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Pfizer's Neurontin: A Drug for All Seasons – A Lesson in Big Pharma Mass Marketing Manipulation

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At one time or another, most of us have been subjected to a cornucopia of television commercials, colorful doctor's office brochures, and physicians "advice" all making grandiose claims about the benefits of the latest-and-greatest pharmaceutical "blockbuster" pills and potions. The TV endorsements trail off with the all-too-familiar auctioneer's rapid-fire warnings of possible adverse reactions, and the print ads sneak in a few lines of microscopic text alerting us to the panoply of potential "side effects."

While the monolithic pharmaceutical marketing machine is an acknowledged, impossible-to-ignore presence, the mechanisms that bring to life these well-orchestrated promotional productions are not always understood.

So, to gain a full appreciation of Big Pharma's maneuverings and machinations—all of which develop into the industry's "finished products" presented to the public—we will take a close-up look at the ignominious path one prominent drug traveled to "get to market."

Neurontin, the trade name for Gabapentin, is a popular drug used for the treatment of seizure disorders or to relieve nerve pain. Developed by Parke-Davis, a unit of Warner-Lambert (which Pfizer acquired in 2000), Neurontin was patented in 1977 and approved for use in 1993.

Although it was approved for use in patients with epilepsy, by 2001 "over 80% of its $1.8 billion in sales were for indications unapproved by the FDA."

How is it possible that the primary purpose for this drug had come to represent only a fraction of its actual usage, whereas unapproved—and presumably illegal—applications had grown to represent the majority of its use? Let us find out.

To tell the story of the illicit practices associated with Neurontin, we must start with the

numerous deceptive marketing tactics that are part and parcel of the pharmaceutical industry—an industry that holds the distinction of being the biggest defrauder of the federal government.

Specifically, to boost its sales of this blockbuster drug, Parke-Davis employed an illegal tactic known as "illegal off-label marketing practices."

This method of marketing Neurontin "helped propel its sales to nearly $3 billion a year before it lost patent protection in 2004." While off-label *prescribing* of a drug is allowed; off-label *marketing* of that same drug is not.

The case of Neurontin came to light when whistleblower David Franklin became concerned that he "was participating in illegal marketing." On April 16, 1996, at a seminar for "medical liaisons," Franklin was told that the FDA strictly prohibited the promotion of any drug for off-label uses.

One week later, a Parke–Davis executive reportedly told Franklin:

> I want you out there every day selling Neurontin. . . . We all know Neurontin's not growing for adjunctive therapy, besides that's not where the money is. Pain management, now that's money. Monotherapy [for epilepsy], that's money. . . . We can't wait for [physicians] to ask, we need [to] get out there and tell them up front. Dinner programs, CME programs, consultantships all work great but don't forget the one-on-one. That's where we need to be, holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything. I don't want to see a single patient coming off Neurontin before they've been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

Three months later, Franklin would leave Parke–Davis and file a lawsuit*, United States of America ex rel. David Franklin vs. Pfizer, Inc., and Parke-Davis Division of Warner-Lambert Company,* against his former employer, alleging it "engaged in a fraudulent scheme to promote the sale of the drug Neurontin for 'off-label' uses."

The case would be settled in May 2004, when Pfizer unit Warner-Lambert admitted it had "aggressively marketed the epilepsy drug by illicit means for unrelated conditions including bipolar disorder, pain, migraine headaches, and drug and alcohol withdrawal."

The $430 million settlement was one of the largest False Claims Act recoveries against a pharmaceutical company in U.S. history. The lawsuit also became a landmark case for revealing how publication bias distorts randomized controlled studies conducted by pharmaceutical companies.

Of the many things this case put on full display, perhaps none were more important than the detailed revelations of the "marketing plan" for Neurontin—a plan that, we would discover, utilized every manipulation in the Big Pharma playbook.

A short list of the dirty tricks implemented includes:

- promoting Neurontin use among high prescribing physicians;

- cultivating thought leaders, recruiting and training local physicians and paying them to serve as speakers in "peer-to-peer selling" programs;
- soliciting academic leaders with educational grants, research grants, and speaking opportunities, and paying some of them up to $158,250 over a four-year period;
- establishing teleconferences moderated by physicians who were paid as much as $176,100 over a four-year period;
- forming speakers bureaus with "strong Neurontin advocates and users to speak locally for Neurontin";
- making "unrestricted educational grants" available to for-profit medical-education companies that produced programs to discuss unapproved uses of Neurontin;
- designing a "publication strategy" to increase the use of Neurontin for neuropathic pain and bipolar disorder, both off-label indications with great revenue potential.

Amidst the array of vulpine schemes used to promote Neurontin, perhaps none was quite as insidious as the little-known Pharma ploy of "seeding trials."

Seeding trials, often designed by marketing departments, "are clinical trials, deceptively portrayed as patient studies, which are used to promote drugs recently approved or under review by the [FDA] by encouraging prescribers to use these medications under the guise of participating as an investigator in a clinical trial."

In the case of Neurontin, a large seeding trial was conducted, with 772 physicians enlisted as "investigators" for a study ostensibly aimed at determining the efficacy of Neurontin. Precisely 2,759 patients were enrolled in the study. Of them, 11 patients died and 73 others experienced serious adverse events.

These aggressive and dubious marketing tactics would pay dividends:

In 2003, Neurontin accounted for $2.3 billion of Pfizer's sales and was one of the company's top-selling drugs. Pfizer said in court papers that **more than 78 percent of Neurontin prescriptions in 2000 were written for unapproved uses.** [Emphasis added.]

Even after Pfizer pled guilty to charges of falsely marketing Neurontin and defrauding the federal government—and even after fines related to Neurontin escalated to $945 million—the popularity of Neurontin continued, mostly, sad to say, for off-label uses.

In 2020, Neurontin was the 10th most commonly prescribed medication in the United States, with more than 49 million prescriptions.

Similar marketing tricks and underhanded tactics by other companies have been well documented over the years. A skeptic would be right in calling this "business as usual" for the pharmaceutical industry, as evidenced by:

- the $1.4 billion settlement and criminal fines paid by Eli Lilly for illegally marketing Zyprexa in 2009;
- the $2.3 billion paid by Pfizer in 2009 for illegally marketing 13 different drugs, including Lyrica, Geodon, and Bextra;
- the $3 billion paid by GlaxoSmithKline in 2010 for illegally marketing Paxil,

Wellbutrin, and Avandia;
- the $2.2 billion paid by Johnson & Johnson for illegally marketing Risperdal in 2013.

Indeed, the significance of the Neurontin case lies not in its singularity but in the graphic images portrayed in the 8,000 pages of corporate documentation that are now in the public record. That documentation is illustrative of the measures pharmaceutical companies take to get their products to market.

The story of Neurontin demonstrates in graphic detail how Big Pharma, with no compunction, will unleash a plethora of unscrupulous tactics in order to get a product to market, and how, once that product hits the market, the industry throws all ethical standards out the window in service to the lords of profit.

Once we understand how the magician does a trick, we are immune to his sorcery. We are no longer spellbound. Similarly, now that we've seen a snapshot of the Neurontin saga, we can no longer be fooled by the dark arts of Big Pharma's marketing machine.

This machine has no interest in creating a cure for disease. Its only desire is to create a customer for life.

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