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5 HORRIFYING FACTS ABOUT THE FDA VACCINE APPROVAL PROCESS

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Most people think that the government is watching out for them, and when they are told that vaccines are safe and effective, they believe it in part because they know that these products have been approved by the US Food and Drug Administration (FDA). However, most people also know little to nothing about vaccines or how they go through the FDA vaccine approval process and on to the market. Here are five horrifying facts about this process that neither public health officials nor the mainstream media are disclosing to you:

1. The Government *Is* the Vaccine Industry

There's a perception that agencies like the FDA, the Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH) exist to serve the public and act as oversight agencies to keep the public safe. This perception, however, is incorrect. It isn't so much that the government oversees the vaccine industry as that the government is the vaccine industry.

There is no clear line where the pharmaceutical industry ends and the government begins. Government agencies serve effectively as an extension of pharmaceutical companies. The NIH acts as one of their research and development departments. The FDA is involved in marketing. And the CDC does distribution while pushing sales of vaccine products.

Unable to persuade the public of the value of their vaccine products in a free market, Big Pharma also resorts to government coercion to reap profits, such as laws mandating vaccination for children to be able to attend public school.

Most people are probably aware that the pharmaceutical industry has one of the most powerful lobbies in Washington. The industry has a direct influence on policy, both in Congress and in Executive agencies like the CDC and FDA.

The pharmaceutical giant Merck is quite transparent about its own lobbying efforts and campaign contributions. The corporation has a website explaining its "responsibility" to participate "in the political process", such as to "advocate for public policies that foster research into innovative medicines and that improve access to medicines, vaccines and healthcare." Another focus of its lobbying efforts is to "Encourage innovation by protecting intellectual property rights, advocating for government support of basic research, and supporting efficient and effective regulatory systems, among other issues".[1]

Translated, Merck is talking about patent licensing, government grants, and an expedited FDA approval process (which we'll come to).

As Hunter Lewis writes in his book *Crony Capitalism in America: 2008 – 2012*, "The drug industry at one time was called the patent medicine industry. This is still the more revealing name."[2]

The pharmaceutical companies, for understandable reasons, aren't too fond of natural remedies for ailments for the simple reason that they can't be patented. So they dedicate themselves to inventing products for which they can obtain a virtual monopoly, thanks to government intervention in the market.

But did you know that the government itself also patents technology and then reaps financial rewards by licensing it to private corporations?

The website of the National Institutes of Health has a page listing tens of thousands of "Licensing Opportunities". Corporations seeking to license any of the government's patents submit an application explaining the intended use and specifying whether they are seeking exclusive or non-exclusive use. If accepted, the government enters negotiations with the company over terms.[3] (For licensing to non-profit organizations, the government accepts a "$2,000 up front fee and modest royalties on sales of 1.5% for exclusive and 0.75% for non-exclusive licenses".[4])

In February 2005, for example, the NIH sold vaccine technology to Merck and GlaxoSmithKline (GSK) under a co-exclusive license.[5] Essentially, what this means is that Merck and GSK were granted a guarantee that the government would use force to protect their duopoly over the use of this technology for the purpose of profiting from sales of vaccines—with the government no doubt collecting royalties (after all, if it doesn't drop this term for non-profits, why would it do so for Merck and GSK?).

Merck then used that licensed technology in its Gardasil vaccine, for which the FDA gave its stamp of approval in 2006. (More on *that* process shortly.) By doing so, the FDA backs the claims of the pharmaceutical industry about its products while companies selling, say, essential vitamins and minerals with known vital functions for human health must by law include on their product

labels the meaningless disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease".[6]

In effect, only *patented* drugs can legally make such claims. (In addition to applying different labeling standards to patented drugs, it also doesn't hurt the pharmaceutical industry to have government policies in place like the criminalization of the use or possession of the safe and effective medicinal plant *cannabis*, or marijuana, which can be grown and harvested at home.)[7]

By getting the FDA's approval, Merck can avoid having to include that pesky warning discouraging consumers from purchasing its products when making such Gardasil advertising claims as: "your daughter could become one less life affected by cervical cancer".

An article in the *Journal of Law, Medicine & Ethics* noted that Merck's Gardasil advertising "seemed more designed to promote fear rather than evidence-based decision making".

The journal also noted that vaccine manufacturers are intimately involved in helping to shape public health policies and questioned whether this was appropriate given such obvious conflicts of interest.

Moreover, public health officials were strongly recommending Gardasil vaccination despite increasing concerns about its safety and efficacy.[8] As *Slate* has observed, "the trials weren't designed to properly assess safety."[9]

Furthermore, no clinical trials actually determined that the vaccine can reduce the risk of cervical cancer. In fact, no studies to date have shown this to be true. As a systematic review of the medical literature published in May 2018 observed, studies to date "were not large enough or of sufficient duration to evaluate cervical cancer outcomes."[10] The FDA lets Merck market it as a

cancer-prevention vaccine anyway (again, *without* Merck having to warn on the product label that its marketing claim has not been evaluated by the FDA).

Gardasil was approved by the FDA in 2006. The director of the NIH at the time was Elias Zerhouni, who "faced several big controversies over conflict-of-interest policies for researchers there" under his tenure, as *Forbes* has noted.[11] Zerhouni headed the NIH from 2002 until 2008 and left his government job to become president of Global R&D for vaccine manufacturer Sanofi Pasteur.[12]

Similarly, the CDC director from 2002 to 2009 was Dr. Julie Gerberding, who left her government job to become president of Merck's vaccine division, a $5 billion global business. The company's Chief CEO, Richard Clark, quite understandably described her as "the ideal choice to lead Merck's engagement with organizations around the world that share our commitment to the use of vaccines to prevent disease and save lives".

Gerberding said she was "very excited to be joining Merck" so she could "help expand access to vaccines around the world"—that is, essentially, so she could continue the job she was doing at the CDC, but even more lucratively.[13]

2. The FDA Relies on the Vaccine Manufacturer's Own Studies

The FDA describes itself as a "consumer watchdog" whose role is in part "to evaluate new drugs before they can be sold", which "not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely."[14]

Surely, then, the FDA relies on independent studies during the vaccine approval process to ensure the safety and effectiveness of the products to be licensed for sale on the market?

Well . . . , no.

Actually, instead, the drug companies conduct *their own* studies.

The first step is the submission of the study design to the FDA for review. Then there are three stages of clinical trials. After that, the product is submitted for final approval. The FDA reviews the drug company's studies, and then the product moves on to phase four: post-marketing risk assessment—which is to say, the drug goes to market and the role of guinea pig passes along to the consumer.[15]

There is actually a long history of unwitting members of the public effectively being used as test subjects for vaccines—going back at least to 1930, when an incident known as the "Lübeck vaccine disaster" occurred.[16]

(As a bit of additional trivia: Did you know that scientists have studied parents who choose not to vaccinate their children strictly according to the CDC's recommended schedule to learn what "motivating forces" led them to make that decision? The purpose of these studies is for vaccine manufacturers to learn how to "design and execute pediatric vaccine trials.")[17]

3. Vaccine Manufacturers Don't Do Safety Studies The Way You Think They Do…

When you think of a clinical study, what probably comes to your mind is when they take one group of people and give them the vaccine, and they take another group of people and give them a placebo of sterile saline.

Vaccine manufacturers, with the government's kind permission, however, do things quite a bit differently.[18]

Oftentimes, drug companies just give both groups *two different experimental injections*. (One of them isn't *considered* experimental, of course, but that's just a semantic technicality.) A 2010 review of published trials showed that in at some instances, instead of a placebo, *another vaccine* is used. Other times, the supposed "placebo" contains ingredients like aluminum hydroxide or thimerosal (mercury)—with both aluminum and mercury being known neurotoxins.[19]

Among the concerns about Gardasil's HPV vaccine is the lack of placebo control groups in the clinical trials the FDA relied upon for licensing. Instead, subjects in "control" groups received an injection *containing aluminum*.[20]

As *ScienceDaily* has explained, "Much of medicine is based on what is considered the strongest possible evidence: The placebo-controlled trial. A paper published in the October 19 issue of *Annals of Internal Medicine*—entitled 'What's in Placebos: Who Knows?' calls into question this foundation upon which much of medicine rests, by showing that there is no standard behind the standard—no standard for the placebo."

The author of the journal paper further observed that "concerns" about this practice of vaccine manufacturers "aren't just theoretical." (Instructively, she then immediately defended the practice by assuring that it wasn't willful manipulation on the part of vaccine manufacturers; rather, there is really a perfectly rational explanation for this practice, which is that "it can in fact be difficult to come up with a placebo that does not have some kind of problem." You can use your imagination to figure out what "problem" using a placebo might pose for vaccine manufacturers seeking for their clinical trials to show that their product's use

didn't increase the risk for "adverse events", i.e., negative health consequences caused by the vaccine.)[21]

So the industry's safety studies that the FDA relies on to approve vaccines typically do not compare the rate of adverse reactions from the vaccine being tested to those from a placebo; rather, in effect, vaccine manufacturers compare the rate of adverse reactions from one experimental drug with another experimental injection. If the rate is not significantly greater for the study group than the "control" group, then the vaccine they received is said to be "safe". This, of course, has the effect of inflating the "background" rate of adverse events, or the rate at which such events would occur normally within the general population, which is what the use of the placebo is *supposed* to help determine. In essence, clinical trials for vaccines are *designed to obscure the true rate of adverse events*. (Vaccine manufacturers also typically look only at short-term adverse events, not long-term negative health consequences, but that's a whole other story.)

And, yes, this practice by vaccine manufacturers of doing "placebo"-controlled studies *without a placebo* is all perfectly legal. The government *doesn't regulate* what goes into whatever it is the drug companies decide to call a "placebo".[22] An article in the journal *Vaccine* forgoes any euphemisms and appropriately describes it as "alternatives to placebos".[23] Euphemisms are for the general public; no need for them in the medical literature (after all, it's not as though there are too many parents out there doing their own research into vaccines by digging into the literature . . .).

Moreover, during the three clinical trial phases, the pharmaceutical companies are allowed to pick and choose which studies to submit to the FDA to gain approval—hence studies that don't produce the desired outcome are buried. (And then there is the practice of getting studies published in journals that were

written by ghostwriters hired by drug companies, but again we digress . . . .)[24]

4. Pharmaceutical Companies Can Pay the FDA to "Fast Track" Their Products

In addition to the above concerns, if the drug companies want to expedite the approval process, as of the 1992 Prescription Drug User Fee Act, they can *pay* the FDA to put their product on the fast track. More than 60 percent of the drug review expenditure of the FDA's Center for Drug Evaluation and Research is *drug industry money*—over $760 million.

According to an article in the *BMJ* (formerly British Medical Journal), one study found that drugs approved through this expedited process "were associated with a higher rate of subsequent safety withdrawals". A survey of FDA medical officers found that many respondents "expressed concern that drugs they thought should not have been approved had been, despite negative safety conclusions. Respondents thought that standards of safety and efficacy had been weakened since the passage of the law."

Consumers are advised to follow the "seven year rule"—that is, to wait at least seven years after a drug is approved before using it.[25]

Of course, the average consumer doesn't pore through medical journals, and such warnings are not communicated to the general public. The industry and public health officials certainly aren't passing along such helpful little consumer spending tips (although members of Congress and other government officials are presumably well enough informed).

Merck's painkiller Vioxx offers a useful example. It went to market in 1999. Merck withdrew it in 2004 due to widespread

criticism about its safety—and after a clinical trial found that it increased the risk of heart attacks and strokes in long-term users. Faced with around 10,000 personal injury lawsuits, Merck reached a $4.85 billion settlement in 2007. Merck nevertheless maintained that Vioxx did not cause heart attacks, strokes, or death.[26]

In 2008, the *Journal of the American Medical Association* (JAMA) published two studies disclosing the findings of researchers who had gained access to thousands of documents through lawsuits over Vioxx.

One JAMA study examined data from two arms of a clinical trial in patients with dementia, a number of whom dropped out of the trial because they experienced side-effects, changed their minds, or moved. In 2001, Merck filed a report with the FDA showing that, in a trial of about 1,000 people, twenty-nine people taking Vioxx had died compared with seventeen who were on a placebo.

But that data only included deaths of test subjects who had either remained on the treatment or who had died within two weeks of dropping out. An internal analysis from the other arm of the clinical trial included outcomes for up to three months after cessation of treatment. It showed that there were *thirty-four* deaths in the Vioxx group compared to *twelve* in the placebo. *This* data was withheld from the FDA for another two years.

The other JAMA study showed how the drug giant hired ghostwriters to produce research that was then published in medical journals under the names of high-profile academic physicians paid to review and pass off the papers as their own.

Merck dismissed these findings with the charge that the JAMA authors were "people in the pay of trial lawyers".[27]

Incidentally, that was also one of the charges levied against Andrew Wakefield, the lead author of the infamous retracted 1998 *Lancet* paper acknowledging the theoretical possibility of a link between vaccination and autism. So, on one hand, even just the appearance of a conflict of interest is completely unacceptable if a study has implications contrary to the interests of the pharmaceutical industry and government policy; whereas, on the other, clinical trials conducted by people in the pay of vaccine makers to obtain approval for their own product is a perfectly acceptable practice—good enough for the FDA, at least.

In 2009, a paper was published in the journal *Archives of Internal Medicine* showing that Merck's own post-marketing studies had already indicated by 2001 that Vioxx increased the risk of heart-related problems by 35 percent. Merck wasn't required to disclose the data used in the review study. The only way the paper's authors were able to obtain the patient information was through a lawsuit.[28]

After it was published, Merck dismissed the *Archives* review of its clinical trials by saying that the authors "used unreliable methods and reached incorrect conclusions."[29] Merck spokesman Ron Rogers said, "There is nothing new here. We studied Vioxx before and after it was on the market. We studied it extensively using more rigorous methods than these authors used and we didn't see any cardiovascular risk."[30]

They were making lots of money, of course, by not seeing it.

5. Vaccine Manufacturers Have Legal Immunity from Damages

Drugs like painkillers are one thing. Vaccines are an entirely different matter. Merck withdrew Vioxx because it was facing injury

lawsuits. When it comes to vaccines, however, the pharmaceutical companies cannot be sued for damages caused by their products. *The government has granted broad legal immunity to vaccine manufacturers* to protect them from being held liable for injuries or deaths caused by vaccines.

This is, as the *Wall Street Journal* has noted, "an important reason why the vaccine business has been transformed from a risky, low-profit venture in the 1970s to one of the pharmaceutical industry's most attractive product lines today."[31]

See, throughout the 1970s and 1980s, the government was growing increasingly concerned because its public vaccination policy was being threatened by injury lawsuits against vaccine manufacturers. There were so many injury claims that it was putting them out of business.[32] As Barbara Loe Fisher of the non-profit National Vaccine Information Center (NVIC) explains, "The pharmaceutical industry knew they were in big trouble because the old, crude whooping cough vaccine in the DPT shot was causing brain inflammation and death in many children; the live oral polio vaccine was crippling children and adults with vaccine strain polio; and Americans were filing lawsuits to hold drug companies responsible for the safety of their products."[33] So in stepped the government with the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660). Under the Act, on October 1, 1988, the National Vaccine Injury Compensation Program (VICP) was established under the Department of Health and Human Services (HHS), which has explained its purpose thus (emphasis added):

"The VICP was established to *ensure an adequate supply of vaccines*, *stabilize vaccine costs*, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. The VICP is a *no-fault alternative* to the traditional tort

system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines."[34]

Note the euphemistic language: "ensure an adequate supply of vaccines" and "stabilize vaccine costs", meaning to maintain public policy by keeping the vaccine manufacturers in business; and "a no-fault alternative", meaning that filing a lawsuit against a vaccine maker for causing injury was no longer an option available to consumers.

The VICP is funded by an excise tax on each vaccine on the schedule recommended by the CDC for routine use in children. A $0.75 excise tax is levied on every dose, so for a combination vaccine like MMR, the amount taxed for every shot is $2.25.

In other words, rather than manufacturers being held liable to pay compensation for vaccine injuries, that financial burden has been shifted by the government onto the consumers—including those whose families suffer from vaccine injury.[35]

The Supreme Court has upheld this legal immunity for vaccine manufacturers on the grounds that certain adverse reactions are "unavoidable" and "design defects" are "not a basis for liability."

Justice Antonin Scalia described this special accommodation for Big Pharma as a "societal bargain".[36]

For the purposes of implementing the VICP, the National Childhood Vaccine Injury Act established a special government tribunal, the Office of Special Masters at the US Court of Federal Claims—more commonly known as the "Vaccine Court". Certain known adverse reactions to vaccines are listed under a vaccine injury table kept by the Court. Injured parties filing for compensation must show that: (a) they suffered one of the injuries listed on the table and (b) the injury occurred immediately after vaccination. For adverse reactions not listed on the table, claimants must prove that the injury was caused by the vaccine.

But there's a catch: the government can also settle claims, in which case the awarding of compensation is not considered to be an acknowledgment by the government that the vaccine caused the injury. Favoring settlements better enables public health officials to maintain that mandated vaccines are "safe and effective" even while shielding the vaccine industry from liability for known serious harms caused by their products.

This is all done, of course, in the name of preventing "a public health emergency"—namely, the collapse of the vaccine industry due to the lack of consumer demand for their products that would otherwise exist absent government intervention into the market.[37]

The US Government Accountability Office (GAO) acknowledges that vaccines "can have severe side effects, including death or an injury requiring lifetime medical care." It explains that, under the law, if an injured party has suffered an adverse reaction not listed under the vaccine injury table, they must demonstrate that the vaccine caused the injury. The GAO noted in November 2014 that, since 1999, the Department of Health and Human Services "has added six vaccines to the vaccine injury table, but it has not added covered injuries associated with these vaccines to the table."[38]

From 1999 through November 2014, more than 9,800 claims were filed with the VICP. "Since 2006, about 80 percent of compensated claims have been resolved through a negotiated settlement." Over half took more than five years to adjudicate.[39]

It takes on average two to three years to adjudicate a claim. From 1988 to February 2015, more than 15,000 petitions were filed under the VICP, including 1,156 (7 percent) for deaths. Of those, more than 62 percent were dismissed and 25 percent resulted in compensations totaling over $3 billion. As of October

2019, total compensation amounted to approximately $4.2 billion.

Most claims used to be filed for children, but since the influenza vaccine was added to the VICP in 2005, claims for adults have increased. The flu shot has been a national bestseller. From 2006 through 2017, over 1.5 *billion* doses were distributed in the US. A majority of claims are now filed for flu shot injuries.[40]

The vaccine industry, of course, rightly considers the National Childhood Vaccine Injury Act as absolutely essential to its business model.

Merck lawyer Daniel Thomasch told the *Wall Street Journal* in 2009, "The Act remains an important and relevant protection against baseless litigation that may dissuade parents from having their kids receive important vaccines."

The *Journal* also quoted Mark Feinberg, vice president for medical affairs and policy at Merck's vaccine division, expressing his main concern: "Today, there are a number of important infectious diseases that don't have vaccines."

So there you have it, the goal of the industry: to make profits through the manufacture and sale of liability-free vaccines for every infectious disease considered to be of any importance.

Feinberg added that the system created by the law provides "clarity" for vaccine manufacturers "as they go forward with new development."[41]

Indeed.

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About the Author

Hey there! I hope you found this booklet valuable. To give you a little bit of my background, I'm an independent journalist,

publisher and editor of *Foreign Policy Journal*, author, and writing coach. While much of my work focuses on US foreign policy (with a special focus on the Israel-Palestine conflict), as both a journalist and as a father, I've also put my research and analytic skills to use helping to better inform the public about vaccines.

My work has been praised by Dr. Joseph Mercola of the leading health website Mercola.com, and I've been described by Dr. Kelly Brogan, author of the *New York Times* bestselling book *A Mind of Your Own*, as a "rare journalist" who "actually digs deep for the truth on a matter."

If you found this booklet informative, please take a moment to share the link with your friends, family, and social media followers, so they can sign up for my free newsletter to stay informed about this topic and download this free report, too! Here's the link to share:

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- Connect with me on LinkedIn

I look forward to continuing to empower you with invaluable knowledge about the critically important issue of vaccines.

— Jeremy R. Hammond

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