CHAPTER 1

Merck, Where the Patients Die First: The Vioxx Scandal

Merck is a US drug company located in Rahway, New Jersey. It is the fourth-biggest drug company in the world.[1] Outside the United States and Canada, it is known as Merck Sharp & Dohme or MSD.

The fifty biggest drug companies make up a combined $4.7 trillion in market capitalization, and American drugmakers have the greatest worldwide market share by far, supported by high prices in a poorly regulated market. With a market cap of over $578 billion, American drug company Eli Lilly is the world's most valuable, known for diabetes medications and its newly launched weight-loss drug. The average price of insulin in the United States is more than five times higher than in other countries.

Much of this colossal wealth stems from organized crime, and Merck is no exception. According to US law, organized crime is the act of engaging in a certain type of offense more than once. The offenses include extortion, fraud, federal drug offenses, bribery, embezzlement, obstruction of justice, obstruction of law enforcement, tampering with witnesses, and political corruption.

Big Pharma does so much of this all the time that there can be no doubt that its business model meets the criteria for organized crime. Fraud, bribery, and political corruption are particularly prevalent offenses.

Bribery is routine and involves large amounts of money. Almost every type of person who can affect the interests of the industry has been bribed: doctors, hospital administrators, cabinet ministers, health inspectors,

customs officers, tax assessors, drug registration officials, factory inspectors, pricing officials, and political parties.

The organized crime and the pervasive fraud in drug research and marketing are highly lethal. Most of the many millions of patients that have been killed by drugs didn't even need the drugs that killed them. This makes the drug industry far worse than the mob, and my book about organized crime in the drug industry, *Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare*,[2] which documents this and describes Merck's misdeeds, therefore ends with a cartoon I asked Franz Füchsel, one of the cartoonists from the *Jyllands-Posten* newspaper Muhammad incident, to draw for me:

Merck has a lot to be accountable for. When I was in the United States in 2006, I saw a TV commercial on CNN that ended with a very deep voice of the type that sells shaving tools to men: "Merck, where the patients come first." I couldn't help thinking, "Merck, where the patients die first," because of the many patients Merck killed by committing fraud

in research and marketing related to their arthritis drug Vioxx (rofecoxib). I have estimated that Vioxx killed 120,000 people due to thrombosis. None of the patients needed the drug that killed them, as other drugs were available with similar effects on pain conditions.

Two years earlier, I was in Canada and couldn't sleep because of jet lag. I browsed the TV stations expecting to become tired, but then Fox News suddenly announced that Merck had pulled its blockbuster Vioxx from the market the same day. This was September 30, 2004.

I was not surprised, as I knew the drug caused heart attacks. But I was surprised that Fox News allowed the president of the US Arthritis Foundation to lament for about ten minutes about what a great loss it was for the patients that Vioxx was no longer available. If I hadn't known who was talking, I would have guessed it was the CEO of Merck. It was company propaganda all over.

This speaks volumes about the extent to which patient organizations collude with Big Pharma. I checked the website for the Arthritis Foundation, and it had Pfizer's logo on its opening page. Highly embarrassing for a patient organization, indeed.

The truth was that there were no losses for the patients, only for the relatives who lost a loved one. Vioxx wasn't any better than its competitors but was more deadly, which Merck had concealed for many years by its fraudulent actions.

Vioxx is a Cox-2 inhibitor, and it was known right from the start that its mechanism of action predicted that it would cause thrombosis. In 1996, Merck scientists discussed the heart attack risk,[3] and investigators sponsored by Merck found that Vioxx reduced urinary metabolites of prostacyclin in healthy volunteers by about half,[4] which also indicated that Vioxx causes thrombosis. However, Merck concealed this by convincing the authors to change what they had written into a meaningless sentence: "Cox-2 may play a role in the systemic biosynthesis of prostacyclin." Very few readers would have any idea about what this means for the patients' survival.

In 1997, a Merck scientist said that if they didn't allow patients to use aspirin (which decreases the risk of heart attacks) in their trials, patients on Vioxx might have more heart attacks and that would "kill the drug."[5]

The US Food and Drug Administration (FDA) did not protect public health even though this is the agency's primary responsibility. The FDA had serious concerns about Vioxx but approved it for marketing in May 1999, despite disconcerting evidence in the application. The FDA stated that they lacked "complete certainty" that the drug increases cardiovascular risk.[6]

Imagine if a doctor says to a patient: "I'm not completely certain that this drug might kill you, so please take it." I have a cartoon where a doctor says to a patient: "Take one of these tablets tonight, Mr. Tate, and one more if you wake up tomorrow morning."

When a drug can cause thrombosis, the risk starts with the intake of the first tablet. But Merck cheated also with this truism from clinical pharmacology: they claimed that the increase in cardiovascular risk begins after eighteen months of therapy, which was widely believed, even by clinical pharmacologists who should have known better.

Merck's misleading claim[7] came from a trial in colorectal adenomas where they found that Vioxx doubled thrombotic events, compared to placebo (P = 0.008). The trial was published in the *New England Journal of Medicine*, and the authors—who included Merck employees—noted in the abstract that "The increased relative risk became apparent after 18 months of treatment."[8] Merck had not used a correct statistical test, and they had excluded all events that occurred more than two weeks after stopping treatment, although some of these patients would be expected to have, and actually had,[9] thrombotic events. It took fifteen months before Merck was forced to retract its erroneous claim from the journal,[10] which a witty person renamed because it is so beholden to the drug industry:

The **NEW ENGLAND**
JOURNAL *of* **MEDICALIZATION**

None of the trials in Merck's submission to the FDA were designed to evaluate the cardiovascular risk.[11] People with arthritis tend to be old, and they also have a much greater risk of heart attack than young people, but Merck had generally avoided recruiting such people for their trials. Medicare patients in Tennessee treated with Vioxx in clinical practice had

a risk of heart attack that was eight times higher than that for the patients in the trials.[12]

As it was clear that the drug must cause thrombosis, the FDA should have rejected Merck's application and demanded of the company that it test its drug in a relevant patient population.

When Merck planned their big VIGOR study, which included 8,076 patients, one of their senior scientists proposed to leave out people with a high risk of cardiovascular problems so that the difference in heart complications between Vioxx and naproxen, another arthritis drug, "would not be evident."[13] This trial, which was published in the *New England Journal of Medicine* in 2000,[14] was fraudulent. Forensic IT work on the submitted disc revealed that three cases of myocardial infarction on Vioxx had been omitted from the manuscript two days before it was submitted to the journal.[15] Merck had also selected an earlier cutoff date shortly before the trial ended for thrombotic events than the cutoff date for the other important harm, gastrointestinal events,[16] which they did not tell the editors about. This was, of course, also scientific misconduct.

There were two full tables of gastrointestinal adverse effects in the article, but no table of thromboses; they were only mentioned in a few lines in the text, and only as percentages, which made it impossible to calculate the true number of events, as not all of them were included. Based on the percentages, I calculated 32 versus 17 thrombotic events on Vioxx and naproxen, respectively, but there were actually another 15 versus 3 events.[17] An FDA reviewer found a death from a heart attack on Vioxx that was coded as something else and, conversely, two deaths too many on naproxen.[18] Two deaths, four heart attacks, and three strokes with Vioxx were missing in the VIGOR publication compared with the data FDA had access to.[19] Many more additional events disappeared on Vioxx than on naproxen in the published report. In 2001, independent researchers using FDA data documented that Vioxx doubled the risk of serious cardiovascular events significantly in the VIGOR trial.[20]

In 2003, Merck published another trial that compared Vioxx with naproxen, in *Annals of Internal Medicine*. This trial was also fraudulent.[21] Eight patients suffered heart attacks or sudden cardiac death on Vioxx compared with only one on naproxen, but in the publication, three of

the Vioxx cases had disappeared, so that the difference was no longer statistically significant. One of Merck's scientists who had judged that a woman died from a heart attack was overruled by his boss, "so that we don't raise concerns." The cause of death was now called unknown, also in Merck's report to the FDA. Merck's top scientist, Edward Scolnick, noted in emails that he would personally pressure senior officials at the FDA if it took action against Vioxx.

A meta-analysis performed by independent researchers showed that a clear relationship between Vioxx and an increased risk of myocardial infarction existed already by the end of 2000.[22] These researchers also found that those studies that had an external endpoint committee reported four times more heart attacks with Vioxx than with the comparator, whereas trials without an external endpoint committee reported fewer heart attacks with Vioxx.

In February 2001, the FDA discussed the VIGOR study with Merck because of a fivefold increase in myocardial infarction with rofecoxib in comparison with naproxen, and the FDA asked Merck to make the doctors aware of these results.[23] However, the next day, Merck instructed its sales force of more than three thousand people, in capital letters: "DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE . . . OR THE RESULTS OF THE . . . VIGOR STUDY."

If a physician inquired about VIGOR, the salesperson should indicate that the study showed a gastrointestinal benefit and then say, "I cannot discuss the study with you."

Merck also produced a pamphlet to its sales force indicating that Vioxx was associated with one-eighth the mortality from cardiovascular causes of that found with other NSAIDs.[24] The pamphlet presented a misleading analysis of short-term studies and didn't include any data from the large VIGOR study. Its two references were "data on file" at Merck and a brief research abstract.

Trials in Alzheimer's disease were also fraudulent.[25] Merck showed in April 2001 that Vioxx increased total mortality significantly by a factor of three, but these analyses were not submitted to the FDA until two years later and were not made public. Merck continued to recruit patients in one of the trials for an additional two years after they knew that Vioxx was

deadly. Despite the deaths, the two published papers stated that Vioxx was "well tolerated." Merck discarded all deaths that occurred more than two weeks after the patients got off the drug, e.g. because of adverse effects, in violation of Merck's own protocol that stated that such deaths should be included in the results.[26] The fact is that the risk of thrombosis may be increased a whole year after patients come off the drug. Finally, Merck spokespeople lied to the FDA and Congress about when the company knew that Vioxx was deadly.

Seven weeks after Merck pulled Vioxx, there were hearings in the US Senate where David J. Graham, Associate Director for Science, Office of Drug Safety at the FDA, testified about events at the FDA.[27] Graham's superiors had tried to prevent his testimony by telling Senator Charles Grassley that Graham was a liar, a cheat, and a bully not worth listening to.[28]

Prior to approval of Vioxx, a study was performed by Merck named 090, which found nearly a sevenfold increase in heart attack risk with low-dose Vioxx, but the labeling at approval said nothing about the heart attack risk.

About eighteen months after the VIGOR results were published, FDA made a labeling change about heart attack risk with high-dose Vioxx, but did not place this in the "Warnings" section and did not ban the high-dose formulation and its use.

Graham had planned to present the data from an observational study at a conference in Bordeaux, but he was pressured to change his conclusions and recommendations and was threatened that if he did not change them, he would not be permitted to present the paper at the meeting. An email from the Director for the Office of New Drugs said that since the FDA was not contemplating a warning against the use of high-dose Vioxx, Graham's conclusions should be changed. The Center for Drug Evaluation and Research and the Office of New Drugs had repeatedly expressed the view that the Office of Drug Safety should not reach any conclusions or make any recommendations that would contradict what the Office of New Drugs wanted to do or was doing. Even more revealing, a mere six weeks before Merck pulled Vioxx from the market, the management of all three offices did not believe there was an outstanding safety concern with Vioxx.

Graham had shown that Vioxx increases serious coronary heart disease, but his case-control study was pulled at the last minute from *The Lancet* after Steven Galson, director of the FDA's Center for Drug Evaluation and Research, had raised allegations of scientific misconduct with the editor, which Graham's supervisors knew were untrue when they raised them.[29] The study was later published,[30] but just a week before Merck withdrew Vioxx from the market, senior people at the FDA questioned why Graham studied the harms of Vioxx, as FDA had no regulatory problems with it, and they also wanted him to stop, saying he had done "junk science."

Graham needed congressional protection to keep his job after threats, abuse, intimidation and lies that culminated in his sacking from the agency.[31] Fearing for his job, he had contacted a public interest group, the Government Accountability Project, which uncovered what had happened.[32] People who had claimed to be anonymous whistleblowers and had accused Graham of bullying them turned out be higher-ups at the FDA management. The FDA flunked every test of credibility while Graham passed all of them.

An email showed that an FDA director promised to notify Merck before Graham's findings became public so that Merck could prepare for the media attention.[33] That left no doubt about whose side the FDA was on.

Hearings were also held at the FDA, but the agency barred the participation of one of its own experts, Curt Furberg, after he had criticized Pfizer for having withheld data showing that valdecoxib, which was later taken off the market, increased cardiovascular events, which Pfizer had denied.[34]

Unsurprisingly, *The Lancet* concluded: "With Vioxx, Merck and the FDA acted out of ruthless, short-sighted, and irresponsible self-interest."[35] The Cox-2 inhibitors have taught us a lesson, not only about fraud but also about threats. When *The Lancet* raised questions with the authors over a paper on Cox-2 inhibitors, the drug company (not named) sponsoring the research rang *Lancet*'s editor, asking him to "stop being so critical," adding, "If you carry on like this we are going to pull the paper, and that means no income for the journal."[36]

In his Senate testimony, Graham gave examples of other drugs where FDA's management had been extremely resistant to full and open disclosure

of safety information, especially when it called into question an existing regulatory position. When a serious safety issue arises post-marketing, the FDA's immediate reaction is almost always one of denial, rejection, and heat. They approved the drug so there can't possibly be anything wrong with it. And the same group that approved the drug is also responsible for taking regulatory action against it, post-marketing. Graham concluded that the FDA is incapable of protecting America against another Vioxx: "We are virtually defenseless."

In 2007, the jury in a court case stated that Merck showed "malicious, oppressive, and outrageous" conduct and found it guilty of four counts of fraud in marketing Vioxx.[37] Merck announced a settlement worth $4.85 billion.[38] The crimes involved off-label marketing of Vioxx and false statements about the drug's cardiovascular safety.

In 2012, Merck pleaded guilty to a criminal violation of federal law related to its promotion and marketing of Vioxx and was to pay nearly a billion dollars in a criminal fine and civil damages.[39]

The Vioxx scandal confirms what has been shown in abundance: we cannot trust drug companies. They routinely cheat with their trial results, particularly when they publish them in medical journals, and they can threaten doctors, researchers, editors of medical journals, and officials in drug agencies. In published psychiatric drug trials, about half of all deaths and half of all suicides are missing.[40] The selective reporting of outcomes is the rule, not the exception,[41] and it means that we have no idea about how dangerous the individual drugs are. But what we do know is that our drugs, collectively, are the leading cause of death, killing even more people than heart disease or cancer.[42]

Merck selectively targeted doctors who raised questions about Vioxx and pressured some of them through deans and department chairs, often with the hint of loss of funding.[43] This bullying could be highly effective. A few days after Eric Topol had testified for a federal jury that Merck's former chair, Raymond Gilmartin, had called the chair of the clinic's board of trustees to complain about Topol's views on Vioxx, his titles as provost and chief academic officer at the medical school in Cleveland were removed.

Lawsuits against Merck have uncovered details about how the company systematically persecuted critical doctors and tried to win opinion leaders

over to their side. A spreadsheet contained information about named doctors and the Merck people who were responsible for haunting them, and an email said: "We may need to seek them out and destroy them where they live,"[44] as if Merck had started a rat extermination campaign.

There was detailed information about each doctor's influence and of Merck's plans and outcomes of the harassments, e.g. "NEUTRALIZED" and "DISCREDIT." One strategy was to invite critical doctors to "thought-leader events," which reminds me of George Orwell's thought police, the secret police of Oceania in his novel *1984*.

Journal editors know where the evil comes from. According to my good friend, Drummond Rennie, a previous editor of *JAMA* and the *New England Journal of Medicine*, "The pharmaceutical companies, by their arrogant behavior and their naked disregard for the well-being of the public, have lost our trust. The FDA, by spinelessly knuckling under to every whim of the drug companies, has thrown away its high reputation, and in so doing, forfeited our trust."[45] Drummond noted that, as soon as they left their posts as editor in chief of the *New England Journal of Medicine* and *BMJ*, Jerome Kassirer, Marcia Angell, and Richard Smith each bemoaned the appalling influence of drug company money on the morals and practices of their profession in a book.[46]

Litigation Against Merck

I became involved in litigation against Merck in 2019. In 2015, the European Medicines Agency (EMA) was asked to investigate if the HPV vaccines—the vaccines against the human papillomavirus intended to decrease the risk of cervical cancer—could cause serious neurological harms, which was a suspicion raised by Denmark based on Danish research. As I shall describe below, in its investigation, EMA trusted what Merck reported to them, even though EMA already knew—not only in relation to Vioxx but also in relation to harms of Merck's two HPV vaccines, Gardasil and Gardasil 9—that Merck cannot be trusted. This was of course highly disappointing.

I have not been able to find out when the suspicion about serious neurological harms was first raised and what it was based on. But it came early.

Merck's Gardasil vaccine was approved by the FDA in 2006 and Cervarix from GlaxoSmithKline (GSK) in 2009, but GSK had already found signals of neurological harms in 2007.

I found this out in February 2008. Upon our oldest daughter's twelfth birthday, my wife and I received a letter from a doctor asking us to enroll her in an HPV vaccine trial conducted by GSK.[47] I asked to see the trial protocol and after having read it, I alerted my colleague to two issues.

First, there was nothing about harmful effects in the 105-page protocol, only some non-informative industry mantras like Cervarix being "generally safe and well-tolerated." The readers were referred to the *Investigator's Brochure* about this.

Second, in the information for parents, we read that the vaccine had "affected the nervous system, blood cells, the thyroid and the kidneys." We wanted to know what that meant and how often such potentially serious harms had been observed. I explained to my colleague that without this information, we were unable to make an informed choice, and if the information was included in the *Investigator's Brochure*, we hoped he would send it to us. He responded that it was not possible for him to send the *Investigator's Brochure*, but did not explain why. I have no doubt that GSK vetoed this, which I found unethical.

There were other issues. The protocol made it clear that GSK owned the data and that they must approve publications. Furthermore, individual investigators would not gain access to all the data from the trial, only their own data. I encouraged my colleague to ensure that the trial would be published no matter what the results showed.

We did not enroll our daughter in the trial on these premises. The harms looked potentially serious, but we could not get relevant information about them. Furthermore, even that long ago, thousands of reports had already been submitted to the authorities of serious adverse events, including a few deaths. There were public debates about the rare but serious harms possibly caused by the vaccines and many people were worried,[48] even though it is difficult to know if the events were caused by the vaccines.

My wife, Helle Krogh Johansen, is a professor of clinical microbiology. We both got all the recommended childhood vaccines and also gave

them to our two daughters. We had not perceived vaccines to be a problem before the HPV vaccines appeared. But now we were in doubt. We decided to vaccinate both of our girls but today, after my own research on these vaccines, we would not have done it. As I shall describe in this book, there are too many uncertainties, and screening for cell changes in the cervix is a highly effective alternative.

Ten years after these events, I took an interest in vaccines in general and wrote a book, *Vaccines: Truth, Lies, and Controversy*, to help people decide which vaccines they needed to take and which vaccines had a more doubtful benefit-to-harm balance, e.g. the one against Japanese encephalitis, which is rarely a good idea to take even when traveling to endemic areas.[49] I provided an extensive account of the HPV vaccines and concluded that no one in a leading official position was interested in elucidating the harms of any vaccine.

In June 2019, I gave a lecture at CrossFit's headquarters in Santa Cruz in California, "Death of a whistleblower and Cochrane's moral collapse," based on my book with the same title. The lecture is publicly available.[50] While I was there, three lawyers from the Baum Hedlund (now Wisner Baum) law firm from Los Angeles came up, as they wanted to hire me as an expert witness in their litigation against Merck, which had started three years earlier and was about serious harms of Gardasil.[51] It was not a class action. Rather, the attorneys are in active litigation against Merck in several state and federal courts. The lawsuits "allege Merck conducted fraudulent clinical trials for the Gardasil vaccine and failed to warn about severe side effects, which can remain serious for years after the Gardasil shot."

One of the lawyers, Michael Baum, recently stated in an interview with my deputy director at our Institute for Scientific Freedom, Maryanne Demasi, that "For many young men and women suffering from POTS, Gardasil is the common denominator. So many of our clients grew up healthy and active only to be broadsided by this life-changing condition after receiving the vaccine. It's time for Merck to do the right thing and admit that this dangerous vaccine is capable of causing POTS and other serious health issues."[52]

I met with Michael for the first time in 2014, in Los Angeles. I lectured at the annual conference of the International Society for Ethical Psychology and Psychiatry at the meeting, "Transforming mad science and reimagining mental health care." The press release announced that the speakers shared the belief that the medical model of psychiatric care—the idea that distress and misbehavior have physical causes that are best treated with drugs—is harmful. The meeting was fascinating, and the lectures are available.[53]

The organizer, psychologist David Cohen, gave me the society's award for "Intellectual honesty and bravery in tackling the biomedical-industrial complex." He confirmed that fifty years of so-called progress in psychiatry had increased the burden of mental disorders.[54]

Michael had won lawsuits against manufacturers of depression drugs, including GSK, and he invited me for dinner, together with psychiatrist David Healy, Cindy Hall and Leemon McHenry from his law firm, and four women who had lost their husband or daughter to suicide that was clearly caused by the drugs.

It is unusual for a law firm to have a deep interest in medical science, but when I opened my Institute for Scientific Freedom in Copenhagen in March 2019, Michael came to attend the lectures[55] with Cindy and Leemon. In October 2022, Michael, Leemon, and Lucija Tomljenovic, a scientist who works for Michael and is an expert witness in the litigation against Merck, also came to Copenhagen, for the meeting about the lack of scientific freedom I had arranged with Carl Heneghan, Director of the Centre for Evidence-based Medicine in Oxford.[56] Leemon is a philosopher and has published important papers about vaccines and ethics and scientific misconduct in psychiatry.

Right from our first encounter in 2014, I perceived Michael and his law firm associates as colleagues who, like me, wanted to change the world a little for the better. Lawsuits can sometimes result in changes that would not otherwise have happened.

For example, they try to stop the use of electroshock in psychiatry, which is a very harmful therapy,[57] via lawsuits. One of my close collaborators, consumer advocate Kim Witczak from Minneapolis, has this to say:

"Wisner Baum are not only amazing attorneys but more importantly, they are activists. They are about changing the systems which got us into

Michael Baum

Bijan Esfandiari

Leemon McHenry

trouble in the first place. They understand their role in the process of making change."

When Michael and his team, which included lawyer Bijan Esfandiari, came to see me in 2019 in Santa Cruz, lawyer Robert F. Kennedy Jr., with whom they sometimes collaborate, also showed up. He wanted to meet with me because he respected me for my science and my criticism of the drug industry, and we have kept in contact, even during his presidential campaign in 2024 and now, when he has taken on the role of US Secretary of Health and Human Services.

Lucija Tomljenovic

Cindy Hall

Robert F. Kennedy Jr.

Bob helped the Sioux avoid an oil pipeline being built through their Pine Ridge Reservation and he has saved the environment in other ways. He wrote a very interesting book, *American Values: Lessons I Learned from My Family,* which he sent to me. Bob mentions in his book that a

high-standing CIA official admitted on his deathbed that he was involved with the murder of his uncle, John F. Kennedy. I have studied this assassination a great deal and we both believe the CIA was involved. Back then, they murdered or attempted to murder a string of leaders around the world.[58] And JFK was shot from the front, and not from the back. In my view, Lee Harvey Oswald was just a scapegoat who was murdered very quickly while in police custody so that he couldn't reveal anything.

I was disappointed when Bob supported Trump in 2024, but I understand his reasons. For the Democrats, everything that is big is good, which includes Big Pharma, Big Food, and Big Tech. Bob wants to remove the corruption at the FDA and to bar drugmakers from advertising on TV. Time will tell how far he can get when the corporations show their muscle and corrupt the politicians even more, but he might obtain the greatest progress in US health care for decades. The advertising is an important reason why prescription drugs are the major killer in the United States. But with a very conservative Supreme Court, I doubt he will succeed. They will likely defend the First Amendment regarding free speech.

Vaccine Controversy: Where Are the Long-Term Studies?

I don't like calling people names, but Bob is considered the most prominent anti-vaxxer in the United States.

I disagree profoundly with Bob's views on vaccines. He firmly believes that the measles vaccine causes autism even though this hypothesis has been rebutted in high-quality studies.[59] Unfortunately, Andrew Wakefield, who launched the hypothesis, is a star in anti-vaccine circles. The true story about his immense fraud, and how harmful it has been, is not well-known among anti-vaxxers. I have talked to Bob several times about this but have not been able to move him from his positions on vaccines. We should not forget that the polio and measles vaccines have saved millions of lives.

But I do agree with Bob about two issues. It is wrong that vaccines get approved without having been compared to placebo, which is mandatory for other drugs. And we don't know what the many childhood vaccinations may lead to. We know very little about what happens when we use many vaccines and what their long-term effects are on the immune system.

We need large trials with long follow-up, conducted independently of the drug industry, that allows registration of late-occurring benefits and harms. They could be simple, pragmatic, and cheap, and they would likely be very cost-effective, as we might find out that some vaccines or combinations are harmful, and others are beneficial.

Unfortunately, it is difficult to get support for this idea. The vaccine area is characterized by dogma, and people in leading positions in health care know what is expected of them. You don't get popular with politicians by raising questions about vaccines.

The childhood vaccination programs differ markedly from country to country. When I looked this up, seventeen vaccines were recommended in the United States and only ten in Denmark. Sometimes, three, four, or even five vaccines are given simultaneously in the United States, even though we don't know what the net effect of this is, and none of them contain live attenuated microorganisms.

Vaccine programs have not taken the important results by Danish researchers Peter Aaby and his wife, Christine Stabell Benn, into account. Peter and Christine's most important findings are that live attenuated vaccines decrease total mortality more than what can be predicted from their specific effect while non-live vaccines increase total mortality.[60] They have also shown that the sequence of vaccinations is important; that it is best to end with a live vaccine; and that the harms of non-live vaccines predominantly affect girls.

Peter started this research decades ago and his results are so groundbreaking that they are on the list of milestones in *Nature*,[61] which starts with the discovery of the smallpox vaccine.

Since vaccinations can weaken the immune system and some vaccines increase total mortality, it is reasonable to ask if the many childhood vaccinations could result in net harm. I am aware of only two researchers who have studied this.[62] They did several studies and found that nations that require more vaccines for their infants have higher mortality rates in small children. This is alarming and should lead to other studies as a matter of urgency.

The HPV Vaccines

In 2019, Michael asked me to review Merck's internal study reports of their human and animal studies of their HPV vaccines. The methodology I employed was the same as I have used throughout my career, close to what I did with Lars Jørgensen and Tom Jefferson when we reviewed the clinical study reports of Cervarix, GSK's HPV vaccine, and Gardasil.[63]

Michael's team explained in Zoom meetings what they expected of me, which was to judge, for each study, if the design, conduct, analysis, and reporting were adequate. I should also evaluate if there were any signs in the trials of serious neurological harms, in particular postural orthostatic tachycardia syndrome (POTS) and complex regional pain syndrome (CRPS). In contrast to the Jørgensen review, I should not look at vaccine benefits.

I used six and a half months, full-time, reading the 112,452 pages I received from Wisner Baum, corresponding to five hundred medium-sized books, and writing an expert report of 350 pages. I did not read every single page in the study reports, as many pages were about the effects of Merck's vaccines on the production of antibodies against HPV strains and the effect on cancer precursors. There were endless tables with lab values and irrelevant information such as the number of sexual partners the girls had had and contraceptive use, even though this was none of Merck's business to ask about.

I must be the only person in the world to have read and digested all these pages. It gave me a unique insight into the many ways in which Merck had manipulated its research so that the risk that they would find important harms of their vaccines was close to zero.

There is much more than what I have seen. When I interviewed Michael in November 2023 in his home for the film and interview channel I established with historian and filmmaker Janus Bang in September 2023, *Broken Medical Science*,[64] he said they had close to 30 million pages of internal Merck documents.