

The Forbidden COVID-19 Chronicles April 5, 2021
The Makers of COVID-19 Vaccines: AstraZeneca
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Since the year 2000, twenty-one civil and criminal complaints have been levied against AstraZeneca, and the company has paid a total of \$1,148,775,284 in fines.¹ The company can boast that it has been charged fewer times and has paid less money in fines than some of the other criminal enterprises currently approved to make and sell vaccines in the U.S., like Pfizer and Johnson and Johnson.

In 2003, AstraZeneca paid \$355,000,000 to settle criminal and civil charges concerning Zoladex, a drug used primarily for the treatment of prostate cancer. The company admitted submitting thousands of claims for payment for drugs that were provided as free samples to doctors; filing false and fraudulent claims to Medicare, Tricare, The Department of Defense and Railroad Retirement Board Medicare programs.

The company also engaged in a bribery scheme that involved giving illegal remuneration in the form of free samples, unrestricted educational grants, business assistance grants, travel and entertainment, consulting services and honoraria to doctors. As further inducement to get physicians to purchase Zoladex, AstraZeneca marketed a "Return-to-Practice" program that involved inflating the Average Wholesale Price ("AWP") used by Medicare and others for reimbursement of the drug, deeply discounting the price paid by physicians to AstraZeneca for it; and returning the spread between the AWP and the discounted price to physicians as additional profit for the physician's practice.²

In 2007, a judge ordered the company to pay an additional \$12.9 million in fines, and in 2010 the company was hit with another \$103 million judgement. Both of these fines were levied for engaging in the same activities described above with both Zoladex and an asthma medication.³ The continuation of practices which have been determined to be illegal and for which the company has paid fines shows that drug companies in the U.S. consider fines a cost of doing business, not a mandate for changing their practices. In 2010, the company reported over eleven billion dollars in profit;⁴ the \$103 million judgment was less than 1% of the company's total profits for that year.

In 2010, the company also paid \$520 million dollars in response to charges that its reps marketed the antipsychotic drug Seroquel for uses that were not safe, effective, or approved. The drug was approved only for short-term treatment of Schizophrenia, short-term treatment of acute manic episodes associated with bipolar mania, and for bipolar depression.

But from 2001-2006, AstraZeneca promoted the drug to psychiatrists for the treatment of aggression, Alzheimer's disease, anger management, anxiety, attention deficit

hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, PTSD, and insomnia. In addition to psychiatrists, reps marketed Seroquel for a long list of conditions for which it was not approved to doctors who did not normally treat schizophrenia or bipolar such as geriatric doctors, primary care doctors, and pediatricians; and long-term care facilities and prisons. The company routinely included information about unapproved uses for Seroquel in continuing education programs for doctors.

Additionally, the company paid doctors to conduct studies on humans using Seroquel for unapproved uses. Articles reporting the results of these unauthorized studies were ghostwritten by medical literature companies. AstraZeneca paid doctors for the use of their name as authors of these articles, even though they did not conduct the studies themselves. These studies and articles citing them were then used to promote unauthorized uses for Seroquel.⁵

In 2016, the company paid another fine after being charged with violating the Foreign Corrupt Practices Act. The company was caught making improper payments in cash, gifts and other items to doctors working at government-owned clinics in China and Russia in order to incentivize them to prescribe drugs made by AstraZeneca.⁶ The company kept written charts and schedules detailing the illegal gifts, and hired a travel agency to submit fake invoices to generate cash that was used to pay off doctors and healthcare institutions. In China, AstraZeneca staff set up bank accounts in doctors' names. Speaker's fees were paid with no meeting date or subject noted in the files. In many cases, the events at which the doctors were supposedly hired to speak never even took place. The company also paid off government officials for not pursuing sanctions for its illegal activities.⁷

Along the way, AstraZeneca employed some unsavory characters to help with its criminal activities. Take Wayne McFadden, for example. For five years, he was U.S. medical director for Seroquel. In this capacity, he planned and monitored clinical trials, was involved in discussions about increased risk of diabetes as a side effect of Seroquel, directed the marketing and promotion of the drug, and served as the company's liaison to "key opinion leaders," who promoted Seroquel to medical doctors. He also was actively involved in the decision to market Seroquel off-label for the treatment of dementia.

McFadden acknowledged that while in his position as medical director, he had sexual relationships with two women who he hired to write favorable articles about Seroquel. One of them was a researcher with the Institute of Psychiatry (IOP) who was involved in clinical research and preparation of abstracts concerning the efficacy of Seroquel for use in the treatment of schizophrenia. While involved with her, he also became involved with another woman who helped to write two papers that were influential in getting Seroquel approved for the treatment of bipolar depression. In court records, both relationships were characterized as involving "control and dependence."⁸ McFadden

regularly prescribed prescription painkillers to the woman with IOP.⁹ These relationships call into question the integrity of the work produced by these women and whether or not the reports of the trial results can be trusted.

These events resemble more the activities of crime families in New York City, not people and companies entrusted with the health of humans. How can the FDA and CDC possibly justify allowing and rewarding this type of behavior??

¹ <https://violationtracker.goodjobsfirst.org/parent/astrazeneca>

² https://www.justice.gov/archive/opa/pr/2003/June/03_civ_371.htm

³ <https://www.corp-research.org/astrazeneca>

⁴ <https://www.statista.com/statistics/266544/astrazeneca-operating-profit-since-2006/>

⁵ <https://www.justice.gov/opa/pr/pharmaceutical-giant-astrazeneca-pay-520-million-label-drug-marketing>

⁶ <https://www.sec.gov/litigation/admin/2016/34-78730.pdf>

⁷ Randy L. Cassin. AstraZeneca pays \$5.5 million to resolve China, Russia FDPA offenses. *The FCPA Blog* August 31, 2016

⁸ Seroquel Litigation Documents – Sexual Exploitation. Feb 25 1009 <https://ahrp.org/seroquel-litigation-documents-sexual-exploitation/>

⁹ Jim Edwards. AstraZeneca's Sex-for-Studies Seroquel Scandal: Did Research Chief Bias the Science? *CBS News* Feb 25 2009