

The Story of Pfizer Inc. A Case Study in Pharmaceutical Empire and Corporate Corruption

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The extensive history of the pharmaceutical industry is filled with stories and deeds of adventures, misadventures, profit-making, profit-taking, fraud, bribery, false claims, messianic promises, and criminal conduct.

Few companies in the history of medicine have received as much attention as Pfizer Inc. has received these last three years of the Corona Crisis.

Through the course of relentless media coverage and amidst all the sound and fury, **Pfizer** has managed to avoid scrutiny of its previous criminal conduct and is universally portrayed in the mainstream media as a benevolent enterprise whose mission is to nobly service humanity.

In an effort to set the record straight we embark upon a comprehensive historical examination of this company which sprouted from humble beginnings into one of the most influential corporate behemoths walking the earth today.

History

The story of Pfizer begins in New York City in 1849, when a pair of German immigrants, cousins **Charles Pfizer** and **Charles F. Erhart**, received a \$2,500 loan from Charles Pfizer's father to purchase a commercial building in Williamsburg, Brooklyn where they would embark upon a joint business venture in the nascent chemical manufacturing industry.

Charles Pfizer had been a pharmacist's apprentice in Germany and possessed commercial training as a chemist. Charles Erhart was a confectioner.

Originally named Charles Pfizer and Company the business would initially focus on the production of chemical compounds. Their first product was a pharmaceutical called <u>Santonin</u> which was used to treat parasitic worms.

Combining their talents the cousins housed their product within tasty confections such as candy lozenges and toffee-flavored sugar cream cones. This strategy proved to be a success, setting the stage for the company's future development.

The drug Santonin would be used as an anthelmintic up until the 1950's, when it fell out of favor due to <u>noted toxic effects</u> which posed serious risks to patients.

Pfizer would quickly expand into the realm of <u>fine chemicals</u> for commercial sale to wholesalers and retailers.

In 1862, Pfizer would become the first U.S. company to domestically produce tartaric acid and cream of tartar.

With the outbreak of the American Civil War a massive need for <u>painkillers and antiseptics</u> erupted, creating an "opportunity" for the pharmaceutical industry.

Pfizer quickly expanded its production of both, as well as of iodine, morphine, chloroform, camphor, and mercurials. By 1868, <u>Pfizer revenues had doubled</u> and its product line had increased substantially.

The big boon for the company would come in the 1880's with its production of industrial grade <u>citric acid</u>, widely used in soft drinks like Coca-Cola and Dr. Pepper. This would become the company's centerpiece and drive their growth for decades.

Another fortuitous change for the <u>"small New York firm"</u> would arrive in 1919, when its scientists would pioneer and develop a <u>deep tank fermentation process</u>, the principles of which would later be applied to the production of penicillin.

This prowess in fermentation and large-scale pharmaceutical production would put Pfizer in a lead position in WW2, when the US government appealed to the pharma industry for support in producing penicillin for the war effort.

Working with government scientists, Pfizer began pursuing mass production of penicillin utilizing its deep-tank fermentation technology and in 1944 became the first company to mass produce penicillin.

As penicillin prices and usage declined post-WW2, Pfizer began searching for more profitable antibiotics. The move into commercial production of antibiotics signaled a pivot in Pfizer's business model.

The company's operations shifted from the manufacture of fine chemicals to research-based pharmaceuticals, giving birth to Pfizer's new drug discovery program, which focused on vitro synthesis.

In 1950 Pfizer would develop its first proprietary pharmaceutical product, <u>Terramycin</u>, a broad-spectrum antibiotic.

By 1951, Pfizer had established offices in Belgium, Brazil, Canada, Cuba, England, Mexico,

Panama, and Puerto Rico. As its power and profits mushroomed, Pfizer would augment its portfolio through various acquisitions and entries into multiple areas of research and development, including an <u>animal health division</u>.

As the Pfizer pharmaceutical kingdom expanded, however, questions about salacious business practices began to surface.

Violations

Despite portraying itself as a righteous corporate citizen, Pfizer is no stranger to controversies and scandals. As early as 1958 it was one of six drug companies accused of price fixing by the Federal Trade Commission.

In 1961 the Justice Department filed criminal <u>antitrust charges</u> against Pfizer, American Cyanamid, and Bristol-Myers, accusing top executives at each company of charging egregiously high prices and monopolizing the production and distribution of drugs dating back to 1953.

In 1963 the <u>FTC ruled</u> that the accused companies in its 1958 complaint did in fact rig antibiotic prices. The FTC also noted that "unclean hands and bad faith played a major role" in Pfizer being granted the tetracycline patent.

By the 1960s, Pfizer was at its most diversified point in history, with interests ranging from pills to perfume to petrochemicals to pet products.

The company's shift toward bringing out new products culminated with the establishment of the Central Research Division in the early 1970s. A full 15% of Pfizer's revenue was directed to this research department.

This focus on innovation brought about Pfizer's development of <u>blockbuster drugs</u>, which are described as "drugs that generate at least \$1 billion in revenue a year for the pharmaceutical companies that produce them."

While these drugs can be extremely profitable for pharmaceutical companies, the blockbuster drug business model presents certain long-term problems. Beyond the time and money that goes into their development, there are the exigencies of patent issues. Pharma companies see the "patent window" of 20 years as a severe limitation, since it often takes them a full decade to bring a new drug to market, thus shortening both the time allowed to reclaim profits from development costs and the time allotted to reap maximum profits from their new product.

Due to patent laws, the success of blockbuster drugs is often short-lived. Also, reliance on blockbusters means that if a product fails, the consequences for the manufacturer can be catastrophic.

Using this business model, the need for pharmaceutical companies to constantly produce blockbuster drugs is difficult to overstate. Naturally, they go to great lengths to protect their golden goose.

Accompanying Pfizer's string of blockbusters was a massive surge in the company's fortunes in tandem with a procession of controversial products, felony offenses and multiple fines—including the <u>largest criminal fine in US history</u>.

Take, for example, Pfizer's first blockbuster drug, the anti-inflammatory <u>Feldene</u>, which would also become one of its initial contentious products.

Pfizer submitted a new-drug application for Feldene to the FDA in March 1978 and again in May 1980. The applications were rejected due to poor testing protocols. In September 1981, Pfizer resubmitted an application to the FDA, using old data.

Multiple questions surrounding Feldene, including the route taken toward its ultimate approval, would make it one of Project Censored's top "Censored" news stories in 2015.

In that story, Project Censored noted:

"Then, while the FDA was still considering the application, Pfizer sponsored a reception at the meeting of the American Rheumatism Association in Boston and showed a film promoting Feldene which the FDA said was illegal. Nevertheless, on April 6, 1982, the FDA approved Feldene for use in the U.S."

Even though Feldene would go on to become Pfizer's most lucrative product, questions about the drug quickly surfaced. By 1986 the FDA was being <u>petitioned</u> to relabel the drug due to serious concerns about its long half-life and its tendency to accumulate in the blood.

The watchdog organization <u>Public Citizen Health Research Group</u> (PCHRG) would later charge that this widely prescribed arthritis drug created risks of gastrointestinal bleeding among the elderly.

Citing reports of 2,621 adverse events and as many as 182 deaths among patients taking the drug, PCHRG requested that the FDA ban Feldene for patients 60 and over, "as an imminent hazard to the public health."

Dr. Sidney Wolfe, director of the PCHRG stated, "At least 1.75 million elderly American people now receiving this drug are at risk of developing life-threatening gastrointestinal reactions."

Meanwhile, the National Council of Senior Citizens urged the FDA to <u>take the drug</u> <u>completely off the market.</u>

PCHRG's Wolfe would later cite <u>internal documents from Pfizer</u> that voiced concerns about the drug. By 1995 he called for a complete ban on the drug for all ages.

This was just the beginning of a series of high-profile scandals and legal problems that would come to define Pfizer's business-as-usual practices.

For instance, reports of serious issues surrounding a <u>heart valve</u> produced by Pfizer's Shiley division began to plague the company. This problem would result in the cessation of production of all models of the faulty valves by 1986.

A 1991 FDA task force charged that Shiley <u>withheld information</u> about safety problems from regulators in order to get initial approval for its valves. A November 7, 1991, investigation in *The Wall Street Journal* asserted that Shiley had deliberately falsified manufacturing records relating to valve fractures.

These fractures resulted in catastrophic consequences for numerous patients. By 2012 it was reported that <u>663 individuals had died</u> as a result of the defective valves.

Pfizer ultimately <u>agreed to pay</u> between \$165 million and \$215 million to settle lawsuits related to the <u>The Björk-Shiley Convexo-Concave Heart Valve.</u>

It also <u>agreed</u> to pay \$10.75 million to settle US Justice Department charges that it lied to regulators in seeking approval for the valves.

The parade of corrupt practices and legal problems that has come to define this pharmaceutical Leviathan was just getting underway. From then on, Pfizer was cited and prosecuted for a litany of illegal acts ranging from price fixing, product safety, bribery, advertising and marketing scandals all the way to environmental and human rights violations.

In 1999 Pfizer <u>pled guilty</u> to criminal antitrust charges and agreed to pay fines totaling \$20 million. In that case, Pfizer was charged with "participating in a conspiracy to raise and fix prices and allocate market shares in the U.S. for a food preservative called sodium erythorbate, and to allocate customers and territories for a flavoring agent called maltol."

In 2000 The Washington Post published a <u>six-part exposé</u> accusing Pfizer of testing a dangerous experimental antibiotic Trovafloxacin (trade name Trovan) on children in Nigeria without receiving proper consent from their parents.

Trovan was slated to become Pfizer's next blockbuster drug, according to Wall Street analysts, one of whom claimed, "Pfizer might reap \$1 billion a year if Trovan could gain approval for all its potential uses." But when the company was unable to find enough patients in the United States, its researchers went in search of new patients in Kano, Nigeria.

This unapproved clinical trial on 200 Nigerian children resulted in the <u>death of 11</u> <u>children</u>. It is alleged that many more children later suffered "serious side-effects ranging from organ failure to brain damage."

In 2001 Pfizer was sued by <u>30 Nigerian families</u>, who accused the company of using their children as "human guinea pigs." The families contended that "Pfizer violated the Nuremberg Code as well as UN human rights standards and other ethical guidelines" and alleged that Pfizer exposed the children to "cruel, inhuman and degrading treatment."

After years of legal battles, Pfizer agreed in 2009 to pay \$75 million to settle some of the lawsuits that had been brought in Nigerian courts.

<u>Trovan</u> never became the blockbuster Pfizer had envisioned. The company admitted to stockholders it had <u>"suffered a disappointment"</u> with this experimental meningitis drug. Trovan was never approved for use by children in the United States, so production was halted. The European Union <u>banned it in 1999</u>.

Below is a chronology of still more Pfizer misadventures.

— In 2002 Pfizer agreed to pay <u>\$49 million</u> to settle charges that one of its subsidiaries defrauded the federal Medicaid program by overcharging for its cholesterol-lowering drug Lipitor.

- In 2003 Pfizer paid \$6 million to settle with 19 states that accused it of using <u>misleading</u> <u>ads</u> to promote the antibiotic Zithromax (also called Z-Pak), used for children's ear infections. The claim alleged that Pfizer "overstated the benefits and efficiency of Zithromax when compared to other comparable antibiotics."
- In 2004 Pfizer agreed to a \$60 million settlement in a class-action suit brought by users of a diabetic medication developed by Warner-Lambert, which Pfizer acquired in 2000. The drug Rezulin had been withdrawn from the market after numerous patients died from acute liver failure said to be caused by the drug.
- In 2004 Pfizer agreed to halt ads for its painkiller Celebrex, and the following year it admitted that <u>1999 clinical trials</u> found that elderly patients taking the drug were far more likely to incur risks of heart problems.
- 2004 also saw Pfizer <u>plead guilty</u> to two felonies and pay \$430 million in penalties for fraudulently promoting the epilepsy blockbuster drug Neurontin for unapproved uses. Pfizer claimed it could also be used for "bipolar disorder, pain, migraine headaches, and drug and alcohol withdrawal."

Pfizer's underhanded tactics involving Neurontin also included bribing doctors with luxury trips and monies to promote the drug and planting operatives at medical education events.

Documents later came to light suggesting that Pfizer <u>arranged for delays</u> in the publication of scientific studies that undermined its claim for the other uses of Neurontin. In one of these documents, it was found that a Neurontin team leader at Pfizer said, "I think we can limit the potential downside of the 224 study by delaying publication for as long as possible."

Finally, in 2010, a federal jury found that Pfizer <u>committed</u> racketeering fraud in its marketing of Neurontin; the judge in the case subsequently ordered the company to pay \$142 million in damages.

- In 2005 Pfizer <u>withdrew</u> its painkiller Bextra from the market after the FDA cited "inadequate information on possible heart risks from long-term use of the drug as well as 'life-threatening' skin reactions, including deaths."
- That same year the FDA approved a black box warning on Pfizer's other blockbuster painkiller, <u>Celebrex</u>, citing elevated risks of "cardiovascular events and life-threatening gastrointestinal bleeding."
- In 2007 Pfizer agreed to pay \$34.7 million to settle federal charges relating to the marketing of its Genotropin human growth hormone. Pharmacia & Upjohn Co., a Pfizer subsidiary, agreed to pay \$19.7 million for "offering a kickback to a pharmacy benefit manager to sell more of the drug," while Pfizer agreed to pay another \$15 million for "promotion of Genotropin for uses not approved by the Food and Drug Administration."
- In 2008 Pfizer paid out a whopping \$894 million fine to settle lawsuits "alleging that its withdrawn Bextra painkiller and widely used Celebrex arthritis drug harmed U.S. patients and defrauded consumers." Of the total fine, \$745 million was set aside to "resolve personal injury claims."
- The very next year, 2009, Pfizer was fined \$2.3 billion gaining the dubious

distinction of being tagged with the largest <u>health care settlement in history</u>. GlaxoSmithKline would up the ante with a <u>\$3 billion settlement</u> in 2012.

The fine was a combination of <u>civil and criminal settlements</u> relating to Pfizer's "allegedly illegal promotion of certain drugs, most notably Bextra." **Pfizer pled guilty to** "<u>misbranding the painkiller Bextra</u> with the intent to defraud or mislead, promoting the drug to treat acute pain at dosages the FDA had previously deemed dangerously high."

The <u>Justice Department</u> also noted Pfizer had "allegedly paid kickbacks to compliant doctors and promoted three other drugs illegally: the antipsychotic Geodon, an antibiotic Zyvox, and the antiepileptic drug Lyrica."

When interviewed by <u>The New York Times</u>, former Pfizer sales representative John Kopchinski, who helped initiate the federal investigation, stated, "The whole culture of Pfizer is driven by sales, and if you didn't sell drugs illegally, you were not seen as a team player."

The criminal fine of \$1.195 billion in that settlement still represents the largest criminal fine ever imposed in the United States for any matter.

Even after entering an <u>expansive corporate integrity agreement</u> with the Office of Inspector General of the Department of Health and Human Services as part of the 2009 settlement, Pfizer's unprincipled and injurious behavior continued. The band played on.

In 2010 *The New York Times* reported on Pfizer's admission that it had paid around "\$20 million to 4,500 doctors and other medical professionals for consulting and speaking on its behalf in the last six months of 2009."

The Times also mentioned that Pfizer had paid "\$15.3 million to 250 academic medical centers and other research groups for clinical trials in the same period."

In reference to the amounts disclosed by Pfizer, <u>Dr. Marcia Angell</u>, former editor of *The New England Journal of Medicine* and author of <u>The Truth About the Drug Companies: How They Deceive Us and What to Do About It</u>, admitted that while she had no specific knowledge of the matter, she believed the publicly revealed amounts Pfizer disclosed "seemed low." She added: "I can't help but think something has escaped."

In 2011 Pfizer agreed to pay \$14.5 million to resolve <u>False Claims Act accusations</u> that it illegally marketed its bladder drug Detrol.

In 2012 the U.S. Securities and Exchange Commission announced that it had reached a \$45 million settlement with Pfizer to resolve charges that its subsidiaries had <u>bribed overseas</u> <u>doctors and other healthcare professionals</u>.

The SEC alleged that "employees and agents of Pfizer's subsidiaries in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia made improper payments to foreign officials to obtain regulatory and formulary approvals, sales, and increased prescriptions for the company's pharmaceutical products."

According to Kara Brockmeyer, Chief of the SEC Enforcement Division's Foreign Corrupt Practices Act Unit, "Pfizer subsidiaries in several countries had bribery so entwined in their sales culture that they offered points and bonus programs to improperly reward foreign

officials who proved to be their best customers."

In 2012, Pfizer was hit with another massive fine—this time to settle claims that the side effects of its Hormone Replacement Therapy (HRT) drug Prempro cause breast cancer. Around 10,000 women filed a lawsuit against the company, alleging that the drug maker withheld information about the potential risks of breast cancer from HRTs. The \$1.2 billion settlement came after six years of trials.

In 2013, Pfizer agreed to a <u>\$288 million settlement</u> for claims by 2,700 people that its <u>smoking-cessation drug Chantix</u> caused suicidal thoughts and severe psychological disorders.

The FDA had placed a <u>black box warning</u> on Chantix, the highest safety-related warning assigned by the FDA, "to alert patients and doctors to the risk of psychiatric side effects" and had noted that the drug is "probably associated with a higher risk of a heart attack."

Pharmaceutical companies make every effort to circumvent black box warnings. They generate bad publicity and negatively impact the marketability of the drug in question, which leads to adverse financial consequences for the company.

<u>In 2016,</u> after years of lobbying, Pfizer managed to get the FDA to lift the black box designation from Chantrix in a <u>10-9 vote</u>, giving the controversial blockbuster drug a "new lease on life."

In 2013 Pfizer reached a \$35 million settlement relating to the alleged improper marketing and promotion of the immunosuppressive drug Rapamune. When New York Attorney General Eric T. Schneiderman announced that he and 40 other state attorneys general had arrived at the settlement, he remarked, "There has to be one set of rules for everyone, no matter how rich or powerful, and that includes big pharmaceutical companies that make unapproved and unsubstantiated claims about products in order to boost profits."

While this article's list of Pfizer's corporate crimes is prodigious by any measure of shady business practices, it is far from exhaustive. In total, since 2000 Pfizer has accumulated \$10,945,838,549 in penalties and incurred 96 violations covering a wide range of offenses.

A Company You Can Trust?

Pfizer's portfolio of corporate crimes rivals that of the most corrupt companies in history. But that did not stop Pfizer from becoming a corporate celebrity with its COVID-19 vaccine. Indeed, the company has benefited handsomely from that product, whose \$36.8 billion in 2021 sales made it the highest-selling pharmaceutical product in history.

When the pharma company's 2022 revenues reached an all-time, single-year high of \$100.3 billion, COVID-19 vaccine sales accounted for nearly 38 percent of those revenues.

Yet, while Pfizer was basking in the glow of mainstream media cheerleading and recordsetting profits, honest inquiries into its unremitting record of corruption were kept from public view.

We were told we must "Trust in Pfizer" to vaccinate the world and save humanity from the so-called COVID crisis.

Given Pfizer's documented record of misdeeds, any reasonable person would ask:

"Is this a company that belongs behind the wheel of the most widespread mass vaccination campaign in history?"

"Is this a company we should trust with experimental medical technology?"

"Is this a company we want to be in control of the most radical mass medical experiment in human history?"

"How is it that a company that habitually engaged in such illegal practices was able to reinvent itself as the savior of humanity?"

In a <u>June 12, 2008, ceremony</u>, at the original Pfizer manufacturing site in Brooklyn, New York, the American Chemical Society designated Pfizer's development of deep-tank fermentation as a <u>National Historic Chemical Landmark</u>.

At that commemoration, then-president of Pfizer Global Manufacturing Natale Ricciardi told attendees, "We have always had a very noble mission." Despite cryptically lamenting, "A lot of things have changed at Pfizer, and unfortunately, we had to make certain decisions," Ricciardi went on to assert, "But the nobility of what we do, the nobility of what has been done and continues to be done has never changed and will never change."

All these years later—and despite Mr. Ricciardi's insistence on Pfizer's magnanimity—a thinking person might look through the company's checkered catalog of crimes and fines and recognize that noble experiments are *hardly* the realm of "alleged" serial felons like Pfizer.

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