Medical Dark Age

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To the victims of the pharmaceutical industry

The ultimate measure of a man is not where he stands in moments of comfort and convenience, but where he stands in times of challenge and controversy.

— Martin Luther King, Jr., *Strength to Love*, 1963.

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1

Introduction

In this book, we examine the relationship of the pharmaceutical sector with medicine and the government and a disturbing and noxious transformation that slowly took place in the pharmaceutical sector since the 1970s.

Using data and various examples as evidence, we claim that the *replication crisis*[†] in medicine is the result of human greed and corruption rather than honest human error and fallibility. The evidence is extensive and it implies that the crisis is only the tip of the iceberg; that corruption and greed have long reached a critical mass in the pharmaceutical sector; and that big pharmaceutical companies (a.k.a. *big pharma*) constitute a fraudulent racketeering system that operates under an extensive web of power and influence.

The extent, power, and detrimental effects of the pharmaceutical industry are hard to fathom. Let us start with some facts.

1. In the last 50 years, the pharmaceutical industry has corrupted government and science, it has shaped policy about medicine and health care, and it has dictated decisions and laws that gave them unjustifiable privilege and protection.

2. The pharmaceutical industry has reached an unprecedented level of fraud with a staggering human and so-

[†]The concept of replication crisis is defined in chapter 8, item A.

cial cost. It is far beyond any other sector or industry in the US with a total death of millions and a cost of trillions US dollars (the *opioid epidemic* cost the U.S. $504 billion in the year 2015 alone).

3. The pharmaceutical industry (with help from the insurance sector) has ballooned health care costs to be about one fifth of the GDP in the United States, making them a major burden on the nation's budget.

4. Big pharma has repeatedly manipulated public opinion and continues to do so on a daily basis. It has utilized extensive advertising revenue to secure the assistance of complicit popular media.

5. The pharmaceutical industry has created a nexus of deception where various fallacies and fabrications are disguised as science and research, while any criticism of such practices is presented or labeled as misinformation or conspiracy theories – especially when they relate to lucrative products such as vaccines.

6. The pharmaceutical industry has turned a large part of medicine and medical research into a religion of convenient beliefs and harmful but profitable fallacies and fabrications.

Let us elaborate on the last item in the above list. There is a new *religion of false medicine* that has spread in medical research and publications, the current medical beliefs, and the practice of medicine. Big pharma is effectively the church of this new religion. In a manner similar to the medieval church, they operate under a status of universal authority – across everything that relates even remotely to medicine or health care. They did not declare or advertise their authority but they apply it to all affairs consistently and continuously.

A vaccine-centered approach to infectious diseases is a central component of their religion because vaccines are by far their most lucrative product. It is a shortsighted and

reckless approach with adverse effects on health and human society that are already visible. This religion has intentionally created a toxic environment to discourage debate and reduce or eliminate dissent; and it has introduced a new form of bias and prejudice not only in science and medicine but also in government and human society.

We can thus argue that big pharma and their emergent authority and power represent a partial return to the Dark Ages. It is a far more complex and sophisticated version of the Dark Ages; it is modern, evolved, and more restrained; and it is primarily about medicine, medical research, and medical policies and legislation. We have called it the *Medical Dark Age*. If our term seems like hyperbole, let us consider some key facts.

Since the 1070s, the following changes have occurred. Health care costs in the US have increased from 5% of the GDP in the 1960s to nearly 20% in 2020. An ordinary industrial sector has become the most fraudulent sector in American history, accounting for more than two thirds of all fraud against the federal government; and it has transformed into a new type of organized crime. Their trade association has dramatically increased lobbying efforts; in 2017 alone, they had revenue of $455 million and spent $128 million on direct lobbying activities. (This does not include lobbying or other spending that is taken up by individual pharmaceutical companies. The total expenses are probably more than a billion US dollars.)

Big pharma has been allowed to settle fraud lawsuits on a regular basis without admitting wrongdoing, usually for a small fraction of their profits and always for a negligible fraction of the total cost to society and the nation. The total economic cost is trillions. The human cost is immeasurable suffering and a disturbing death toll. There have been various health crises, including the opioid epidemic, the coronavirus pandemic, the autoimmune disorder epidemic, and the autism and diabetes epidemics. Humanity has suffered

new forms of oppression, such as lockdowns and vaccine mandates, while science has witnessed a substantial degradation of medicine and medical research with a majority of questionable or patently false medical publications.

It is not hyperbole but an undeniable failure to be well into the 21st century and a single virus locks down significant portions of the planet, including the most developed nations. The situation in 2020–2022 with the Covid-19 pandemic, vaccines and vaccine mandates, lockdowns, and the associated social and economic hardship and decline is a long-term effect of greed, corruption, and shortsightedness. It is the unfortunate consequence and the legacy of big pharma, which has effectively forced their mercantile vaccine-centered approach to infectious diseases in medicine and medical research for decades now because vaccines are their most lucrative product. And they did so with the aid of complicit governments and an obedient medical establishment. (They have secured such assistance through lobbying, funding, corruption, conflicts of interests, misinformation, manipulation of public opinion, and other means of influence.)

The damage to democracy, society, and science has been significant, and continues to increase over time. The trend is clear. The only question is whether the harm will be irreparable in the end when big pharma is finally displaced.

In general, a skeptical viewpoint is advisable, especially upon extraordinary claims like the above. However, we would like to invite the readers to consider the evidence that we present in this book and make a more informed decision about our claims and their consequences. Disbelief is not an uncommon reaction to disturbing information; but we believe that the evidence leaves little room for doubt.

2

The False Claims Act

The *False Claims Act* (FCA) is an American federal law that imposes liability on persons and companies who defraud the government. It is the federal government's primary litigation tool against fraud that affects the government and it programs or institutions.

Congress enacted the False Claims Act on March 2, 1863, under president Lincoln during the Civil War, as a response to widespread defense contractor fraud that involved defective, ill, or subpar equipment, animals, clothing, and supplies (such as faulty rifles and ammunition, decrepit or ill horses and mules, and rancid rations and provisions) sold to the Union Army.

FCA includes a *qui tam* provision that permits a private party (called a *relator* under the law) to bring an action on behalf of the government. In such cases, the government is considered the real plaintiff; and if the government succeeds, the relator receives a share (up to 30%) of the recovery. Informally, the term *whistleblower* is used for relators, especially when they are employed by the organization or the individuals accused in the qui tam action.

In 1943, Congress amended the FCA and curtailed its qui tam provisions. However, in 1985, a government report noted that "45 of the 100 largest defense contractors, including 9 of the top 10, were under investigation for multiple fraud offenses" and estimated that "fraud against the Government

could be costing taxpayers anywhere from $10 to $100 billion annually." About a year later, in 1986, Congress reinvigorated the qui tam provisions of the FCA and increased both penalties and the relator's share of the recovered amounts.

3

A Sector of Fraud

Current statistics from the US Department of Justice show that the federal government has recovered more than $64.450 billion under the False Claims Act from October 1, 1986 to September 30, 2020. They also show that $43.375 billion, or approximately 67.3% of the recovered amounts, are in health and human services (or more precisely, "matters in which the Department of Health and Human Services is the primary client agency"), $6.211 billion, or 9.6%, cover matters related to the Department of Defense, while the remaining $14.864 billion, or 23.1% relates to other categories, agencies, and departments. A chart with the above numbers is shown in figure 3.1.

As can be seen from the pie chart, the distribution has changed dramatically since the 1980s and the bulk of fraud is no longer in the defense sector but rather in the health sector, which accounts for about seven times more fraud than the defense sector. In other words, fraud has shifted from the military-industrial complex to the *medical-industrial complex*. There is no evidence that fraud has significantly decreased in defense but it has dramatically increased in health care and the pharmaceutical industry in the last 40 years.

In all of recorded history and records of fraud, there is no other sector or area of science, commerce, or any other human activity and endeavor that can even compare with the staggering record of the pharmaceutical and health care

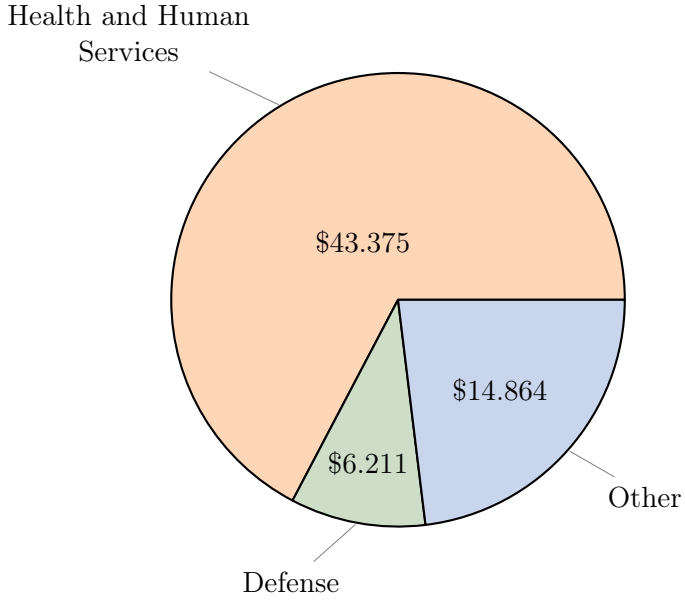

Figure 3.1: FCA recovered amounts (in billions US dollars), October 1, 1986 – September 30, 2020.

sectors. The overall annual cost to taxpayers is now harder to measure or estimate. There is a human and social toll as well as degrading effects on medicine and medical research, too. Even if we limit ourselves to financial effects, the annual cost is much greater than the $10 to $100 billion estimates from 1985. (As we explain later, it is estimated that the opioid epidemic cost the U.S. $504 billion in the year 2015 alone.)

Furthermore, we believe that the current fraud statistics from the Department of Justice only represent a small fraction of the total amount of fraud and the total number of cases. There are many reasons for that.

First, as stated on the Wikipedia False Claims Act page, over 71% percent of all FCA actions have been initiated by whistleblowers and those actions dominate the list of the largest pharmaceutical settlements. This large majority of

cases probably represents only a minority of all cases. It is largely the set of cases in which pharmaceutical corporations were not careful enough and allowed whistleblower loose ends, or failed to intimidate potential whistleblowers. Hence, if they represent the bulk or all fraud cases, the perpetrators must be incompetent amateurs who are almost always caught, and the pharmaceutical sector must somehow keep committing acts of fraud – and at increasing magnitude and frequency – even though they know that they would most likely or certainly be caught.

Second, the exposed fraud cases are unlikely to include various fraud cases where the recovered amount is not sufficient to make potential whistleblowers risk or effectively terminate their careers in the pharmaceutical sector by a qui tam action. This is demonstrated with FCA lawsuits on patent fraud. According to 35 USC 292, false representations of products as being patented (when they are not) is a formal legal offense. The relevant statute, when patents insignias are not removed from product labels after patent expiration, permits qui tam relators to share a maximum $500 award with the government. The small sum provided little incentive for such lawsuits and whistleblowers. However, in September 2010, the US Court of Appeals for the Federal Circuit ruled that the $500 penalty was applicable to each falsely marked item or article of merchandise sold. According to the website www.whistleblowingprotection.org, the ruling has sparked a rash of patent fraud suits.

Third, the FCA statistics do not include vaccine related fraud, injury, and settlements. Incredibly, the federal government has provided legal immunity to the pharmaceutical sector and has undertaken most of the responsibility and associated liabilities for vaccines – including liability for manufacturing or design defects. We shall examine this issue in more detail in chapter 10.

Finally, the above statistics only include fraud recovered by the federal government. They do not include settlements

of individual plaintiffs or settlements where one or more states was the prosecuting plaintiff. For example, they do not include the current multi-billion settlements on the *opioid epidemic* in the US, which dwarf all prior pharmaceutical fraud settlements. It is estimated that the epidemic cost the U.S. $504 billion in the year 2015 alone, while collective settlements are up to $26 billion.*

We will not examine the opioid epidemic further. It is an elaborate case with various complexities; and litigation and settlements are not complete yet. The litigation contains even peripheral cases like a $1.4 billion settlement to resolve false marketing claims about the effectiveness of the opioid addiction drug, Suboxone.

However, we would like to point out that the associated costs and overall settlements are much greater not only because of the extent and severity of the epidemic but also because the opioid fraud, unlike many other cases of pharmaceutical fraud, has been largely or fully exposed.

We should also point out and emphasize that the current and proposed settlements represent a trivial fraction of the human, social, and economic costs of such fraud; and that all three branches of government are excessively, if not immorally, generous and forgiving to the pharmaceutical sector – allowing this criminal state of fraud and human suffering and death to perpetuate and pharmaceutical corporations to settle one case of fraud after another without admitting wrongdoing, usually for a small fraction of their profits, and almost always for a tiny fraction of the total cost to society and the nation.

Finally, we will not examine the *Covid-19 pandemic* and how it was handled by governments in detail. It is currently an ongoing case and the final amounts will probably be larger in the end. However, we would like to point out that it is

*The death toll is perhaps more disturbing. Estimates are shown on Wikipedia, in the article about the epidemic in the U.S.: "From 1999 to 2020, nearly 841,000 people died from drug overdoses, with prescription and illicit opioids being responsible for more than 500,000 of those deaths, up to 2019."

arguably one of the biggest plunders of taxpayer money by the pharmaceutical industry, which received billions in funding. The U.S. government's Covid-19 relief program alone accounts for $18 billion given to big pharma. Big pharma will certainly return the favor, or rather a fraction of those amounts to the political system through lobbying, campaign financing, political donations, and various other forms of influence and corruption. (For example, in 2016, they put $100 million into the elections. In 2017, they spent $128 million on lobbying activities.)

Instead of being gifted to big pharma, government funding for Covid-19 should have been directed to universities and research centers on a non-profit basis while the pharmaceutical industry should have been contracted only in the end to manufacture the final products, if at all. Given their record of fraud, they should not have been trusted with any amount, let alone billions. If this recommended approach had been used, the overall costs and the price of the final products would have been lower and the process would most likely have been faster.* At the very least, some significant portion of the funding should have been directed to universities and research centers so that we could evaluate whether they could do better and by how much. The funds would have also helped universities, research, and education instead of bankrolling the most corrupt sector on earth to record earnings, revenue, and growth and further enriching pharmaceutical executives, who are allegedly involved in fraud on an annual basis. Subsidizing such extraordinary profitability and growth with government funding is a direct consequence of the pharmaceutical web of power, influence, and corruption.

*Large corporations have significant legacy issues, preventing them from being as nimble and effective as startups or academic institutions.

4

A Sector of Organized Crime

The cases that we examined or briefly described in the previous chapter represent the injury to society and the nation by the pharmaceutical sector. Yet, that is not all. There is insult to the injury. The cost of health care in the United States is more than double the average of most developed nations as a percentage of GDP (adjusted for differences in cost of living); and the gap follows a clear increasing trend over time since 1980 as shown in figure 4.1.

Moreover, the quality of health care is the US as measured by various indicators (such as life expectancy, mortality rates, premature death rates, disease burden, health care access, maternal mortality, infant mortality, diabetes and congestive heart failure hospitalizations, post-operative complications, and even medication and treatment errors) is clearly worse than in other developed countries and the gap tends to increase over time.

Some of those indicators are dramatically worse in the US. For example, pregnancy related deaths have been slowly decreasing in developed countries from an average of 6.6 deaths per 100,000 births in 1987 to about 5.4 such deaths in 2019. Yet, the corresponding number in the United States is not only much greater but it has almost tripled from 7.2 deaths in 1987 to 20.1 deaths in 2019.

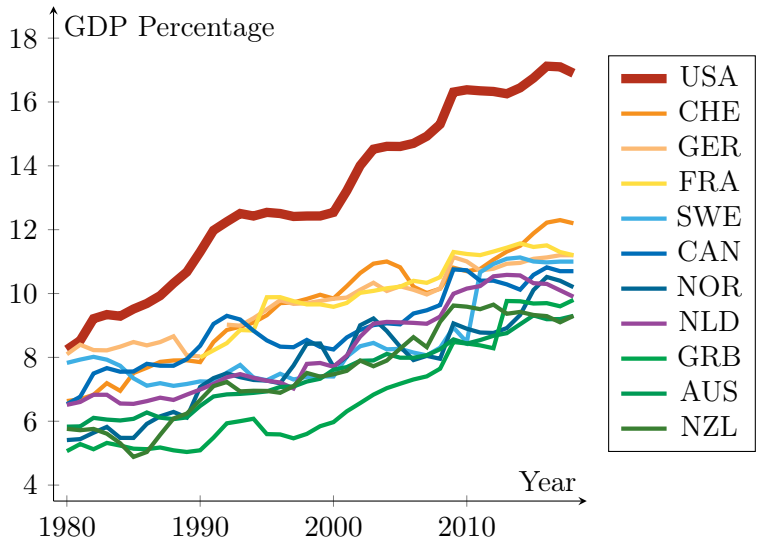

Figure 4.1: Health care costs from 1980 to 2018 as a percentage of GDP, adjusted for differences in cost of living across different nations. Source: Organization for Economic Cooperation and Development (OECD) Health Statistics 2019.

Research has demonstrated that the higher per-capita spending on health care in the United States is not because of greater health care utilization but because of higher prices – including higher drug prices, higher salaries for doctors and nurses, higher hospital administration costs, and higher prices for many medical services.

For example, a study by the *RAND Corporation* in 2021 found that prescription drug prices in the United States are 256% higher on average than in 32 other nations and 344% higher for brand-name drugs. The study found that the prices for unbranded generic drugs were slightly lower in the United States than in most other nations. However, those drugs account for 84% of drugs sold in the United States by volume but only for 12% of U.S. spending. Those findings imply that brand-name drugs are the primary driver of the higher

prescription drug prices in the United States; and that the pricing has little to do with the cost of living but it is primarily inflated brand name pricing to increase earnings with the permission or complicity of the government.

The above arguments about higher prices are reinforced by the fact that the United States has higher mortality rates (and lower life expectancy). The population is aging at a lower rate than in other developed nations but the difference in the health care costs between the United States and those developed nations is increasing over the years instead of decreasing.

In other words, in the United States, we have a poor health care system but instead of paying less for it, we pay double or more, and we pay more every year. The expenses are actually so high that they are major and increasing burden to the nation's budget. U.S. health care spending grew 9.7% in 2020 reaching $4.1 trillion and accounting for 19.7% of the GDP.

Let us pause for a moment. We spend about one fifth of our GDP on health care costs. This is excessive with any possible measure. For comparison, in 1960, the health care spending accounted for only 5% of the GDP.

One can only wonder how such a development is even possible. The answer is simple. The pharmaceutical sector has effectively become a sector of organized crime where the various big pharmaceutical corporations are the equivalent of mafia families or factions within the mob, while their actions are loosely coordinated by their trade association, the *Pharmaceutical Research and Manufacturers of America* (PhRMA). The association includes virtually all American manufacturers of brand-name drugs, and many foreign manufacturers, too.

We are not the first to make this claim. A. S. Relman. M. Angel, and J. Kassirer have provided ample evidence in at least two articles and two related books.

E. McCarthy, assistant professor of business law, has au-

thored a call to prosecute drug company fraud as organized crime under the *Racketeering Influenced and Corrupt Organizations Act* (RICO) of 1970. He explains that prescription drug fraud "contributes to more than 100,000 American fatalities every year" while "few (if any) drug company executives or other complicit parties face criminal charges for fraudulently developing and marketing these drugs."

In his book *Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare*, P. C. Gøtzsche has provided an extraordinary number of examples, details, and evidence that the pharmaceutical sector is organized crime. He includes an insightful quote from P. Rost, a former Pfizer marketing vice president:

> "It is scary how many similarities there are between this industry and the mob. The mob makes obscene amounts of money, as does this industry. The side effects of organized crime are killings and deaths, and the side effects are the same in this industry. The mob bribes politicians and others, and so does the drug industry [...] The difference is, all these people in the drug industry look upon themselves – well, I'd say 99 percent, anyway – look upon themselves as law-abiding citizens, not as citizens who would ever rob a bank [...] However, when they get together as a group and manage these corporations, something seems to happen [...] to otherwise good citizens when they are part of a corporation. It's almost like when you have war atrocities; people do things they don't think they're capable of."

R. Smith wrote the book's foreword and pointed out that the characteristics of organized crime include extortion, fraud, federal drug offenses, bribery, embezzlement, obstruction of justice, obstruction of law enforcement, tampering with witnesses and political corruption. He explained that the author "produces evidence, most of it detailed, to support his case

that pharmaceutical companies are guilty of most of these offenses."

We can only support the above claims and arguments. Every counterargument or effort to portray big pharma in a less liable form is relatively easy to refute with evidence and numerous examples across multiple decades. However, as we shall argue in chapter 6, the pharmaceutical sector represents a case and threat that is more severe than organized crime.

R. F. Kennedy, Jr. has also described big pharma as a racketeering syndicate. In return, big pharma has tried to discredit and portray him as a conspiracy theorist based on his arguments for health freedom and against vaccines – most of which are valid or deserve more attention as we shall demonstrate in chapter 11. Big pharma's smear campaigns are part of their propaganda and agenda to manipulate public opinion. Kennedy's arguments against vaccines are actually a greater threat to pharmaceutical revenue because vaccines are their most lucrative product.

However, such a smear approach could not possibly work with esteemed and distinguished researchers in medicine or law like the above authors.

A. S. Relman was an American internist and professor emeritus at the Harvard Medical School at the end of his career. He was editor of The New England Journal of Medicine from 1977 to 1991. In 2002, he published an article with M. Angell about unscrupulous practices, fraud, and corruption in the pharmaceutical industry that earned them the prestigious George Polk award in journalism.

M. Angell is an American physician and a Senior Lecturer in the Department of Global Health and Social Medicine at Harvard Medical School. She is also an author and the first woman to serve as editor-in-chief of the New England Journal of Medicine. She shared the George Polk award with Relman in 2002.

J. P. Kassirer is an American nephrologist and medical researcher as well as a professor at Tufts University School

of Medicine. He was the editor-in-chief of the New England Journal of Medicine from 1991 to 1999.

E. McCarthy is an assistant professor on business law in the College of Business at James Madison University.

R. Smith is a British medical doctor, editor, and businessman. He is director of the *Ovations initiative* to combat chronic disease in the developing world and also chairman of the board of directors of *Patients Know Best*. Previously, he served as chief executive of UnitedHealth Europe, editor of The British Medical Journal (BMJ), and chief executive of the BMJ Group.

P. C. Gøtzsche is a Danish physician, medical researcher, and former leader of the Nordic Cochrane Center at Rigshospitalet in Copenhagen. He is a co-founder of the Cochrane Collaboration and he was a member until 2017.*

We mention all this in order to demonstrate not only the credentials and the credibility of the above researchers but also the strength, extent, and corrosive power and influence of big pharma – which continues on its criminal path virtually undisturbed.

*P. C. Gøtzsche was expelled from the board and the organization of Cochrane in 2017 on arguments about supposed "disruptive and inappropriate behaviors" but, we believe, the real reason was his honest and uncompromising criticism of the pharmaceutical industry. As Gøtzsche stated in an article published in The British Medical Journal, "Cochrane no longer lives up to its core values of collaboration, openness, transparency, accountability, democracy and keeping the drug industry at arm's length." After the expulsion, four other members of the board resigned and two had to leave to restore a balance between appointed and elected members.

5

Corruption and Complicity

The data, books, and other publications from the previous chapter raise many questions. How is all this possible? How can such a fraudulent and racketeering criminal organization be allowed to exist and for so long? What are our governments doing? Especially in the United States where the problem is most acute, why does government refrains from using their power to address and correct the problem? Is it incompetence, corruption, or something else?

The answers to those questions have various components but the main element is influence and corruption.

Dr. R. Brown, a pediatric anesthesia specialist at the UK Kentucky Children's Hospital and chair of the *Food and Drug Administration* (FDA) Committee on Analgesics and Anesthetics, has explained this unfortunate condition. Many politicians, particularly presidential candidates, have begun to criticize big pharma. Yet, as Brown explained, nothing can change in the end because "Congress is owned by pharma." He elaborated on an interview with Yahoo Finance:

> " The pharmaceutical industry pours millions of dollars into the legislative branch every single year. In 2016, they put $100 million into the elections. [...] Congress is supposed to have over-

> sight for the FDA. If the FDA isn't going to hold pharma accountable, and Congress is getting paid to not hold pharma accountable, then it really doesn't matter who the president is because it's really about Congress. ”

In their 2002 article that won the George Polk award, Relman and Angel describe this situation in far greater detail. They explain that big pharma manipulates the government through PhRMA. PhRMA employs hundreds of full-time staff and lobbyists, and conducts an extensive and nonstop campaign on behalf of their clients. In 2002, PhRMA had "a core budget of some $60 million and large additional subsidies from the industry for special projects". In 2017, PhRMA had revenue of $455 million, $128 million of which was spent on lobbying activities. The size and growth their budget effectively demonstrate their firm and expanding grasp on the U.S. Congress and explains their success in fighting efforts to control drug prices. It also explains why no true action has been taken against the many crimes of the pharmaceutical sector.

For example, as Relman and Angel point out, American expenditures on prescription drugs were virtually steady as a percent of U.S. gross domestic product from 1960 to 1980. However, from 1980 to 2000, they tripled. More recently, spending increased 4.3% in 2019 and 3.0% in 2020, amounting to $348.4 billion. Over the next decade, the Centers for Medicare and Medicaid Services project that spending for retail prescription drugs will be the fastest-growing health care category and will consistently outpace that of other health care spending. Yet, no action has been taken by Congress against big pharma.* On the contrary, big pharma has been offered legal immunity (for vaccine injuries) and a government granted monopoly – through patents and FDA-approved exclusive marketing rights – so that they can inflate drug prices

*There are a few notable exceptions in Congress but their efforts and influence are limited.

almost at will.

Many Senators and Representatives may begin their careers with the best intentions but they are often forced into submission by the pharmaceutical sector. Those who only have a small margin in their states or constituencies or within their own party cannot afford to lose the support of the pharmaceutical sector. If they do, and especially if big pharma starts pouring millions into the campaigns of their opponents, they will most likely lose the nomination or the elections. Of course, this does not justify their complicity but it explains how politicians who start with good intentions have to compromise their integrity and adopt a less ethical stance in order to survive in the political arena.

Big pharma similarly controls or influences medicine, medical research institutions, and the medical profession. The methods are different but the effects are the same: influence, corruption, and submission.

As Relman and Angell point out in 2002, "virtually every research-intensive medical center in the country now has contractual ties with one or more drug firms." Clinical trials have already shifted from academic medical centers and teaching hospitals to *contract research organizations* (CROs), which are hired by pharmaceutical companies. The design and execution of those trials are now completely under the control of the pharmaceutical sector and subject to numerous conflicts of interest. (This can explain why clinical trials have become so biased and useless.)

Conflicts of interest have become one of the most common affairs in medicine. In her article. "Drug companies & doctors: a story of corruption," Angell provides prominent examples and demonstrates that even the most prestigious universities and research institutions in the country are not immune, or even resistant, to corruption and manipulation by the pharmaceutical sector.

Angell furthermore explains that most doctors receive money or gifts from pharmaceutical companies. They serve

as consultants, speakers in meetings, ghost-authors, and ostensible "researchers" who would put their patients on specific drugs; and they often receive kick-backs if they prescribe specific brand-name drugs as well as subsidies or assistance for the costs of their continuing medical education, which is required to maintain their state licenses.

From the annual reports of the top nine US drug companies, Angell estimates that the total amount provided by drug companies to physicians is tens of billions of dollars a year. Those companies understand the importance of highly influential faculty physicians, which they call "key opinion leaders" (KOLs); and they spend large amounts on them in order to bias them, create conflicts of interest, and enable avenues that would introduce falsities, bias, and preferable treatment recommendations in medicine.

Physicians, who are often affected by such financial interests or are swayed by prestigious medical school faculty, "learn to prescribe drugs for off-label uses without good evidence of effectiveness." Big pharma has settled numerous charges of fraud, off-label marketing, and various other offenses. However, the penalties are trivial compared to the profits, the companies admit no wrongdoing in their settlements, and they continue in their fraudulent and criminal course undeterred.

"By such means," as Angel explains, "the pharmaceutical industry has gained enormous control over how doctors evaluate and use its own products. Its extensive ties to physicians, particularly senior faculty at prestigious medical schools, affect the results of research, the way medicine is practiced, and even the definition of what constitutes a disease."

Angell furthermore explains that pharmaceutical companies have developed a new method to expand their markets: "Instead of promoting drugs to treat diseases, they have begun to promote diseases to fit their drugs. The strategy is to convince as many people as possible (along with their doctors, of course) that they have medical conditions that

require long-term drug treatment." For that purpose, they have introduced new and more serious-sounding names and abbreviations. Hence, shyness in now "social anxiety disorder," heartburn is "gastroesophageal reflux disease" or GERD, and premenstrual tension is "premenstrual dysphoric disorder" or PPMD. And of course, the medical establishment cannot stand in their way. Doctors like Relman, Angel, Kassirer or Gøtzsche are the exception, not the norm.

The above is typical of how big pharma has operated in the last few decades. Relman and Angell have demonstrated that the pharmaceutical industry falsely calls itself a "research-based industry". Marketing and advertising constitute the larger part of big pharma budgets while research and development (R&D) is a much smaller part, usually around 15%. Innovation is scarce, new molecular entities are a small minority, while the great majority of new drugs are patented variations of older drugs sold at higher prices.

Relman and Angell furthermore explain that big pharma greatly exaggerates their role in the scientific discovery of new drugs. Most of the groundbreaking research and the many discoveries in basic science that precede the development of innovative new drugs comes from public investment in research, not corporate research expenses. In 1998, only about 15% of the scientific articles cited in patent applications for clinical medicine came from industry research (54% came from academic centers, 13% from government, and the rest from various other public and nonprofit institutions). Similarly, a 1995 NIH study selected the five top-selling drugs in that year and found that "16 of the 17 key scientific papers leading to the discovery and development of these drugs came from outside the industry." In other words, big pharma does not represent innovation and research but largely marketing and manipulation – as well as lobbying, corruption, and fraud.

The final piece of the puzzle is public opinion and the media. Big pharma understands that both public opinion and the media are important components in their overall en-

terprise and criminal activities. Hence, they have directed enormous amount of advertising money to popular media – to ensure their complicity or at least a reluctance to publish articles critical of the pharmaceutical sector. They have produced or paid for countless biased articles, they have generated an endless stream of medical propaganda in the media and the internet, and they have infested research journals with similar propaganda that is in a more formal form and is disguised as science and research.

However, Congress – or rather big pharma's influence and hold over Congress – is indeed the most crucial part. It is the safety layer that guarantees no real action will ever be taken against big pharma. The legislative branch provides a virtually immovable protection, and it guarantees that laws will always permit this condition to perpetuate: big pharma will keep settling one case of fraud after another without admitting wrongdoing, while settlements and penalties for fraud will be a trivial fraction of the profits from fraud. Occasionally, when big pharma becomes too greedy and there is public outcry, as with the opioid epidemic, there may be a bankruptcy or some other notable event for appearances and public consumption, but then business, including corruption, fraud, and associated crimes, will continue as usual.

The net effect of all this is hundreds of thousands or millions of deaths and countless injuries over the last few decades, the total financial cost is probably many trillion. (We should recall that the opioid epidemic was estimated to have cost the U.S. $504 billion in the year 2015, alone.)

Yet, this is not all. There is one more component and perspective, as we shall explain in the next chapter.

6

The Religion of False Medicine

Organized crime is a power structure with centralized enterprises that engage in criminal activity most commonly for profit. Various crime syndicates may make money at the cost of human life but they have no interest in scientific truth, the knowledge that humanity has painstakingly accumulated over thousands of years, and the set of beliefs and paradigms that drive science and research.

However, this is not the case with all power structures. For example, the medieval church was a power structure that alleged universal authority, declared Christian faith as comprehending all phenomena, suppressed intellectual individualism and scientific progress, and controlled the set of permissible beliefs.

Big pharma is a similar example, albeit more limited in scope. Their fraud requires falsification of science and scientific facts. It requires control or decisive influence of the medical establishment and medical knowledge and beliefs. It requires fabrications, statistical manipulation, bias, and various other forms of deceit – as well as an overall environment where there is limited criticism and fallacies are treated as established facts. The term "backed by science" is widely used in various false claims by the pharmaceutical industry and so often that, in our view, it has become a synonym for false

marketing, lies, and deceit. Whenever this term appears in popular media, it can safely be assumed that the associated claims are false.

Overall, big pharma and the medical-industrial complex represent a power structure that fits the description not only of organized crime but also of a new religion and medieval church within medicine and the medical establishment.

In the following chapters, we will try to understand how this transformation and expansion of power and authority became possible on the first place. We will also present evidence that the transformation is now complete and adversely affects not only medical research and the practice of medicine but also human health, human societies, and our lives almost on a daily basis.

7

Replication Crisis

Replication is an essential and indispensable component of empiricism, empirical research, and the *scientific method*. It serves multiple purposes. It can limit and expose sampling errors, publication biases, questionable research practices, malpractice, and fraud; it can test whether results generalize to different or larger samples; and it can support or reject an underlying theory or hypothesis and determine its true scope. When it is successful, replication can increase credibility within a scientific field.

On the other hand, it is a crisis in a field when replication efforts broadly fail in that field; and it is a crisis in science when such failures occur across multiple fields. Non-replicable studies can diffuse facts and taint the scientific record with various fallacies and fabrications. Such studies can become a source of misinformation, false marketing, propaganda, and fraud when there are financial or other interests behind the related claims. In the health sector, the replication crisis has actually become a tool that is used to achieve unprecedented levels of fraud, as shown in chapter 3.

In general, the replication crisis seems to have started in the second half of the 20th century. It primarily affects medicine and social science but also natural science to some extent. It is a complex and extensive topic but it is also a condition that can facilitate fraud and deceit.

We can get an idea of the extent of the replication crisis

with some concrete examples. Those examples represent only a tiny fraction of all cases in approximate chronological order, starting with the earliest known reference. Overall, the literature on the replication crisis is extensive. The cases are so widespread and their total number so large that is hard to produce a precise estimate.

In a study published in 1959, psychology articles that were published in 1955-56 were examined and 97% of them were found to reject the null hypothesis. Given that insignificant results are not published, significant results are bound to occur by mere chance after a number of experiments. It is possible then, as the author stated, that "the literature of such a field consists in substantial part of false conclusions resulting from errors of the first kind in statistical tests of significance." The results of this study also suggest that the replication crisis started in the 1950s or earlier.

In 1966, another study examined 295 papers published in ten highly-esteemed and peer-reviewed medical journals and found that "conclusions were drawn when the justification for these conclusions was invalid" in about 73% of the reports. This implies that almost 3 out of 4 conclusions were effectively noise; and if we assume that the estimate is accurate across most medical research, it implies that most of the conclusions in published medical research are noise. The results also indicate that the replication crisis had already reached a critical mass by the late 1960s. However, and despite its severity, the replication crisis received very little attention until 2005.

In 2005, John Ioannidis published a seminal paper where he argued that a majority of medical research publications produce false conclusions. His paper, "Why most published research findings are false", is currently the most downloaded paper in the *Public Library of Science*.

Ioannidis used a statistical approach to demonstrate the high probability of fallacies in published research. He identified a number of factors that make research findings less

likely to be true such as small studies, flexibility in designs, financial interests and conflicts of interests, prejudice within a field, popularity of a field etc. We will examine his publication and some of its effects on science and medical research in the next chapter. Overall, Ioannidis' paper paints a bleak picture of medicine; and if we assume it to be true, it brings medical research dangerously close to superstition.

In 2009, a meta-analysis combined 39 research surveys and found that 1.97% of scientists admitted that they have had fabricated, falsified or modified data or results at least once, and up to 33.7% admitted other questionable research practices. The rates for such behavior among colleagues were 14.12% and up to 72%, respectively. As the study indicated, given the sensitive nature of such questions and limitations of surveys, the above estimates are probably conservative estimates of the true prevalence of scientific misconduct.

In 2012, an analysis of 53 pre-clinical cancer studies found that only 11% of them could be replicated. The non-replicable studies shared a number of common features and flaws in their execution or design. The overall result represents one of the highest rates of replication failures in literature. It arguably demonstrates the extent of the replication crisis in medicine.

In 2013, B. Nosek and J. Spies founded the *Center for Open Science*, which is a non-profit organization with the mission to "increase the openness, integrity, and reproducibility of scientific research." Likewise, recognizing the replication crisis and its extent and implications, the *Defense Advanced Research Projects Agency* (DARPA) initiated the *Systematizing Confidence in Open Research and Evidence* (SCORE) program with the goal to develop automated tools that assign "confidence scores" to different social and behavioral science research results and claims. The overall goal of such institutions and programs is not to eliminate human bias but rather to expose and contain it.

In 2015, the *Open Science Collaboration*, which is a program by the Center for Open Science, evaluated 100 experi-

mental and correlational studies that were published in three psychology journals. 97% of the original studies had significant results (p-value < 0.05) but only 36% of the replications had significant results. It found that 47% of original effect sizes were in the 95% confidence interval of the replication effect size; 39% of effects were subjectively rated to have replicated the original result; and if no bias in original results is assumed, combining original and replication results left 68% with statistically significant effects.

In 2016, the journal *Nature* conducted a poll of 1576 scientists and reported that more than 70% of researchers had failed to reproduce one or more of another scientist's experiments, more than 50% had failed to reproduce one or more of their own experiments, 24% had been able to publish a successful replication, and 13% had published a failed replication.

In an article published in 2016, Ioannidis explained that clinical research should be useful in the sense that "it should make a difference for health and disease outcomes or should be undertaken with that as a realistic prospect"; but he estimated that 85% of the funding for all medical research is not useful.

In 2018, economists tried to measure the extent of the waste. They combined prior studies and estimated that non-reproducible preclinical research represents a majority that exceeds 50% and it consumes approximately $28 billion per year in the United States alone. They furthermore indicated that such studies "undermine cumulative knowledge production and contribute to both delays and costs of therapeutic drug development."

In our view, this is the most detrimental effect of the replication crisis. It undermines science and our knowledge, which we have painstakingly acquired and accumulated over thousands of years, and it diffuses the scientific record with fallacies and falsities. We should also note that the above estimates of waste are consistent with Ioannidis estimates that the majority of published medical research is simply false.

In two studies published in 2018 and 2020, respectively, it was found that replication relates to plausibility. Using surveys and a prediction market, the first study found that "peer beliefs of replicability are strongly related to replicability, suggesting that the research community could predict which results would replicate and that failures to replicate were not the result of chance alone." The second study found similar results among non-experts, thus establishing a relation between intuitive plausibility and replication. The study considered 27 high-profile social-science findings, used a sample of 233 people without a Ph.D. in psychology, and found that the participants predicted replication success with 59% accuracy – or 67% accuracy when they were informed about the strength of evidence from the original studies. In other words, even non-experts can predict which results would probably not hold up to scrutiny, and yet the reviewers, who should be experts or at least more informed about the relevant areas, allow them to be published.

In 2021, a study showed that published papers in top psychology, economics, and general interest journals that fail to replicate are cited more than those that replicate; that the difference in citation does not change after the failure to replicate is published; and that only 12% of citations acknowledge the replication failure. Given the evidence that experts can predict which papers can be replicated, the authors postulated that reviewers applied lower standards to papers that seemed more "interesting" even when they were unlikely to replicate.

There are many more replication studies. Failure rates vary across scientific fields and journals but the studies generally support the premise that the replication failures represent a widespread crisis that is more common and severe in medicine and social science.

8

Metascience

Metascience is an emerging scientific field that seeks to improve the quality and reliability of scientific research and empirical results.

A first indication of the field's necessity appeared in 1966 with the publication of a research paper that examined the statistical methods of 295 papers published in ten esteemed and peer-reviewed medical journals and found that about 73% of the papers derived conclusions from invalid justifications.

Ioannidis provided the foundational publication for metascience with his paper in 2005 – where he argued that a majority of medical research publications produce false conclusions. He identified the following factors that make research findings less likely to be true.

a. Small studies, which can more easily lead to biased versions of the error probabilities.

b. Small *effect size* (this is the a priori probability of a condition under study), which results in small numbers of positive samples and thus less reliable estimates of the corresponding probabilities.

c. Large number and limited selection of tested hypotheses. When numerous hypotheses are being tested, it is more likely that some correlation may emerge out of statistical chance (especially, when the sample size or effect

size are small). This phenomenon is aggravated by the fact that positive results are reported but negative ones are often dismissed.

d. Flexibility in designs, definitions, outcomes, and analytical modes in studies. For the same reasons as before, increased experimental 'creativity' can lead to erroneous correlations.

e. Financial and other interests, conflicts of interest, and prejudice in a scientific field. Financial interests create pressure for positive results and novelty derived in a timely manner. They create conflicts of interest that introduce bias. Prejudice can be the result of such conflicts but it can also emerge from beliefs (in certain theories or approaches) and career objectives and constraints (such as tenure-track positions or institutional appointments). In either case, prejudice can produce similar forms of bias and lead to erroneous conclusions.

f. Increased popularity of a scientific field (with more scientific teams involved). The more teams that test a set of hypotheses, the more likely that some will find positive correlations. The more popular a field, the greater the pressure to arrive at positive results earlier. Negative results are often dismissed and not disseminated except when they refute earlier published claims. (This has led to the *Proteus phenomenon*, which represents a tendency to refute early or original claims through failed or contradictory replications of a work and often replace them with similarly erroneous and refutable claims.)

In more recent years, the field of metascience grew rapidly and developed further in terms of complexity, scope, and initiatives. We briefly describe some of its main areas below as well as the primary sources of bias in scientific studies.

A. The replication crisis (a.k.a. *reproducibility crisis*) is a current condition in science where many or most of the

published studies are difficult or impossible to reproduce.

B. Conflicts of interest, corruption, and fraud are not uncommon in science. They are particularly common in medicine and the pharmaceutical industry as we demonstrated in chapters 3, 4, and 5.

C. A scientific foundation and a well-defined platform for peer review and evaluation of research is imperative. It can prevent bias, eliminate ad hoc procedures, reduce subjectivity, identify errors or omissions, and expose conflicts of interest and attempts to diffuse certain scientific facts and effects (to make them appear as if they are debatable because they are financially or otherwise undesirable). Overall, such a platform can protect science from the many perils of empiricism and contain the effects of human fallibility and corruption.

D. Poor design of studies and experiments and improper use of statistics (especially p-values and statistical significance) can introduce significant bias in the data and lead to incorrect interpretations of the data and unjustifiable conclusions.

E. Poor practices, reduced transparency, and omissions in documentation, explanation, and dissemination of research can make it difficult to interpret the results, replicate them, and identify biases and conflicts of interest in the authors.

F. *Publication bias* is a bias in published research that occurs when the outcome of a research study affects the decision to publish or disseminate the results. It usually produces a bias in favor of significant positive results. However, publishing only positive results creates a bias that distorts the underlying distribution regardless of how statistically significant the results are. This

is effectively an aversion to null or negative results. Research indicates that studies with statistically significant positive results are about three times more likely to be published than papers with null results and despite comparable design quality in the experiments.

G. A current *publish-or-perish* environment in academia promotes low quality research, false positives, and questionable outcomes. It emphasizes the number of publications and 'interesting' plausible results rather than high-quality research and true discoveries. Metascience attempts to promote higher-quality research through improved incentive systems.

H. *Observer bias* (a.k.a. *experimenter bias*) occurs when the beliefs and expectations of a researcher about the results of their research study bias the research outcome or its interpretation. *Blind experiments* are experiments where information that may affect or influence the participants is withheld until after the experiments are complete. Such experiments are often used to limit or eliminate observer bias. However, blinding is not always properly reported or implemented, especially in medical literature, while failure of blinding is rarely measured or reported. Ideally, all research should assess and report the quality of blinding.

I. Career considerations and a desire for media attention can introduce a bias for misleading claims, exaggerations, and reduced epistemological modesty.

9

Ulterior Motives

In this chapter, we will focus more on the causes of the replication crisis rather than its various effects and forms – which can misdirect from the true nature of the crisis. We will attempt to create a binary classification for the causes but we will argue that this is primarily a singular problem where a single class defines the vast majority of all cases.

Let us start with a blog, *Fantastic Anachronism*. In a related entry, the author, A. De Menard, states that he participated in DARPA's SCORE program about replication markets and explains that prediction markets are accurate because predicting replication is easy. Papers that fail have "obvious, surface-level problems." He also explains that it is impossible to accept the popular belief that weak studies are the result of unconscious biases, subtle statistical errors, or questionable theories.

We can only echo the sentiment – for we indeed find such a belief "impossible to accept." De Menard demonstrates its incredibility in unequivocal terms: "even if the authors really are misled by the forking paths, what are the editors and reviewers doing? Are we supposed to believe they are all gullible rubes?"

De Menard furthermore explains that the problem is aggravated by the fact that students or researchers do not always read the publications they cite or they merely skim through them. (In a prior publication, it has been estimated that only

about 20% of cited papers are read before citation.) We believe that this factor adds to the proliferation of citations of weak or non-replicable studies. It may partly explain why citations continue even after replication fails but it does not explain how and why the weak studies came to be on they first place, or why the reviewers and the editors failed to detect the flaws or weaknesses and block the papers from publication. The very existence of such publications, their alarming frequency, and the associated editorial negligence suggest a different explanation.

It is almost trivial to argue that scientific research and publications are not as much related to skimmed papers or incidental negligence as they are to a complex of financial interests, conflicts of interest, and career objectives. Most researchers cannot afford to oppose such interests. They have to secure grants, publish in journals, and attend conferences and faculty meetings. They greatly dependent on their sources of funding and their peers too. It is more convenient to attribute poor research to the intricacies of the subject rather than the ethics of the researchers and the interests behind them. Fraud will not always be exposed; and when it is, sometimes many years or decades later, "the fraudster can admit, without much of a hit to their reputation, that indeed they were misled by that dastardly garden", if we may quote A. De Menard again.

The relationship between academia and various industry sectors is a delicate affair. When academia depends heavily on a sector for funding, corruption can spread quickly from the sector to the corresponding academic fields.

Professor A. Relman concisely and accurately described the situation in medicine: "The medical profession is being bought by the pharmaceutical industry, not only in terms of the practice of medicine, but also in terms of teaching and research. The academic institutions of this country are allowing themselves to be the paid agents of the pharmaceutical industry. I think it's disgraceful."

There have been a number of publications and books that

make the same argument and demonstrate the intricate web of conflicts of interests in medicine and the extent of the corruption – and with many specific examples. However, this is not the bulk of the problem but only part of it and a mechanism for big pharma and their fraudulent activities.

Over the years, a considerable number of researchers and politicians or governments and institutions have made various erroneous or extreme statements. In the same manner, business leaders and executive boards have seemingly committed strategic errors. We can potentially attribute those statements and failures to various factors such as ignorance, shortsightedness, incompetence, naivety, or even coincidence and bad luck. We call the above the *naive interpretation* and we consider it to be a highly unlikely explanation.

In most cases, there are undeclared motives behind such statements or actions. When those motives are not taken into account, the statements may appear as fallacies and the actions as miscalculations. They are effectively taken out of context and they appear as errors.

However, when the true motives are considered, the statements and actions become more deliberate and calculated. They are often strategic or tactical responses with specific purposes. Those purposes vary. The intent is often to hide the truth and make facts appear as debatable, promote careers or certain beliefs, manipulate public opinion and scientific consensus, and more commonly protect financial interests by influencing markets, maximizing revenue or profits, and minimizing damage or losses. Sometimes there are combinations of such motives but financial motives are present in most cases.

We refer to the above as the *ulterior motive hypothesis* and we consider it to be the true explanation for the vast majority of cases.

Business leaders are neither incompetent nor naive. Politicians are not driven by ignorance or inexperience but rather by ambition. Institutions are likewise neither gullible nor

shortsighted. Researchers are not ignorant fools who make outrageous statements. When such events occur, there is always an ulterior motive. Arguably, there may be some exceptions, such as politicians who are not astute enough to comprehend all the factors sometimes, but their actions are usually the result of their ambitions, desire for power, or plain greed. Their potential ignorance or incompetence is irrelevant.

Hanlon's razor states that we should "never attribute to malice that which is adequately explained by stupidity." It is an adage that may apply to certain human affairs but has no application whatsoever when there are financial interests and billions to be made, power to be grabbed, and careers to advance or make. In such cases, the main factors are not stupidity or ignorance but rather profit, authority, and ambition as well as greed, corruption, and fraud. If we choose to call all this malice, the *opposite* of Hanlon's razor would be true. In the end, it does not matter what term we apply for it, or whether a naive and simplistic razor reverses. The result is the same and it is detrimental – or disastrous. (We can think of climate change as an example.)

It is always instructive to look at specific cases in order to understand an argument. We provide a number of examples in the remaining of this book and apply the ulterior motive hypothesis. For comparison, we also present the naive interpretation. Our readers can decide for themselves which one is more likely to be true.

10

The National Childhood Vaccine Injury Act

In 1986, the *National Childhood Vaccine Injury Act* (NCVIA) was signed into law by United States President R. Reagan as part of a larger health bill. According to *New York Times*, President Reagan "approved the bill 'with mixed feelings' because he had 'serious reservations' about the vaccine compensation program"; he considered it an "unprecedented arrangement"; while the Justice Department "urged a veto of the bill because of its objections to the new system of compensating people injured by vaccines."

However, there was heavy lobbying in support of the bill by a coalition led by pharmaceutical companies, and as is often the case in politics, lobbying (and big pharma) won.[†]

Vaccine injury no-fault compensation programs exist in 25 other WHO member states, with 16 of them in Europe. Those programs vary in scope, provisions, compensation, and funding. However, they share a common characteristic. They create a vacuum, in which safety is at the discretion of pharmaceutical companies.

Let us understand why.

Government assistance exists in various countries and a

[†]According to NYT, vice president Bush, commerce secretary M. Baldrige, secretary of HHS O. R. Bowen, and secretary of the treasury J. A. Baker urged Reagan to sign the bill.

number of sectors. For example, many countries and the European Union as a whole provide subsidies to their agricultural sectors. In the United States, there are also subsidies to the energy sector in order to keep energy prices low; as well as subsidies or tax incentives for certain technologies such as renewable energy or electric vehicles. Nuclear plants are insured by governments because private insurers cannot undertake the potentially catastrophic risk of a nuclear accident.

However, those programs do not eliminate liability from manufacturers – as for errors or defects of their products. To the best of our knowledge, such immunity from liability is a unique privilege that exists only in the pharmaceutical sector. It is also an indicator of the political power the sector yields.

Liability and safety are two interrelated concepts. When we eliminate or undermine liability, safety is reduced and efforts, programs, or research for improved safety suffer. This is best described in *Bruesewitz v. Wyeth*, which is a United States Supreme Court case that decided whether a section of NCVIA preempts all vaccine design defect claims against vaccine manufacturers. Supreme Court Justices Sotomayor and Ginsburg dissented. We include a small excerpt below.

Justice Sotomayor, with whom Justice Ginsburg joins, dissenting.

> “ Vaccine manufacturers have long been subject to a legal duty, rooted in basic principles of products liability law, to improve the designs of their vaccines in light of advances in science and technology. Until today, that duty was enforceable through a traditional state-law tort action for defective design...
>
> I believe §22(b)(1) [of NCVIA] exempts vaccine manufacturers from tort liability only upon a showing by the manufacturer in each case that the vaccine was properly manufactured and labeled, and that the side effects stemming from the vaccine's design could not have been prevented by a

> feasible alternative design that would have eliminated the adverse side effects without compromising the vaccine's cost and utility...
>
> In enacting the Vaccine Act, Congress established a carefully wrought federal scheme that balances the competing interests of vaccine-injured persons and vaccine manufacturers...
>
> Instead of eliminating design defect liability entirely, Congress enacted numerous measures to reduce manufacturers' liability exposure...
>
> By construing §22(b)(1) to preempt all design defect claims against vaccine manufacturers for covered vaccines, the majority's decision leaves a regulatory vacuum in which no one – neither the FDA nor any other federal agency, nor state and federal juries – ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers, given the lack of robust competition in the vaccine market, will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins. Nothing in the text, structure, or legislative history remotely suggests that Congress intended that result.
>
> I respectfully dissent. ”

R. F. Kennedy, Jr. accurately summarized the decision, its effects, and the interests behind it: “Scalia and his corporatist brethren interpreted the National Childhood Vaccine Injury Act of 1986 (NCVIA) to shield Big Pharma with full immunity from liability for vaccine injuries. Their decision removed all incentives for pharmaceutical corporations to make vaccines safe, and Americans forfeited their seventh amendment right to jury trial against vaccine companies that

harmed them, no matter how negligent."

Kennedy furthermore explained that, "Scalia's decision made vaccines immensely profitable" and "gave blanket immunity" to the 72 vaccine doses currently on the mandatory schedule.

In other words, extraordinary profitability is the cause of all this. The pharmaceutical sector has enjoyed profit margins that are greater than the margins of any other industry. Yet, they are so driven by greed that their main interest is to increase their margins further – no matter what the political, social, and human cost might be. Vaccine safety is thus an inconvenient and unpopular topic that is intentionally surrounded by toxic debates, denigrating terms, and smear campaigns.

The situation with vaccines is furthermore aggravated by the *Prescription Drug User Fee Act* (PDUFA), which is a law passed by Congress in 1992 that allows FDA to collect fees from drug manufacturers to fund the new drug approval process. The unintended consequence of the act, according to M. Carome, director of the Washington-based consumer watch group *Public Citizen*, is that it effectively turned companies into customers of the agency; and the agency has since been inclined to treat them accordingly.

All this was demonstrated in 2013 when *Sanofi Pasteur's* Monroe County plant discovered tiny pieces of glass in batches of a vaccine intended for babies. The source turned out to be *delamination*, which occurs when vials shed flakes of glass.

Most medical manufacturers tend to be cautious on this issue, and they have alerted the public and issued product recalls upon glass contamination. For example, *Baxter*, *Amgen*, *American Regent*, *Fresenius Kabi*, and *Merck* recalled products contaminated with glass particulates between 2010 and 2013. This applies to vaccines, too. Merck recalled 743,000 shipments of the Gardasil HPV vaccine in 2013. A 2012 a study found that, in the previous five years, glass issues (including contamination from delamination) had resulted in the

recall of more than 100 million units of drugs packaged in vials or syringes.

However, Sanofi did not issue a recall and allowed their potentially contaminated vaccines to be injected into babies for a year and a half. The company offered assurances to the FDA that the vaccines were safe and FDA took no further action.

Sanofi's assertions were speculation at best. There have not been studies about the physiological impacts of delamination because experiments that intentionally inject glass fragments into people, and babies in particular, would raise obvious ethical questions. Furthermore, their decision demonstrated not only a callous disregard for potential harm to human babies but also extraordinary greed. Sanofi earned $43 billion in 2014 and ranked as the fifth-largest pharmaceutical company in the world. Yet, the year before they did not recall the contaminated vaccines even though they represented a trivial and utterly negligible fraction of their revenue.

Despite all this, the FDA took no action. M. Carome explained the incident: "Too often the FDA is not an effective regulator. They are often too slow to act when there are serious problems. The industry is more like a client or customer of the agency, and less like a regulated entity."

Even if we assume that Sanofi had data that somehow demonstrated that delamination in their vaccines was not harmful to babies, the FDA never received such data and effectively trusted the manufacturer about their asserted safety of their vaccines. At best, this is self-regulation; at worst, it is experimentation on humans and without consent.

On top of all this, on January 23, 2015, Sanofi informed the FDA it had found particulates in a new batch of vaccines. A subsequent analysis determined that only a fraction of those were caused by delamination, some were mysterious bits of glass, and one was a piece of stainless steel.

The above example is not a coincidence. It is a direct result of NCVIA and PDUFA and their safety and regulatory

vacuum. Those acts have transferred control from the authorities and the government to the pharmaceutical sector, which is arguably the most fraudulent and criminal sector on earth. If that is a reckless and unjustifiable decision and policy, the enabling acts are of the same nature.

11

Vaccines

Let us start with a statement.

It is hard to believe that we are in the 21st century and we still rely entirely or primarily on vaccines to fight infectious diseases. In this chapter, we will explain how irrational, short-sighted, and reckless this approach is – especially in the long run. Its unfortunate consequences are slowly becoming more visible; and they include an autoimmune disorder epidemic, a viral pandemic, vaccine mandates, lockdowns, oppression, and the associated economic and social hardship and decline. All this is the aggregate effect and the legacy of the pharmaceutical industry and its web of power and influence that has effectively forced their religion upon medicine and their vaccine-centered approach.

Now, let us consider some key factors and the evidence in order to understand this unfortunate condition better.

11.1 Immune Systems are Learning Systems

Our immune systems are incredibly complex *learning systems*. Scientific understanding of immune functions, structure, and organization as well as the immune system as whole is very limited, if not rudimentary. This is perfectly demonstrated by the inability of medicine to understand the source of au-

toimmune disorders and the failure to explain their alarming rise in recent years and decades. It is also demonstrated by many other less important facts. For example, *immunologic adjuvants* were not the result of some detailed and rigorous theory or understanding of the immune system but rather an accidental empirical find from contamination in vaccines.

Consequently, when we tweak our immune system with vaccines and their adjuvants, we effectively tweak a system we do not understand and hope for the best. We may reap some short-term benefits, but in the long run, this is a recipe for disaster – especially as we increase the number of vaccines, administer them at young age uniformly across the population and with the same constitution for all children.

Let us establish some basic facts about learning systems and processes.

In statistics, independent and repeated occurrences of an event with exactly two possible outcomes are called *Bernoulli trials*. If we denote the event as E and its two outcomes as E and $\bar{E}$ and if we assume the probability of the first outcome is $P(E) = p \in [0, 1]$ then the probability of the other outcome is $P(\bar{E}) = 1 - p \in [0, 1]$. Consequently, if we repeat the event k times, and denote the i-th repetition as E_i, the probability that the first outcome will appear at least once is

$$p_k = P\Big(\bigcup_{i=1}^{k} E_i\Big) = 1 - P\Big(\bigcap_{i=1}^{k} \bar{E}_i\Big) = 1 - (1 - p)^k \qquad (11.1)$$

given that the trials are assumed to be independent.

Now, it is a well-known fact that $\lim_{x\to 0}(1 - x)^{1/x} = \lim_{n\to\infty}(1 - 1/n)^n = 1/e$. Consequently, if p is assumed to be small, equation (11.1) leads to the following approximation

$$p_k \simeq 1 - e^{-pk} \qquad (11.2)$$

Therefore, if we wish to make the probability p_k relatively large (e.g. $p_k \geq 0.5$), k must be chosen to be of the order of $1/p$ (mathematically, it should be $k = \Theta(1/p)$). For specific

values of p and p_k we can actually use equation (11.1) directly and solve for k:

$$k = \log(1 - p_k) / \log(1 - p).$$

As a result, if $p_k \geq 0.5$ and $p = 1/10000$ then $k \geq 6932$.

Learning systems, on the other hand, do not represent Bernoulli trials. They have greater *learning efficacy*, which means they require fewer than $\Theta(1/p)$ trials to achieve a learning event. The probability p_k increases much faster with every repeated trial. This implies that the exponent of the approximation in (11.2) is super-linear or linear of the form λpk, for some large constant λ. (The exponent can be formally defined as $e_k = \ln(1 - p_k)$.)

Biological systems, in particular, have impressive learning efficacy and can thus learn from few trials. This is the reason that vaccines and our immune systems work on the first place. We can develop immunity against viruses because of the learning efficacy of our immune system. Conversely, if our immune system required thousands of infections in order to develop immunity against any given virus, it would be practically useless as a defense system while vaccines would be impossible and absurd.

However, the great learning efficacy of our immune system is a double-edged sword. It means that our system can transition from one *equilibrium* to another with relatively limited effort. Thus, if a child grows up in an environment that is dense with viruses and pathogens, their immune system would eventually become more aggressive (it will shift to a more aggressive equilibrium) in order to protect its host from the many pathogens in their environment.

Evolutionary pressure over millions of years have thus led immune systems to an appropriate equilibrium. The evolved systems are sufficiently aggressive to protect their hosts from pathogens in their environments but not as aggressive and easily triggered as to misfire or overreact and attack their hosts, creating chronic or lethal autoimmune disorders and

conditions.

Another property of learning systems is that events early in their life or existence have a disproportionately large effect on the systems. This property is evident with *artificial neural networks* where the first 10% of their training usually accounts for more than 90% of their accuracy. It also manifests in human learning – which gradually becomes harder with age. (Thus the expression "you can't teach an old dog new tricks.")

Consequently, when we inject vaccines to a newborn child at the very first few hours (or even minutes) outside the body of their mother, and when we have 26 such injections in the first year of their life, we introduce a bias that can eventually shift their immune system to a more aggressive and potentially detrimental equilibrium.

The argument from the pharmaceutical industry – echoed by their numerous mouthpieces in the medical profession – is that the human body is bombarded with pathogens daily from the beginning of their life outside the womb and that vaccines are just one more such exposure or infection.

This is not a scientific argument. It is vaccine propaganda. And it is false and absurd.

Vaccines are not even comparable to regular exposures or infections. The fact is best demonstrated with the severe side effects or adverse effects in certain adults or children.

For example, in 2021, the Food and Drug Administration warned the public that the Johnson & Johnson's coronavirus vaccine can lead to an increased risk of a neurological condition known as *Guillain-Barré syndrome*. (It was reported that the vaccine increased the chance of the syndrome by 300% to 500%.) The syndrome is relatively rare and it is usually the result of an autoimmune disorder in which the body's immune system mistakenly attacks the peripheral nerves and damages their myelin insulation. The syndrome can cause muscle weakness and sometimes paralysis; and it can be life-threatening during its acute phase – about 15% of the people

develop breathing muscle weaknesses and require mechanical ventilation. Sometimes, the syndrome leads to changes in the function of the autonomic nervous system and dangerous abnormalities in heart rate and blood pressure.

In December of that same year, concerns over another side effect – blood clots in recipients of the Johnson & Johnson vaccine – lead the *Centers for Disease Control* (CDC) to endorse a clinical preference for the Pfizer-BioNTech and Moderna shots.

Now, if humans only receive a vaccine once in a while but they are exposed to numerous pathogens every day, and if the pathogens are equivalent or comparable to vaccines, the Guillain-Barré syndrome and blood clots would be a frequent concern for a significant percentage of the population and across age ranges. Yet, they are not – not even close. For example, Guillain-Barré syndrome occurs at a rate of one or two cases per 100,000 people every year. The tremendous difference in the projected and actual frequency (which is multiple orders of magnitude even with very conservative estimates of exposure to pathogens) demonstrates how dramatically more severe vaccines are when compared to regular exposures to pathogens.

We will explain the severity of vaccines and the factors behind such severity below. However, we would like to pause for a moment and attempt to find an explanation for such a ludicrous claim by the medical establishment. Are doctors and medical researchers so limited that they cannot estimate the difference? Are they so negligent that they failed to notice the discrepancy? This is the naive interpretation and it is virtually impossible.

The ulterior motive hypothesis is the more likely explanation. There is an ulterior motive behind such statements and the tacit complicity of the medical establishment. As professor Relman stated, "the medical profession is being bought by the pharmaceutical industry." Those who are sold to the pharmaceutical industry cannot possibly attack or criticize

the most lucrative product of the industry. If they dare do so, their research funding and their speaking and consulting fees will evaporate, kick-backs for drug prescriptions and various other expenses, including those for their required continuing education will likewise vanish, they will be personally attacked and smeared by the industry and more obedient colleagues, their claims will be 'contradicted' by numerous biased studies published in various journals, their reputation will suffer a great blow, and their careers may wither away. The pharmaceutical sector has become the church and the universal authority within the new religion of false medicine. Anyone who dares question the authority of the church will be declared a heretic, and their careers will 'burn' in some glorious pseudo-scientific 'pyre'. The Medical Dark Age is clearly a milder version of the Dark Ages. The pharmaceutical industry does not burn living human beings, it only destroys the careers and reputations of those who dare question and dissent.

Let us now return to vaccines and understand the great risks behind them.

Vaccines bypass our skin, mucous membranes, and digestive system, they can create great levels of inflammation, they sometimes contain human DNA which can aggravate inflammation in certain individuals, they may be tainted with various other pathogens (which now escape the regular protection of our skin, mucous membranes, and digestive system too), they may be contaminated with glass, steel, or other harmful substances and not be recalled thanks to the NCVIA, but most importantly, they contain substances, known as *immunologic adjuvants*, which are used to accelerate, prolong, or enhance antigen-specific immune responses to a vaccine so that the vaccine can elicit a sufficient immune response that would lead to immunity in most cases.

There are many other concerns with vaccines. If we were to describe the problem and the underlying issues in their entirety, we would need to dedicate multiple chapters, if not

an entire book. In this book, we will focus on the adjuvants only because they relate to learning and they represent one of the two most severe problems with vaccines.

Learning systems tend to have great variance in their responses and internal structure and state. At any given time, the state of a learning system is not uniquely defined by its architecture, structure, capacity, or genetic/hereditary information. It is as much affected by the experiences of the learning system and the knowledge or set of beliefs in the system – and to such an extent that beliefs can affect perception, as various optical illusions demonstrate. The result is that human brains demonstrate extraordinary diversity and human responses vary significantly or dramatically even under identical conditions.

The same applies to immune systems because they are learning systems. There is less complexity compared to brains, but there is still a large degree of variance and diversity across immune systems even when we consider the systems of relatives or siblings. One may develop an autoimmune disorder and asthma while the other may have a more robust immune system and be a marathon runner.

Variance across learning systems is inevitable because it is a reflection of the diversity of complex environments and the experiences of the systems in such environments. Our immune systems are not exempt from that condition; and their relatively large variance implies that there cannot be an effective dosage for a stimulant of the immune system, such as the immunologic adjuvants, that will not over-stimulate the immune systems of a non-trivial fraction of the recipients, if the group of recipients is sufficiently large. (Over-stimulation is not a formal or predefined term, but we use it in a relative way to refer to immune responses that are considerably more extensive or acute than what is necessary for immunity to be developed.) When such acute stimulation occurs repeatedly and early in the life of an individual, it can eventually shift their immune system to an overly aggressive state and create

chronic or life-threatening autoimmune disorders.

Furthermore, an over-stimulated immune system can attack its host, it can attack the nervous system, as it happens with the Guillain-Barré syndrome, it can potentially cause permanent neurological damage that can lead to autism, it can manifest as eczema (which was shown to be an autoimmune disease in 2014), it can lead to asthma, diabetes, arthritis etc. There is not really an organ or any tissue in the body that is safe from the immune system. Hence, the set of conditions and complications that autoimmune disorders can create is open-ended and it keeps growing as we begin to realize their extent.

Let us now examine the problem mathematically. We assume that the statistical event E is a random variable that represents the potential shift of the immune system to an aggressive state or equilibrium that can create an autoimmune disorder. We furthermore assume that D is a random variable representing the number of administered vaccine dosages and that $p = P(E/D = 1)$ is the probability of an immune shift due to a single vaccine dosage. $p_k = P(E/D = k)$ is similarly the probability of an immune shift after k vaccine dosages. There may be exceptions due to genetic predisposition, but, in general, p is a small number for most people. However, because the immune system is a learning system with great learning efficacy, it can and should shift to an aggressive equilibrium, if the organism is placed in an environment with high pathogen density early enough in their life or for a sufficiently long time. As a result, and because the immune system cannot distinguish between serious infections due to pathogen density and repeated over-stimulation due to vaccines and their adjuvants, p_k is bound by evolution to grow quickly with k, if a considerable number of the vaccine dosages k over-stimulate the immune system. Unfortunately, the latter is inevitable for a fraction of the population, given the variance of immune systems and the fact that a fixed amount of adjuvants is used in each vaccine.

In other words, when we use the same adjuvant dosage for all people and we repeatedly vaccinate them, especially at young age, we are likely to create an autoimmune liability for a portion of the population. And that portion will only grow with the number of vaccine dosages k or with more aggressive vaccination schedules.

Now, if we assume this to be the case, we can see that vaccines (and particularly the current, predefined, aggressive, and required vaccine schedules) represent a goldmine for the pharmaceutical industry. Not only they constitute their greatest source of revenue, but they create chronic autoimmune disorders that force people to be their permanent clients. For example, according to Wikipedia, the top 1 and top 3 best-selling pharmaceuticals in the US are adalimumab and etanercept (under trade names Humira and Enbrel, respectively) and they generated revenues of $21.4 and $8.1 billion in 2019. They are both drugs primarily for rheumatoid arthritis, which is an autoimmune disorder. This is truly a pharmaceutical goldmine – at the expense of public health.

11.2 Autoimmune Disorders and Autism

Let us now adopt a more skeptical viewpoint. Most vaccines were introduced in the second half of the 20th century. Consequently, if the above analysis is correct, there must already be a significant or at least non-trivial fraction of the population that suffers from autoimmune disorders; and as vaccines become more prevalent and their numbers grow, the affected fraction of the population should grow, too. The same should apply to autism, if we assume that a significant percentage of the cases are related to the immune system and/or neurological damage caused by the immune system.

Let us now consider some statistics to see if there is any such evidence in the records. In 2017, the *National Institutes of Health* (NIH) estimated that approximately 23.5 million Americans live with an autoimmune disease and that their

prevalence is on the rise. The *American Autoimmune Related Diseases Association* (AARDA) increased the estimate to 50 million – which corresponds to more than 15% of the population or one case for every six or seven Americans. The difference between the two estimates derives primarily from the fact that NIH only included 24 diseases for which they had epidemiology studies they considered appropriate. Consequently, the estimate by AARDA is probably more accurate. The cost of those diseases are estimated to be $86 billion per year by AARDA.

A study by NIH researchers was published in 2020 based on the prevalence of antinuclear antibodies. It estimated that there has been a 50% increase of autoimmune disorders in the US in the course of 25 years. Now, if we assume that the current estimates of autoimmune disorders are accurate and that their trend continues, the implications are dire: autoimmune disorders will more than double in the next 50 years, and the majority of the US population will suffer from autoimmune disorders within 75 years. (We actually expect the situation to be much worse than that and the estimates and projections to be corrected upwards as more vaccines are introduced, more autoimmune disorders are identified, and more conditions and diseases are linked to autoimmune disorders.)

In 2018, research from Connect Immune Research, which is a group of medical research charities in the UK, estimated that direct and indirect costs to the UK for three autoimmune conditions – type 1 diabetes, rheumatoid arthritis and multiple sclerosis – currently add up to more than £13 billion per year in the UK. (This is equivalent to approximately $17.54 billion.) The group estimated that about 400,000 people are living with type 1 diabetes in the UK, over 400,000 with rheumatoid arthritis, and over 100,000 with multiple sclerosis. It furthermore estimated that four million people in the UK are living with an autoimmune condition – which is more than 6% of the population. The group also indicated

that there are more than 80 autoimmune conditions known to science and it found that the incidence of some conditions is increasing by as much as 9% each year in the UK.

In a related webpage in the site statista.com, there is a plot of the distribution of autoimmune conditions across adult age groups in the UK and the estimates are between 10% and 18% for self-reported cases and between 6% and 15% for diagnosed cases. The totals are 14% and 11%, respectively.

The statistics on autism in the US are as alarming. The number of children diagnosed with autism has increased dramatically since the 1980s. Table 11.1 shows some brief autism statistics derived from CDC reports. The first column is the year that the data were collected, the second is the prevalence of diagnosed *autism spectrum disorder* (ASD) cases among children, and the last two columns are the average annual increase and total increase from 2000, respectively.

As we can see from the table, not only the annual rate is high but also it seems to be increasing. It was 7.05% in 2018. This is an extraordinary growth rate. It implies that autism cases among children virtually double every 10 years. And if the trend continues, the rate will increase more.

The latest CDC report, which used 2018 data from 11 states, found a considerable variance in diagnosed ASD cases across states from 1.7% or 1 in 60 children in Missouri to 3.9% or 1 in 26 children in California.

We believe the above estimates are conservative because not all autism cases are diagnosed or reported. This premise is furthermore supported by the fact that autism prevalence tends to be higher in the National Survey of Children's Health and the National Health Interview Survey, both of which rely on parent-reported ASD diagnoses. For example, according to the former survey, 1 in 40 children had autism in 2016, which 35% greater that the prevalence of 1 in 54 children that CDC reported. (In general, the CDC tends to exaggerate estimates or premises when they translate to greater pharmaceutical revenue, and underestimate or downplay them when

Year	ASD	Annual Increase (%)	Total Increase (%)
2000	1/150		
2006	1/110	5.30	36.36
2014	1/59	6.89	154.24
2016	1/54	6.59	177.78
2018	1/44	7.05	240.91

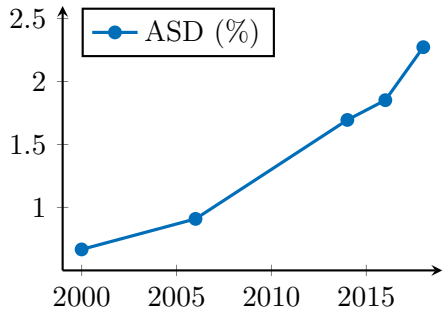

Table 11.1: Autism spectrum disorder (ASD) prevalence among children in the United States.

they have the opposite effect or may have negative consequences for pharmaceutical products.)

The above numbers establish that both autoimmune disorders and autism are epidemics with increasing prevalence. The current rates are alarming and their growth even more so. Yet, they do not receive much attention in the media. Such attention is clearly not in the best interests of big pharma and complicit establishments or governments.

Medicine has failed to provide a substantial explanation for those epidemics. Various attempts are not merely without merit. They are usually pharmaceutical propaganda. They are not worth scrutiny or a detailed examination – but they demonstrate the level of corruption, misinformation, and mis-

direction in the new religion of false medicine.

One particular misdirection effort is the argument that the supposed link between autism and vaccines has been refuted. This is yet another fabrication by big pharma. To the best of our knowledge, the link has neither been established nor refuted. Supporting evidence is limited, questionable, or flawed; but contradicting evidence is much worse. The entire literature on vaccine safety is abysmal. It is relatively rare to find a study that is not flawed, fraudulent, or fabricated. Many are less conspicuous in their effort to confuse and misdirect but they share a common approach – and flaw. Instead of examining vaccines and vaccination schedules as a whole and the potentially detrimental synergistic effect of such schedules, each 'refuting' paper focuses on an individual vaccine. Then they combine all data into a single group without considering age, the number of prior vaccine dosages, and more importantly the symptoms or any other evidence of an acute immune response to prior vaccine dosages. Not surprisingly, their coarse mixture and singular approach do not produce a significant correlation with autism; and the authors report their results without mentioning the obvious limitations of their method. Even worse, some authors make an inferential quantum leap in the end and claim that their finding implies that vaccines (note the plural) do not cause autism.

Invariably, those studies are subsequently cited in other papers and public media with various inaccurate, sensational, and propagandist descriptions that the supposed link between autism and vaccines has been "refuted" or "debunked". (The latter verb appears far more frequently in popular media in order to make an impression, exploiting the fact that the average person does not have the time to study the related publication(s) or the skills to identify the falsities and deceit.)

In general, vaccines are not as dangerous individually.* As we have explained, the probability p that any given vaccine would cause a specific adverse effect tends to be relatively

*The Gardasil HPV vaccine is probably a notable exception.

small. However, this is not the case for the probability p_k as the number of dosages k grows, if the source of the adverse effect is the immune system or persistent changes in the immune system as a learning system. This is a very simple fact. Studies that examine the safety of individual vaccines have limited or zero value and utility – except as a tool to spread misinformation and fallacies.

Once more we should consider the ulterior motive hypothesis. Are all those researchers and doctors so ignorant and naive that they do not see the errors in their approach and the use of their work for misinformation and propaganda purposes? Do they not understand that they contribute to the new religion of false medicine and thus damage their field and science and the credibility of science as well? Even if there are some researchers that fit this unlikely description, the vast majority does not. There is an ulterior motive behind such misleading publications – and it is almost always financial or career-related.

Studies that focus on the synergistic effects of vaccines are relatively rare but they do exist. For example, a comparative study was published in 2011 in the Human and Experimental Toxicology journal. The study examined the synergistic effect of vaccines on *infant mortality rate* (IMR) across nations with different immunization schedules. The authors considered 34 such nations* and found a correlation coefficient of 0.70 ($p < 0.0001$) between IMRs and the number of vaccine doses routinely given to infants. They also grouped the nations into five different ranges of vaccine doses: 12–14, 15–17, 18–20, 21–23, and 24–26. (The U.S. childhood immunization schedule specifies 26 vaccine doses for infants aged less than 1 year – and those are the most in the world.) Using linear regression,

*There is a bias in the study for lower IMRs since those are the 34 nations with the lowest IMR globally, the U.S. being the last one. However, the list includes most developed nations and those have more reliable statistics and they are more appropriate for a comparison with the U.S. Conversely, we can say that the study is primarily about developed nations.

the authors found a correlation of 0.992 (p=0.0009) between the average number of vaccine doses and average IMR of each group. Furthermore, they found statistically significant differences in mean IMRs between nations giving 12–14 vaccine doses and those giving 21–23 and 24–26.

The same authors published another study in 2012 about the relationship of infant mortality and hospitalization rates in the U.S. using the nation's *Vaccine Adverse Event Reporting System* (VAERS). They found a positive correlation between the number of vaccine doses administered and the percentage of hospitalizations and deaths. They also pointed out an issue of missing evidence from clinical trials and unjustified extrapolations. As the authors explained, "2-, 4-, and 6-month-old infants are expected to receive vaccines for polio, hepatitis B, diphtheria, tetanus, pertussis, rotavirus, Haemophilus influenzae type B, and pneumococcal, all during a single well – baby visit – [sic] even though this combination of 8 vaccine doses was never tested in clinical trials." We consider such a practice to be dangerous and unjustifiable. We cannot be using such extrapolations and assume them to be science. It is imperative to collect data and perform synergistic studies on all combinations of vaccines that infants regularly receive.

In order to understand the synergistic adverse effects of vaccines in detail, we need considerably more extensive and fine-grained studies. However, the above two studies suggest that the number of vaccine dosages recommended by the vaccination schedules of various countries have already surpassed the inflection point – where the risks of adverse effects of vaccines outweigh their benefits. The current *CDC vaccination schedule* includes 72 doses of vaccines for children up to age 18; and that is probably excessive. Vaccines do not seem to scale well, and if that is the case, their numbers should not be increased arbitrarily or indefinitely. The risks are greatly aggravated by the use of immunologic adjuvants and particularly by the easier but over-simplifying convention to use the

same amount of adjuvants for all children.

Overall, it is highly unlikely that the current vaccination schedules and vaccines with predefined amounts of adjuvants have nothing to do with the autoimmune disorder and autism epidemics. The only question is whether they are the primary cause of it, or how much they contribute to it. In order to obtain estimates, we need elaborate studies that treat the immune system not as stateless automaton but as a complex learning system. Yet, such studies can only be independent. They will never be funded or promoted by the pharmaceutical sector and are unlikely to be implemented by governments. The pharmaceutical sector will keep spreading fallacies and fabrications, expanding their new religion as much as they can; and governments will most likely do nothing to stop, impede, or even inconvenience them.

11.3 Rationality versus Profit and Greed

A counterargument in support of vaccines is about the considerable number of deaths and hospitalizations that vaccines have probably prevented, especially among children. As an example, it is sometimes pointed out that most pertussis deaths occur in infants of age of 3 months or younger. This is not surprising. The younger the infant, the more likely the death from such a disease. However, there is often an argument that pertussis is largely prevented by vaccination for older infants. (The CDC immunization schedule recommends the first 4 doses of the *DTaP vaccine* to be administered at 2, 4, 6, and 15 months of age, respectively.)

The above are complex arguments and they have both valid and invalid elements that are not directly evident. Some of those elements are arguably against vaccines and especially the current medical paradigm where vaccines are the primary tool against infectious diseases. Let us examine them in more detail.

The first of the above two arguments derives from the im-

plicit assumption that vaccines and the immune system are the best or the most effective way to fight diseases. There are cases where this is most likely true. For example, vaccines could be a great tool for certain non-infectious but likely fatal diseases. *Immunotherapy* is an important and promising direction in treating various forms of cancer. Different strategies are currently used or explored. Vaccines are neither the only nor the main approach, but one of the oldest cases is the *BCG vaccine*, which was originally developed for tuberculosis but was later used to treat bladder cancer. In general, if a vaccine can be used to train the immune system to attack or inhibit cancerous cells and tumors in patients, its chronic adverse effects would be largely irrelevant.

However, the situation is not so clear for infectious diseases and it leans in the opposite direction.

For bacterial diseases, the typical alternative is antibiotics, which sometimes have significant adverse effects. It is not clear which approach is better. If the number of vaccines is reduced and the schedules are modified so that vaccinations take place at a later age in children, it is possible that vaccines may turn out to be a better approach. Of course, the greater the age the more likely that a child may contract an infectious disease prior to the corresponding vaccination. The immunization schedule thus represents a trade-off that should be fine-tuned – and preferably on an individual basis.

The argument in favor of vaccines can furthermore be strengthened by research and development of methods and screening that determine the proper amount of the various immunologic adjuvants for each child. Such research is imperative if vaccines are to remain as a tool against infectious diseases.

On the other hand, an argument in favor of antibiotics is that they have received much less attention and funding in medical research and especially in big pharma because they are incomparable with vaccines in terms of revenue. Vaccines are the most lucrative pharmaceutical product, while antibi-

otics represent a negligible fraction of revenue. Fungi are a potential goldmine for future antibiotics as researchers at Chalmers University of Technology in Sweden have pointed out. Would a new generation of antibiotics work better than vaccines and with fewer or less severe adverse effects and chronic conditions? We will not know until we investigate. The comparison cannot be fair or accurate until we provide comparable amounts of funding for antibiotic research.

Moreover, it is probably this deficit in antibiotic research that is the main reason for the pertussis deaths in infants. If we had equally invested in antibiotic research and discovered more effective molecules, many pertussis-related infant deaths may have been avoided. The current paradigm where vaccines dominate infectious disease research derives from revenue and greed, not rationality. It has an excessive emphasis on prevention and it suffers when treatment is required.

Overall, the argument of vaccines versus antibiotics is open. Further research is required. If a hybrid approach is used, better antibiotics that significantly reduce the probability of death in children would also allow for vaccinations to be delayed further and thus reduce their probability of severe adverse effects and chronic autoimmune disorders.

The situation is a less uncertain – and more revealing – when we consider viral diseases. Vaccines and the immune system ought to be the last line or defense, not the first one. The real solution to viral diseases is to develop an antiviral neural system that is trained on viruses and learns to fold proteins that target the molecular structure and/or the DNA/RNA of the viruses. Such an expert system can discover and encode treatments for potentially millions or billions of different pathogens.

The same approach can apply to bacterial diseases, too. For example, the protein NOD2 is known to fight off bacterial infections by sensing the presence of bacteria and alerting immune cells. The key element in fighting infectious diseases is protein treatment. Proteins are described as building blocks

of life. Their primary and essential role in fighting infectious diseases is not a coincidence but a direct consequence of the very structure of life.

On the other hand, our immune system is largely a reactive learning system. Efforts to use it or transform it into an expert antiviral or antibacterial system are likely to be futile – and dangerous. It is a form or intervention that demonstrates hubris and ignorance. Life and evolution are highly unlikely to produce such a system or provide a basis for it inside our bodies. If such an expert system existed inside each living organism or human being it would represent an excessive waste of time and resources and it would require increased amounts of hereditary information to be passed from each generation to the next. Furthermore, viruses and bacteria are a potential stabilizing factor in ecosystems because they can be used to cull populations that grow excessively. Consequently, an expert antiviral immune system would constitute a dangerous and destabilizing factor. Evolutionary pressure would be against it, not in favor of it.

In short, an expert antiviral system should be an independent system outside our bodies developed by science and technology. Our immune system cannot be anything of the sort.

As a result, research and development against infectious diseases should have focused on the development of such a system. Data and sufficient computing power have been available for at least two or three decades now. Yet, very little research and even less funding has been allocated to that direction. Instead, the emphasis is on vaccines and drugs for chronic conditions, which are developed with a slow and painstaking human-centered approach. Big pharma understands that cheap protein treatments are a direct threat to vaccines that could diminish their revenue. They would never support such research and they would only use their power and influence to bias governments and the medical establishment against it and in favor of vaccines.

A direct consequence of the above is that protein structure prediction breakthroughs in 2021 came from the technology sector, not the pharmaceutical sector or medicine. Another direct – and considerably more severe – consequence is that current medical research is trapped in a strategy and approach that can only lead to failure. This failure has many forms as we pointed out in the beginning of this chapter (autoimmune and autism epidemics, viral pandemics, vaccine mandates, lockdowns, oppression, and the associated economic and social hardship and decline.) This is indeed the unfortunate legacy and the outcome of the vaccine-centered approach to infectious diseases that big pharma has effectively imposed upon medicine and humanity with the assistance of complicit governments and the medical establishment.

Vaccines remain the main tool against infectious diseases to this day because they are a lucrative product for the pharmaceutical industry. They represent an irrational, shortsighted, and problematic approach because they have been used without restraint, early in the lives of children, uniformly across the entire population, and with the same constitution for all human subjects; but more importantly because they have displaced other approaches to infectious diseases that are more durable and effective, more scalable and strategic, and less expensive.

In a sense, vaccines – and particularly current vaccine schedules and potential vaccine mandates – represent a battle between rationality on one side and profit and human greed on the other side. One might think that rationality should easily win such battles. However, rationality is not always a factor in human affairs, it may not prevail in the end, and it may suffer for a long period of time before it becomes common wisdom.

12

10,000 Vaccines!

At present, there is no bound to the vaccine propaganda that is generated or promoted by the pharmaceutical sector. One of the most egregious examples is summarized below.

In 2002, an article was published in the *Pediatrics* journal where the authors included a sophomoric estimate that each infant has "the theoretical capacity to respond to about 10,000 vaccines at any one time (obtained by dividing 10^7 B cells per mL [of circulating blood] by 10^3 epitopes per vaccine)." They then stated that "if 11 vaccines were given to infants at one time, then about 0.1% of the immune system would be 'used up'." Their estimate was subsequently used in various publications and articles on the internet to claim that the immune system of infants can handle up to 10,000 vaccines simultaneously. The estimate was also upgraded to 100,000 vaccines in a newsletter from the Children's Hospital of Philadelphia, which employs the article's main author. We quote from the newsletter: "In fact, Dr. Offit's studies show that in theory, healthy infants could safely get up to 100,000 vaccines at once."

Let us now demonstrate that all this is not science. It is not alchemy either. It is absurdity and propaganda that has been deployed for public consumption. We explain the many flaws of the argument below.

First, there is no concept of a 'used up' immune system. There is no such term in medicine. It is meaningless for learn-

ing systems and processes. This fabrication by the authors is a relatively minor indiscretion but it is indicative about the low quality and non-scientific nature of their publication.

Second, what the authors define as 'capacity' is the *channel capacity* of circulating blood as a *communication channel* to the immune system. Mathematically, the transmission of information from a vaccine to the immune system requires a communication channel (which, in this case, is circulating blood in infants); and the capacity of the channel is the upper bound on the rate at which information can be reliably transmitted over the channel. This is basic *information theory* – which the authors of the above article do not seem to understand.

Third, the immune system is a learning system and its response to any stimuli is largely determined by its learning efficacy and internal state (and thus prior history). It is not determined by the capacity of its input channel(s) by any means. For example, the number of pixels in visual stimuli have nothing to do with the response of an organism to such stimuli. Even a tiny percentage of those pixels could put the organism in high alert if they indicate the presence of a predator. The same is true for the immune system. A relatively small number of epitopes can elicit an acute response.

Conversely, if the response of a learning system were determined by the bulk of the information in its input communication channels that system could not possibly be sufficiently discriminant; it would be unresponsive and practically useless because, most of the time, most of the input capacity would be irrelevant or not even used. Such an immune system could not offer any protection against pathogens; and it could not process vaccines either and create an immune response except if thousands of vaccines were administered simultaneously.

The fourth flaw of their argument is that the authors of the above study compare routine exposures to environmental pathogens with combinations of derived pathogens from serious diseases. They treat them as similar or equivalent

without ever providing any evidence that they are.

More importantly, in their fifth flaw, the authors completely ignore inflammation from vaccines and the immunologic adjuvants that are used in vaccines. Adjuvants, in particular, have a significant effect on the learning process in immune systems. They substantially enhance the immune response to a vaccine. If they were so irrelevant or insignificant that they could be completely ignored, as the above authors did in their 'method', they would not be used in vaccines in the first place.

Finally, in their sixth and most serious flaw, the authors ignore the synergistic effect of multiple vaccines to the immune system and thus treat it as though it were not a learning system at all bur rather a finite-state automaton. This is a dramatic reduction and oversimplification. Even if we could somehow ignore the rest of the sophomoric flaws in their argument, this failure alone completely invalidates it. If 10,000 vaccine are administered to an infant, the probability p_{10000} would be significant or even close to 1.0 for most adverse effects of the vaccines, death included.

We can only recommend that the authors of the above paper obtain some laboratory evidence, which is conspicuously absent from the article, in order to understand the magnitude of their fallacy and folly. However, we must also warn about the consequences of any such experiment. If a person or an institution administers 10,000 vaccines to a laboratory animal, they would be accused of cruelty to animals; if they administer them to an infant, they would be charged with murder.

We can now consider the ulterior motive hypothesis. Are the above authors so ignorant and foolish that they do not see the many flaws of their approach and they do not understand how ludicrous and sophomoric it is? This is the naive interpretation, and it is highly unlikely in our opinion. It is almost certain that there is an ulterior motive behind their false and outlandish claim.

We cannot be certain about the exact motives of all the authors and they may vary per person, but, for example, the main author holds vaccine patents, he has vested interests in the vaccine market, he has made his career on vaccines, and he has clear ties to the pharmaceutical sector and probably financial interests. His case corresponds to an avalanche of conflicts of interest.

Furthermore, if we assume that the authors are not ignorant fools and they intentionally misled the medical community and the public into an argument that 10,000 vaccines are somehow safe for infants, their actions and their publication constitute a violation of the Hippocratic oath – which explicitly requires physicians to "abstain from all intentional wrong-doing and harm." We will refrain from using an epithet for the above authors. Readers can decide whether their case is about ignorance, misinformation, dishonesty, or a more severe and unethical condition and state of mind.

In general, when such absurd claims are made, it is reasonable to expect a vigorous response from the medical establishment that challenges, criticizes, or refutes the claims. Given that the main author was a professor of medicine at the University of Pennsylvania and a director in The Children's Hospital of Philadelphia at the time of his publication, it is equally reasonable to expect that the university and the hospital would issue a letter to distance themselves from those false and reckless claims. Given that the main author was also a member of the CDC Advisory Committee on Immunization Practices, it is perhaps reasonable that the CDC issued a statement, too, if we could assume that the CDC is not utterly corrupt.

However, such expectations and assumptions are naive. They do not take into account big pharma, their extensive web of power and influence, the propaganda they have deployed, and the corruption, conflicts of interest, and connections that they have created in the government, medical and regulatory institutions, and medicine as a profession and sci-

entific field. In short, such expectations and assumptions underestimate the extent and the authority of the new religion of false medicine and its church.

Therefore, it is no surprise that the authors of the above study did not receive any criticism from the system, and they did not suffer any detrimental consequence. Their case is just one more incident in the religion of false medicine. Yet, it demonstrates that there are no bounds in this religion, there is no accountability whatsoever, the related businesses will go on, and they will not be adversely affected – no matter how outrageous their actions or statements might be.

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Third and Fourth Generation Contraceptives

In this chapter, we will examine the case of third and fourth generation contraceptive products, namely the *NuvaRing*, the *Ortho Evra patch*, and the *Yasmin* and *Yaz* pills.

in order to demonstrate how the pharmaceutical industry manipulates or corrupts regulatory institutions.

We will start with financial details, lawsuits, and settlements because those are usually more informative and indicative than biased studies. Here are some relevant facts:

1. NuvaRing is a contraceptive vaginal ring that was developed in the 1990s by the Dutch drug company *Organon*. It was approved in the European Union and the United States in 2001. *Schering-Plough* acquired Organon in 2007 while Merck acquired Schering-Plough in 2009.

2. A first lawsuit in 2008 alleged that the manufacturers, distributors, and marketers of NuvaRing concealed associated health risks. One of the most serious risks is *venous thromboembolism* (VTE), which is life-threatening blood clotting. The first trial from a pool of 1850 lawsuits was scheduled to begin in April 2014 but in February Merck & Co proposed a settlement of the lawsuits

for $100 million. The settlement was approved in June 2014 with about 3800 claimants sharing it. In comparison, NuvaRing earned Merck $623 million in 2012 alone.

3. The contraceptive patch Ortho Evra was developed by *Ortho-McNeil Pharmaceutical* (a subsidiary of Johnson & Johnson). According to a *Los Angeles Times* article in 2006, Johnson & Johnson had sold patches to 5 million women since Ortho Evra's launch in 2002. In 2005, the FDA ordered a black-box warning in the package, and sales eventually dropped by 80%. The initial warning indicated that higher doses of estrogens were delivered via the patch than traditional contraceptives, which might increase the risk of side effects such as blood clots and strokes. The warning label was strengthened in 2006 and 2008, warning that women were exposed to 60% higher levels of estrogen than other contraceptives.

4. By 2008, at least 4000 complaints had been filed against Johnson & Johnson, alleging that the company "failed to investigate the safety of the drug properly and deceived the public about the severity of the side effects." According to documents obtained by Bloomberg News, Johnson & Johnson paid out about $68.7 million to settle hundreds of lawsuits by women who had allegedly been harmed by the patch; the company settled the suits privately and failed to release the financial details to investors.

5. The birth control pills Yaz and Yasmin were developed *Bayer AG* and they were approved in the U.S. by the FDA in 2001 and 2006, respectively. According to New York Times, the Yaz and Yasmin franchise was marketed not only as a contraceptive but also as a quality-of-life treatment to combat acne and severe premenstrual depression. It had worldwide sales of about $1.8

billion in 2008.

6. By 2019, more than 19,000 lawsuits about Yaz and Yasmin were resolved. Settlement amounts were estimated to be $2.13 billion ($2.04 billion for blood-clotting cases, $56.9 million for heart attack and stroke cases, $21.6 million for gallbladder cases, and $20 million for misleading advertising).

As it can be seen from the above numbers and perhaps inferred from FDA's warning about the Ortho Evra patch, the main issue with third and fourth generation contraceptives is VTE (blood-clotting).

Ethinylestradiol (EE) is as estrogen that is used in birth control products in combination with *progestins*.* It has been combined with the second generation progestin *levonorgestrel* to make combination birth control pills. In more recent years, it is combined with third and fourth generation progestins. For example, it is combined with the progestins *etonogestrel*, *norelgestromin*, *drospirenone* in the NuvaRing, the Ortho Evra patch, and Yaz and Yasmin pills, respectively. (Yaz contain 0.02 mg of EE while Yasmin contains 0.03 mg.)

Studies have shown that birth control products containing EE and a progestin increase the incidence of VTE in women by about 400%. The combinations with third and fourth generation progestins seem to increase the risk further. For example, the combination with drospirenone (which is used in Yaz and Yasmin) has been estimated to increase the risk by an additional 200% to 300% when compared to a combination with levonorgestrel. Similarly, a study with over 1.6 million women concluded that vaginal rings and transdermal patches increase the risk of VTE by 650% and 790%, respectively, compared to non-users. Additional studies estimated that third and fourth generation oral contraceptives increase the

*A progestin is a synthetic progestogen; and a progestogen is medication that produces effects in the body that are similar to those of the natural female sex hormone progesterone.

risk of VTE by 150% to 240% compared to second generation oral contraceptives.

The third and fourth generation contraceptives are typical examples like those described by Relman and Angell in their articles about the pharmaceutical sector and Angell's book. They do not represent innovations; they are marginally better, if at all, when compared to previous similar products; and they introduce higher risks of side effects, including life-threatening conditions like VTE. Patents of existing contraceptives were expiring. (Patent expirations allow third parties to manufacture the corresponding drugs and sell them at a lower price, often 80% lower, as Relman and Angell explain.) The new contraceptives introduced new patents and allowed the drug companies to keep the prices high. They were marketed aggressively not only to potential users but also to doctors who prescribe them (kick backs and other incentives for prescribing new brand name drugs are common in the medical profession according to Relman and Angell). Their increased risks were meticulously concealed. The result of all this is about 25,000 lawsuits, extensive and unnecessary human suffering, and at least 100 alleged deaths of young and healthy women.

The cases of the above three contraceptives are virtually copies of each other – particularly regarding how they manipulated, deceived, or corrupted regulatory processes and institutions. In the rest of this chapter, we will focus on the NuvaRing only and show how it was approved in the U.S.

In 2013, the magazine *Vanity Fair* published an article about the NuvaRing and its side effects titled "Danger in the ring." In the same year, *The Huffington Post* published an article on the same topic "Side effects may include death: the story of the biggest advance in birth control since the pill."

Those two articles contain such a wealth of information that is hard to summarize. They are examples of critical investigative journalism, and they illustrate human injury and death. The Vanity Fair article shows the suffering of the

family of the diseased and their efforts to seek justice for their daughter's death. It also describes the arduous legal process to bring a case against big pharma to courts and the various tactics that big pharma uses to overwhelm the process and intimidate plaintiffs in order discourage or suppress litigation.

Referencing internal emails, the Vanity Fair article shows how Schering-Plough drug representatives were instructed to downplay the risks of NuvaRing compared to other contraceptives in their discussions with doctors. They were given scripts to steer the conversation and favorably compare the NuvaRing to competing products like the Ortho-Evra patch. The Vanity Fair reporters even sent two women to seek the vaginal rings and found that the two health care providers assured the patients of the safety of the ring despite a family history of heart disease and diabetes in one case.

Both articles cite literature that points out the increased VTE risk of third and fourth generation birth control. Both articles demonstrate the regulatory failure in great detail and point at potential corruption in the FDA.

Let us consider some of the details in order to understand how and why the FDA has failed to protect the public with proper warnings and labeling on the NuvaRing – to this day. (The information below is primarily from the above two articles and their various sources and referenced publications.)

In one of the clinical trials for the approval of NuvaRing, a healthy woman in her 20s developed a blood clot. The FDA subsequently instructed the maker of the NuvaRing, Organon, to include a statement in NuvaRing's packaging insert with a warning of a higher risk of blood clots.

Organon executives, who were planning to market NuvaRing as an innovative, easier to use, and safer product, started a negotiation with FDA to remove the statement. Pharmaceutical companies usually have the upper hand in such negotiations. They not only control clinical trials and provide results and data for review but also pay fees that account for about 70% of the funds for such reviews. As a result, the approved

label for NuvaRing in 2001 included only a general warning about the risk of blood clots without mentioning their occurrence during the clinical trial and its probable connection to NuvaRing. In internal Organon emails and memos, there was clear satisfaction about the "deletion of the singe VTE case", according to the Huffington Post article.

Another issue with the FDA approval was the trial No. 34218, which included only 16 women and yet two women had massive estrogen spikes in the first days of the trial and two other women has similar estrogen spikes midway through the trial. This is a substantial side effect that should have been prominently displayed in the application and should have prompted a more detailed examination. However, those facts were not even included in the 30-page summary prepared by Organon for the FDA. Instead, they were buried within the thousands of supporting materials of the NuvaRing application, and they may have evaded notice by the regulatory authorities. Although such an action is not illegal, it is an obvious effort to conceal important but inconvenient facts. When we combine those facts with an actual case of deleted VTE and we consider the limited size of those trials, the evidence should be more than alarming.

Did the FDA miss those important facts about estrogen spikes? We cannot be certain. In 2008, amid the furor and as evidence emerged and FDA strengthened the black label that eventually led to the demise of the Ortho Evra patch, FDA commissioner A. von Eschenbach stated that "the F.D.A. of the 20th century is not adequate to regulate the food and drugs of the 21st century," according to the Vanity Fair article.

Organon and Schering-Plough clearly did not miss the spikes. According to court documents for one of the cases covered in the Vanity Fair article, Organon scientists were concerned with "the burst release" in "large-scale NuvaRing batches" in 2001. A member of the regulatory-affairs team e-mailed a colleague, "This is a very serious issue, in that FDA

is very sensitive to the 'burst release' phenomenon and release in general. Going to FDA to change these specifications is absolutely the LAST thing we should consider, i.e., that's the worse possible scenario."

T. Hadley, who supervised marketing in Schering-Plough was also concerned about a type of VTE called *deep-vein thrombosis* (DVT), which is the formation of blood clots in one or more deep veins. In October 2009, he emailed a colleague: "Do we have anything for the reps to use to help direct the conversation away from DVT? Didn't we create a letter for them to use reactively?"

Perhaps the more remarkable aspect of FDA's failure in this case is how it extended considerably beyond the initial approval of the NuvaRing and against significant evidence.

Dr. S. Parisian, who was a former chief medical officer at the FDA, prepared a report for the legal team of the plaintiffs. She explained that after the NuvaRing had been on the market for two years, there were enough DVT cases that Organon should have updated the launch label with "relevant warnings" in order to be in compliance with FDA rules. However, Organon handled those cases as separate spontaneous events documented in annual reports scattered over several years and "did not highlight their occurrences or recalculate the incidence rate of VTEs until its 2006 Expert Clinical Documentation report – a possible violation of federal safety regulations."

As the Huffington Post article indicates, the increasing number of reported VTE cases forced Organon to form an "issue team" to address the growing crisis in August 2006. They met with S. Allen, who had recently left her job as a director of the FDA's Reproductive and Urologic Drug Products Division – the very division that had signed off the NuvaRing approval. Few months later they hired her as a consultant to "develop a strategy to respond to an FDA letter requesting that Organon conduct a U.S. safety study to assess NuvaRing's VTE risk."

The case of S. Allen is not unique. J. Gerberding, who served as CDC director from 2002 to 2009 and may have helped with efficacy and safety issues of Merck's Gardasil HPV vaccine, subsequently accepted a position as Merck's Vaccine Division president – a sinecure with stock options for her courtesies, per R. F. Kennedy, Jr.*

Such cases demonstrate the revolving door between regulatory institutions and the pharmaceutical industry. It is a process that allows officials to oversee products and regulation of prospective or forthcoming employers. It is a mechanism of corruption; and it should be outlawed. At the very least, when such transitions take place, they should trigger an automatic review of associated decisions and approvals by an independent committee.

In 2012, an important development was an extensive study by Ø. Lidegaard et al. that was published in The BMJ. As we mentioned earlier the study involved 1.6 million women and concluded that vaginal rings and transdermal patches increase the risk of VTE by 650% and 790%, respectively, compared to non-users.

Lidegaard's prior study on the contraceptives Yaz and Yasmin had indicated increased VTE risk and effectively forced a label change for both of them by Bayer AG. His results on the NuvaRing also resulted in a label change for NuvaRing in Canada.

In the United States, the FDA chose to ignore Lidegaard's extensive study and use much smaller studies – a clinical

*We quote R. F. Kennedy, Jr. from childrenshealthdefense.org: "As Centers for Disease Control (CDC) Director from 2002-2009, Gerberding helped Merck paper over these efficacy and safety problems. In 2006 she gave Merck the CDC recommendation that made Gardasil a $5 Billion blockbuster. Gerberding did other lucrative favors for Merck; blocking whistleblower Gary Goldman from disclosing that Merck's chicken pox vaccine was causing a deadly shingles epidemic, silencing and punishing whistleblower Dr. William Thompson when he told her that CDC bigwigs were destroying data linking Merck's MMR to autism, and allowing the company to illegally reformulate its MMR mumps component. Those courtesies earned her the Merck sinecure and stock options."

trial by Merck and a 2011 FDA-funded study. Merck's study showed no increased VTE risk from the NuvaRing compared to combined oral contraceptives, while the FDA-study showed only a slightly higher risk for NuvaRing users.

However, those studies are not only smaller and less reliable, especially given the way clinical studies are performed in the U.S., but also misleading. The difference between combination oral contraceptives, the NuvaRing, and transdermal patches is important but secondary. The main issue is whether third or fourth generation contraceptives have higher VTE risks than second generation combination pills. The latter difference has been shown to be significant. There have not been any results that support the opposite argument – albeit we are certain that big pharma can easily conjure up some 'evidence' with a sufficient small clinical trial, all the control they have over such trials, and cherry-picking participants.

The above results and actions by the FDA suggest corruption. We can understand that the FDA may have missed the estrogen spikes in Organon's initial application. We can be generous about their deletion of the VTE case. However, we cannot possibly justify their actions beyond that point, as evidence accumulated about the higher risk of third and fourth generation contraceptives and the above facts about Organon's application became public knowledge. The FDA effectively used double standards, ordering a black-box warning for the Ortho Evra patch but not for the NuvaRing. Although transdermal patches tend to have higher VTE risk than the NuvaRing, as Lidegaard work demonstrated, the increase is limited ($790/650 - 1 = 21.54\%$). If one of them comes with a black-box warning so must the other.

Moreover, the FDA not only ignored Lidegaard's work but also used smaller and possibly biased or irreproducible studies by Merck and themselves that compared pills and rings instead of second and third or fourth generation contraceptives.

In our view, there is an overall effort for misdirection and cover up in the FDA actions; and those suggest corruption.

On the other hand, we do not feel that the FDA is largely a corrupt institution – even though corruption maybe a perennial issue. There are many people in the FDA with high integrity standards and uncompromising ethical and moral values. They try to do their jobs but they are up against the corruptive influence of the most fraudulent sector on earth and their web of power and against a system of revolving doors as well as a record of clinical trials and medical literature that is replete with biased and irreproducible studies, questionable results, and fallacies.

Examples that support our assertion about the FDA are outspoken FDA members who have openly discussed the influence and the power of big pharma; or statements by the FDA that contested CDC claims – such as claims about the effectiveness of the antiviral drug Tamiflu. (We believe that if an independent and thorough investigation were launched into those two institutions, it would find the CDC to be far more corrupt, if not the most corrupt institution in all of American history.)

On the human side, the FDA's decisions prevented a family from seeking justice for their daughter's death. E. Langhart died at the age of 24 after she suffered pulmonary embolism and two heart attacks that were allegedly caused by the NuvaRing. Her parents refused the Merck-proposed settlement and sought to take their case to the courts. According to the newspaper The Durango Herald, "the lawsuit against Merck was complicated by a move by the U.S. Food and Drug Administration in 2013, which changed the NuvaRing label, but stopped short of including a stricter warning. If the label didn't require a tougher health warning following Erika Langhart's death, then it didn't need one before her passing, attorneys argued, paving the way for a dismissal." The case was finally dismissed by a San Francisco Superior Court on September 10, 2015.

Finally, there is a letter by a chief medical officer at Merck that was sent to Huffington Post after they published their article on the NuvaRing. The letter is attached at the end of the article and it is full of marketing generalities. Its only substantial argument is the claim that "More than 44 million prescriptions for NUVARING have been filled in the United States. Your report focuses on a small number of potential adverse events, with little acknowledgement of the substantial evidence of the safety and efficacy of NUVARING."

However, the above claim is inaccurate and misleading. According to Wikipedia,* "In two large studies, over a one-year period, 15.1% of users discontinued NuvaRing because of adverse events." If we assume those estimates to be accurate then one in 6 or 7 women experience adverse events and, as a result, the number of adverse events among 44 million prescriptions cannot be small. We trust that a chief medical officer at Merck can do multiplication and thus be aware of the fact, despite their opposite claim.

More importantly, the issue with the proper warnings on NuvaRing, or any medical product for that matter, is not about the trivial claim that it is safe for the majority of its users. This is true for almost every drug that has ever been developed. Even Merck's drug Vioxx, which was withdrawn after a study associated its use with approximately 60,000 deaths, was safe for most of its users and it clearly did not kill the majority of them. The intent of warning labels is about the minority of people who are more likely to be injured or

*Wikipedia fails to mention that one of those studies was funded by Organon and that the main author was an employee of Organon – which may imply that the actual rejection rates were higher. The claim that those were large studies is also an exaggeration. A total of 2322 women participated in the first study and 2501 women in five clinical trials of NuvaRing. Those are not large sample sizes by any means and they cannot provide reliable estimates for adverse effects with small probabilities. Those incidents support our argument that Wikipedia is vulnerable to pharmaceutical propaganda – especially when it is disguised as science – and it can be used to spread misinformation as we shall demonstrate with a specific example in chapter 14.

die of potential adverse effects. Warning labels have to be detailed and accurate so that such people and their doctors can make more informed decisions. When the labels downplay the risks, the doctors will usually follow them without further research. It is hard or impossible for practicing doctors to do such research and for all drugs they can potentially prescribe. Big pharma has furthermore secured their cooperation with aggressive marketing, misinformation, kick backs, and various other incentives for prescribing new and patented brand name drugs – as Relman and Angell have explained in great detail.

The result of all this is that, even today, the NuvaRing does not come with appropriate warnings. We can thus claim that the negative publicity and private media like Vanity Fair and Huffington Post have contributed more than the FDA in public awareness and protection from the adverse effects of the NuvaRing. This is a major regulatory failure and a typical example of manipulation or control of regulatory institutions by big pharma.

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False Medicine

In this chapter, we will consider a specific example in order to understand (or begin to understand) how fallacies and falsifications enter the medical record and scientific publications, propagate through the media and the internet, and eventually rise to the level of established facts not only in medicine but also in public opinion. Let us examine this specific case in detail.

Some reports after the first Gulf War have attempted to link *squalene* as an anthrax vaccine adjuvant to the Gulf War syndrome. The evidence is significant but it is not indisputable. We cannot confidently say that the link is established at this point. There are various complicating factors, too. Veterans were actually given a pertussis vaccine as an adjuvant to the anthrax vaccine – which is a medical decision that raises many questions and permits (and has received) serious criticism.

However, we would like to focus not on the claim itself and whether it is correct or not but rather on some of the reactions to it – which are quite revealing about the motivation and the forces behind them, the current state of medicine, and public opinion of medicine.

For example, a paper that was published in the *Clinical and Vaccine Immunology Journal* in 2006 studied the effect of an influenza vaccine with *MF59*, which is an immunologic adjuvant that was invented in the 1990s and uses squalene.

The study found that vaccination with the influenza vaccine "neither induced antisqualene antibodies nor enhanced preexisting antisqualene antibody titers." The authors of the study then concluded that "antisqualene antibodies are not increased by immunization with *vaccines* with the MF59 adjuvant. These data extend the safety profile of the MF59 emulsion adjuvant." (We have added italics in the previous sentence to indicate the spin and the fabrication.)

Even if we ignore the tiny size of the study, which invalidates it entirely, the above is not a scientific conclusion. It is neither deductive nor empirical. It is a fabrication and a manipulation of a plausible result to make it appear broader than it truly is. Let us understand why.

It would not be a surprising finding if the influenza vaccine with the MF59 adjuvant does not cause something comparable to the Gulf War syndrome. If it were, there would have been multiple reports, complaints, and lawsuits. Squalene, as the authors indicated in the very first paragraph of their paper, is a naturally occurring oil "produced by plants" and "also produced abundantly by human beings, for whom it serves as a precursor of cholesterol and steroid hormones."

Such a substance cannot possibly cause anything comparable to the Gulf War syndrome in all contexts. If it does, it must be under very specific conditions, dosage, and/or combinations with other drugs or vaccines. The fact that this adjuvant (or any adjuvant for that matter) does not cause a specific condition with the influenza vaccine does not even remotely imply that it has the same effect with all vaccines or with multiple vaccines.

This is a crucial factor not only for vaccines but also for any study that involves biological immune systems. Human immune systems are extremely complex learning systems. Computationally and mathematically, they cannot be described or represented by context-free grammars. They belong to a much broader class. They heavily depend on not only their current context but also their previous history and

prior experiences. When we remove the context or alter it, as when we substitute a combination of anthrax and pertussis vaccines with an influenza vaccine, we would most likely get different results. And even if the results happen to be the same, we cannot know that in advance. Therefore, we cannot generalize from one case to the other.

Let us now examine the tiny size of the sample that was used in the paper so we can further demonstrate its absurdity. It is not clear how many distinct individuals participated in the study but the four groups that they used had at most 43, 50, 48, and 52 individuals, respectively. The total is thus 193 or less (including the control group). This ludicrously small number is representative of the nonsense that is published in medical journals these days – as well as the abysmal state of publications related to vaccine safety. The paper is supposed to be a study of the effects on one of the most complex learning systems known to humankind, a system that arguably has extraordinary variance, and it uses only 193 individuals. Are we supposed to take something like this seriously? And assume that journals that publish such nonsense are credible? Is this really science or the new religion of false medicine where various convenient (and financially profitable) fallacies are magically turned into 'facts' using appropriately small sample sizes?

The case with the above paper is even more informative about the current conditions in medicine. Because such studies are cited on Wikipedia and in various popular non-academic media with the claim that the link between squalene and the Gulf War syndrome has been "debunked". (As noted previously, whenever the verb "debunk" appears in popular media or even on Wikipedia we can safely assume that it is propaganda with financial interests behind it. This case also demonstrates that sites like Wikipedia are highly vulnerable and they can become a source of misinformation under orchestrated efforts from big pharma and their many employees, contractors, consultants, lobbyists, influencers etc. Against

such an army, Wikipedia is defenseless.)

MF59 was developed in the 1990s by researchers at Chiron Corporation which was acquired by Novartis in 2006. The authors of the above study are researchers of Novartis in Italy and California. Their study is tiny and their conclusions unsupported and invalid because their work is not true research but corporate marketing and propaganda disguised as research in order to promote a product.

In general, as we have pointed out, it is the multiplicity of vaccines and their cumulative synergy with the immune system that are the likely cause of most of their adverse effects. This hypothesis is not new. For example, in a paper published in 1997, the authors considered the symptoms of the Gulf War syndrome and found them compatible with an immune system bias towards a Th2-cytokine pattern. They furthermore stated that "factors that could lead to a Th2 shift among Gulf War veterans include exposure to multiple Th2-inducing vaccinations under stressful circumstances." It is encouraging to see an emphasis on such factors and the overall context and synergy in the above paper. (Medical publications that are not propaganda of the pharmaceutical industry are usually more cautious in their claims and they are often more disciplined and robust.)

In another paper published in 2020, the authors systematically reviewed all original epidemiological studies about the association of vaccines with the Gulf War syndrome and found that all those studies (11 total) found a positive association between vaccination and the development of the syndrome. The authors furthermore discussed the clinical similarities between the Gulf War syndrome, the *post-HPV vaccination syndrome* (somatoform and dysautonomic syndromes after HPV vaccination), and *macrophagic myofasciitis* and found that chronic fatigue, widespread pain, and cognitive impairment characterize those three syndromes. They also considered pathogenetic mechanisms that have been described in patients with post-HPV vaccination syndrome as a relevant or

potential factor in the Gulf War syndrome and macrophagic myofasciitis. The authors concluded that the analogies between those three symptoms suggest that some vaccines or multiple vaccinations administered in a short period of time may induce chronic pain, fatigue and dyscognition in susceptible individuals. They hypothesized *vaccine-induced autoimmune dysautonomia* as the common pathogenetic mechanism and called for more research on the topic.

More research is indeed required to understand such syndromes and the role of vaccines in them. The current evidence is compelling but it is often dismissed because vaccines are a lucrative product and their safety is thus a sensitive topic.

Now, let us return to the MF59 paper and examine how such a paper can exist or be possibly published in an academic journal. We can always assume that its authors are so ignorant and foolish that they do not understand statistics and statistical significance, over-generalize, and they do not see anything wrong in their approach. That is the naive interpretation and, once more, it is highly unlikely or impossible, especially when we consider the conflicts of interest – given that the authors are employees of Novartis – or extend the above argument to the reviewers and editors of the Clinical and Vaccine Immunology Journal who must also be ignorant fools to allow such a flawed study to be published.

Most likely there is an ulterior motive behind such a publication. We cannot know for sure what the ulterior motive is but the evidence strongly supports its existence. We can probably make a good guess about it if we consider associated consequences. For example, if adjuvants or vaccines are indisputably linked to the Gulf War syndrome, there would be enormous financial reparations for the many veterans who are affected by the syndrome (estimated to be 250,000 in the US and 33,000 in the UK), the governments will suffer a serious blow to their reputations, and vaccine safety will become a wide open issue and debate. Even if we assume that governments could fail somehow to conceal or suppress such

an inconvenient link, the pharmaceutical industry will not. They will "debunk" all possible links with numerous biased, over-generalizing, or completely bogus and fabricated studies published in various journals by their own researchers or some of the many willing recipients of their funding in medical research. And they will most likely overwhelm critics by the sheer number of such publications.

The result of all this is that a large part if not the majority of medical research and publications are not science anymore but rather building blocks within a religion of convenient beliefs and harmful but profitable fallacies and fabrications. It is the new religion of false medicine.

15

A Technological Renaissance

In medicine, life ought to be the most precious quantity. Yet, in this Medical Dark Age and the new religion of false medicine, life, science, and truth have little value – profit, power, and corruption are the only factors that matter.

On the other hand, the Medical Dark Age does not represent a permanent condition of medicine or humanity. It will not last forever. In a fashion similar to the previous Dark Ages, it will come to an end and they will be followed by a Renaissance. It will be a technological renaissance generated by *neural networks* during this century. By the end of the century, we predict that the pharmaceutical sector will be largely displaced by the technology sector. Big pharma and their web of power and corruption will become history. And they will only leave behind a trail of greed and fraud, falsification of medicine, corruption and manipulation of government, and an extensive human and social cost.

Let us now consider some facts and trends that can help us understand how this transition will happen.

DeepMind's neural network system for *protein structure prediction*, known as *AlphaFold2*, was named the 2021 Breakthrough of the Year by *Science* magazine. *Critical Assessment of protein Structure Prediction* (CASP) is a worldwide biennial competition for protein structure prediction that

started in 1994. It uses metrics between actual and predicted alpha carbon positions in target protein molecules and derives an aggregate score as a measure of protein structure prediction accuracy. In 2020, DeepMind's neural system AlphaFold2 achieved a record median score of 92.4, which is on par with experimental techniques. The result has been hailed as an "astounding" and "transformational" breakthrough. In 2021, DeepMind announced that they had solved the structure for 350,000 proteins found in the human body, which represent 44% of all known human proteins. This result earned AlphaFold2 Science's distinction as breakthrough of the year. The DeepMind team furthermore predicted that their database will soon grow to 100 million proteins across all species, which is about half of all proteins that are believed to exist.

The importance of protein structure prediction was indicated by biochemist C. Anfinsen in his 1972 Nobel Prize acceptance speech. Anfinsen explained that such an advance would have vast applications, offer insights into basic biology, and reveal promising new drugs.

We believe that the above result by DeepMind is a first among a long sequence of breakthroughs that will take place in the next 2-3 decades and will lead to the development of a neural antiviral expert system that will provide protein-based treatment for virtually all or most viruses known to humankind. Such an approach can also be effective against bacteria, because proteins can be used to signal the immune system. For example, the protein NOD2 can fight bacterial infections by sensing the presence of bacteria and alerting immune cells. Proteins are the true answer to infectious diseases because they are building blocks of life. Their essential role in such defense is not a coincidence but a direct consequence of the very structure of life.

The process of developing new drugs with neural networks has already started. In January 2022, DeepMind announced a first new drug discovered by AlphaFold. Their system ef-

fectively marks the beginning of a new era in pharmaceutical research and development.

AlphaFold could have been developed earlier. Data and sufficient computing power have been available for at least two decades now. If development had started in the early 2000s or earlier, we would probably have some early version of a neural antiviral expert system by now. If that system was sophisticated enough by 2020 to provide protein-based treatment for the Covid-19 virus, the entire pandemic and its unfortunate social and economic impact could have been avoided.

However, there has been a major delay in this line of research – for three main reasons.

The first was a computer science prejudice against neural networks that persisted until the early 2010s. It was the result of misinformation and propaganda that was deployed by artificial intelligence researchers in their effort to undermine neural network research and divert funding into artificial intelligence. We have described and explained this unfortunate and highly contemptible situation in more detail in our book *Neural Age*. The prejudice effectively removed neural networks from consideration and dramatically slowed down progress.

The second reason for the delay is a disconnect between artificial neural networks on one side and biology and medicine on the other side that largely persists to this day. Systems like AlphaFold2 will certainly draw more attention to neural approaches, but the gap and the disconnect may persist for a while.

The third and perhaps most important reason for the delay is the pharmaceutical industry. An expert antiviral and antibacterial system will make vaccines for infectious diseases unnecessary; it will replace them with cheaper, safer, and more effective protein-based treatments; and it will most likely mark the beginning of a decline in the autoimmune disorder epidemic, which is a great source of revenue for the phar-

maceutical industry. Consequently, such a system will represent a financially catastrophic development for big pharma as it may reduce their revenue by about 70% to 80%, per our estimates. Big pharma will never truly support, fund, or promote such research. On the contrary, they will use all means possible to divert attention from it and retain an emphasis on a vaccine-centered approach – as detrimental as this may be for everybody else.

However, there will not be any more delays. The technology sector has always been bound to expand into medicine and health care. It is a relatively slow and gradual process that requires considerably more time but it is inevitable. Neural antiviral and antibacterial expert systems will be one important component of the expansion. Diagnostic systems and robotic or computer-assisted surgical systems will be two others.

From a logical standpoint, medical inference tends to be relatively simple. Doctors are not talented mathematicians who apply complex logic and ingenious or extraordinary new methods to derive spectacular diagnoses. Most of the time, they detect patterns and apply rules. The main complexity in this process is the large number and diversity of all possible symptoms, diseases, diagnostic tests, and treatments – as well as the medical history of the patient, which may affect certain decisions. This diversity is so great and with such enormous underlying detail that it is impossible for a human to be a medical expert across all medicine. However, this is not necessarily the case with neural systems dedicated to medical diagnoses.

As neural systems improve their natural language processing capabilities, they will eventually be able to process millions or even billions of medical textbooks, publications, studies, and even individual clinical trials. They will be able to detect and ignore or discount small studies and trial, studies that are unlikely to replicate, and studies that are likely to be biased or false. In the end, they will develop medi-

cal expertise that dwarfs the expertise of any human doctor. Most likely, they will reject certain medical practices such as prescribing expensive new brand name drugs that offer little or no advantage over older and cheaper drugs while they may introduce higher risks of adverse effect (as is the case with third and fourth generation contraceptives that we discuss in chapter 13). And they will certainly reject over-prescription and over-medication, which is a problem in some countries and particularly the United States.

Finally, computer-assisted or robotic surgical systems are already a reality, albeit very limited in their functions and capabilities. Those systems will only become more sophisticated over time and they will eventually be fully autonomous. Even partially autonomous systems that operate under the supervision of a doctor can have a tremendous effect on the accuracy, efficiency, and cost of surgical operations. Such systems will most likely be developed and become widely available within this century.

All those medical systems (for diagnosis, treatment, and surgery) will be guided and controlled by advanced neural networks and neural technology. In a sense, neural networks will pave the way of the technology sector into medicine and the pharmaceutical sector and they will displace the pharmaceutical industry.

Such medical systems will significantly decrease the cost of health care and diminish pharmaceutical revenue. We estimate the total reduction to be close to 90%. Furthermore, the majority of whatever revenue is left will be taken up by technology companies. Those companies will create health platforms that provide diagnosis and treatment; and people will subscribe to those platforms the same way they subscribe to media streaming or e-commerce services today. Technology companies do not need large profit margins for drugs – and certainly not the bloated margins that pharmaceutical companies currently enjoy. The main financial goal of those platforms will be to maximize their number of subscribers

because they could then steer them to other products, have additional advertising revenue, and obtain data that would allow them to create more accurate systems and services. As a result, drugs and health services will be offered at a discount – like everything else.

The pharmaceutical sector cannot possibly compete with all that. The most fraudulent sector on earth cannot hope to compete with the most innovative and fastest-growing sector, which also happens to be much larger. However, big pharma will try to delay their displacement and obsolescence as much as possible and with all means possible, both legal and illegal. Their reckless disregard for human life and knowledge demonstrates that they will stop at nothing to secure profits and retain revenue and power.

We believe that big pharma will launch a coordinated attack against neural network research and related medical innovations. We think that their attack will utilize three main elements: public opinion, the government, and scientific literature.

Their strategy on public opinion will most likely take the form of a fearmongering campaign to create public alarm or concern about neural networks (or artificial intelligence, if the latter term persists). They will use the media and the internet to promote propaganda that neural networks and automation will lead to excessive unemployment and poverty; that medical services and treatment will be under the control of a new and possibly evil intelligence; that privacy will be eroded further by big technology corporations and their medical neural networks; and that those corporations will use all those systems to control the population.

The second element of big pharma's attack on neural networks is likely their strongest weapon. The pharmaceutical trade association has a large budget and spends exorbitant amounts on lobbying each year. As we explained in chapter 5, big pharma has such extensive influence and control of Congress that it has been argued that "Congress is owned by

pharma" and that "it really doesn't matter who the president is."

The pharmaceutical web of power and influence will be used against neural network research and the technology sector. Their main line of attack will be to mobilize the government against large technology corporations on various pretexts – accusing them of monopolies and violations of antitrust laws, tax evasion, unfair trade practices, privacy issues and violations, discrimination etc. Their second line of attack will be on neural network research for medical purposes. They will again use the government and they will try to pass laws that prevent or limit such applications on a pretext that they represent a liability and a threat to public health, a supposed destabilizing factor for the pharmaceutical market, and an unconscionable effort to replace life-saving vaccines with various unproven, questionable, and less effective methods.

The third area and target of the pharmaceutical industry's attack will be scientific literature and the scientific record. They have already introduced an extraordinary level of fallacies and fabrications into the medical literature and they will do the same for neural network research that relates to medicine and medical applications. For every publication that demonstrates an effective protein-based treatment for an infectious disease (for which there are vaccines or expensive newly patented drugs) they will publish various biased or fabricated articles that supposedly show the opposite; they will claim that vaccine-based prevention is better than treatment; and they will conjure up all sorts of studies that 'demonstrate' the advantages of prevention and the potential adverse effects of protein treatments. For every diagnostic system that rejects over-prescription, over-medication, or over-vaccination, they will employ third parties to develop similar systems that supposedly support the opposite. They will furthermore attack the credibility of neural research, digging up questionable results as examples; they will claim that neural networks are black boxes that have no place in science; and they will argue

that they introduce unethical biases and discrimination.

In this book, we will not discuss or refute fearmongering campaigns or other methods to manipulate public opinion. We believe that other researchers can provide a more detailed and effective strategy for defending neural-network based medicine and medical research.

For the technology sector, we would like to point out a simple fact – and issue a warning. Innovation and strategy are the only things that matter. For technology companies, all other factors are negligible and irrelevant in the long run. This has been repeatedly demonstrated by various companies such as Apple, Google, Amazon, and Tesla. Technology companies do not need to evade taxes, employ unfair trade practices, sell their users' data or compromise their privacy; and they certainly do not need to associate themselves with big pharma. Such actions will always be strategic blunders. They may have some short-term benefits and increase the bonuses of some executives, but in the long run they can have no other effect than to tarnish the public image of a corporation. The technology sector will be paramount in the 21st century. Individual corporations must rise to the occasion. Those that do not will simply be left behind.

The case with the government, and Congress in particular, seems hopeless to us. The level of corruption and influence from big pharma may already be beyond remedy. It is not merely hypocritical for various senators and representatives to be so focused and determined on various issues and alleged violations by technology companies while turning a blind eye to the pharmaceutical sector. They have permitted big pharma to settle one case of fraud after another, for negligible amounts compared to their profits from fraud, and they have tolerated an economic cost to society that is measured in trillions. They have allowed health care expenses to balloon to one fifth of the GDP of the nation. Worst of all, they have accepted an extensive record of human suffering and a death toll of millions. Those actions are not merely hypocritical.

They constitute a breach of duty of elected officials to their constituents, and they are often the result of corruption and submission to big pharma.

The technology sector can easily outspend the pharmaceutical on lobbying activities, if they choose to do so. However, we believe that a better use of funds will be to demonstrate the extent of influence by big pharma and the corruption in Congress with a media campaign, especially given that the pharmaceutical sector is bound to attack neural networks and the technology sector.

We can always invite the government to disassociate themselves from big pharma, remove protections that they have given to the pharmaceutical sector, implement new laws and prosecute pharmaceutical fraud as organized crime*, limit drug pricing and health expenses and bring them down to a level that is comparable with other nations etc. We could also invite the government to maintain a neutral stance in the conflict between the technology and pharmaceutical sector that will take place in the next few decades.

However, such invitations are naive. The government is too deep in pharmaceutical pockets, they will take sides, and they will lose credibility and power. The final impact to the nation and democracy is hard to estimate.†

*In chapter 4, we mentioned a proposal by business law professor E. McCarthy to prosecute drug company fraud as organized crime under the Racketeering Influenced and Corrupt Organizations Act of 1970.

†We anticipate that the U.S. military will rise as a fourth branch of government in this century. Historically, the military has played an important role in shaping the U.S. democracy; and it will do so once more in the coming decades. Climate change and an annual stream of environmental challenges, disasters, and crises will bring the military to a more prominent position as it is the main element of government and society that can adapt to those challenges effectively. Furthermore, there is a significant overlap and various opportunities between the military and technology but a clear antithesis between the military and the pharmaceutical sector – not only because the latter drains 20% of the GDP and thus leaves less room for military expenditures but also because the military does not want a future where most of its personnel require daily doses of autoimmune disorder drugs.

We can argue that the attack on neural networks by the medical establishment and the pharmaceutical sector has already started – albeit in a limited and rather academic manner. For example, in 2020, Google researchers published a paper in the journal *Nature* about breast cancer screening using a neural network – which they called an AI system. They claimed that their system was "capable of surpassing human experts in breast cancer prediction." A few months later, a group of more than 20 medical researchers, who were frustrated by the lack of details of the methods and access to the algorithm and the code, published a rebuttal in *Nature* that was centered around "transparency and reproducibility in artificial intelligence." They argued that the absence of such important information undermined the "scientific value" of the publication, made replication virtually impossible, and restricted the ability for a proper peer review that could identity potential issues with the methodology.

We largely agree with the rebuttal and we will not dispute it. We will not question the motivation of the authors either. On the contrary, we would like to believe that we all share a genuine interest in scientific discovery, truth, and the scientific method, and that the purpose of the rebuttal is to point out significant omissions in the paper that should be addressed.

However, we cannot help but notice the double standards. With the exception perhaps of J. Ioannidis, who is a coauthor of the rebuttal but has published extensively on the replication crisis, where are the publications, rebuttals, and letters of protests of the rest of the authors? Why are they silent and tacitly complicit with the falsities and fallacies that are published regularly in medical journals? Small or statistically negligible studies are common in medical literature. Clinical trials are largely a waste of resources and funds. Conflicts of interests and creative designs abound in medical research. Vaccine studies and publications are abysmal. Blind placebo tests have sometimes been replaced with tests with a reduced amount of an immunologic adjuvant. Children too young to

be diagnosed with autism or too ill to be vaccinated are not always excluded from studies. Individual vaccines are targeted in studies but the claims are 'magically' transferred to all vaccines. Over-generalization takes place among cases that are not established as equivalent or compatible. Despite its extraordinary complexity and learning sophistication, the immune system is regularly reduced to a finite-state automaton in peer-reviewed and published vaccine articles. Even outrageous and utterly unsupported claims such that "healthy infants could safely get up to 100,000 vaccines at once" are published and promoted. When all those 'scientific' indiscretions take place, where are the rebuttals and protests of those academics and researchers? Where is their otherwise genuine interest for scientific truth? Are they hypocritical, corrupt, or misinformed? We understand that the medical literature and clinical studies are now so replete with bias, fallacies, and misinformation that it is virtually impossible to counter or refute all or most of them. We sympathize with the predicament of those researchers. However, a claim of safety for 10,000 or 100,000 vaccines simultaneously administered to an infant and not a single article of protest from the medical establishment? How can one subsequently trust such an establishment with anything? When researchers and academics have demonstrated such levels of complicity, can they still be trusted and be taken seriously? Can they still criticize others or have they lost such privilege – permanently?

Overall, we cannot do much about this invalid state of medicine, the new religion of false medicine, and the lax standards of various medical journals that permit an endless stream of fallacies and falsities to be published. Most of those conditions are a direct product of big pharma and they will virtually disappear with it. Neural networks and the technology sector will displace and diminish the entire pharmaceutical industry and thus put an end to all this. There will be great resistance. It will be a spectacular display. Yet, in the long run, it does not matter what big pharma will

do or attempt to do. They may manage to delay or impede progress for a while but the final outcome is inevitable. Their very existence and their threat to neural networks and neural technology are strictly ephemeral.

However, we cannot ignore big pharma's fabrications and corruption of human knowledge. We cannot possibly forgive their many crimes and the endless human suffering and death that they have caused and continue to cause. This is the reason we have dedicated this book to their many victims. We cannot hope for justice for those who have been lost or injured, but we must remember them, open our eyes to the truths before us, and stand firm against unconscionable wrongs.

16

Historical and Bibliographical Remarks

Information about the FCA can be found at the Department of Justice and on Wikipedia [65, 101]. The website www.whistleblowingprotection.org also contains information on the topic as well more information about various cases of fraud, whistleblowers, qui tam action, and a qui tam timeline [98]. Official information about qui tam actions, the FCA, and related federal statuses as well a reference to the $10 to $100 estimate of defense contractor fraud in the 1980s can be found in a related Congressional Research Service report [16].

Fraud recovery statistics under the FCA are provided by the Department of Justice [10]. The term medical-industrial complex first appeared in 1969 [18]. It was used in various publication during the 1970s and it became more common after it was used by A. S. Relman in 1980 [74].

Information about the top best-selling pharmaceutical products can be found on Wikipedia [103]. Our claims and comments about patent fraud under qui tam action and the FCA are from [98].

Detailed information and statistics about the opioid epidemic can be found in government sites and on Wikipedia, too [62, 97, 108, 109]. The case and settlement on the opioid treatment drug, Suboxone, is described is [36].

The U.S. government's Covid-19 relief program was called

Operation Warp Speed. Information about it can be found in [69].

Pfizer is the U.S. pharmaceutical corporation with the highest boost from Covid-19 with a record 92% growth in Q2 2021 and increased revenue guidance to \$78 – \$80 billion for the full year 2021 [93].

Data and an analysis of health care costs as percentage of GDP across developed nations can be found in [95]. Our estimates about US health care spending in 2020 are from the Centers for Medicare and Medicaid Services, which is an official website of the United States [23]. A comparative analysis of quality of the U.S. health care system using various indicators can be found in [46]. Data and analyses that demonstrate that the higher per-capita spending on health care in the United States is not because of greater health care utilization but because of higher prices can be found in [2, 1].

In 2021, the RAND Corporation published a comparative study on drug prices in the US and other nations [60, 59].

In 2002, A. S. Relman and M. Angell published a paper about unscrupulous practices, fraud, and political influence or corruption in the pharmaceutical industry that earned them the prestigious George Polk award in journalism [75]. M. Angell published a more detailed book about the same topic in 2005 [3]. In both cases, the authors proposed various measures to address or reduce the problem but their recommendations have had no effect on the government.

J. P. Kassirer published a similar book in 2004 [42].

In 2009, M. Angel published an article that explained and demonstrated in detail the virtual control of the pharmaceutical industry over medicine and medical research [4].

Four years later, P. C. Gøtzsche published a remarkable book. In *Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare*, he makes the case that the pharmaceutical industry is organized crime and it operates like organized crime [33]. The arguments are supported by numerous examples and detailed in-depth evidence.

In 2018, Gøtzsche published an article in The BMJ where he explained his expulsion from Cochrane and the drift of the organization from its initial core values and goals [34].

In 2019, E. McCarthy, assistant professor on business law at James Madison University, published a call to prosecute drug company fraud as organized crime under the Racketeering Influenced and Corrupt Organizations Act of 1970 [55].

Information about PhRMA and our numbers of their 2017 revenue and lobbying expenditures are from Wikipedia [104]. Information and statistics about prescription drug spending in the United States and national health expenditures can be found in [64, 24]

The earliest publication that identified the issue of false conclusions from errors in statistical tests of significance appeared in 1959 [90].

One of the earliest publications that indicated the replication crisis in science – and indirectly implied the necessity of metascience – appeared in 1966 [81]. The study examined 295 papers published in ten peer-reviewed medical journals and found that "conclusions were drawn when the justification for these conclusions was invalid" in about 73% of the reports.

Ioannidis' seminal paper on the replication crisis and falsities in medical research appeared in 2005 [37]. A subsequent study about reducing the waste in biomedical research with Ioannidis as a coauthor appeared in 2014 [51]. Ioannidis published a more extensive paper about wasteful or useless research – which he generously called "not useful" – on the same topic two years later [38]. The economic study on the cost of such wasteful and non-reproducible research was published in 2018 [28].

The term Proteus phenomenon was coined by J. Ioannidis and T. Trikalinos [39]. It was named after the Hellenic deity Proteus who could rapidly change his appearance.

Publication bias is discussed in detail in [70]. The report intends to identify and appraise empirical studies on publication and related biases published since 1998. The bias for

statistically significant positive results and the aversion to null results is discussed in [20]. Design quality is often comparable between studies with significant results and studies with a null result [17]. However, the former studies have been shown to be about three times more likely to be published [14]. A publication bottleneck has been attributed to the limited number of publication outputs compared to the much larger number of research studies [29]. It has similarly been argued that journals increasingly derive their authority from selectivity, create an *artificial scarcity** of publication opportunities, an illusion of exclusivity, and more competition among scientists [112].

Selective reporting regarded as a questionable research practice is discussed in [40]. Flexibility in data analysis and the associated biases are discussed in [87] and the productivity and novelty pressure in [50]. The desire for media attention and a plea for more epistemological modesty appear in [8]. A data analysis that demonstrates a general preference for non-replicable results (being cited more often than replicable ones) is presented [83].

An early analysis of the effects of publication bias in rejecting the null hypothesis appears in [90].

Scientific misconduct rates have been estimated using a meta-analysis of 39 research surveys containing relevant misconduct questions [19]. The estimated rates are assumed to be conservative.

An analysis of 53 pre-clinical cancer studies with a replication rate of just 11% appears in [31].

An analysis of a survey of the journal *Nature* about reproducibility appears in [7].

Information about the Center for Open Science can be found in [26, 99]. Their study about reproducibility in psychology appears in [11].

*In [112], artificial scarcity is defined as "any situation where, even though a commodity exists in abundance, restrictions of access, distribution, or availability make it seem rare, and thus overpriced."

Information about DARPA's SCORE program can be found in [111]. The announcement that the Center for Open Science joined the SCORE program is available in [25].

A. De Menard's blog entry about the replication crisis in social science can be found in [58]. As early as 2002, it was argued that papers are cited without being read [86]. The authors applied stochastic modeling to the citation process and misprints in citations (arguing that those are similar to Freudian slips) and they estimated that cited papers were read prior to citation in only about 20% of the cases.

Hanlon's razor, its origin (as a submission to a joke book), and its variations are discussed in a Wikipedia article [100]. In the same article, it is stated that earlier versions of the razor were provided by W. James and R. Heinlein.

Reports about side effects of Johnson & Johnson's coronavirus vaccine can be found in [43, 47]. Information about the Guillain-Barré syndrome and related articles can be found on Wikipedia [102]. A meta-analysis with estimates of population incidence of the syndrome appeared in [82].

Statistics and various facts and estimates about the prevalence and cost of autoimmune disorders in the US can be found in [79, 27]. A paper that estimated the prevalence of autoimmune disorders from the prevalence of antinuclear antibodies was published by NIH researchers in 2020 [15].

Research and a report from Connect Immune Research on the prevalence, rise, and cost of autoimmune conditions in the UK can be found in [77, 78]. (The report seems to have marketing and commercial elements, but we did not find any compelling reason to doubt their findings.) A plot about the distribution of autoimmune conditions across age groups in the UK for 2018 can be found in [91]. It includes adults only and shows the share of adult population with autoimmune conditions.

A CDC study about the prevalence of autism using data from 2018 can be found in [21]. Prevalence in previous years (2000, 2006, 2014, 2016 and 2018) in the United States as well

as various international studies are mentioned or summarized on Wikipedia [106]. The National Survey of Children's Health that reported an autism prevalence of 1 in 40 children in 2016 can be found in [45].

Studies about the synergistic effects of vaccines on infant mortality and hospitalization rates can be found in [32, 68].

The statement that most pertussis deaths occur in infants of age of 3 months or younger is from [110]. The CDC recommended child and adolescent immunization schedule for ages 18 years or younger can be found in [22].

Researchers from the Chalmers University of Technology in Sweden published an article about potential new antibiotics derived from fungi in 2017 [63, 52].

The New York Times article about NCVIA signed into law by President R. Reagan can be found in [71]. Information about no-fault compensation programs in WHO member states can be found in [61].

The records of the United States Supreme Court contain official information about the case Bruesewitz v. Wyeth, including the opinion of the court and the dissent by justices Sotomayor and Ginsburg [13]. Comments by R. F. Kennedy, Jr. on the above case can be found in his obituary for Supreme Court justice R. B. Ginsburg [73].

Our information about contamination from delamination and the Sanofi Pasteur case are from the newspaper The Morning Call [44].

The article with the claim about the safety of 10,000 vaccines administered to infants was published in 2002 [67]. The main author of the article worked at the Children's Hospital of Philadelphia at the time; and the hospital subsequently published a newsletter where they upgraded the claim to 100,000 vaccines. The newsletter is harder to find now but it has been archived on web.archive.org [66].

Our information about the Ortho Evra contraceptive patch, its sales, litigation, and settlements are from [57, 5, 41]. Similar information about the Yaz and Yasmin birth control

pills are from [88, 12, 49, 89, 105].

The Vanity Fair article "Danger in the ring" and the Huffington Post article "Side effects may include death: the story of the biggest advance in birth control since the pill" were published in 2013 [41, 85]. Information about the ethinylestradiol and etonogestrel combination that is used in the NuvaRing can be found on Wikipedia – as well as a summary and references to medium size studies that examined user tolerance and discontinuation (among other things) of the NuvaRing [107]. An extensive study on VTE risks by non-oral hormone contraception by Ø. Lidegaard et al. was published in The BMJ in 2012 [48] The Durango Herald article about the dismissed NuvaRing lawsuit can be found in [53].

The dispute between the FDA and the CDC about the effectiveness of antiviral influenza drugs is discussed in [6].

The quote by R. F. Kennedy, Jr. about J. Gerberding's employment by Merck is from his organization's website Children's Health Defense [72].

Information about a potential link between adjuvants in vaccines and the Gulf War syndrome can be found in [9, 94]. The study that argued about a connection of the Gulf War syndrome and multiple Th2-inducing vaccinations under stressful circumstances appeared in 1997 [80]. The trivial and flawed study by researchers at Novartis about MF59 was published in the Clinical and Vaccine Immunology Journal in 2006 [30]. A systematic review of original epidemiological studies about the association of vaccines with the Gulf War syndrome appeared in 2020 [54]. The study found positive association between vaccination and the development of the syndrome, identified clinical similarities between the Gulf War syndrome, the post-HPV vaccination syndrome, and macrophagic myofasciitis and hypothesized vaccine-induced autoimmune dysautonomia as the common pathogenetic mechanism.

Information about DeepMind's AlphaFold and its distinction as 2021 Breakthrough of the Year by Science magazine

can be found in [92, 96, 84]. AlphaFold's first discovery of a new drug was announced in January 2022 [76].

The paper by Google researchers for breast cancer screening using a neural network and its rebuttal were published in 2020 [56, 35].

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