their ideal and have paid for a specific Baby-Friendly USA certification.<sup>1</sup> The remaining 80% may or may not follow this practice.

Where the “undisturbed first hour” ideal is not practiced or upheld, the sequence of events is as follows. The cord is cut within seconds of birth, and the baby is immediately taken from the mother to a radiant warmer across the room or down the hall. There in a heated bassinet under a heat lamp, the baby is dried, suctioned if needed, scored, measured, given a vitamin K injection, erythromycin eye ointment, ID bands, and a hepatitis B vaccine injection.

Whether given an undisturbed first hour with their mother or not after the momentous occasion of being born, all babies are eventually removed from their mother’s care for the procedures listed above. In the U.S., universal vitamin K injections at birth started in 1961. Universal hepatitis B vaccine injections started in the U.S. 30 years later, in 1991.

On the surface, the rationale for injecting newborns with vitamin K appears to be very straightforward. It’s stated that all newborns are born with a vitamin K deficiency, and since vitamin K is essential to clotting, insufficient vitamin K can

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1 This number comes from Baby-Friendly USA, a private nonprofit that is a US licensee of a program created by the WHO and UNICEF, which certifies hospitals meeting a specific set of breastfeeding support standards, the Baby-Friendly Hospital Initiative.

lead to uncontrolled bleeding of the gastrointestinal system, the umbilical stump, or blood vessels in or around the brain. The latter case, a serious one that really causes grave harm, is said to occur in 1 in 14,000 and 1 in 25,000 births.

Missing from the official rationale are three well-established medical facts:

First, the vitamin K deficiency is measured against adult levels. By that standard, infants are “deficient” in numerous substances, including the liver enzymes needed to neutralize substances injected into them.

Second, serious vitamin K deficiencies that have an elevated bleeding risk do not appear out of the blue. Women with epilepsy, clotting disorders, heart conditions, and tuberculosis have their conditions managed by a variety of medications that cross the placenta and actively deplete fetal vitamin K during pregnancy.

Third, if there is a serious bleeding issue, a vitamin K injection after birth is too little too late. The treatment for intracranial bleeding is a full IV of vitamin K. A newborn-sized injection carries only a small fraction of what is needed in an emergency situation.

Without getting too detailed about the content of these injections, there are two brands used in the U.S. – preservative-free Amphastar from International Medication Systems and AquaMEPHYTON from Pfizer.

The primary difference between the two brands is that the one from Pfizer contains benzyl alcohol as a preservative. Pfizer’s FDA-approved product clearly states in its FDA-mandated package insert that benzyl alcohol can cause gasping syndrome, neurological deterioration, seizures, intracranial hemorrhage, and death in premature and low birth weight infants. It then goes on to say: “Use benzyl alcohol-free phytonadione formulations in neonates and infants, if available,” and “Whenever possible, use preservative-free phytonadione (vitamin K) formulations in neonates (newborns).”

Given the choice between a product known to have serious side effects – and one that the manufacturer’s own warning label counsels against using – and using one that does not contain harmful preservatives, which brand do most hospitals choose? Getting a precise answer is not easy. It’s up to whoever occupies the hospital’s purchasing offices, but this we do know. A look at International Medication System’s SEC filings reveals that their vitamin K sales are in decline, which they attribute to “increased competition”. Given that they only have one FDA-authorized competitor, that means Pfizer’s product is gaining market share.

What is the special virtue of the Pfizer product that makes it increasingly more attractive to hospitals?

The preservative-free International Medication System product comes in single-dose vials. Open it, use it, discard it. Every infant gets a fresh vial. Given that packaging and shipping a vial costs at least as much, maybe more, than what’s in it, this safer approach is more expensive than the Pfizer approach.

Pfizer puts ten doses in a single vial. This means that once opened for an injection, a single vial can be closed and put back on the shelf and drawn from again later up to nine more times. During this period, the vial is not refrigerated. According to United States Pharmacopeia standards, once opened, the vial that contains 10 doses is “good” for 28 days.

How is this 28-day standard enforced and by whom? The pharmacy department delivers the vials to the labor and delivery unit. According to The Joint Commission on Accreditation of Healthcare Organizations, the nurses who open the vials are supposed to note their open date and expiration date on the vial and dispose of any vial past its expiration date. It’s an honor system, and hospitals receive outside audits on this and other medication management practices every three years by the Joint Commission. Dates of when inspections are most likely to occur are predictable (they take place as part of the regular accreditation cycle). Despite this advanced notice and the well-documented phenomenon of hospitals tightening compliance in the period when a survey is expected, between 2020

and 2021, up to 13% of hospitals received Joint Commission citations specifically related to general medication storage violations.

The vitamin K injection, like the hepatitis B vaccine injection, which we will discuss at length in the coming chapters, is made in the following way.

The nurse loads the syringe from the vial and then, holding the newborn's leg steady with one arm, makes the injections with the other. A newborn will pull away from pain, so the leg has to be held firmly.

The injection is made in the part of the newborn's thigh that faces outward, midway between the ankle and knee (anterolateral thigh). Newborns have very little muscle. For example, at birth, the deltoid is quite undeveloped, but there is muscular development of the thigh. The reason this part of the thigh is injected is that there are no major blood vessels in it, unlike the inner thighs, which have the femoral artery and vein running through them.

There are some settings in which two practitioners are involved in the process, one to steady the newborn's leg and one to make the injection, but this is not mandated in U.S. medical practice, where the procedure is usually carried out by a single practitioner. When done according to plan, the needle goes in at a 90-degree angle and is inserted to its full length,  $5/8$  of an inch, through the skin, through the layer of fat underneath the skin, and directly into the muscle.

There are no large blood vessels on the outer part of the thigh, but that doesn't mean there are no blood vessels. It's an anatomical fact that all muscle tissue is infused with blood vessels.

If the goal is to avoid injecting into a blood vessel (and it is in this case), there is a method to ensure that the needle has not inadvertently punctured a blood vessel. It's called aspiration. In aspiration, the needle is inserted, and the plunger is pulled back. If blood appears in the plunger, that indicates that the

needle has punctured a blood vessel, and the practitioner tries in another spot.

For reasons not clear, this traditional common-sense safety protocol has been officially removed from U.S. medical practice when it comes to vaccinations, and no guidance whatsoever has been given regarding the vitamin K injection. In any event, the CDC's General Best Practice Guidelines for Immunization from the Advisory Committee on Immunization Practices are crystal clear:

“Aspiration before injection of vaccines or toxoids (i.e., pulling back on the syringe plunger after needle insertion but before injection) is not necessary because no large blood vessels are present at the recommended injection sites, and a process that includes aspiration might be more painful for infants.”

In his book *The Needle's Secret*, researcher Marc Girardot relays a report he received from an expert familiar with the practices of bodybuilders who frequently self-inject steroids. Despite taking great care with the process, including aspirating the needle before the ultimate injection, they report accidentally injecting directly into a blood vessel, and thus the bloodstream itself, on average, 1 to 3 times per 100 injections. The result of this is the carrier oil going directly to the lung, a painful condition called “tren cough” which is accompanied by violent coughing, tightness in the chest, shortness of breath, dizziness, and, subjectively, a feeling of impending doom.

Steroid users are motivated by instant, painful consequences to avoid hitting blood vessels, and yet they do often. Readers will have to speculate on how often a system that injects newborns, without bothering with even the basic precaution of aspiration, routinely creates injection-related adverse reactions in its patients. The reason speculation is needed is that the question had never been researched because the assumption is that it doesn't happen because “no large blood vessels are present”. When an intact reacts to an injection with crying, color change, and breathing irregularity, is it a reaction to the pain of the injection or something else?

Roughly thirty years after the introduction of routine vitamin K injections for newborns, the United States adopted a policy of universal hepatitis B vaccination for infants. Current guidelines recommend that the first dose be given within 24 hours of birth.

In practice, the injection is usually administered during the newborn's first round of processing. Shortly after birth, the infant receives a vitamin K injection, and erythromycin ointment is applied to its eyes (a nineteenth-century German innovation beyond the scope of this book). Basic measurements such as weight and length are recorded, and an identification bracelet is affixed. The hepatitis B vaccine is given either during this first round of processing or at some point within the first 24 hours of life, almost always before the mother leaves the hospital with her baby.

Since 1991, when this procedure was initiated, over 100 million newborns in America have received the Hep B injection at birth. Among developed nations, the U.S. is an outlier. Germany, France, Italy, Spain, the United Kingdom, Sweden, Denmark, Norway, Finland, the Netherlands, and Japan, all countries with measurably better health outcomes for their infants and children, do not recommend the hepatitis B vaccine at birth unless there is a specific medical justification relevant to the child. In contrast, the World Health Organization (WHO) has aggressively and successfully promoted Hep B vaccines at birth in over 110 nations, mostly low- or middle-income countries, particularly in Asia and Africa.

In the chapters that follow, we'll trace why the U.S. is alone among developed nations in requiring Hep B vaccines at birth, specifically how the idea was sold to the federal government and by whom.

# Chapter 2

## *The Liver and Its Vulnerabilities*

Discussing the hepatitis B vaccine without knowing what hepatitis is and how the liver works and what its vulnerabilities are is like evaluating car repair and maintenance options without knowing the first thing about how cars are put together and how they work.

First, what is hepatitis? In Greek, hepatitis simply means liver (“hepat”) inflammation (“itis”). It’s a disease that Eastern Mediterranean, Chinese, and Persian doctors have recognized for millennia. Hippocrates wrote about the condition in the 5th century BCE. The Egyptian Ebers Papyrus, written around 1550 BCE, contains a description of it.

The symptoms of the disease the physicians described include fatigue, nausea, loss of appetite, abdominal pain, dark urine, and jaundice, the yellowing of the skin and eyes associated with liver disease. Using the excess presence of liver bile as a clue, they accurately tracked the symptoms to a disorder of the liver.

It would be hard to overstate how essential the liver is to human health. Built somewhat like a sponge, it serves as the body’s largest reservoir of blood among the organs. At any given moment, the liver contains roughly 10–15 percent of the body’s total blood supply, compared with about 2 percent in the brain and roughly 1–2 percent in the kidneys. Equally impressive is the amount of the body’s blood that flows through it: roughly a quarter of the blood pumped by the heart passes through the liver every minute.

Now that we have a picture of how the liver is made and its central place in the body’s circulatory system, we can look at its many functions.

The liver: (1) cleans toxins from the blood, (2) converts digested food into nutrients the body can use, (3) helps regulate blood sugar, (4) produces bile that aids in the digestion of fats, (5) contains specialized cells that help fight infections, (6) stores vitamins and minerals for later use, and (7) assembles proteins from amino acids that are needed to repair tissues, carry substances through the blood, and allow the blood to clot after injury.

One testament to the liver's role as a metabolic powerhouse is the fact that the average liver cell contains roughly 1,000 to 2,000 mitochondria. Mitochondria are the structures inside cells that generate most of the energy the cell needs to do its work. Liver cells are literally packed with them, and they make up about 20–25% of a liver cell's total volume. Only a few types of cells contain more mitochondria than liver cells – most notably heart muscle cells, certain kidney cells, and neurons in some parts of the brain.

Among its many other virtues, the liver is unique in its ability to regenerate itself. Ancient Greek physicians – perhaps drawing on Egyptian and Persian sources – recognized this. The idea even appears in the myth of Prometheus, the Titan who angered the gods by giving fire to mankind.

As punishment, he was chained to a rock where an eagle repeatedly tore at his liver, which then grew back so the torment could continue. In addition to having an eagle peck at it at the command of angry gods, the liver has other vulnerabilities. Despite its remarkable regenerative capacity, the liver, like all biological systems, can be overwhelmed. When that happens, mild, passing inflammation can become severe and sustained inflammation of the liver, killing liver cells. This is hepatitis. Toxins, both man-made and biological, are among the principal drivers of this process.

Alcohol consumption, which directly damages liver cells, often appears at the top of the list when causes of liver disease are cited. Pharmaceutical products, even when taken as directed, can also cause hepatitis. In fact, one of the

leading causes of acute liver failure in the United States is overdose of a common over-the-counter pain reliever, acetaminophen, better known by its brand name Tylenol. Food and water contaminated by industrial chemicals, heavy metals such as arsenic, agricultural runoff containing pesticides and herbicides, or natural toxins produced during algae blooms can also damage the liver and cause hepatitis and other liver diseases. Some bacteria, like *Leptospira* from water contaminated by animal urine, and typhoid fever caused by *Salmonella typhi*, can also directly trigger hepatitis. Infections from other sources can contribute to an inflamed liver as well.

There are other causes of hepatitis, the most common being a diet-related metabolic issue: the buildup of fat in the liver. This is a common source of liver disorders.

People who are malnourished, chronically stressed, living in poor sanitary conditions, exposed to high levels of biological or chemical toxins, regularly consuming alcohol or illicit drugs, or maintaining diets and lifestyles that promote fatty liver are all candidates for hepatitis. As you can imagine, many – sometimes all – of these factors can be present in a single individual. Like many disorders, hepatitis is largely associated with poverty; where poverty is not the primary driver, lifestyle factors often are.

In some cases, the immune system may mistakenly attack liver cells, or inherited metabolic disorders may interfere with the liver's ability to process certain substances, but these are both rare.

Strangely absent from many epidemiologists' lists of factors contributing to hepatitis is the repeated injection of illicit drugs directly into the bloodstream. Epidemiologists often cite "virus transmission" from shared or otherwise contaminated needles, but, for reasons known only to them, they frequently omit mentioning the direct toxic effects that come from the contents of the drugs themselves. Illicit drugs are very often contaminated, diluted, or mixed with other substances. They may also contain

biological contaminants such as bacteria and fungi, including *Staphylococcus*, *Streptococcus*, *Clostridium*, and *Candida*. These are introduced during production, storage, or preparation for injection. In addition to substances such as talc, starch, and powdered milk used to “cut” street drugs, and substances such as fentanyl and xylazine added to boost their effects, street drugs may also contain toxic residual solvents, byproducts of incomplete chemical reactions, and other industrial chemicals. We will return to this omission later.

Now that we know what hepatitis is, the next logical question is what exactly is hepatitis B (Hep B), and why are infants considered to be at such risk from it that it justifies giving every newborn a Hep B vaccination at birth and two more before the age of six months?

The original name for Hep B was “serum hepatitis” because it was first observed in people who received blood transfusions or injections. It was distinguished from “infectious hepatitis,” which was commonly transmitted through contaminated food or water.

The first well-documented outbreak of what later became known as “serum hepatitis” occurred in 1883 among workers at a shipyard in Bremen, Germany. As industrial workers, these men – like infants, schoolchildren, and military recruits – were required under the German Empire’s 1874 Imperial Vaccination Law (*Reichsimpfgesetz*) to accept smallpox vaccination. Early smallpox vaccinations were not injected with a syringe but introduced through small scratches in the skin, a method known as scarification. Although the method of delivery differed from injection with a hypodermic needle, the underlying principle was the same: foreign biological material was introduced into the body through a break in the skin.

It took some time for doctors and medical science to distinguish between infectious hepatitis and serum hepatitis. The term “serum hepatitis” did not begin appearing in the medical literature until the 1930s and 1940s – more than fifty years after the phenomenon had first been observed. In the meantime, many thousands of people contracted the disease, including

one dramatic episode in 1942 during the mass vaccination of American troops early in WWII. Between 40,000 and 50,000<sup>1</sup> of the roughly 330,000 soldiers who received a contaminated batch of yellow fever vaccine developed acute hepatitis as a result. At least 62 died. Soldiers who did not receive injections from the contaminated lot had zero cases.

Contaminated vaccines and injectables were not the only source of serum hepatitis. The common use of shared or poorly sterilized equipment in mass vaccination campaigns contributed to this. Routine medical practice itself was also a major source of transmission. While it may seem hard to believe from today's perspective, hypodermics and syringes were routinely reused in advanced economies as late as the 1980s.

In theory, glass syringes and metal needles were sterilized between patients, though in practice, sterilization was often inconsistent. Busy clinics, especially during mass vaccination campaigns, required large numbers of injections to be given quickly, and equipment was frequently reused many times in a single day. Sterilization methods varied in effectiveness and were not always carefully monitored.

When cleaned at all, reusable syringes and needles were typically sterilized by boiling or by chemical disinfectants such as ethyl alcohol or phenol (carbolic acid), methods now known to be unreliable. Steam sterilization using autoclaves – the most reliable method – did not become widely adopted in routine medical practice until the mid-twentieth century. In short, the two largest sources of what was then called “serum hepatitis” –

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1 The institution that manufactured the tainted vaccine, the Rockefeller Foundation, conducted an internal investigation of this public health disaster. It was the US Secretary of War Henry L. Stimson who revealed this case and the Rockefeller Foundation injury estimate (28,525) to the public. *The Chicago Tribune* pointed out the absurdity of the Rockefeller Foundation or the Army investigating itself and called for an independent investigation. Morris Fishbein, then editor of *JAMA*, the *Journal of the American Medical Association*, dismissed the *Tribune's* call for independent investigation, arguing it presumed unjustified stupidity on the part of medical science and could harm soldier morale and hamper the war effort. *The New York Times* followed suit, characterizing the *Tribune's* legitimate concern as overblown hysteria.

now known as hepatitis B – were mass vaccination campaigns and the poor sanitation standards of routine medical practice.

Though unsafe reuse of hypodermic needles is largely a thing of the past in developed countries, it remains a problem in low-resource settings where equipment and training are limited. Disposable syringes are reused, sometimes with nothing more than a quick alcohol wipe or nothing at all. Shortages of syringes lead to scavenging and resale.

Added to this problem is the widespread emergence of a “therapeutic injection culture” – the belief that injected treatments (antibiotics, vitamins, painkillers, etc.) are more advanced and act faster and more powerfully than equally effective oral medications. Injection culture is especially common among low-income populations in rural areas and urban slums who rely on informal or low-cost care, where oversight is weak, and education levels are low. This is not a marginal phenomenon. It affects hundreds of millions, if not billions, of people living under these conditions. These are also the very same people most likely to be suffering from malnutrition, exposure to biological and chemical toxins, and all the other conditions that promote hepatitis.

At this point, perceptive readers may be wondering how this reality led to all newborn infants in the United States being compelled to receive Hep B vaccinations.

The United States largely stands alone among developed countries in recommending that all newborns receive a Hep B vaccine at birth. Countries with better overall health outcomes and stronger infant health statistics than the United States – Germany, France, Switzerland, Denmark, Sweden, Japan, and Norway, to name a few – do not follow this policy. In contrast, supporters of universal newborn Hep B vaccination outside the United States include countries such as Laos, Cambodia, Mongolia, Iraq, Vietnam, China, Indonesia, the Philippines, India, Pakistan, Nigeria, Ethiopia, and the Democratic Republic of the Congo.

We’ll begin to untangle this mystifying state of affairs in the next chapter.

# Chapter 3

## *Hepatitis B: The Birth of a New Viral Disease and the Illusion of Knowledge*

Logic would seem to dictate that the secrets to preventing hepatitis B, or “serum hepatitis,” were straightforward: (a) don’t inject contaminated substances into people, (b) don’t reuse dirty needles, and (c) practice good hygiene in medical settings. But, as often happens in the history of compulsory mass vaccination campaigns, once a virus was identified, it came to be treated as the primary cause of the disease.

In the case of hepatitis B, the story begins with Baruch Samuel “Barry” Blumberg (1925–2011). He was studying genetic differences in blood proteins among human populations in an attempt to understand why some people were more susceptible to certain diseases – he was not looking for a virus. In the process, he came across a previously unidentified antigen. (An antigen is a molecule that the immune system recognizes as foreign – it is not itself a pathogen, a virus, or a cause of disease. It is simply a molecule that triggers an immune response.)

Blumberg first found this antigen in the blood of an Aboriginal Australian, which is why he called it the “Australia antigen.” It was his colleague Alton Sutnick who theorized on the basis of correlation, not proof, that the antigen was likely part of a hepatitis virus. It was an educated guess, not an observation, and certainly not proof of anything.

The fact is that the immune system reacts to a vast range of things: damaged cells, foreign proteins, environmental compounds, as well as pathogens. Finding a novel antigen that appears with a disease state does not tell you what produced that antigen. It also doesn’t tell you whether it is harmful in itself. Finally, it doesn’t tell you that it is a cause or a conse-

quence of the condition you are looking at, or any diseases for that matter.

Following Blumberg's published studies, in 1970, the British virologist David Dane reported that he had visualized virus-like particles in the blood of patients with hepatitis associated with the Australia antigen using an electron microscope. The word "visualized" has to be used when electron microscope results are reported because, due to the nature of the tool, "seeing" anything through an electron microscope is at least as much interpretation as it is observation. Dane admitted as much when he called what he visualized virus-like particles.

Like Blumberg, Dane practiced scientific accuracy in presenting his conclusions. Blumberg only claimed to have found a novel antigen in the blood of a patient with hepatitis. Dane only claimed to have visualized a novel virus-like particle. Neither claimed to have identified a virus. However, just as Alton Sutnick theorized that the antigen was part of a hepatitis virus, it was an FDA-employed researcher, Lewellys F. Barker, and a team of other federal scientists, who not only claimed these particles were part of a virus, but also that the virus conclusively had the power to cause hepatitis.

Henceforth, this claim was accepted as fact, and thus the belief that the hepatitis B virus is the cause of a unique form of hepatitis – Hep B – was born. The paper in question was Lewellys F. Barker et al. "Transmission of type B viral hepatitis to chimpanzees." It was published in the *Journal of Infectious Diseases* in June 1973, Volume 127, Issue 6, pages 648–662. Its co-authors – Chisari, McGrath, Dalgard, Kirschstein, Almeida, Edington, Sharp, and Peterson – were drawn from the FDA, NIH, and CDC.

The title of this landmark paper, which birthed a brand new viral disease, was a little misleading. First, the experiment itself involved testing the blood of chimpanzees, injecting them with the blood from multiple human donors who tested positive for the "Australia antigen" (a fragment of the suspected Hep B) virus, and then testing them for the next three months.

The “testing” involved the following. During the three-month period the test animals had blood drawn an estimated 36 times each and were subjected to at least six liver biopsies. Each biopsy required anesthesia. You don’t have to be a research pathologist to surmise that injecting caged animals with blood from a mixture of human sources and then drawing blood from them 36 times and performing six operations (biopsies) on their livers over a three-month period is likely to cause liver inflammation.

The Barker study used six chimpanzees in total. At the end of what can only be called a medical ordeal, the biopsies revealed that only two showed observable physical evidence of liver damage, and the frequent blood tests showed that only three had Australian antigen in their blood. Somehow, these results morphed into proof that human blood transmits type B viral hepatitis.

It’s useful to note here that testing positive for whatever is considered the hepatitis virus does not mean you have an inflamed liver or are sick in any way. It merely means you have what medical science has deemed “a hepatitis B infection”. This is entirely a linguistic construct. What this means in practice is that you can have the hepatitis B virus (or presumed fragments thereof) coursing through your veins and not have the slightest bit of liver inflammation. Conversely, you can be near-death with hepatitis and test negative for the virus.

If what I’ve stated is true then why should anyone worry about having a hepatitis B infection, or testing positive for Hep B fragments? The reason is that medical science has deemed that the virus is a wily and patient being (even though viruses are not considered living beings by any scientific standard). The virus has the capacity to lurk within your symptomless body not for weeks and months, but for years and decades, at which point it will strike you down with liver cancer. In any event, that’s the official story.

The story continues. Even if you do have the dreaded virus, as an adult, there is a likelihood that your case is transitory, and you will clear it from your system without any medical

intervention, and it will not become chronic. 95% of adult cases accomplish this. The numbers look less favorable for children (70% to 80%) and even dire for infants (10% to 20%). However, as has been the case throughout this discussion, the language bears close examination. “Chronic” does not mean lifelong according to medical science. It merely means a patient tests positive for six months or more after the first positive test. If they happen to clear it in the seventh month or even six months and one day, they are forever listed as a chronic Hep B sufferer in their medical records.

Epidemiologists, whose contribution to the Hep B narrative we will examine in detail in a future chapter, add those cases to their evidence that chronic “Hep B infections” are rampant. I repeat – because it’s more difficult to untangle a dodgy narrative that it is to perpetuate an existing one – a Hep B infection merely means a positive test for a fragment of what is presumed to be the Hep B virus; a virus which has never been isolated whole, whose role as the sole or primary cause of liver disease is a theory, and whose pathological effects are assumed, but have never been proven.

If you are a confirmed believer in the Hep B virus and its stealth and deadly effects, the preceding may be difficult to swallow, especially if your career and livelihood depend on you not swallowing it, at least in public. To accommodate you and the rest of the majority, and in the interest of moving the narrative along, we will, for the time being, accept that the hepatitis B virus causes a distinct type of hepatitis, hepatitis B, that is different from other forms of hepatitis.

Even accepting this, we still don’t have the answer to the question of why, starting in 1991, the federal government recommended that all newborns in America, regardless of the health status of the mother, receive a (quantity injection) of a Hep B vaccine the day they are born. We also don’t know why American obstetricians, pediatricians, and hospital administrators fell in line while the medical systems of countries with objectively better health outcomes for infants than our own

– the UK, Germany, France, Switzerland, Denmark, Sweden, Norway, Japan, etc. – said no.

To answer this, we have to take a brief detour through the world of epidemiology.

# Chapter 4

## *What's in the Syringe?*

What exactly is in the hepatitis B vial that has been injected into virtually all American newborns since 1991? The answer is “it depends”.

Sometimes it's Product A. Other times it's Product B. In this case, Product A is made and marketed by Merck and is called Recombivax HB. Product B comes from GlaxoSmithKline (GSK) and is marketed under the brand name Engerix-B. The ingredients are similar, but different. The basic components of both are: (a) what is called hepatitis B surface antigen (HBsAg), (b) an adjuvant, (c) water, and (d) trace yeast proteins.

How is it that trace yeast proteins appear in the vaccine? The answer is that, using their own separate proprietary methods (i.e., not for public review), the companies make their hepatitis B antigens from yeast. Merck originally developed the technique in conjunction with the Chiron Corporation, which was acquired by Novartis in 2006 and became the property of GlaxoSmithKline in 2015.

The process involves injecting the gene encoding HBsAg into common yeast (*Saccharomyces cerevisiae*), thereby genetically modifying the yeast cells and turning them into the equivalent of mini HBsAg factories. The modified yeast is grown in large fermentation tanks. The antigen is then squeezed from the yeast and purified, but of course, there is no industrial process on earth that guarantees 100% purity. Therefore, some of the yeast protein ends up in the vaccine that's injected into the newborns.

Depending on who makes it, there is a difference in the adjuvant, which is the part of the injection that is designed to create a response. Merck uses aluminum hydroxyphosphate sulfate. GlaxoSmithKline uses aluminum hydroxide. Aluminum in its pure form is a neurotoxin. Vaccine makers and their apologists

tell us that it is entirely safe to inject these aluminum compounds into newborns.

All invasive medical procedures – including the puncturing of the skin to introduce foreign material into the bloodstream, which is the very definition of an invasive procedure – come with risks.

Documented adverse reactions to the Hep B vaccine include:

- injection site soreness, pain, tenderness, redness, swelling, and nodule formation
- irritability
- fever
- diarrhea
- fatigue and weakness
- diminished appetite
- headache
- malaise
- nausea
- rhinitis
- pharyngitis
- upper respiratory infection

Documented adverse reactions are the adverse reactions known about before a pharmaceutical product is launched to the public. Though bureaucrats, politicians, and the news media like to claim that FDA approval means that the FDA has found a given product to be safe, it means no such thing. The FDA itself never designates any pharmaceutical product as “safe”. It merely reports that, in its estimate, the “benefits outweigh the risks” and the product has a “favorable benefit-risk profile”.

In addition to what is known about a given product's risk profile before it is launched, there are also adverse reactions reported post-marketing. Adverse reactions reported post-mar-

keting are the adverse reactions that are reported after the product has been used by the public.

Post-marketing reports include the reactions of millions of patients versus the hundreds or, in some cases, thousands who serve as volunteer test subjects during the FDA certification process. In a very real sense, the “post-marketing” period is actually the final trial of a pharma product’s safety, with the general public serving as unsuspecting test subjects.

These are the adverse reactions to the hepatitis B vaccine that have been reported during the post-marketing phase:

- anaphylaxis
- hypersensitivity reactions, including serum sickness
- arthritis and joint pain
- urticaria (hives)
- angioedema
- erythema multiforme
- alopecia (hair loss)
- encephalitis
- encephalopathy
- migraine
- multiple sclerosis
- optic neuritis
- visual disturbances
- vertigo
- tinnitus
- earache
- vasculitis
- thrombocytopenia
- palpitations
- tachycardia

- bronchospasm and asthma-like symptoms
- apnea in premature infants
- meningitis
- herpes zoster
- and death.

Those not familiar with any of the above may be shocked by the realities of the Hep B vaccine. The facts are especially concerning when you consider that the federal government has engineered a situation whereby this substance is injected into virtually every American newborn on their first day of life. How could such a thing be possible?

To answer this question, we have to make the acquaintance of something called epidemiology and the underreported reality of how it's come to dominate both public policy and subvert the day-to-day practice of medicine.

# Chapter 5

## *The Dance of the Epidemiologists*

Epidemiology is a relatively new profession. The first formal academic program in the subject was offered by the Johns Hopkins School of Hygiene and Public Health in 1919.

The concept of epidemics is an ancient one. The meaning is built into the original Greek: *epidemic*, from *epi* (“upon”) and *demos* (“the people”), describes a disorder that comes upon a population rather than an individual, and includes patterns of mental or social disturbance such as panic.

The first professional body devoted to the subject was the Epidemiological Society of London, which was founded in 1850 in response to urban cholera and related outbreaks, which were later determined to be the result of contaminated water caused by poor sanitation.

Epidemiologists are not clinical physicians. They don’t see or work with patients. Epidemiologists are also not diagnostic physicians. They don’t assist physicians in their clinical work the way radiologists and pathologists do. In fact, epidemiologists are not physicians at all, though there are some physicians who’ve also received degrees in epidemiology.

What do modern epidemiologists do? They’re trained in statistics, research methodology, population science, and a subject called public health. They work with data, not patients. Their tools are cohort studies, case-control studies, surveillance systems, statistical modeling, and mortality records. They do not examine patients, they do not diagnose, and they do not treat. In short, they crunch numbers.

“Public Health” sounds like a grand and noble discipline. Many people mistakenly believe it means teaching the public ways to safeguard and improve their health, as well as promot-

ing conditions that make healthy lives possible. The truth is quite different.

The first academic program in public health was started in 1916 by the founding dean of Johns Hopkins Medical School, William Henry Welch. Welch was not a clinical physician. He was not even a diagnostic physician. His professional experience centered around the field of experimental pathology, which he studied in Germany with the pioneers of the field. Without putting too fine a point on it, experimental pathology involves sickening and injuring experimental animals in measured ways and documenting the outcomes in detail.

The organization that wrote the check to fund this and other Welch brainstorms was the Rockefeller Foundation.<sup>1</sup> The original name, now called The Johns Hopkins Bloomberg School of Public Health, was the School of Hygiene and Public Health. Hygiene – sanitation engineering, water supply – was then, and continues to be, fundamental to human health.

There was another dimension to the concept of hygiene current at the time among people inclined to social engineering: eugenics. This most definitely included the managers of the Rockefeller Foundation and Welch himself.

The grant was funded through the Rockefeller philanthropy complex, primarily via the Rockefeller Foundation. Eugenics was an influential movement between the 1880s and 1940s, especially among wealthy and academic elites. A short list of

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1 One of the peaks of this line of thinking was summed up in a 1942 book, *Arzt im Kampf* (*Doctor at War*) by Kurt Blome, the Nazi's Deputy Reich Health (Public Health) Leader and also the head of Nazi's biological warfare program. He framed public health as a racial struggle and defined medicine as a duty to protect the "biological strength" of the nation and to eliminate threats to the health of the Volk. "Medical and military power are engaged in the same struggle for life and death."

Blome was a defendant in the Nuremberg Doctors' Trial, was acquitted due to the intervention of the United States, and was hired by the U.S. government as a consultant for several years. He was listed among the scientists recruited under Operation Paperclip, worked at Camp King — the CIA's clandestine interrogation facility in Germany — and was employed by the CIA officer who ran MKUltra, Sidney Gottlieb. Whether he was a formal MKUltra asset, the CIA will not say. In 1973, CIA director Richard Helms ordered most MKUltra records destroyed.

its enthusiastic advocates included college presidents (David Starr Jordan of Stanford and Abbott Lawrence Lowell of Harvard), Supreme Court justices (Oliver Wendell Holmes and Louis Brandeis), American presidents (Theodore Roosevelt and Woodrow Wilson), and Nobel laureates (Hermann Muller and Alex Carrel).

Eugenics had a simple proposition. Some people were made of better stock than others, and the world would be a better place if those of poor stock were to be discouraged from reproducing. "Discouragement" ultimately took the form of immigration restrictions, forced sterilization, involuntary institutionalization, and, in its ultimate expression, the Nazi extermination program.

The American eugenics movement, funded by Rockefeller, Carnegie, and Harriman money, built the conceptual and institutional framework that defined populations rather than individuals as the subject of medical intervention. The Nazis took that framework and ran it to its logical and diabolical conclusion. It would be unfair to state that advocates of what was then a branch of public health – Welch, Starr, Howell, Rockefeller, Carnegie, Harriman, and many others – caused the Holocaust, but they did provide the vocabulary.

Population-level data – the stock in trade of the epidemiologist – is genuinely useful. Knowing that smoking causes lung cancer at the population level is valuable even if you cannot predict which smoker will get cancer. However, it's essential to understand that the epidemiological lens is strictly statistical.

Epidemiologists do not examine individual patients. They do not take medical histories. They do not diagnose or treat. They do not take clinical responsibility for individual patients. Instead, they work with rates, ratios, correlations, confidence intervals, and probabilities. They design cohort studies, case-control studies, and randomized trials with the focus on statistical associations, not causation, and certainly not individual outcomes.

Epidemiologists use statistics to create models that predict how a given therapy or vaccine will affect a population, a simple statement that merits being broken down carefully.

Statistics is a branch of mathematics, and mathematics has a reputation for objectivity, accuracy, and certainty. However, as honest statisticians will admit, it's a borrowed reputation. In every case, statistical projections flow from human decisions that are anything but objective.

Before a single calculation is performed, someone has already decided: what to measure and what to ignore; what counts as a case and what does not; how to define the population being studied; what the comparison group will be; what counts as an outcome; how long to follow the subjects; and which confounding variables to account for – and which ones to leave out.

There is also the question of how to handle data that does not fit the hypothesis – the expected pattern the epidemiologist is looking for. The reality is that published epidemiological findings have a heavily curated relationship to the data collected – and to the data ignored or deliberately discarded.

Each of those decisions is a judgment call. Each reflects assumptions, priorities, and sometimes special interests. None are mathematical. The mathematics begins only after those preliminary choices have been made, and it operates within the boundaries they establish. The numbers that come out are therefore only as objective as the choices that went in.

With its rates, ratios, correlations, confidence intervals, and probabilities, epidemiology gives the appearance of certainty. The subjective decisions that shaped the inputs become invisible, and what remains is a number carrying the borrowed authority of mathematical proof.

This diversion into the history and nature of modern epidemiology would be interesting trivia were it not for this fact: Starting in the early 20th century and accelerating wildly after WWII, epidemiological studies – theoretical projections of population-wide impacts of specific drugs and vaccines – have pro-

gressively taken over the details of clinical practice. What this means is that how your doctor examines, considers, and treats you is increasingly not the product of his clinical judgment and experience as it applies to you, but instead is determined by an epidemiological study with all the limitations previously described.

The pipeline from epidemiology to what happens in your doctor's office works as follows:

First, an epidemiological study is produced on a disease and proposed treatments or preventative measures (vaccines classified as preventative). The focus is not on the realities of the practice of clinical medicine with its responsibility to consider the individual patient, but instead on the theoretical ideal of "reducing population-level disease burden".

Second, the study is then passed along to federal bureaucrats who fundamentally share the epidemiological outlook, one that thinks in terms of public or population health, not with clinical practice or individual patient outcomes. These bureaucrats, who are, by definition, not practicing physicians, then issue 'recommendations' for policy.

In the case of vaccines for children in the United States, the bureaucrats in question are the Advisory Committee on Immunization Practices (ACIP). Their recommendations are reviewed and usually approved by the CDC director, who may or may not have ever had meaningful experience as a practicing physician. Once adopted, the recommendation triggers a cascade of institutional consequences – insurance coverage requirements, hospital protocols, state school-entry mandates, and federal purchasing programs.

None of these downstream effects requires a federal law to be passed, the public to consent, or physicians, either individually or as a group, to agree. The people with the most at stake in these decisions – children and families – are never consulted during the process, and their physicians have been reduced to mere delivery mechanisms.

If epidemiological conclusions carry such power, the logical question is who pays for and promotes, and thereby influences, what the accepted epidemiology is?

We have a recent and clear example of how this works in practice from the COVID Panic. In the case of COVID, two institutions – Imperial College London and the University of Washington in Seattle – were elevated as the only meaningful sources of projections of how fast COVID would spread and how many people would die as a result. There were other legitimate sources for these projections, but somehow these two institutions became, for all practical purposes, the sole authority as far as the news media was concerned.

As pointed out in a previous chapter, it just so happened that both were abundantly supported by Bill Gates, an individual with a large financial stake in COVID vaccine development. In addition to supporting these two centers of epidemiology, Gates, through his foundation, had also given news outlets around the world in excess of \$250 million to “support public health and science reporting,” thus having an understandably significant influence on how the COVID epidemiology story would be told. Recipients included the BBC, NBC, Al Jazeera, ProPublica, The Guardian, the Financial Times, The Atlantic, Gannett, Le Monde, and others.

This mattered greatly because the projections from the University of Washington’s Institute for Health Metrics and Evaluation (IHME) were the ones used by the White House Coronavirus Task Force. Their projections shaped federal guidance on closing schools and businesses, six feet of separation, mandatory masking, and who endorsed the accelerated development and coercive deployment of vaccines. The IHME was created in 2007 with a major grant from the Gates Foundation. In 2016, Gates gave the Institute \$210 million to construct a new building, and in 2017, provided an additional \$279 million in the form of a ten-year grant.

In any event, if you’re getting the idea that current medical care, the kind you and your families receive, is guided more by theoretical population goals driven by statistical projections

and not by individual care, you have gotten the point of this chapter. There is another form of medicine that takes this approach. It's called veterinary epidemiology. It's not the form of veterinary medicine that deals with house pets, but with the kind of medicine practiced in factory farms. In a factory farm, the individual animal is not the focus of care. The goal is simply: "get to the numbers up" (i.e., deliver as many marketable animals to the slaughterhouse with the greatest economy possible).

To bring this back to Hep B: who conceived, created the epidemiological justification for, and advanced the idea of Hep B vaccines for all newborns regardless of clinical need? What was the public reasoning for promoting such an extreme and medically unjustified policy?

# Chapter 6

## *Testing and Crunching the Numbers*

We've covered a lot of ground, and it might be worthwhile to do a quick review before we continue the narrative and introduce the practice of testing for hepatitis.

The body responds to assaults on the liver and other parts of itself with inflammation. Inflammation is the body's repair process in which it sends extra blood and fluid to an affected area and brings in immune cells to clean up and repair damage. It's often experienced as redness, swelling, heat, and pain.

In the case of the liver, inflammation can disrupt the organ's functioning. It can vary in intensity from mild and passing to severe and chronic. Hepatitis, inflammation of the liver, is a condition that physicians have been aware of for millennia.

Before the viral explanation started forming in the 1960s, hepatitis was most often linked with contaminated food and water, toxins, drugs, poor sanitation, and general liver stress or damage from environmental and dietary causes, like alcohol. It was known to appear among soldiers and others living in crowded, unsanitary conditions and thus had an "epidemic" quality.

In the early 20th century, a new form of hepatitis, called serum hepatitis, was recognized, and it was linked to injections, blood exposure, and other medical procedures. The earliest well-documented case came as a result of the mass vaccination of ship workers in Bremen, Germany.

We know that in order to conduct and publish studies and projections, epidemiologists have to start with data. Previous to the 1970s, hepatitis cases were recorded based on reports from physicians' evaluation of symptoms – primarily jaundice. What happened to change things is the subject of this chapter.

Like all viruses, the Hep B virus was put on the clinical map by a blood test. In 1972, Abbott Laboratories submitted an application for the hepatitis B surface antigen (HBsAg) test to the FDA, received approval for it, and started distributing it first to blood banks and then to medical practices across the United States. Medical offices could now draw blood, order a test, and learn whether or not a given patient's blood showed the presence of the hepatitis B surface antigen.

Most importantly, a positive test was automatically reported to public health authorities as an active hepatitis B infection, whether the patient had symptoms or not. Perfectly healthy patients who tested positive were told they had an active Hep B infection, and their physicians regarded them as if they did. If they tested positive again anytime six months or more after their first test, their case was classified as chronic, regardless of symptoms or the total lack thereof.

In doctors' offices, serum hepatitis, a disease known to be associated with medical procedures and which produced visible symptoms, disappeared as a diagnosis. It was replaced by a hepatitis B diagnosis, the product of a presumed virus, which may or may not manifest as illness. Krugman's ghastly and immoral experiments on children at Willowbrook and the nomenclature he coined (hepatitis A and hepatitis B) had been successfully laundered into standard clinic practice, with most physicians or patients being entirely unaware how the so-called proof was obtained.

The presence of the Hep B antibody is said to indicate the presence of an immune response to the Hep B virus. However, it does not prove that the virus is currently present. It only indicates that fragments of what is said to be the virus are present and causing an immune response.

I use the term “what is said to be the virus” because, in fact, the virus has not only failed the Koch postulates<sup>1</sup> as a provable cause of disease, it has also never been fully visualized as an intact entity. It is presumed to exist, and it is presumed to cause disease.

However, again, for the sake of argument, we will assume the virus exists, and we will ignore the fact that one can be chock full of what are called hepatitis B surface antigens and never have a single hepatitis symptom for an entire lifetime. Conversely, one could be ravaged with a visible and unmistakable case of severe hepatitis and never have antigens appear in a blood test.

The practical outcome of all this is that before the FDA approved the Abbott Laboratories antigen test, the only people who were ever diagnosed with Hepatitis were people who had symptoms of the disease. After that, thousands of otherwise healthy people who tested positive for the antigens were considered and reported as “hepatitis B infection” cases. The result: an explosion in “hepatitis cases”.

Not everyone is tested for Hep B, but millions are. Currently, the list includes blood donors, pregnant women, health care workers with blood exposure risk, as well as this wide net: people born in countries or regions with high rates of the Hep B virus. Starting in 2023, the CDC cast the net still further and recommended that every person get at least one Hep B test in their lifetime, whether they have symptoms of hepatitis or not.

There’s one more wrinkle to consider. Given how many people are tested in the United States for Hep B, how many people actually test positive (symptomatic and asymptomatic)?

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1 In order for a pathogen to be a proven source of disease using the Koch postulates it must (1) be found in all cases of the disease, (2) be isolated from the diseased host and grown in pure culture, (3) cause the same disease when introduced into a healthy host, and (4) be re-isolated from the experimentally diseased host and shown to be identical to the original.

Virologists have modified the Koch postulates to make it easier to prove that a virus is the source of a disease, but even with these loosened standards, the presumed Hep B does not meet the first two points and only partly meets points 3 and 4, and it is charitable to say they “partially meet” them.

In 2023, the number was 2,214. This represents 0.00067% of the total U.S. population. That works out to an average of 44 cases per state, and it's not clear how many of these people have even a single symptom of hepatitis B or otherwise.

The CDC claims that due to "underascertainment and underreporting," the real number is higher, so its statisticians ran it through a "model" and came up with 14,400 cases, an additional 12,186 who no one can name. This raises the number of new cases (positive tests) to 0.0043% of the U.S. population. While testing positive for an antigen that may or may not ever give you symptom can't be a pleasant thing, it's hard to understand how this qualifies as a public health emergency.

But there's more. The CDC's most recent claim is that 640,000 Americans have chronic hepatitis B, which, to be clear, means they tested positive once, then again at least six months later, with or without symptoms. An estimate published in 2016 put the number at 840,000. The data comes from NHANES, the National Health and Nutrition Examination Survey, and the statisticians there explain the difference as follows: It's not statistically different given the small sample size used to estimate the number. In other words, 200,000 extra or less, more or less.

The CDC isn't the only group in the Hep B case estimate business. Another group says the real number is 1.7 to 2.4 million. That group happens to be the hepatitis B Foundation, which we'll discuss in a future chapter.

One does not have to be a mathematician to recognize that there is something strange about these numbers. How does 2,214 or even the CDC's "modeled" 14,400 new cases get to 1,000,000 chronic cases (we're splitting the difference between the CDC's numbers and the hepatitis B Foundation's numbers)? It would take 69 years of 14,400 new cases per year to create the raw material for 1 million chronic cases. We know that not all people who test positive for Hep B become chronic. Recall earlier, we learned that 95% of acute cases in adults resolve

and thus never become chronic.<sup>2</sup> Where are all these many hundreds of thousands of chronic hepatitis cases coming from?

The CDC and the Hepatitis B Foundation have a simple answer: “It’s the immigrants.”

Neither of these groups has actually tested 640,000 or 840,000 or 1,700,000 or 2,400,000 immigrants and found them to have the Hep B virus (or really an antigen that indicates the presence of the fragment of a virus that’s never been satisfactorily proven to be a cause of disease). Instead, they used the magic of epidemiology and grammar school arithmetic.

The Hepatitis B Foundation derived its figures by repeating the conclusions of published academic studies by researchers such as Robert Wong,<sup>3</sup> not by conducting its own independent analysis.

To make their estimates, the authors used census and immigration population data for foreign-born residents and then applied those data to hepatitis B rates in countries like China, Vietnam, and Nigeria. Then they multiplied one number by the other.

To use a slight oversimplification of their process, if 8% of people in a given country “have hepatitis B” (a positive antigen test, not a disease), and a million people from that country live in the United States, they counted 80,000 Americans with hepatitis B without personally testing a single one of them. They did this for many countries, and it all added up to the hepatitis B Foundation’s public announcement that 2.4 million Americans have chronic hepatitis B.

In short, assigning high rates of Hep B to Americans born in other countries with statistical projections is how they got the

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2        Infants and children are not generally tested for Hep B. The only exception is in the case of children born to mothers who tested positive during their pregnancy. Given that only about 17,000 pregnant women per year are deemed to have acute or chronic Hep B (according to the standard of a positive antigen test), and how rarely Hep B is “transmitted” from mother to child (just 16 cases in 2019), babies and children are clearly not the source of the 1 million chronic cases.

3        “Chronic Hepatitis B Prevalence Among Foreign-Born and U.S.-Born Adults in the United States,” 1999–2016. *Hepatology* (2020).

number so high. The CDC supports this with its own estimate that 60% to 70% of all Americans with Hep B are foreign-born. They supported this number by testing 1,000 to 3,000 foreign individuals living in the U.S. over several years.<sup>4</sup>

Is there a Hep B crisis in America? Is it so serious that it merits every newborn getting injected with a Hep B vaccine on the day of their birth? Clearly not. We are missing important parts of the story, and indeed we are.

In the next chapter, we'll meet the crusading scientist (a lifetime CDC employee) who sold the imperative and its urgency to the CDC-administered Advisory Committee on Immunization Practices (ACIP).

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4 If these numbers are to be believed, then 14% to 15% of the U.S. population accounts for 60% to 70% of the Hep B cases in the U.S. That works out to about 1% of the roughly 45–48 million foreign-born people in the U.S. It's important to remember that a Hep B case means a positive antigen test, which may or may not mean having symptoms or being ill in any way. In fact, the majority of "Hep B" cases have no symptoms and never develop any.

# Chapter 7

## *The Subterranean Story*

We know the following about the scientific lineage of hepatitis B.

There is the official story, which heaps praise on Baruch S. Blumberg and David Dane, Blumberg for identifying a previously undiscovered antigen and Dane for the visualization, via electron microscopy, of structures in the blood of patients who tested positive for the antigen identified by Blumberg.

Neither claimed to have discovered a virus, much less that it caused hepatitis. They simply said they had identified an antigen and visualized particles, respectively. Despite their scientifically precise assertions, their names are often the first cited in discussions of the scientific origins of hepatitis B. The Blumberg<sup>1</sup> and Dane narratives are, for all practical purposes, the official version of events when the story of the discovery of the hepatitis B virus is told.

Official stories usually have backstories, and in the case of hepatitis B, the backstory is the work of Lewellys F. Barker, who led a large team of federal researchers in the chimpanzee experiments described in detail in the previous chapter. These experiments, imperfect as they were and documented in *Transmission of type B viral hepatitis to chimpanzees*,<sup>2</sup> are the foundation of the widely accepted belief that there is a hepatitis B virus, that it is transmissible, and that it is the cause of the disease. The reader is advised that being familiar with the broad-stroke details of these experiments is essential for

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1 In 1976, Blumberg was awarded the Nobel Prize in Physiology or Medicine, which he shared with D. Carleton Gajdusek. The Nobel Committee did not cite either man for a specific disease, but instead for ‘their discoveries concerning new mechanisms for the origin and dissemination of infectious diseases.’ Many mistakenly believe that this award validated the existence of two different transmissible viruses that caused two specific diseases. It did not.

2 *Transmission of type B viral hepatitis to chimpanzees. Journal of Infectious Diseases* June 1973, Volume 127, Issue 6, pp. 648–662)

fully grasping the history of hepatitis B. In any event, we will classify Barker's work as the back story.

In addition to the official story and the backstory, there is a third stream that merits its own chapter: the subterranean story. This is the one that is never cited in histories made available to the public, but is well known to informed medical ethicists. It is the story of Saul Krugman, the medical researcher and physician who advanced the use of the nomenclature of Hepatitis A and B, first suggested by Francis O. MacCallum in 1947, which we will discuss in more detail later in this chapter.

Krugman's work does not constitute a pretty story. If you've just eaten or are about to eat or are reading this in preparation for sleep, you might want to put it off to read for another time. Regardless of when you choose to read it, this story is essential for understanding the scientific origins of the idea of hepatitis B.

Between 1955 and 1970,<sup>3</sup> Krugman, working at a state-run institution for the developmentally disabled, systematically attempted to infect children between the ages of 3 and 10 with hepatitis.

He used two different methods to accomplish this. One involved taking the feces of children who'd been clinically assessed as having hepatitis (jaundice, vomiting, and loss of appetite), processing it into a liquid suspension, and putting it in chocolate milk, which he then gave to the children to drink. The other method involved pooled blood, which he gathered from children with obvious symptoms of hepatitis. The blood was run through a centrifuge to separate the blood fluid (serum) from blood cells, and the fluid was injected into healthy children.

After administering this deliberately contaminated material to the children, the researcher would then watch for and record symptoms of the onset of full-blown hepatitis, which was pre-

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3 Sources don't agree on the precise time span of Krugman's work at Willowbrook. Some, including Krugman himself, list the start year as 1955. As for the ending date, it has been cited as the late 1960s, 1970, 1972, and even as late as 1975. We can safely assume the program ran for a minimum of 15 years.

viously described as including jaundice, vomiting, and loss of appetite. At the time these experiments were conducted, there was no treatment for hepatitis. A child who developed the disease was given rest, fluids, and nutrition and left to recover on their own.

If you were to assume, based on this narrative, that the researcher was a rogue madman who carried out these atrocities for 15 years before he was detected, you'd be wrong. Saul Krugman was a licensed medical doctor and professor of pediatric medicine at the NYU School of Medicine. In 1960, five years into his research, he was made Chairman of the school's Department of Pediatrics.

The specific nature of Krugman's methods and work was far from secret. The details of his studies were published in the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and other major peer-reviewed journals starting in the late 1950s. He had the full cooperation and support of the New York State Department of Mental Hygiene, which gave him access to his subjects, and he was amply funded by the U.S. Army. The Army's support came from the Armed Forces Epidemiological Board, which is under the Office of the Surgeon General, U.S. Army. It flowed to NYU, which took its cut<sup>4</sup> and passed the remainder to Krugman to fund his salary, his staff, and the research operations at Willowbrook.

What was Krugman trying to prove, and why did the U.S. military support him?

To answer the last question first, throughout history, all militaries have faced serious problems from disease. In fact, it's not uncommon for more troops to die from illness than in battle. Further, sick troops become a drag on resources. Many

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<sup>4</sup> Most research grants follow this path. Research grants go to the researcher's employer, which deducts for grant administration and institutional overhead before it passes the remainder to the researcher. Playing the role of middleman between grantors and the researchers who do the actual work is a cash cow for universities. Overhead rates can be substantial (30 to 70% currently). Professors who are good at getting grants, as Krugman obviously was, are rewarded by their employers with promotions, tenure, higher salaries, and department chairs. Krugman and his work were a reliable money maker for NYU Medical School.

of these illnesses are the predictable outcome of war conditions: stress, poor nutrition, contaminated food and water, overcrowding, substandard housing, and poor sanitation. Hepatitis is a common outcome of such conditions. Also, as we discussed in the previous chapter, the U.S. Army accidentally gave hepatitis to thousands of troops, killing at least dozens of them, by injecting them with what proved to be a contaminated vaccine. Obviously, just like NYU Medical School, the Armed Forces Epidemiological Board believed that the ends - more information about hepatitis - justified Krugman's means.

If you are a reader who needs an indication of whether the ends justified the means in this case, you should know that Krugman's work is ranked with the Tuskegee Syphilis Study as one of the worst violations of medical ethics in the history of U.S. medical research.<sup>5</sup> No less a "true believer" than Maurice Hilleman, who was the chief vaccine developer at Merck for decades, called Krugman's work "the most unethical medical experiments ever performed on children in the United States."

Now that we know why the various institutions supported him, what specific science was Krugman pursuing by carrying out these atrocities against disabled children? The answer is most unimpressive, but it had far-reaching effects.

Krugman assumed that hepatitis was caused by a virus. At the time he did his experiments, this had not been proven or demonstrated. Researchers - including U.S. and British military investigators during World War II - were unable to identify a bacterium involved in what they called the transmission of the disease. They also found that when they injected the filtered blood of hepatitis patients into healthy people, they could sometimes, but not always, create a case of clinical hepatitis. With this as their evidence, they assumed hepatitis had to be transmitted by something other than a bacterium. Thus, a virus became the suspect, and Krugman accepted this consensus.

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<sup>5</sup> There are a few exceptions to this opinion. *The Oxford Textbook of Clinical Research Ethics* argues that criticism of Krugman's work has cast a "restrictive ethical pall" over pediatric research.

Based on this thin foundation, Krugman set out to discover whether there was a difference between infectious hepatitis (from contaminated food and water) and serum hepatitis (from the breaking of the skin barrier and addition of foreign material with hypodermic needles and other causes). As stated earlier, his work solidified the replacement of the original terms used to describe these disorders with Hepatitis A (in place of infectious hepatitis) and hepatitis B (in place of serum hepatitis).

The replacement of serum hepatitis with the opaque and scientific-sounding term hepatitis B did two things. First, it obscured that this disease was most closely associated with injections and blood transfusions and thus was iatrogenic or medically caused. Second, by doing this, it left the door open to greatly expand the potential source of infection from injection<sup>6</sup> to all conceivable methods of blood-borne transmission, which were later to include sexual contact and birth.

As stated earlier, the renaming of infectious and serum hepatitis, hepatitis A and hepatitis B, came at the suggestion of a Canadian-born medical doctor and research scientist, Francis O. MacCallum. In 1947, he was employed by the Public Health Laboratory Service (PHLS), an arm of the British government.

The Emergency Public Health Laboratory Service (EPHLS) was established in 1939 at the start of the Second World War under the direction of the Medical Research Council to support the detection and control of infectious disease.<sup>7</sup>

During World War II, he was put in charge of yellow fever vaccine production for British soldiers at the Wellcome Institute.

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6 In the 1930s and 1940s, as the awareness of the existence of a different form of hepatitis spread, serum hepatitis was originally understood as a disease transmitted by medical intervention. These included blood transfusions and many medical practices long since discontinued: shared needles among diabetic insulin users, yellow fever vaccinations stabilized with human serum, arsenic injections for syphilis, and gold salt injections for arthritis.

7 The EPHLS later developed into the Public Health Laboratory Service (PHLS). The Medical Research Council itself evolved from the Medical Research Committee, which was created in 1913 as part of an early and modest attempt by the UK government to provide health insurance. The PHLS was abolished in 2003 and ultimately replaced by the UK Health Security Agency (UKHSA) in 2021.

It soon became obvious that soldiers who received the vaccine were developing jaundice and other symptoms of hepatitis months after receiving it. It was a massive problem and one of the worst acknowledged self-inflicted medical disasters in military history. There were tens of thousands of recorded cases, and dozens of soldiers died. (The exact number is not known.)

Like the U.S. Army, the British military made its yellow fever vaccines using a production method that had been identified as early as 1940 by the Rockefeller-funded Brazilian Yellow Fever Service as a source of hepatitis. Inexplicably, despite this finding, the Rockefeller Foundation and its colleagues in the UK, the Wellcome Institute, continued to use the failed and dangerous method to make the vaccines that were injected into Allied troops in the early years of the war.

MacCallum was no stranger to vaccine-caused hepatitis. In the 1930s, he and his superior at the time, George Marshall Findlay, observed, documented, and published papers about the connection between the yellow fever vaccine and jaundice outbreaks. Their papers, which appeared in 1937 and 1938, were among the first times anyone clearly articulated the hypothesis (guess) that hepatitis was transmitted by a virus. Despite his firsthand awareness that there was something in the vaccine that caused jaundice, MacCallum went on to later produce the flawed yellow fever vaccine that was administered to millions of troops with catastrophic results.

Following the yellow fever vaccine disaster, MacCallum was not fired or demoted. Instead, he was put in charge of what was called The Jaundice Team, which operated out of Cambridge. The historical record indicates that MacCallum's work included epidemiological studies, outbreak investigations, and clinical observations only, but the records are, in fact, quite hazy.

Meanwhile, across the ocean, and very well documented, Yale University School of Medicine, the University of Pennsylvania School of Medicine, and the Rockefeller Institute for Medical Research were receiving funds from the U.S. Army and the U.S. Public Health Service to conduct hepatitis studies with human subjects.

Healthy adult men, conscientious objectors who were part of the Civilian Public Service (CPS), a quasi-military organization, volunteered to participate as test subjects. Like the children at Willowbrook, they were injected with blood serum from patients who showed clinical symptoms of hepatitis. They were also given fecal extracts in food and drink from hepatitis patients. The stated purpose was to distinguish between “infectious hepatitis” and “serum hepatitis”.

Participants were subjected to repeated blood draws and liver function assessments. Many were sickened and developed clinical hepatitis. Some were infected several times. The subjects were told, in a general way, that they would be exposed to hepatitis and might contract it. This was the basis on which they granted their consent. Once in the program, withdrawing from it was difficult and discouraged.

As an inducement to participate, volunteers in the hepatitis experiments were relieved of their normal Civilian Public Service (CPS) duties during the course of the program. Standard assignments in the CPS typically involved hard physical labor such as forestry, agriculture, or road work and were carried out under strictly regimented camp conditions. The idea of being freed from that, no doubt, appealed to some.

It’s important to note that no institutional review board oversaw the work. The researchers were self-policed, as was the case for all medical experimentation on human subjects at the time. The professors and others who conducted these experiments were, for all practical purposes, unsupervised.

It’s clear that Krugman’s experiments on children at Willowbrook (1955 -1970) were a continuation of this program. They even had the same sponsor, the U.S. Army. NYU Medical School channeled the funds. The New York State Department of Mental Hygiene provided him with access to the children. As in the 1940s experiments that Krugman modeled, there was no institutional review board supervising his work. The difference is that in Krugman’s case, the subjects were developmentally disabled children who were institutionalized.

Which raises this question: Who gave consent for these children to be subjected to these experiments, and how was that consent obtained?

To answer this question, we have to take a brief look at Willowbrook State School itself. It was operated by the State of New York and was located on Staten Island, one of the five boroughs of New York City. In 1947, the facility was dedicated to the stated purpose of providing residential care and education for children with intellectual disabilities. The idea was that the children would receive education, therapy, and appropriate medical care in a supervised setting.

The intention and the reality quickly diverged.

Less than 20 years later (1965), Robert F Kennedy (former Attorney General and a year into his term as U.S. Senator from New York), conducted a surprise inspection of the facility and was deeply disturbed by what he saw. The facility, designed for 4,000, held 6,000. He described the children as “living in filth and dirt, their clothing in rags, in rooms less comfortable and cheerful than the cages in which we put animals in a zoo.”

Lawsuits filed years later described overcrowding, inadequate clothing, inadequate food, no meaningful education or therapy, no speech, occupational or physical therapy, physical and sexual abuse by staff, use of improper physical and chemical restraints, use of seclusion, failure to conduct periodic evaluations of residents, understaffing, and incompetence in professional staff.

State officials responded to the Allnational news generated by Kennedy’s inspection by publishing a five-year improvement plan and making changes that proved to be little more than window-dressing. In fact, they did nothing, and conditions continued to deteriorate.

In 1971, two forces converged to finally bring sustained public attention to this horrific situation.

In response to a budget crisis, the New York State Department of Mental Hygiene announced the closure of a facility that served severely disabled children, most of whom were non-ver-

bal and non-ambulatory. It was located in Manhattan's Lower East Side and was housed in the former Gouverneur Hospital, and had been offering services since 1962. All residents would be moved to Willowbrook. Parents objected to their children being moved to another borough and to a facility not equipped to address their needs.

Meanwhile, at Willowbrook itself, a social worker, Elizabeth Lee, reached out to families with children in the facility, informed them of the details behind the closed walls of the institution, and helped organize them to press for change. Two physicians who worked at the institution, William Bronston, MD, and Michael Wilkins, MD, were also involved in the effort. Wilkins focused on reaching out to the news media while Bronston gathered evidence for a legal case against the state and helped organize the parents and staff.

In 1971, Dr. Bronston and Dr. Wilkins interested a local reporter, Jane Kurtin, in the story. The local newspaper, *The Staten Island Advance*, gave Kurtin the space to publish a series of articles about conditions at the institution. Using their authority as doctors, Bronston and Wilkins walked Kurtin and photojournalist Eric Aerts past security into what was for all practical purposes, a locked-down facility.

Willowbrook was what is known as a Total Institution, a term coined by sociologist Erving Goffman to describe prisons, military camps, and psychiatric hospitals. Entry to and exit from Willowbrook were carefully controlled. Parents or relatives who wanted to see their children had to book an appointment in advance and wait for the child to be delivered to them in a designated area of the institution. They never saw the inside of the facility or the conditions their children were living in, or how they were being treated.

Children ended up there for a wide range of reasons — severe intellectual disabilities, physical disabilities, and conditions that were poorly understood at the time, and in some cases, mis-

diagnosis.<sup>8</sup> Once a doctor recommended institutionalization, families often had little choice and a limited understanding of what they were agreeing to. And once a child was admitted, regardless of the accuracy of the diagnosis, they were absorbed into the same overcrowded, understaffed system.

Not long after Kurtin's series appeared in the local newspaper, television reporter Geraldo Rivera entered the facility surreptitiously with a camera crew and documented the conditions he discovered. He commented: "There was one attendant for perhaps fifty severely and profoundly retarded children... Children lying on the floor naked and smeared with their own feces...It smelled of filth, it smelled of disease, and it smelled of death."<sup>9</sup>

Weeks after the documentary aired, a class action lawsuit was filed by parents of 5,000 residents against Governor Rockefeller and the state of New York. The case was settled three years later with the Willowbrook Consent Decree, signed in May 1975. It established that residents had a constitutional right to be protected from harm, set specific standards for care,

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8 Bernard Carabello, who had cerebral palsy, was misdiagnosed as intellectually disabled at age 3 and spent 18 years at Willowbrook. Against inconceivable odds, he not only survived the ordeal but also went on to become a prominent disability rights advocate, eventually working for the New York State Office for People with Developmental Disabilities. During the 2025 ceremony marking the 50th anniversary of the Willowbrook Consent Decree, he was honored by having an annual self-advocacy award named after him.

Carabello, not a passive victim, furnished the doctors with eye-witness accounts from the various wards at Willowbrook, providing Wilkins and Bronston with information about conditions throughout the facility. He was, in effect, their inside man. Television reporter Geraldo Rivera said of him: "If Willowbrook is ever closed or fundamentally improved, it will be more because of Bernard Carabello than anyone else."

Carabello escaped from Willowbrook with the help of Dr. Wilkins, who arranged to have himself named Carabello's guardian and secured his legal release from the facility. Wilkins was fired shortly thereafter for this and other acts of advocacy on behalf of the residents.

9 Rivera produced a documentary on the subject "Willowbrook: The Last Great Disgrace," which aired on the local ABC-TV affiliate on February 2, 1972. It won a Peabody Award. Rivera was able to gain access to the facility thanks to a key provided to him by Dr. Wilkins, one of the whistleblowers.

and, most importantly, committed New York State to moving residents out of Willowbrook and into community-based settings.

The public outrage generated by this case contributed directly to a cascade of landmark legislation: the Developmental Disabilities Assistance and Bill of Rights Act (1975), the Education for All Handicapped Children Act (1975), and the Civil Rights of Institutionalized Persons Act (1980), and ultimately helped pave the way for the Americans with Disabilities Act of 1990.

To bring this full circle, Willowbrook is where, for at least fifteen years between 1955 and 1970, Saul Krugman - employed by NYU Medical School and funded by the Armed Forces Epidemiological Board - recruited subjects for his hepatitis experiments.

Which leads us to this question: How did Krugman get consent?

Krugman used what he described as “modified consent procedures” to obtain consent from the children’s parents and other legal guardians. He had two sets of prospects: families who were applying for admission to the facility and families whose children were already in the facility and were seeking better care for their children.

In a state with 18 million residents (1965 estimate) and limited facilities for the profoundly disabled, Willowbrook had a long waiting list. In the application process, parents were informed, unofficially, that if they agreed to consent for their child to be part of a medical study, their application would be likely to be expedited.

They were further told that hepatitis was common in the facility and that their children would likely be exposed to it anyway. If they gave consent for their children to be in the program, they would be placed in a special hepatitis ward where they’d receive expert care. The hepatitis research unit was presented as being cleaner, less crowded, and offering more services than the general wards. It was explained to them

that the program would expose their children to hepatitis, but the details - injecting them with tainted blood products and feeding them fecal matter from the sick - were not included in the description of the program.

Children in the experiment were only kept in the cleaner, better-managed hepatitis ward for as long as they were needed for the purposes of the experiment. Once Krugman was done with them, they were put back in the general population.

As for the children who developed hepatitis as a result of the experiments, the care they received was minimal. They received bed rest, basic nursing care, and a controlled diet. Other than that, there was no special care or therapy. Most cases were self-limited, lasting weeks to months, as most cases of hepatitis are, but there were children who had severe and prolonged cases. The fate of these children is unknown because, as the historians of this case report state, "Long-term outcomes for those individuals are not well documented in the available record".

This dark chapter in the long history of the abuse of human subjects in medical experimentation is part of the chain of science that ultimately led to the decision in 1992 that every baby born in the U.S. should receive a hepatitis B vaccination within 24 hours of being born. However, it wasn't science alone that led to this decision. It was policy, and how that policy was formed is the subject of the chapters that follow.

# Chapter 8

## *From Science to Policy*

The road from the lab work of research scientists (like Blumberg and Dane) and the human experimentation of clinical scientists (like Krugman) to policy is a long one. In order for a new medical procedure, like a vaccine for newborns, to become government-mandated, someone had to embrace and become its tireless advocate. It doesn't happen by itself. In this chapter, we'll look at how the science of hepatitis B transformed into an imperative to inject every newborn in the United States with a hepatitis B vaccine.

Before we do, it's worthwhile to repeat what we know about epidemiology and epidemiologists

Epidemiologists are not clinical physicians. They don't see, work with, or take responsibility for patients. Epidemiologists are also not diagnostic physicians. They don't assist physicians in their clinical work the way radiologists and pathologists do. In fact, epidemiologists are not physicians at all, though there are some physicians who've also received degrees in epidemiology.

What do epidemiologists do? They're trained in statistics, research methodology, population science, and a subject called public health. They work with data, not patients. Their tools are cohort studies, case-control studies, surveillance systems, statistical modeling, and mortality records. They do not examine patients, they do not diagnose, and they do not treat. They are number crunchers.

Now the question naturally arises, who specifically conceived, created the epidemiological justification for, and advanced the idea of hepatitis B vaccines for all newborns regardless of clinical need? More importantly, what was their

reasoning for promoting such an extreme, and frankly, clinically questionable, policy?

The agent of this policy of hepatitis B vaccine for all newborns was Harold S. Margolis, MD. Like most bureaucrats who happen to have an MD after their name, he did earn a medical degree (University of Arizona Medical School '72), and like all medical school graduates who want a license to practice medicine, he did a residency, in his case in pediatrics. In 1975, without ever having had clinical accountability for a single child, he joined the CDC's Epidemic Intelligence Service.<sup>1</sup>

The CDC's Epidemic Intelligence Service sent Margolis to Anchorage, Alaska, where he was an EIS officer in their Arctic Investigations Program. His job was to study the hepatitis burden among Alaska Native populations.

Contrary to National Geographic documentaries, the life of many Native Alaskans is one of sorrow and dysfunction. Russian colonization, which started in 1741, and American colonization, which started in 1867, were characterized by savage violence, abuse, and resource theft. Some estimate that as few as 20% of the Aleut population survived contact with the 18th century invasion of Russian fur traders.

Land and resource theft and forced relocation undermined sophisticated hunting, fishing, gathering, and food and medicine preparation traditions that sustained Alaskan natives for thousands of years. They were violently thrust into the same position we'd all be in if

every supermarket and pharmacy were to be permanently shuttered overnight – and then your children were taken away from you. The United States added a particularly insidious twist to this genocidal history. It was summed up by Richard Henry Pratt, the United States Army officer who founded the Carlisle Indian Industrial School in Pennsylvania in 1879. He infamously stated: "Kill the Indian in him, and save the man".

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1 The CDC's Epidemic Intelligence Service deserves a book of its own. The molecular biologist and professor at UC Berkeley, Peter Duesberg, provides a useful history of this organization, its origin, purpose, and impact in his book *Inventing the AIDS Virus*.

As in other parts of North America, Native Alaskan children were forcibly removed from their families and incarcerated in residential schools where they were forbidden to speak their languages, practice their traditions, or maintain contact with their communities. In addition to being cut off from the emotional support of their families and the spiritual support of their traditions, the children were the victims of widespread physical and sexual abuse.

The fact of this abuse had been officially denied for decades through a process that is best described as systemic non-documentation. Today, this ugly history has been thoroughly documented and affirmed both by the courts and formal federal government admissions in Canada and the United States. Official state apologies to the victims have been issued both by a Canadian Prime Minister (Stephen Harper, 2008) and a U.S. President (Joseph Biden, 2024).

The traumatized communities Margolis studied were mired in poverty, malnourished, and living in substandard housing with inadequate sanitation. Not surprisingly, substance abuse, in the form of alcohol, was rampant. Currently, the Alaska Native alcohol-related mortality rate is 16.1 times higher than the rate for whites in the US, and alcohol is responsible for 14.1% of premature deaths among Alaska Natives. Alcohol abuse is the leading cause of death for Alaska Native men. A 1989 study recorded fetal alcohol syndrome rates among Alaska Natives at 5.2 cases per 1,000 births, with regional variations reaching as high as 20.6 per 1,000 births in some communities, in comparison to a US national rate of 1 to 3 per 1,000.

Understandably, the community has had, and continues to have, a high incidence of hepatitis. Mothers with chronic hepatitis, compounded by alcohol-related liver disease, malnutrition, inadequate prenatal care, and the physiological consequences of generations of trauma and poverty, gave birth to children with a variety of serious health challenges, including liver disorders rarely seen in healthy populations.

Margolis looked at the situation described above...and concluded that the hepatitis B virus was the problem. With this

remarkably limited perspective as his foundation, he reasoned that the best thing that could be done to help infants born into this situation would be to vaccinate them with the hepatitis B vaccine at birth.

In the early 1980s, Margolis joined the CDC's Division of Hepatitis, which was then based in Phoenix. There, he jockeyed to have it moved to the CDC's headquarters in Atlanta. In 1983, he succeeded and became the division's director. He was now in a position to advance his belief, which evolved gradually, but relentlessly, into the conviction that not only should the newborns of Native Alaska be injected with the hepatitis B vaccination, but also all American children should be as well.

In 1991, Margolis pitched his idea to the Advisory Committee on Immunization Practices (ACIP). His argument appears in a paper published on November 22, 1991, in the CDC's *Morbidity and Mortality Weekly Report* (MMWR) entitled "Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)." The paper was unsigned. Instead, it was published under the imprimatur of the ACIP as a whole.

If you're wondering how something of such far-reaching importance – a policy to inject every American newborn with a hepatitis B vaccine – could have been advanced with no single person accepting responsibility for the proposal, here's how it works.

First, the CDC's *Morbidity and Mortality Weekly Report* (MMWR) is not a peer-reviewed journal. If the editor at the time feels an article should go in, it goes in. Second, ACIP recommendations are institutional documents. They are not meant to be scientific papers. They are policy recommendations. Theoretically, the members of the ACIP are responsible for their recommendations and the consequences of their recommendations, but in practice, no one is. The system as it is creates a near-perfectly engineered accountability vacuum.

Accountability vacuums aside, Margolis, the epidemiologist who witnessed the extreme multi-dimensional suffering of

a community and reduced its liver problems to a single virus, did take credit for the 1991 decision to inject every American newborn with the hepatitis B vaccine on the day of their birth. He is also widely credited by the official narrative.

Interestingly, in memorials posted about Margolis, who died in 2022, no one praised him for his clinical skill (he had none) or his scientific rigor (another area where he appears to be deficient). Instead, he was called “driven by a single-minded vision”, “fierce, unafraid, and unapologetic about the critical importance of his work”, and “his genius was to educate, cajole, and yet befriend those he recruited into his army of believers.”

To this author, this reads more like a eulogy for an evangelist than an obituary for a scientist.

However, as we’ve seen in previous chapters, there is more to the story, and it is often left out of the telling of the official history of the hepatitis B vaccine. It involves an earlier paper that Margolis did put his name to. This paper had a co-author who, along with several of his colleagues, was arguably far more important in advancing hepatitis B vaccination policy than any of the figures we’ve discussed so far. We will look at the paper, the co-author, his colleagues, and their wide-ranging and ambitious operations in the next chapter.

# Chapter 9

## “Foreign Aid”

Harvey Margolis may not have had his name anywhere on the article that appeared in the CDC’s *MMWR* in advance of the Advisory Committee on Immunization Practices’ (ACIP) recommendation that every newborn in America receive an injection of the hepatitis B vaccine at birth.

However, his name did appear on two related articles: “Cost-effectiveness of hepatitis B vaccination” (1990), and “Global control of hepatitis B through vaccination: role of hepatitis B vaccine in the Expanded Programme on Immunization” (1991).<sup>1</sup> One of his co-authors, G. C. Schatz, is an obscure figure who worked for the Hepatitis Branch of the CDC in Atlanta. The other, Michael A. Kane, conveys the nature and scope of the institutional and financial winds at Margolis’s back as he was advocating for the shot.

It turns out Margolis was not alone in his crusade, far from it. However, in order to fully appreciate the significance of Kane’s name on the article, it’s necessary to know something about the evolution of U.S. foreign aid after WWII.

The year is 1976. The United States is celebrating the 200th anniversary of its Declaration of Independence.

Approximately 7,500 miles away, it’s 3 AM in the village of Uttawar, just southwest of New Delhi. Police surround the village and, with loudspeakers, order all the men to provide government certificates that affirm that they have been sterilized. Roughly eight hundred men of fertile age cannot. They are loaded into buses and taken to makeshift clinics where they are forcibly sterilized.

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1 Harvey S. Margolis, Michael A. Kane, and G. C. Schatz, Cost-effectiveness of hepatitis B vaccination, *Pediatrics* (1990); Harvey S. Margolis and Michael A. Kane, Global control of hepatitis B through vaccination: role of hepatitis B vaccine in the Expanded Programme on Immunization, *Vaccine* (1991)

The operation, a vasectomy, involves cutting and tying the vas deferens, the tubes that carry sperm, rendering the men permanently infertile. The procedure takes 10 to 12 minutes and is carried out in an assembly line fashion.

Elsewhere, women are seized. In one documented case, doctors performed tubal ligations on school desks, working by flashlight. As with the case of the men, they were discharged immediately after the operations and sent home with a handful of painkillers.<sup>2</sup>

Welcome to the world of population control.

The forced sterilization program was administered by the son of then-Prime Minister Indira Gandhi, Sanjay Gandhi. In 1975, Indira Gandhi declared a National Emergency under the pretense of “national disturbance”. In fact, the same year, a High Court ruling had found her guilty of electoral malpractice in the 1971 election and disqualified her from holding elected office for six years.

The consequences of the National Emergency declaration were severe. Elections were cancelled, opposition leaders were arrested, the press was censored, trade unions were crushed with mass arrests and detention without trial, and Sanjay Gandhi, age 28 and unelected, was deputized to “reform” the country. At the top of his list was a mass sterilization program. Between 1975–77, over 8 million Indian men and women were sterilized, with over 6 million in 1976–77 alone. As is thoroughly documented, much of this was carried out by force.

Sanjay’s program targeted these three groups and put them in its sights. First, the poor, illiterate, and politically powerless, including prisoners and the homeless. Second, Muslims. Third, the country’s indigenous people, non-Hindus, who in India are officially called Scheduled Tribes.

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2 The process continues to this day with financial incentives, social pressure, and promises of medical care replacing guns and bludgeons. In 2014, in a camp in Bilaspur, a district in central India, 13 women died after a single doctor performed 83 tubectomies in a few hours under unsanitary conditions.

In addition to local resources – paramilitary forces and cooperative doctors and nurses – Sanjay had thought leaders, advisors, and funders who inspired and supported his work. They lived 7,500 miles away, and probably attended Fourth of July barbecues while the atrocities were being committed.

One of the thought leaders was Paul Ehrlich, Stanford professor, butterfly scientist, population alarmist, and author of *The Population Bomb* in 1968. Advisors and architects included Douglas Ensminger, in charge of the Ford Foundation’s India operations, Sheldon Segal, a member of the Population Council and sent to India, and Robert McNamara,<sup>3</sup> president of the World Bank (1968 to 1981), which made population control (population reduction) a condition for receiving its loans.

Much-needed money to carry out the campaign came from the Ford Foundation, the Rockefeller Foundation, the World Bank, USAID, the UN Fund for Population Activities, and the Population Council.

The Population Council merits special attention. It was founded by John D. Rockefeller III in 1952. As described in the chapter “The Dance of the Epidemiologists,” in the first half of the 20th century, the idea of controlling population quality was a national obsession among U.S. elites. They called their pseudo-scientific obsession “eugenics”.

The palatable cover of eugenics was that, as a society, we can have a healthier population by making improvements to our current state of affairs, specifically proper nutrition, better housing and sanitation, better medical care, and improved education. It all sounded very good.

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3 This is the same Robert McNamara, Secretary of Defense, who was the architect of the U.S. strategy in the Vietnam War from 1961 to 1968. Prior to the Vietnam War, his career went from planning WWII bombing raids to working as an executive at Ford Motor Company.

McNamara believed that superior technology and management by numbers were the answer to all perceived problems. During the war, he promoted mass chemical defoliation, the removal of farmers from their villages to “strategic hamlets” (concentration camps), and daily body counts as the measure of success.

The problem is that the focus of the eugenics movement was, in fact, population improvement by the reduction, or ideally elimination, of the “inferior”. What exactly constitutes an inferior person by eugenics standards? The definition turned out to be flexible and coincidentally became whatever the people in charge wanted to see less of.

In Greater Germany, it included Romani, people of Jewish ancestry, and Slavs. In the United States, which provided the Nazis with much inspiration, it included black Americans, Mexican Americans, Southern and Central Europeans, and Asian Americans. In both countries, scientists were enlisted to affirm the “scientifically objective” inferiority of the targeted groups. Faculty at schools like Stanford,<sup>4</sup> Harvard, Yale, Princeton, and elsewhere were only too willing to provide whatever rationale was needed.

For obvious reasons, after WWII, eugenics had to go – except that it didn’t. It just changed its name. The same groups, and in some cases members of the families that funded the original movement, kept things rolling along with a rebrand: population control. Thus, John D. Rockefeller III and his Population Council.

After John D. Rockefeller III kickstarted the Population Council, others piled in with funds to help: the Rockefeller Brothers Fund, the Ford Foundation, the Markle Foundation, and the National Institutes of Health. Later, the full roster expanded to include Mellon, MacArthur, Packard, and Hewlett. Eventually, Bill Gates joined the party, but that would not occur until decades later.

The new and improved idea is that there are too many people in the Third World, and life would be much better for everyone if there were simply fewer of them. Thus, forced sterilization migrated from California and Nazi Germany to places like India.

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4 In 1909, with the encouragement of David Starr Jordan – the founding president of Stanford University – the state of California enacted a law authorizing the compulsory sterilization of institutionalized individuals deemed “unfit.” California led the nation in forced sterilizations.

A new twist was added in the post-war era. Thanks to Robert McNamara's World Bank, now there were people who, by their very existence, by adding to the population, threatened to interfere with a country's international loans and grants. Thus, in India, people like the Gandhis could both eliminate people they deemed inferior and improve their country's credit score at the same time.

However, as with the case of the Nazis, the Gandhis had taken things too far and had gotten caught. Widespread unrest created intense political pressure for new elections, a new party took control, and eventually western news outlets like the *New York Times*, the BBC, and *Time Magazine* told the story to the near-universal horror of the public.

Population Control, née Eugenics, needed yet another rebrand.

The rebrand was Global Health. The rebrand would be wrapped around an American-led movement to create a global system in place to make sure every child received every vaccination on the vaccination schedule, especially, but not limited to, the world's poor. Rockefeller's Population Council was one of the primary vehicles for promoting America's population control policy in the developing world, planting seeds through the federal government, medical research, and activist foundations.

One of the groups that formed to advance this new, friendlier form of eugenics was the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT). The founders were Richard Mahoney, a contraceptive development specialist for the Ford Foundation; Gordon Perkin, an obstetrician-gynecologist who had spent the previous fourteen years running the Ford Foundation's contraceptive R&D program;<sup>5</sup> and Gordon Duncan, a pharmaceutical scientist who devel-

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5 Bill Gates Sr., a board member of Planned Parenthood, became involved in global health philanthropy in the 1990s, where he encountered the work of Gordon Perkin. Perkin later joined the Bill & Melinda Gates Foundation in 1999 to lead its Global Health Program, overseeing the foundation's early multibillion-dollar funding commitments.

oped Depo-Provera, one of the most widely used injectable contraceptives globally for his employer Upjohn.

The U.S. Food and Drug Administration refused approval for decades (1960s–1992) over safety concerns. It was demonstrated to increase tumor risk during animal tests. Meanwhile, the WHO and International Planned Parenthood Federation endorsed it for use in developing countries.

The U.S. blocked approval of Depo-Provera for decades on safety grounds (1960s–1992), citing breast tumor findings in animal studies. Several countries in Europe and Japan also delayed or restricted its use over similar concerns. Meanwhile, the World Health Organization and the International Planned Parenthood Federation actively promoted its widespread use in developing countries, relying on international studies that critics argued left key safety questions unresolved.

In the U.S., advocates for the product pointed to the international data gathered by the WHO, which they said demonstrated it was safe. The National Women’s Health Network and the National Black Women’s Health Project, both aligned with reproductive rights, raised safety and informed consent concerns. However, Planned Parenthood Federation of America and the International Planned Parenthood Federation were strongly in favor of it, and in 1992, they prevailed; the Food and Drug Administration approved it for use by American women.

Both Planned Parenthood organizations, which were created in 1916 (with the federation established in 1942) and 1952, respectively, were associated with Margaret Sanger, an ardent and outspoken eugenicist. The Rockefeller Foundation and the Carnegie Institution heavily funded Sanger’s work as part of their eugenics portfolio. In 1939, she launched the Negro Project, whose stated goal was to bring what it called family planning services to Black communities in the South. Some critics say it was intended to reduce the Black population in America. Throughout her career, Sanger was known to make statements that reflected the eugenic movement’s attitudes towards “undesirable” groups.

Cancer concerns surrounding the project arose again when meningioma brain tumor risks emerged in 2024. Europe responded by adding warnings to the product's labels. The FDA rejected the label update. In the United States, Depo-Provera is recommended to and used by Black and Hispanic women, and those with lower incomes use it at significantly higher rates than the rest of the population.

Unbeknownst to the women who have been prescribed Depo-Provera, and probably most of their doctors, is the fact that the active ingredient medroxyprogesterone acetate is also used as chemotherapy for patients with endometrial and renal cancer. In cancer, it presumably works by aggressively disrupting hormonal signals that tumor growth depends on. As a contraceptive, it works by targeting the hypothalamus and the pituitary gland, undermining the hormonal signals they work together to send to the ovaries, which trigger ovulation. Medroxyprogesterone acetate is used in reduced amounts in the injectable contraceptive, but it is the same exact substance.

In 1980, Depo-Provera's developer Gordon Duncan, the former Upjohn employee, and his colleagues, Richard Mahoney and Gordon Perkin, former executives of the Ford Foundation's contraception division, did a rebrand of their own. They changed the name of their Seattle-based organization from PIACT (Program for the Introduction and Adaptation of Contraceptive Technology) to PATH (Program for Appropriate Technology in Health).

One of PATH's most ambitious undertakings proved to be its support of the International Task Force on Hepatitis B Immunization, which was co-founded by one of its leaders, former Ford Foundation employee Richard Mahoney. Mahoney was a master of financial and political strategy. He knew how to push policy, use that policy to raise funds from governments, multilateral agencies, and philanthropic foundations, and, most importantly, scale distribution of previously niche pharmaceutical products for high-risk groups to global, population-wide distribution.

The table was set. Unbeknownst to families and the obstetricians and pediatricians who served them, a new public health threat was taking shape that could only be addressed by an injectable pharmaceutical product.

We will meet Richard Mahoney and his other colleagues at the Task Force and review their work in a future chapter. In the meantime, we need to look at another breakthrough that took place in the mid 1980s: the sudden emergence of a technology that made it possible to mass-produce hepatitis B vaccine shots in vast quantities for a few pennies per shot.

# Chapter 10

## *Big Vats, Tainted Blood, and a Nobel Prize Winner Ignored*

On July 23, 1986, after a four-year process that included animal studies, clinical trials, and the design of a specialized industrial manufacturing process, the FDA approved Merck's application to market a product called Recombivax HB, a hepatitis B vaccine. They also approved the manufacturing process.

This was the kind of breakthrough news that would have made anyone who followed pharmaceutical manufacturing or hepatitis B sit up and take notice. It was only the third pharmaceutical product made from genetically-altered organisms (the other two were insulin in 1982 and human growth hormone in 1985), and it was the very first vaccine of its kind. Given the four-year runway from the start of animal studies to FDA approval, which commenced in 1982, it's reasonable to assume that groups like PATH, which we introduced in the previous chapter, had been tracking this development for years.

Merck's product (it is still being made and injected into newborns today) contains a protein that's made by genetically modifying yeast and growing it in large vats. Using the tools of genetic engineering, the yeast is altered and "trained" to produce the "Australia antigen" (HBsAg) that Baruch Blumberg discovered in 1965.

Normally, when you feed yeast glucose, it produces ethanol and carbon dioxide. The technical name for the yeast they use is *Saccharomyces cerevisiae*. It's also known as baker's yeast, brewer's yeast, and budding yeast. It is all the same organism.

What exactly goes into this brew? The simple answer is, it's complicated.

The yeast is fed with soy peptone for protein nutrients, dextrose as a glucose/sugar energy source, amino acids as build-

ing blocks for proteins, and mineral salts that provide essential minerals like sodium and potassium. Note that in addition to the antigen produced by yeast, what is fed to the yeast is also made from genetically modified organisms: the soy peptone from GMO soybeans, the dextrose from GMO corn, and the amino acid from GMO crops or GMO bacteria. All contain trace amounts of glyphosate.

To focus on just one of these yeast-feeding ingredients, the soy peptone, it is an industrial product. As part of the process of making it, the fat has to be removed from the soybeans. This is done with hexane, a petroleum-based solvent that is neurotoxic and a suspected endocrine disruptor that may damage fertility and has been linked to reproductive and nervous system damage.

Theoretically, all the hexane used to make the soy peptone that feeds the yeast that makes the vaccine is removed using heat and vacuum distillation. However, in practice, residue of hexane is commonly found in everyday manufactured products, including vegetable oil, chicken, butter, milk, and infant formula. Once used in an industrial process (food or vaccine-making), it is physically impossible to remove it 100%.

After the soybeans have been defatted, they are then broken down to make them easier for the yeast to digest using hydrolysis, another industrial process. The elements that accomplish this are industrial-grade enzymes that are made from genetically modified bacteria, yeast, and fungi. As with the case of hexane, it is not possible to fully remove these GMO-derived materials from the mix.

All of this, in trace amounts, finds its way into the “soup” that feeds the yeast: GMO bacterial/yeast/fungal DNA fragments, host organism proteins from the enzyme-producing GMOs, metabolic byproducts from GMO fermentation, cell wall materials and cellular debris, and processing chemicals used in enzyme production.

After being fed, the yeast cells are then processed to extract the protein antigens they produced, which are then added to the vaccine. However, before the protein antigens can be added

to the vaccine, the yeast has to be broken open to get access to them. This involves a number of physical and chemical processes.

The chemicals used to break open the yeast to get to the antigen (called lysis, “breaking apart”) include Triton X-100, PMSF, Tween 20, acids, urea (widely used as a fertilizer), and alkaline chemicals like sodium hydroxide (used to make drain cleaner). PMSF is a genuinely hazardous substance that affects the nervous system. Triton X-100 is an irritant that should be kept away from the eyes and skin (and presumably the bloodstream). Tween 20 (polysorbate 20) is considered a mild irritant and safe at “typical exposures”. It’s used in food production, cosmetics, and pharmaceutical products.

Again, it is not possible to remove 100% of all trace amounts of these materials from the final product. It all goes into the antigen, which goes into the vial, which is injected into the newborns and infants who receive the hepatitis B vaccine. As indicated earlier in the book, GlaxoSmithKline also makes a hepatitis B vaccine using a process similar to Merck’s.

As pointed out in Chapter 5, *What’s in the Syringe?*, the antigen is not the only ingredient in the hepatitis B vaccine vial. It also contains buffering agents like sodium phosphate, potassium phosphate, sodium chloride, and, in some formulations, sodium borate, which are included to help maintain a stable pH.

Earlier multi-dose versions of Recombivax HB by Merck & Co. and Engerix-B by GlaxoSmithKline contained thimerosal (a mercury-containing compound) as a preservative. They are now said to be thimerosal-free.

The FDA regulates the manufacture of vaccines via its Center for Biologics Evaluation and Research (CBER) department. However, it leaves it up to the manufacturers themselves to suggest contaminant limits, which the FDA theoretically can push back on. The FDA also leaves it up to the manufacturers to do their own testing, satisfying themselves by merely reviewing the company-provided data. On the rare occasions when the FDA does independent testing, it’s selective and does

not even attempt to cover all trace chemical residuals listed in this chapter. Functionally, it's a corporate honor system with the FDA conducting occasional and incomplete independent spot checks.

The commercial virtue of this system is that it can produce hundreds of millions of doses of hepatitis B vaccine each year for just pennies per dose. In a future chapter we'll address how that translates to Americans being charged \$20 to \$40 per dose when the vaccine is paid for by private insurance or government benefits.

From a commercial point of view, the genetically-modified-yeast-in-a-vat is a triumph compared to the original system for making hepatitis B vaccines. It's not only much cheaper, but it's also much faster. The details of how the vaccine used to be made are eye-opening to say the least.

First, the plain vanilla facts. From end to end, from plasma collection to release as an injectable product, the old process could take up to a year, versus 6 to 12 weeks for the genetically modified yeast method. Cost to manufacture a single dose using the plasma method could be as high as \$10 (in early 1980s dollars) and, as stated earlier, just pennies for the genetically modified yeast method. Using the plasma method, it was feasible to produce only a few million doses per year. Using the genetically modified yeast method, hundreds of millions were now possible.

What exactly was the plasma method?

First, the plasma method involved sourcing human blood. But not just any blood. It had to be the blood of people who had been infected with hepatitis B and were producing high levels of the surface antigen (HBsAg).

Merck's hepatitis B vaccine developer Maurice Hilleman specifically sought blood from communities that were believed to have high levels of hepatitis B infection, including intravenous drug users and gay men. The most prominent agent in persuading gay men to contribute their blood to the cause was Wolf Szmunes, MD.

Szmunn was initially motivated to undertake this community outreach because of his role running the first large-scale, randomized, double-blind, placebo-controlled trials, which involved testing a blood-derived vaccine in over 1,000 homosexual men from 1978 to 1980. His boss at the time was Alfred Prince, who went on to become one of the four founders of the International Task Force on Hepatitis B Immunization, which, as we'll see in a future chapter, was later the essential instrument pushing for newborn and infant injection with the hepatitis B vaccine.

Though an MD, Szmunn was not a practicing clinician. He was an epidemiologist and public health researcher. Thanks to his role as the director of the epidemiologic research at the New York Blood Center, one of the largest independent blood collection organizations in the United States, he was able to effectively get the word out that blood was needed from gay men for a project to test a hepatitis B vaccine.

When it came to producing a test vaccine, he arranged for a bloodmobile to canvass the gay neighborhood in the Greenwich Village section of Manhattan, looking for homosexual volunteers. Over ten thousand men signed up. Their motivations were medical altruism and social acceptance. Many gay men tested positive for the hepatitis B antigen, and the gay community faced massive social stigma at the time. Participating in legitimate medical research was seen as a way to gain respectability and social standing.

Here it's important to repeat a point that I have made several times throughout this book. Testing positive for the hepatitis B antigen does not mean one "has hepatitis" or even the hepatitis B virus. Hepatitis is a clinically observable irritation of the liver manifesting in nausea, lack of appetite, and jaundice. Testing "positive" for hepatitis B means a lab test found a specific protein substance in your blood. It is possible and common to test positive for hepatitis B, or for any virus, and not be sick with the disease associated with it.

If this sounds like the forerunner of the fallacious belief that a positive HIV test (which is a deeply unreliable test for the

presence of an antigen and not a virus) means infection with AIDS, which means certain miserable death, be aware that this non-medical, non-scientific formula was promoted heavily before the AIDS crisis. Nearly a decade later, hepatitis B and AIDS came to be linked strongly in the public mind with the publication of a paper, "Prevalence, incidence, and progression of human immunodeficiency virus infection in homosexual and bisexual men in hepatitis B vaccine trials, 1978-1988," published by the *American Journal of Epidemiology* and funded by the CDC.

The paper claimed that tests showed that the blood of 328 members of the hepatitis B vaccine trials demonstrated an explosion in "HIV infections" in the gay community. Samples from 1978 were said to show only a 0.3% "infection" rate in 1978. In contrast, the 1988 samples had a rate of 50.9%, a 170-fold increase in ten years.

This study was used by various parties with a variety of agendas to "prove" a number of things:

AIDS came out of nowhere, thus there had to have been a Patient Zero who appeared shortly before 1978 (from Africa, from Haiti, and/or from a wide-ranging Montreal flight attendant)

The gay community, being the most "infected", was one of the prime drivers in spreading AIDS

Gay blood donors had contaminated the blood supply, and

Gay blood donors had contaminated the hepatitis B vaccine supply

Impactful as this CDC-funded study was, it was based on the claim that blood samples of individual donors to the hepatitis B vaccine cause were saved and there were viable samples available from each of the years between 1978 and 1988. Why would anyone bother to do that under these particular cir-

cumstances? Assuming that someone did, how was the blood stored, and what condition was it in ten years later?

Long-term serum storage did exist and was standard by the 1970s with  $-20^{\circ}\text{C}$  and  $-80^{\circ}\text{C}$  freezers. Antibodies, like those said to be associated with the HIV virus, are durable proteins, unlike RNA and other cell parts, which degrade more rapidly even when frozen. The catch is that for the 1978 samples to be useful, they would have to have been stored in freezers that reliably maintained an ideal temperature of around  $-70$  to  $-80^{\circ}\text{C}$ , which is  $-94$  to  $-112^{\circ}\text{F}$ , for ten continuous years. Maybe it happened that way. Maybe it didn't. In any event, it was a "useful" study for people with cases to make.

With all this talk about proteins – from genetically modified yeast and human blood – and using them to make vaccines, we need to go back to 1913 and dust off the records of the Nobel Prize for Medicine or Physiology that year. It went to Charles Richet, a Professor of Physiology at the University of Paris (Sorbonne). The award was for his work on anaphylaxis.

Richet coined the term, which he assembled from the Greek roots *ana* ("against") + *phylaxis* ("protection"). It describes a reaction in which an organism is not only not protected as a result of a previous exposure to something, but it also becomes even more vulnerable to it on additional exposures.

Most people have heard the term anaphylaxis in the context of anaphylactic shock. This is the most severe form of anaphylaxis.

Anaphylactic shock involves a dramatic drop in blood pressure, a weak and rapid pulse, dizziness, fainting or loss of consciousness, pale, cold, clammy skin, confusion or altered mental state, and circulatory collapse with inadequate blood flow to vital organs. Often accompanied by severe difficulty breathing (bronchospasm) and airway swelling of the throat or tongue.

In extreme cases, airway obstruction and/or circulatory collapse starve the brain and heart of oxygen, and death can result. The first-line emergency treatment is an intramuscular

injection of epinephrine. These can be delivered via an auto-injector device called an EpiPen.

In the US, a two-pack of EpiPens costs approximately \$300 to \$700. In Canada, the same device can be had for \$100–\$150, in the UK about \$60, in France around \$100, in Germany about \$85, in Australia \$60–\$80, in Japan roughly \$65–\$70, in India about \$30–\$35, and in Mexico epinephrine is typically sold as single-dose vials for about \$5–\$10 each rather than as a two-pack auto-injector.

However, anaphylaxis is not always as dramatic or as serious as anaphylactic shock, though the symptoms can be alarming and uncomfortable; they include itching, hives, flushing, mild swelling of the lips or face, nasal congestion, sneezing, mild throat discomfort, cough, nausea, abdominal discomfort, dizziness, and a general sense of unease.

When he started his experiments, Richet used a toxin derived from sea anemones, injecting test animals (usually dogs) and recording their reactions. Following the immunization theory advanced by Jenner and Pasteur, he expected that a second injection would produce a lesser reaction. He and his colleague Paul Portier were surprised that the reaction to the second injection was stronger than the reaction to the first.

At first, Richet assumed the unexpected reaction was a special property of the toxin itself. Then he tested other biological substances, blood serum from horses and other animals. Recall that “blood serum” is the liquid portion of the blood, with the red blood cells mostly (but never perfectly) removed. He also experimented with milk, egg white (albumin), meat extracts (broths made from animal tissue), organ extracts (such as liver extracts), and bacterial products (toxins or extracts from microbes).

What he found surprised him and ultimately led to his Nobel Prize: he learned that many biological substances, when introduced directly into the bloodstream, could sensitize the body and trigger severe reactions upon re-exposure, up to and including death. Anaphylaxis is an immune reaction, but it’s an extreme one that can injure, disable, and kill.

Many of the known adverse reactions to specific vaccines, including the hepatitis B vaccine, can resemble an anaphylactic reaction. What is causing these reactions?

In the case of the original hepatitis B vaccine made from blood serum, logic says it could well be the blood serum. In the case of the new and improved hepatitis B vaccine, logic says it could well be any of the trace amounts of biological material that are part of the manufacturing process, which we described in detail earlier.

Since his 1913 Nobel Prize, no one has successfully challenged Richet's core findings. In fact, they have been consistently reproduced and form the foundation of modern immunology and the study of allergy.

If an ambitious post-doc were to come forward and successfully disprove Richet's science, he'd be famous and could probably count on a lifetime of grants from the National Institutes of Health, especially the National Institute of Allergy and Infectious Diseases (NIAID), the organization Anthony Fauci led for thirty-eight years. No one has done so, which means until someone does, we have to accept that introducing foreign proteins into the bloodstream of a human being, newborn or elder, runs the risk of triggering the well-described and thoroughly-accepted symptoms of an anaphylactic reaction.

Now that we've examined how the hepatitis B vaccine is made today and how it was made in its first incarnation, it's time to take a close look at how this science and commerce became a policy of injecting newborns with the hepatitis B vaccine.

But before we go, one last bit of information. In this chapter, we learned the names of the key people who developed the first hepatitis B vaccine, but who was the inspiration for their work? Professor of Urban Studies William Muraskin of Queens College (SUNY) answers that question in his glowingly complimentary history of the International *Task Force Hepatitis B*, *The War Against Hepatitis*. He's quite clear on the subject: "It was Dr. Baruch Blumberg whose discovery of the 'Australia antigen' (hepatitis B surface antigen) and his subsequent drive to

translate that finding into a vaccine inspired the entire research program that led to the first hepatitis B vaccine.”

# Chapter 11

## *Anatomy of a Panic*

We've covered a lot of ground.

We have an idea of what the liver does and why it's so important. We know what hepatitis is and how it presents clinically and what its symptoms are. It's a disease that's been well known for millennia and truth be told treatment methods are not much better today than they were in Hippocrates' time (rest, hydration, careful diet, herbs that support liver function).

We know that during WWII, the military created a self-inflicted vaccine injury disaster that created thousands of cases of hepatitis and this was the start of the "modern" approach to the disease.

Modern research into the disease involved inflicting it on many thousands of test subjects in order to clarify a distinction, the difference between hepatitis triggered by contaminated food and/or water and hepatitis triggered by medical intervention (injections). The names "infectious" for the former and "serum" for the latter, were replaced with hepatitis A and hepatitis B and the range of potential causes for "serum" hepatitis was expanded to include sexual contact and childbirth.

A new antigen was discovered, and despite the fact that the two people most responsible (Blumberg and Dane) did not think it caused or was related to hepatitis, it was promoted as proof that the cause of what had previously been called serum hepatitis was a virus that could be transmitted by blood. Gradually, the mere presence of this antigen in a blood test became the definition of a "case of hepatitis B". Once this leap was made and mass testing commenced, the number of "hepatitis" cases exploded. This despite the fact that it's possible for one to have the antigen in their blood and not only not be sick, but also never become sick with hepatitis. It's also perfectly possible to be sick with obvious signs of hepatitis (nausea, loss of appetite,

jaundice, extreme fatigue) and come up negative on hepatitis B and other routine viral screenings.

For the sake of moving the narrative forward we will accept that there is a hepatitis B virus, that it is transmitted by the means currently attributed to it, and that it causes hepatitis B. This book is not meant to be a comprehensive examination of virus theory.

Assuming all of the above, and assuming it makes sense to set aside Charles Richet's Nobel Prize-winning findings on the reality of anaphylactic responses to foreign proteins introduced to the bloodstream, we will accept that it makes sense to vaccinate against hepatitis B and that the current manufacturing method represents the best of all possible worlds.

Yet, despite all that we know, we still don't know the specific mechanism by which science of sterling quality and the major industrial breakthrough of manufacturing a specialty protein came together to inspire the policy of every newborn in America receiving an injection of this protein, along with other ingredients, on their first day of life.

As anyone who has undertaken an enterprise of any size knows, bright ideas do not automatically become reality without a plan and sustained effort. In this chapter, we begin an account of that sustained effort, who was behind it, and how they achieved their goals.

Close readers of the previous two chapters, "Foreign Aid" and "Vats," may have noticed that the timelines of Merck's foray into the genetically modified yeast hepatitis B vaccine business roughly correspond with the formation of the International Task Force on Hepatitis B Immunization.

In this chapter, we will focus on the Merck leg of the correspondence.

An Ultra Large Crude Carrier (ULCC) carries approximately 3 to 4 million barrels of crude oil, the equivalent of 120–160 million gallons. In the same way that the captain of a ULCC does not take one out for an impromptu Saturday pleasure cruise, pharmaceutical companies do not begin the grueling

and expensive process of seeking FDA approval for a new drug and manufacturing process on a whim.

While it may be easy to imagine that large corporations have unlimited funds with which to place big bets, in fact they are as challenged as any household in using their money wisely. In the case of all public corporations, pharmaceutical companies must generate meaningful returns on their capital. If not, shareholders and the board will forcefully express their disapproval to C-level executives. Careers are at stake.

What gave Merck's leadership the confidence to take the leap to make and market an unprecedented hepatitis B vaccine made from the waste products of genetically modified baker's yeast? What made them confident that the public and obstetric and pediatric physicians would accept such a radical new approach to promised immunity? Major corporations don't make blind bets.

First, Merck was already in the hepatitis B vaccine business inspired by an idea Saul Krugman of Willowbrook infamy first advanced. They originally entered the business of selling hepatitis B vaccines because the results of nearly ten years of the new test for hepatitis B antigens created a demand that hadn't existed before.

Most importantly, the statistical results pointed to well-defined and targetable audiences they could easily reach: health-care workers, hemophiliacs, dialysis patients, intravenous drug users, and men who have sex with men. It's noteworthy that the reason so many "cases" of hepatitis B (positive antigen tests) were found among these populations is that they were among the first groups to be given the new test. The test was not typically given to members of the general public.

Reaching these targetable groups was simply a matter of contacting relevant doctors and clinics and, in the case of men who have sex with men, building bridges to that community, which, as we saw in the last chapter, Wolf Szmunes took great pains to do. (This outreach program helped lay the foundation for AIDS advocacy, which was to become a huge movement in the 1980s and 90s.)

Unfortunately for Merck, along came concerns about the safety of the blood supply and the method they used of deliberately making vaccines from the blood plasma of infected individuals. If Merck was to preserve and grow its hepatitis B vaccine franchise, it needed a more palatable method.

Merck did not have to invent the wheel. South San Francisco-based Genentech had already demonstrated that genetically modified yeast could be used to produce special-purpose pharmaceutical proteins at scale. The first commercial application of this was Humulin, a bio-engineered form of insulin, engineered by Genentech and marketed by Eli Lilly and Company.

The new process and product was a huge commercial hit because it made it possible to make insulin in huge quantities, and at much lower production cost per dose than insulin extracted from the pancreases of slaughtered pigs and cattle, which required large numbers of animals, complex purification, and variable yields.

The entire pharmaceutical industry, including Merck, took notice of Eli Lilly's success and began the work of putting on their own genetically modified yeast processes and products into the FDA approval pipeline. This was the start of the biotechnology era.

When it started its long march towards FDA approval of its bioengineered hepatitis B vaccine, Merck had the wind at its back, but it faced two related challenges.

First, the new process was going to create an enormous amount of product and, lower production cost or not, the niche market it was currently catering to was nowhere near large enough to absorb it.

Second, conceiving of an exponentially larger market for its hepatitis B vaccine was one thing. Selling the idea to the FDA and the ACIP (Advisory Committee on Immunization Practice) was another, no matter how malleable they had had proven to be in the past.

There is some direct overt influence pharmaceutical companies like Merck can wield over the ACIP and CDC. Here are some of the methods they have at their disposal.

First, of course, they are the ones who gather and present data about the proposed vaccine to the ACIP. The ACIP simply evaluates the data as given to it by the vaccine maker. The committee does not run trials, and their research amounts to surveying the opinions of others who are theoretically impartial.

Second, pharmaceutical companies fund epidemiology and cost-effectiveness research, usually conducted by academics and the CDC, which make the case for the presumed need for their product. These have the function of framing the policy discussion.

Beyond these obvious activities, vaccine and drug makers also seek out and engage allies to help promote the vaccine well in advance of their appearance before the committee. These promotional allies include medical societies, opinion leaders, nominally independent clinicians and researchers who can shape the opinions of their colleagues, and what's called "early market conditioning", enrolling the news media to spread the word about the perceived problem the vaccine promises to solve.

This last piece is most important. The news media has the unique ability to reach and influence not only the public, but also physicians, local and national politicians, local public health officials, and the federal bureaucrats who determine policy.

As was demonstrated by the COVID Panic, many people in these roles got their information about the WHO-designated pandemic from the news media first. Sometimes it was their primary source of information and in some cases even their only source.

In addition to its power to influence large numbers of people at all levels of society, the news media also has the feature of being managed by people who, on the one hand, know little if anything about science and medicine and, on the other,

are incentivized not only to exaggerate but also to play fast and loose with the facts. On more than one occasion the news media has been known to cooperate in campaigns that have the function of alarming and panicking people.

Reaching the news media involves engaging advertising agencies and public relations firms. The CDC is also often energetic participant, leveraging its media contacts and producing supporting media that's distributed to state public health departments that in turn carry out their own media campaigns.

The volume and number of impressions made by state-sponsored and news media supportive medical storytelling can be enormous, and if it had to be paid for commercially, might tap the resources of even the largest pharmaceutical companies.

The two forces, the news media and the CDC, both echo and amplify each other's messages. Collaboration between medical research, public health agencies and the news media was not new in the 1980s when the hepatitis B story was being told with the most forcefulness, but there was something different about the 1980s.

CNN was launched January 1, 1980 beginning the era of the 24-hour news channel and the 24-hour news cycle.

Given that there are tens of millions of people who are completely unaware of what radical change this was, a short explanation is in order. Once, news meant the daily morning newspaper and a broadcast of the daily news on television that lasted one to two hours, live. If you wanted more news than that, you could listen to a radio station that ran through the headlines once an hour.

Running a 24-hour news channel meant several things. First, you had to fill a 24-hour, not a two-hour, news hole. It was no longer good enough just to deliver the news. You had to hook viewers and keep them hooked as you essentially repeated versions of the same headline stories over and over all day.

From a viewer's point of view, instead of the news occupying a fixed, defined, and relatively small part of your day, it had the potential to occupy you all day, replaying and amplifying the

impact of the same “hot” stories over and over again. During its pioneering years, CNN learned that the old news business dictum, “if it bleeds, it leads,” was still applicable.

CNN did not have meaningful competition until the financial news channel CNBC (1989), MSNBC (1996), and the Fox News Channel (1996). Thus, the influence it wielded was enormous, and not only among its viewers, but also among all news media outlets.

If a story was featured on CNN (i.e., played on an endless loop all day), other news outlets ignored it at their peril. Not only that, news outlets gradually began to vie with each other to out-CNN CNN.

CNN program directors loved war and the eyeballs it captured. They also loved medical scare stories. And being based in Atlanta, CNN’s reporters were just 6–8 miles from the CDC’s campus headquarters, a 15-minute car ride when the traffic was light.

The CDC has long appreciated the power of using the press to get out its various messages. In 2006, they opened a 200,000 square-foot building on their main campus, the Tom R. Harkin Global Communications Center, dedicated to public education and media relations. It contains TV studios, editing suites, press rooms, media production facilities, conference rooms, and meeting spaces for large groups.

When the CDC wants to get a message out, it is well-equipped. It was no less true in the 1980s and the message it wanted to get out about hepatitis B was as follows:

There’s a new virus, hepatitis B, and it’s spreading out of control

It is 15 times more common than AIDS

It is 200 times more infectious than AIDS

The virus is far more stable than AIDS in the environment

It is responsible for more deaths than AIDS

Unlike HIV, it is spread by casual contact

Hepatitis B was portrayed as a “silent epidemic” and a disease that one could have and spread without knowing it, even to one’s family and friends. Americans were said to be at risk from the nation’s 1-1.25 million chronic carriers. Anyone could be infected. People received public health messages recommending that they get tested and find out and get tested regularly.

As if that were not alarming enough, people were also told that a “chronic HBV (hepatitis B) infection can lead to chronic liver disease, cirrhosis, and hepatocellular carcinoma,” and that “HBV is a major cause of liver cancer.”

And then they dragged the infants in. “Infants infected perinatally have a very high likelihood of chronic infection.” “Chronic infection acquired early in life leads to a high risk of cirrhosis and liver cancer.” The truth is such “infections” (positive tests) in infants were very rare, and a positive hepatitis B test leading in a straight line to liver cancer or cirrhosis lacking other co-factors or contributing causes was simply not a real possibility.

Finally, the “goods news” about the availability of a hepatitis B vaccine was featured by magazines as diverse as *Mademoiselle* and *Gay Community News*, the gay community’s paper of record published out of Boston. Their message to their reader was: “There’s no cure for AIDS, but there is one for hepatitis B, which kills five times as many people each year.”

In the years leading up to the 1991 ACIP meeting on hepatitis B vaccines for newborns, between the news media and the CDC, the fear of hepatitis B well was aggressively and repeatedly pumped.

On the AIDS side, a disease story which was unfolding at the very same time, irresponsible fear-mongering reached such a fevered pitch that Oprah Winfrey, who at the time had a weekly audience of 15 to 20 millions, began one of her programs in early 1987 with the following statement: “Hello everybody.

AIDS has both sexes running scared. Research studies now project that one in five – listen to me, hard to believe – one in five heterosexuals could be dead from AIDS at the end of the next three years. That's by 1990. One in five."

Ironically, even with greatly increased testing, the number of hepatitis B "cases" (remember that all that means is a positive antigen result only) declined 59% from 1985 to 1993 by the CDC's own statistics. It's possible this decline in positive test results came as the result of AIDS education which encouraged intravenous drug users to not share needles and some gay men to change some of their sexual practices.

In addition to the abundant promotional help Merck received from the news media and the CDC, Merck had an additional ace up its sleeve. The NIH, which controlled key blood plasma vaccine, granted Merck the exclusive license to market their blood plasma vaccine internationally. Merck wanted the exclusive U.S. market license too. This request was turned down.

In the next chapter we'll show how, with extraordinary levels of support from the then-recently formed International Task Force of Hepatitis B Immunization, Merck leveraged that edge to not only build a massive volume of hepatitis B vaccine business overseas, but also use the federal government to force its product into every maternity ward in America.

## The Penetrating Wind



Sun - Hexagram 57 - Nine in the second place

“At times, one has to deal with hidden enemies, intangible influences that slink into dark corners and from this hiding affect people by suggestion.

In instances like this, it is necessary to trace things back to the most secret recesses, in order to determine the nature of the influence to be dealt with. This is the task of the priests; removing the influences is the task of the magicians.

The very anonymity of such plotting requires an especially vigorous and indefatigable effort, but this is well worthwhile. For when such elusive influences are brought into the light and branded, they lose their power over the people.”

*The I Ching (Bollinger Edition)*. Translator: Cary F. Baynes.

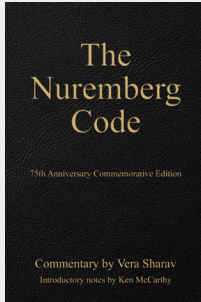
# About the Author

Ken McCarthy is the author of several books on medical history: *Fauci's First Fraud*, *What the Nurses Saw*, and *Unraveling the COVID Con Volumes I and II*. He's also the co-author of the *Nuremberg Code: 75th Anniversary Commemorative Edition*, with medical historian and Holocaust survivor Vera Sharav.

He is currently working on a new book, *The Reality of Vaccine Injuries and Extreme Autism: How Understanding the Mechanism of Harm is Essential to Developing Effective Therapies*.

In a previous career, Ken was an Internet commercialization pioneer. He was one of the co-inventors of the banner ad, and *TIME Magazine* credits him with being the first person to appreciate the value of the click-through rate in digital advertising.

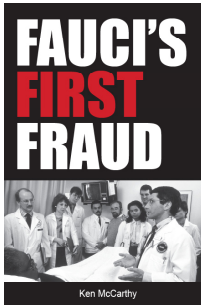
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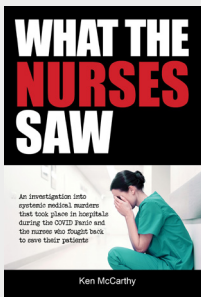
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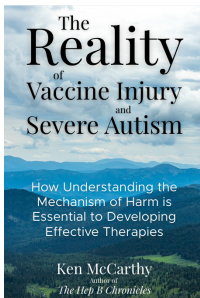


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