# Chapter X: From fluoxetine to Prozac® How the Pharmaceutical Industry Builds Brand Identity through Prescription Drugs Naming

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# From Fluoxetine to Prozac®

## How the Pharmaceutical Industry Builds Brand Identity through Prescription Drug Naming

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The purpose of this chapter is to explore how pharmaceutical companies manage to create strong brand identities for their prescription drugs by using creative names, despite the many rules and regulations imposed upon them by governmental agencies. After providing a concise history of prescription drug naming, this chapter will present the basic types of drug names used by pharmaceutical companies. To illustrate these types, detailed information about the naming history of several prescription drugs is offered. Then a detailed overview is given of the governmental policies and regulations that are imposed to control consumer health and welfare and protect a company's financial interest. Finally, a discussion is provided on the ways in which the international pharmaceutical industry navigates these regulatory best practices to devise drug names that have the potential to facilitate the formation of powerful and profitable ties between the identity of the prescription brand and the consumer.

## Introduction

In 2020, there were more than 20,000 prescription drugs on the US market. In such a highly competitive market, the name given to a pharmaceutical drug must do more than simply designate or denote. According to Dutchen (2009), pharmaceutical companies spend anywhere from $250,000 to $2.5 million to develop names for their drug products. For most companies, this money is more than well-invested. A memorable name can make or break a pharmaceutical product. Stepney (2010) reports that, in the late 1980s, the British pharmaceutical company Zeneca marketed the angiotensin-converting enzyme inhibitor, lisinopril, as a treatment against high blood pressure. The pharmaceutical product was marketed under the name *Zestril*®. At the same time, Zeneca's competitor Merck marketed the same molecule under the name *Carace*®. The name *Zestril*® was made by combining three elements: 1.) "zest," a word selected to convey enthusiasm which underscored the company's promotional campaign promise that patient-consumers would regain their "zest for life"; 2.) the letter "Z" which harkened to the company name, *Zeneca*; and 3.) the suffix "-ril," taken from the final three letters of the molecule, lisinop**ril**. This name creation was a clear success. Zestril was a hit. In 1997, it was Zeneca's highest selling product worldwide, with sales reaching $1.05 billion.[1] By comparison, *Carace*® had a very different trajectory which began with a completely different naming strategy. Putting function before flash, the product name was made up of the first three letters of "**car**e" and the abbreviation ACE, which stands for **a**ngiotensin-**c**onverting **e**nzyme (Paling 2001). Of course, it would be incorrect to infer that the name alone was responsible for

[1] IMS Health, https://www.iqvia.com/

Zestril's success story. Clearly, many other factors came into play as well (e.g., the reputation of the company, the promotional campaign, the packaging, etc.). Still, as considerable research has shown, the name a product is given can have a significant effect on its consumer marketability (Gangwal and Gangwal 2011; Blackett and Robins 2001; Lowrey et al. 2003; Keller et al. 1998; Room 1982).

To ensure that their products are powerfully positioned on the legal drug market, pharmaceutical companies go to great lengths to devise names that are both attractive and distinctive (Faure 2022; 2018; 2014). However, the importance of distinctive naming is not only a question of commercial success. It is also an issue of consumer safety. To minimize medication errors related to look-alike and sound-alike proprietary names, since 2014, the US Food and Drug Administration (FDA) has issued a set of recommendations for developing proprietary names in the pharmaceutical industry (FDA 2020: 2016: 2014). While the guidance focuses primarily on safety-related aspects, the FDA also gives recommendations to avoid misbranding products by making "misrepresentations with respect to safety or efficacy" (FDA 2020: 15) and warns against names that would be considered too "fanciful" (FDA 2020: 3). This chapter presents detailed information about governmental recommendations for prescription drug names (PDNs) in the US. It demonstrates how the names devised by pharmaceutical companies are used to create brand identities for PDNs. Beforehand, however, the chapter gives a brief history of PDNs and reviews the different types of PDNs used in the US market today.

## A Brief History of Prescription Drug Names (PDNs)

The beginnings of contemporary drug science can be traced back to the first quarter of the 19th century and are marked by the emergence of the "clinico-anatomical method" in European hospitals. The clinico-anatomical method was based on a deep understanding of human anatomy, physiology, and nosology—the branch of medicine devoted to the classification of diseases. Using prolonged observations, thorough physical examinations, and detailed autopsies, the popularity of this approach was spread by prominent medical experts in Paris—the leading medical center in 19th century Europe. The aim of this method was to make diagnoses using not only clinical signs, but also quantifiable disruptions in the body's biological functions.

As early as 1809, French physiologist François Magendie (1783–1855) ushered in the era of experimental pharmacology by exploring the effects of recently isolated chemical drugs on various parts of the body (Dachez 2012: 548). Following in his footsteps, Magendie's student

Claude Bernard (1813–1878) studied the muscle relaxant effects of a paralyzing poison called "curare" (Dachez 2012: 552). The name of the toxin was derived from "urari", an Indigenous term from the Carib language spoken by the Macushi of Guyana.

A major milestone in the establishment of pharmacology as an independent science came when the first chair for pharmacology was established at the University of Dorpat, and German pharmacologist Rudolf Buchheim (1820–1879) was appointed for the prestigious position (Scheindlin 2010). It was under Buchheim's tutelage that one of the greatest pharmacologists of the modern age received his start. German chemist Oswald Schmiedeberg (1838–1921) served as an assistant to Buchheim at the University. Afterwards, he went on to publish over 200 articles and books in pharmaceutical science; and he trained more than 150 pharmacologists. His accomplishments played a major role in the success of the German pharmaceutical industry prior to World War II. Today, he is often considered the founder of modern pharmacology.[2]

In the US, one of Schmiedeberg's students, the biochemist John Jacob Abel (1857–1938) also enjoyed an illustrious career. In 1890, he was appointed to serve as the first chair in pharmacology. It is thanks to his pioneering research that, in 1883, epinephrine was isolated from the adrenal medulla of a kidney.[3] The name *epinephrine* is made up of the prefix *epi-* ("upon") and the Greek *nephros* ("kidney").[4] Thousands of kilometers away, Japanese chemist Jōkichi Takamine (1854–1922) was busy isolating the same hormone. In 1901, Takamine trademarked his discovery under the name Adrenalin (Yamashima 2016). The name was based on adrenal, the Latin name for the gland located atop the kidney which he used to harvest the hormone: *adrenal*, meaning "at or near the kidney" (ad- + renal).

At that time, many of the newly isolated substances which needed names were alkaloids, a class of naturally occurring organic compounds that contain at least one nitrogen atom (Hosztafi 1997). The onomastic trend was to name the discoveries after the plants from which the scientists had extracted the substances. For example, the malaria treatment *cinchonine* was discovered in 1811. Its name was formed by adding the suffix *-ine* to the plant used to harvest the pharmaceutical, the *Cinchona officinalis.* The plant was named after the Countess of Chinchon, who is credited as one of the first Europeans to be treated with quinine, and to have introduced the drug into Europe. The name given to the malaria treatment *quinine* (1820) was

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2 International Society for the Study of Xenobiotics, https://www.issx.org/page/Schmiedeberg.

3 https://www.worldofchemicals.com/273/chemistry-articles/john-jacob-abel-father-of-american-pharmacology.html.

4 Etymological data in this section are all extracted from lalanguefrancaise.com, cnrtl.fr and etymonline.com.

derived from the Quechua term *kina*, which the Spanish called *quina* ("bark"). The name *nicotine* (1828) was coined from the tobacco plant *Nicotiana tabacum*. The plant was named after the French ambassador in Portugal, Jean Nicot de Villemain, who sent tobacco to Paris in 1560. The extract from the bark of the willow tree falls into the genus *Salix* and served as the namesake for *salicin* (1828). The antispasmodic agent, *atropine* (1833), takes its name from the New Latin *Atropa*, the genus name of the belladonna plant, which was named after the Greek *Atropos*, one of the three Fates. The namesake of the stimulant *cocaine* (1856) was the coca plant which was originally called *cuca* in Quechua. And finally, the opiate *codeine* (1832) was derived from the Greek term *kōdeia*, meaning "poppyhead."

Botanical names were not the only source of inspiration for naming newly discovered pharmaceuticals in the 19th century. *Morphine* was isolated from the opium poppy in 1803 by the German pharmacist Friedrich Sertürner (1783–1841). Sertürner named his discovery *Morphium* after *Morpheus*, Ovid's name for the God of Dreams. The name was inspired by the drug's sleep-inducing properties. Almost one century later, in 1898, its derivative, *heroin*, was refined in 1874 by the English chemist Alder Wright (1844–1894), as the drug and its name were a registered trademark of the Friedrich Bayer & Company. The drug was named after the Greek term *hḗrōs* ("hero") and was sold as a cough suppressant for children. The substance *narcotine* was also isolated from the opium poppy in 1803 by French chemist Louis-Charles Derosne (1780–1846). Later, in 1832, its name was coined by the French chemist Pierre Robiquet (1780–1840). Derosne coined the term "narcotic" from the Medieval Latin term *narcoticum* (orig. Greek *narkōtikon)* which means to "make numb or stiff." *Narcotine* is still used as a cough suppressant today and is sold under the name *noscapine*, which is the Latinized spelling of *gnoscopine*, from the Greek term *gnosis* meaning "knowledge," and *op-* from "opium." The name *emetine* was coined from Greek term *emetikos*, which means to cause vomiting, because of its emetic properties. The drug itself was originally extracted from the root of the *Carapichea ipecacuanha* plant. The original name of this plant was derived from the Tupi term *ipega'kwãi* which translates into "roadside sick-making plant."

In the 20th century, the botanical names of pharmaceuticals increasingly began to use the suffix *-in(e)*. For example, the name *penicillin* was coined by Alexander Fleming (1881–1955) in 1929 (Brown 2023). Fleming named the substance after the scientific name of the mold from which it was first obtained, *Penicillium rubens*. The Latin term *penicillus* refers to the "paintbrush" structure of the fungus. The immunosuppressant medication *cyclosporine* (1969) has a similar genesis. Also isolated from a fungus (*Tolypocladium inflatum*), its pharmaceutical name indicates its botanical origin and morphology: the word "cyclosporine" is a combination

of the Greek term *cyclo* meaning "round" and the Latin term *spora* meaning "spore." A few years later, *vincristine* (1962) was extracted from and named after the flowering *Vinca rosea*, a species of periwinkle. The suffix *-in(e)* was not only used to create names of plant-based substances. The drug named *imipramine* (1957), for instance, was inspired by its chemical composition, and is made up of the first letters of "**imi**ne" and "**pr**opyl", and the suffix *–amine*. The pharmacopeia of plant-based extracts was further enriched by physiological products such as *pepsin* (1836), which was found in gastric juices. Its name was coined by the German physician Theodor Schwann (1810–1882) from the Greek term *pepsis* meaning "digestion." In 1848, *pancreatin* was isolated from the pancreas. Today, it is better known as "pancreatic lipase enzyme." A digestive hormone produced by the wall of the upper small intestine was isolated in 1902 and named *secretin* after it was found to increase secretion in the pancreas. Two other pharmaceutical names that were inspired from bodily organs are *heparin* (1918) named after the Greek term *hepar*, meaning "liver"; and *insulin* (1922) which is produced by the pancreatic islets of Langerhans and was therefore named after the Latin word *insula* meaning "island." At the same time that these and other physiologically based products were being discovered, harvested, named, and marketed, a breakthrough in pharmacology would lead the way to a new generation of synthesized drugs.

In 1828, the German chemist Friedrich Wöhler (1800–1882) successfully synthesized urea from inorganic precursors. This innovation marked a revolutionary turning point in the history of clinical chemistry and pharmacology. Until then, in-vitro synthesis—the synthetic production of physiologically-occurring compounds in the laboratory through various chemical processes such as oxidation—had been considered impossible. Indeed, the processes that took place within living organisms were believed to involve a unique existential force that could not be duplicated in the laboratory (Wilkinson 2002). Wöhler's success demonstrated that the complex processes that occurred in a living body were simply the result of chemical reactions, and as such they could be replicated to synthesize new pharmaceutical products on an industrial scale.

According to Jones (2011), the first pharmaceutical companies were spin-offs of the textiles and synthetic dye industry and owe much to the rich source of organic chemicals derived from the distillation of coal. An excellent example here is the world-famous pharmaceutical company Bayer, which was founded in the German city of Wuppertal-Barmen in 1863 by dye salesman Friedrich Bayer and dyer Johann Friedrich Weskott. Using their chemical expertise, the two began to investigate the medicinal use of tar, a substance which had long been used as both a coloring agent and a medicinal ingredient. In particular, they and others investigated tar-

derived compounds such as acetanilide, which turned out to have fever-reducing properties and was marketed as *Antifebrin* in 1886. The Bayer company set its sights on exploring the acetylation of tar-derived compounds in hopes of producing other pharmaceutical products. In 1897, one of their chemists, Felix Hoffman (1868–1946), produced a pure, stable, substance called "acetylsalicylic acid" (ASA). Soon thereafter, pharmacologist Heinrich Dreser (1860–1924) discovered ASA's pain-relieving effects, and the substance was formally registered under the name *Aspirin* in 1899. The name was inspired by its synthesis (***a**cetylation*) and ***-spir***, from *Spiraea ulmaria*, the botanical source of salicylic acid. The product became a huge commercial success.

Inspired by the great potential wealth to be had, the late 19th century saw the establishment of many of today's pharmaceutical powerhouses. Just a few include Pfizer, which was founded in 1849; Squibb in 1858; Glaxo, 1873; Lilly, 1876; Johnson & Johnson, 1886; Abbot, 1888; and Merck, 1891. With the discovery and mass-production of antibiotics such as penicillin at the end of World War II, the pharmaceutical industry exploded. By the second half of the 20th century, industry-sponsored research had helped to discover more than 100 essential molecules. It was at this time that a change began to occur in the strategy used to name new pharmaceuticals. As more drug products began to reach the market, the drug companies devised more distinctive, chemical-based names to distinguish their products. One example of this evolution can be seen in the development of barbituric acid. The name was coined in 1863 by German chemist Adolf von Baeyer (1835–1917) allegedly after St Barbara's Day, the day von Baeyer discovered the drug. The name *barbituric acid* became the basis for naming many derivative products like the potent sleeping pill barbital, which was synthetized by German chemists Josef von Mering (1849–1908) and Emil Fischer (1852–1919). A similar substance was marketed in 1904 by Bayer under the trade name *Veronal*®: the name is alleged to have been inspired by the Italian city of Verona which was known as a peaceful tourist attraction. Phenobarbital, another profitable derivative of barbituric acid, was sold as a hypnotic by Bayer, under the trade name *Luminal*®, based on the Latin term *lumen*, meaning "light." In 1923, Abbot launched another barbiturate by the name *Neonal*®, which combined *neo-* ("new") with the familiar suffix *-al*. Within a few years of the discovery of barbituric acid, almost all major pharmaceutical companies had their own barbiturate—each with its own distinctive name.

Along with the chemical composition, pharmaceutical products were also given names to commemorate the research sponsors. One example here is the famous blood thinner, warfarin. In the 1920s, the northern states of the US and Canada were struck by an outbreak of hemorrhagic disease among cattle that were grazing moldy sweet clover hay. In 1941, the US

American biochemist and renowned expert in plant carbohydrate chemistry, Karl Paul Link (1901–1978), and his students managed to isolate a substance that reduced clotting in lab animals. They called it *dicoumarol* because of its structural similarity to coumarin. The name *coumarin* was derived from *kumaru*, the name for "tree" in the South American Indigenous language, Kari'nja. In 1820, French pharmacist Nicolas Guibourt (1790–1867) got the extract from the now outdated genus name, *Coumarouna* (Wardrop and Keeling 2008). Link and his students went on to develop a method for synthesizing dicoumarol in the laboratory. Link realized that some variants of dicoumarol might have many other uses. Link's research was funded by the Wisconsin Alumni Research Foundation (WARF). With their financial support, in 1945, Link developed a type of dicoumarol that was particularly effective as a rat poison. To recognize WARF's assistance in filing the necessary patent, Link named the compound *warfarin* (WARF + *-arin* from *coum**arin***). Link later successfully developed a clinical-grade warfarin for human testing as a blood-thinner. In 1954, Warfarin received FDA-approval for use in the prevention of blood clots and was sold under the brand name *Coumadin*®. Today, warfarin is the most widely used anticoagulant in the world. According to financial estimates, in 2021, the market-size of warfarin globally was valued at $535.66 million and is expected to exceed $550 million by 2027 (Marketwatch 2023).

With profits this large, it is no surprise that pharmaceutical companies continue to invest heavily in expanding their product selection for the global market. Many of these new products are, however, simply variations of a previously released substance. Indeed, by the end of the 1990s, truly novel discoveries had become relatively rare. Instead, the market has been flooded by nearly identical copies of original molecules which allow manufacturers to maximize their profits. According to Angell (2004), from 1998 through to 2003, out of 487 drugs that were approved by the FDA, 68% were so-called "me-too drugs," that is "drugs that contain minor variations of pharmaceuticals already on the market."

The similarity between products has also come with corporate risks. Chief among them is the fierce financial competition which cuts the potential profits to be earned by single companies. To circumvent this problem, in recent years several rival pharmaceutical companies have decided to join forces to form mega-conglomerates. GlaxoSmithKline (GSK), for example, is the product of a merger between Glaxo Wellcome and SmithKline Beecham. Even so, competition on the pharmaceutical market remains tough as manufacturers battle for consumer loyalty using nearly identical chemical substances. In the face of this rivalry, drug names are often the key to making one drug stand out on the market against its competitors. Given the terrific financial stakes involved, pharmaceutical companies invest heavily to hire specialist

agencies to help them find and register winning brand names—sometimes even before a suitable drug product has been released for manufacture (Dutchen 2009).

## The Basic Types of PDNs

Drugs often have at least four names. When it is first discovered, it is given a CHEMICAL NAME by the International Union of Pure and Applied Chemistry (IUPAC). This name describes its atomic or molecular structure. For instance, the chemical name of the so-called "abortion pill" is *(dimethylamino)phenyl]-17α-(1-propynyl)estra-4,9-dien-17β-ol-3-one*. Of course, such names are too complicated for general use (Karet 2019). For that reason, it is common for a shorthand version of the chemical name, or a CODE NAME, to be developed. The code name *RU 486* is used for this pharmaceutical product, derived from the abbreviation for the pharmaceutical company that marketed it, **R**oussel-**U**claf (RU), and the product serial number, *486*.

When drugs undergo clinical trials, they are given a GENERIC NAME—an International Nonproprietary Name (INN)—which is proposed by the WHO. INNs are not subject to proprietary trademark rights but are entirely in the public domain. An INN is made up of stems, which can be prefixes, infixes, and more generally suffixes. These stems typically give information about a drug's composition and class. The INN naming system has been standardized for consistency (e.g., names ending with *-adol* like *tramadol* belong to analgesics; *-caine* like *lidocaine* to local anesthetics; *-tinib* like *imatinib* to tyrosine kinase inhibitors; names starting with *gli-* like *glimepiride* belong to antihyperglycemics, and sulfonamide derivatives; *som-* like *somatropin* to growth hormone derivatives; *rifa-*, like *rifadine* to antibiotic rifamycin derivatives, etc.).[5]

These specification policies help identify pharmaceutical uses. Consider, for example, the INNs used for monoclonal antibodies. They all follow a fixed pattern (prefix + target + source + *mab* for "monoclonal antibody"). Several abbreviated codes are also available for each of these constituents: target (**b***a* for "bacterium," **f***u* for "fungus," **t***u* for "tumor," **c***i* for "cardio," **k***i* for "interleukin," **n***e* for "neural," **s***o* for "bone," **tox***a* for "toxin," **v***i* for "viral," and **l***i* for "immuno"); and source (**u** for "human," **a** for "rat," **xi** for "chimeric," **i** for "primate," **o** for "mouse," **zu** for "humanized," **xizu** for "chimeric human" and **e** for "hamster"). Thanks to this system, it is possible to decipher that the INN *alemtuzumab* is humanized (zu) and used for cancer (tu); *abciximab* is identifiable as a chimeric (xi) that is used for heart problems (ci); and

[5] World Health Organization, https://www.who.int.

*adalimumab* is fully human (u) and indicated for treatment of diseases of the immune system (li).

Once a drug has been assigned an INN, it may also be given a country-specific identifier, depending on the nation in question. There are many country-specific systems (e.g., the British Approved Name (BAN), French Dénomination Commune Française (DCF), Japanese Accepted Name (JAN), or United States Adopted Name (USAN)). These different national naming schemes may yield differing names for the same substances. For example, N-acetyl-para-aminophenol is called *acetaminophen* (**acet**yl + **amino** + **phen**ol) in the US and *paracetamol* (**para**-a**cet**yl + **am**ino + phen**ol**) in the European Union (EU).

In the United States, unique nonproprietary names for medication to be marketed domestically are assigned by the United States Adopted Names Council (USANC). The USANC is an FDA-recognized nomenclature agency responsible for the selection of nonproprietary (generic) names for all chemical and biologic single-entity drugs marketed in the nation. It was established in 1961 as the result of a partnership between three organizations involved in the standardization of drug nomenclature (the American Medical Association, the American Pharmacists Association, and the United States Pharmacopeial Convention) after several major concerns had been raised: (1.) the existing system did not require selection of a nonproprietary name for each drug; (2.) there was no central list of names; and (3.) there was no legal requirement that all firms use the same name for an identical substance.

USANC's role is to systematize drug nomenclature and create useful and conflict-free generic names. The Council works in conjunction with the WHO INN Expert Committee, which is why names rarely differ. For instance, the INN/USAN name of RU 486 is *mifepristone*: its suffix *-pristone* indicates that the drug is a progesterone receptor antagonist. The USAN assignment is a necessary step in drug development before pharmaceutical products can be brought to the US market. Assignment of a USAN is required for any new drug before patients can have access to it. According to Karet (2019), over 10,000 drugs have received nonproprietary names since the WHO, the American Medical Association, the American Pharmacists Association, and the United States Pharmacopeial Convention began assigning names to drugs. In 2018, the USAN program named 198 substances. Since then, the number has grown steadily. The USANC mostly bases its assignments on INN stems, however, some variation does occur. By contrast, the European Commission requires all member states to use recommended INNs for all drugs.

Alongside these names, pharmaceutical companies also develop a PROPRIETARY NAME for each product. These names are subject to regulatory approval. For example, mifepristone was

trademarked as *Mifegyne*®. This name must be approved by the FDA before the pharmaceutical product can be put on the market in the US. Once a pharmaceutical patent has expired, companies that make the drug are free to choose other names for their generic versions. As a result, mifepristone has been marketed as *Medabon*, *Mifabon*, *Mifeprex*, *Mifeprin*, *Korlym*, *Termipil*, etc. As this example shows, the prescription drug market is characterized by a constant introduction of new brands at the expense of existing brands.

This onomastic dynamism is in stark contrast to the time it takes to bring a product to market. Launching a new drug takes an average of 12 years. In addition, only five in 5,000, or 10%, of drugs that begin preclinical testing ever make it to human testing. Only one of these five will ever receive approval for human usage. In the US, once the preclinical research is complete, a pharmaceutical company must file an Investigational New Drug Application (IND) with the FDA to begin to test the potential new drug in humans. The FDA mandates a three-phase clinical trial, with a single phase costing upwards of $100 million. After all three phases of clinical testing have been completed successfully, a pharmaceutical company must then file a New Drug Application (NDA) with the FDA. Once the FDA approves the drug, it can then be made available for physicians to prescribe to patients.[6] In 2020, the median cost of getting a new drug onto the market was estimated to be $985 million.[7]

Drug patents are internationally recognized and regulated by the World Intellectual Property Organization (WIPO). Created in 1970, the WIPO helps to ensure that intellectual property (IP) is protected around the world. Patents issued by the WIPO last 20 years and may be extended by a maximum of seven years under certain special conditions (e.g., to help ensure the continued production of so-called "orphan drugs" for statistically rare diseases).[8] To help make sure their financial stake in a product is secure, drug manufacturers often patent new compounds early in the drug research process to protect their IP. This strategy means that by the time their drug obtains approval, their WIPO patent may only last a few years. This is why some companies go to great lengths to have their patents prolonged. To extend their IP ownership, drug companies may invest considerable funds in hopes of finding new indications, new formulations, or new routes of administration which can be used as an argument for prolonging their patent (Gupta et al. 2010). Once a drug patent fully expires, the way is paved for generic competitors to profit from the product. Therefore, the period of patent protection is

6 FDA, https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved.

7 London School of Economics and Political Science, https://www.lse.ac.uk.

8 WIPO, https://www.wipo.int.

crucial to maintaining a corner on the market and garnering maximum financial return. Pharmaceutical companies make about 80% of their overall revenue for a product during this period. This time is not only crucial for helping a company recoup its drug development costs; it also provides a unique opportunity for them to strengthen a brand's identity to secure consumer loyalty before generic competitors reach the market. In this way, pharmaceutical companies can extend a drug's life or profit long after a patent has expired.

## An Overview of the FDA's Best Practices in Developing Proprietary Names for Prescriptions (PNPs)

The FDA was established in 1906 with the Pure Food and Drugs Act (PFDA) that sought to give consumers more information to help them identify effective medicines. According to Donohue (2006), it was only after more than 100 people had died after taking a drug called *elixir sulfanilamide* that the US Congress passed the 1938 Food Drug and Cosmetic Act (FDCA). With this regulation, for the first time in US history, only drugs that had been proven safe were eligible to receive the FDA approval required for entering the market.

Today, once a PNP is found, company laboratories may apply for marketing authorization with the FDA. The Division of Medication Error Prevention and Analysis (DMEPA) is responsible for PNPs.[9] It reviews proposed names prior to their approval by putting them through a battery of tests. For example, the orthographic and phonetic similarity of a proposed PNP to other names is assessed by using the Phonetic and Orthographic Computer Analysis (POCA) software.[10] Proposed PNPs may be handwritten and presented to healthcare professionals to determine their decipherability. It is also common to test how understandable PNPs are when pronounced in different languages and across various settings, such as on the phone or in a noisy environment. Using these and other procedures, the FDA evaluates approximately 500 names per year and ultimately rejects four out of ten (Scutti 2016).

In May 2014, in response to about 126,000 drug-related incidents, some of which were due to consumers confusing drugs with similar names, the FDA issued recommendations for naming newly branded prescription drugs (FDA 2014). The guidelines were subsequently revised in April 2016 (FDA 2016) and in December 2020 (FDA 2020). In the latest version, the FDA recommends sponsors avoid proposed PNPs that are similar in either spelling or pronunciation

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9 FDA, https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products.

10 FDA, https://www.fda.gov/drugs/information-industry-drugs/phonetic-and-orthographic-computer-analysis-poca-program.

to existing PNPs, established names, proper names, names of ingredients, or other consumer products. The Institute for Safe Medication Practices (ISMP), a nonprofit organization, publishes a list of confusing drug names that contains look-alike and/or sound-alike names. For example, *Aldara*®, which is used to treat superficial basal cell carcinoma, is reported as being unacceptably close to *Alora*®, which is used to treat the symptoms of vulvar and vaginal atrophy in menopause (ISMP 2017). The ISMP's list is published to inform the public and the industry about medications that require special safeguards in hopes of reducing the risk of potentially dangerous errors. However, adherence to ISMP's recommendations is not mandatory.

When the FDA receives a medication error report, generally they make recommended changes to product labelling to avoid consumer confusion. For example, the FDA may suggest that a PNP utilizes a mixture of upper- and lower-case lettering, employs different font sizes, alters layouts, or changes the colors. In rare cases, the FDA may exercise its regulatory authority and require companies to completely change a PNP to eradicate medication errors resulting from name confusion. For example, in July 2005, the maker of the Alzheimer drug *Reminyl*® had to change the brand name to *Razadyne*® to help avoid consumer confusion with the diabetes drug *Amaryl*®. Another example is the blockbuster arthritis drug originally named *Celebra*®. After a pharmacy professor complained that it sounded too similar to the antidepressant *Celexa*®, the FDA required the pharmaceutical company to change the PNP, and the replacement name Celebrex® was selected (Hoffman and Proulx 2003).

The FDA recommends that proposed PNPs refrain from incorporating any reference to inert or inactive ingredients contained in the pharmaceutical compound, such as aspartame or sulfites, as doing so may mislead consumers into thinking that their functional importance to the product is greater than it actually is (FDA 2020: 5). For example, giving the analgesic *Percocet*® the name *Percocet Povidone* simply because it contains povidone—a synthetic polymer vehicle used for dispersing and suspending drugs—would, in all likelihood, make consumers wrongly believe that povidone has a therapeutic value.

The FDA also recommends avoiding PNPs that include or suggest the name of one or more, but not all, of its active ingredients (FDA 2020: 5). Such names can mislead the end-user by implying that the product contains only that ingredient. For example, naming the COVID-19 treatment *Paxlovid*®, which contains the two antivirals, nirmatrelvir and ritonavir, as *Paxlovid ritonavir* would be misleading, as this name makes no mention of nirmatrelvir and could lead consumers to believe that the treatment contains only one anti-viral agent.

The FDA further states that proposed PNPs may not contain an INN/USAN stem (FDA 2020: 5). Using these stems could erroneously suggest that a product has a pharmacological or chemical trait that it does not. For example, the name of the antimalarial drug *Malarone*®, contains the stem *-arone* which is normally reserved for anti-arrhythmic drugs (e.g., *amiodarone*, *dronedarone*, etc.). This name might mislead some into thinking that it is also used to regulate cardiac dysrhythmia. This potential confusion is not the only reason why using INN/USAN stems is discouraged in PNPs. The use of these regulatory onomastic elements for brand names could challenge the power of the USAN and INN to select names in the same series.

Another FDA guideline for devising new drug product names is the avoidance of "brand name extension" (FDA 2020: 6). This naming strategy involves basing a new name on a PNP that is already associated with one or more marketed drug products for a new product that does not share any active ingredient(s) with the pre-existing drug product(s). At the same time, sponsors are also warned to take special onomastic precautions when devising PNPs for products that contain the same active ingredient(s) as a pre-existing product already on the market. When products that contain the same molecule are given entirely different PNPs, consumers may be at risk of either overdosing or experiencing dose-related adverse events when they unwittingly consume the two products. If matters were not complex enough, the FDA also advises against devising PNPs that are identical, or nearly identical, to foreign products on the market that contain an entirely different active ingredient. This warning stands even if the proposed product is to be marketed exclusively in the United States, or when the foreign product is solely sold outside of the United States.

Moreover, the FDA also recommends that drug-makers refrain from using PNPs that are reminiscent of, or identical to, a different product that is no longer marketed. This onomastic warning is given to avoid end-users continuing to associate the name with the original discontinued product (FDA 2020: 7). For example, using the name *Myolastan* for a new drug to help with, for example, weight control, after the muscle relaxant *Myolastan*® was withdrawn from the market in 2013 might cause some patients to wrongly believe that the old product was back on the market and could be used in the same way.

PNPs, according to the FDA directives, should also be readily pronounceable (FDA 2020: 38). This is to help ensure drug products are easily and correctly communicated by healthcare professionals when prescribing, ordering, transcribing, dispensing, and/or administering drugs. It also helps to avoid misunderstandings when healthcare specialists counsel patients on their medications. For those very same reasons, the FDA also discourages sponsors from proposing

PNPs that consist of a string of letters or numbers (FDA 2020: 8). A PNP with digits might be misconstrued by consumers as an indicator of recommended dosage. For much the same reason, sponsors are generally discouraged from incorporating symbols, dose designations, and medical abbreviations commonly used for prescription communication into their proposed PNPs because their inclusion could inadvertently introduce a source of consumer error.

The FDA recommends that sponsors avoid incorporating product-specific attributes, such as manufacturing characteristics, dosage form or route of administration into the proposed root of a PNP (FDA 2020: 8). This recommendation is for a very pragmatic reason: it is not uncommon for a product's attributes to change during a drug's life cycle. Such changes could render the root PNP inaccurate and thus unusable.

Proposed PNPs that incorporate the sponsor's name in its entirety, or in part, are also to be avoided, according to the FDA guidelines (FDA 2020: 15). Some companies find this recommendation particularly annoying as the incorporation of a company name into a series of PNPs can help create a link to a series of other products, already successfully marketed by the company. However, this marketing strategy also risks consumers becoming confused over which product is used for what health problem. The naming practice could pose safety risks when healthcare professionals who distribute or sell drug products store or list them alphabetically.

And finally, the FDA strongly discourages the use of any PNP that can convey false or misleading information (FDA 2020: 15). For instance, a proposed PNP that risks misrepresenting the safety or efficacy of a product must be avoided. Companies are to refrain from creating fanciful misleading PNPs, for instance, that falsely suggest that a pharmaceutical product has a degree of effectiveness which it does not, or that it contains an unusual composition which it has not. To help protect consumers against such names, in March 2021, the FDA announced that it would be conducting an investigation, together with the Office of Prescription Drug Promotion (formerly the Division of Drug Marketing, Advertising, and Communications), to investigate misleading drug names that overstate their product efficacy or understate their risks. The goal of the study was to determine how drug names influence consumers and healthcare providers. The agency has suggested that, depending on the findings, it may update its drug-naming guidelines. As of the writing of this chapter, the research results are not yet published.

While the FDA is principally in charge of reviewing PNPs in the United States, in the EU, the EMA (European Medicines Agency) is responsible for the scientific evaluation of medicines. There are two routes pharmaceutical companies may take to apply for drug marketing

authorization: the "mutual recognition" procedure, and the "centralized" procedure.[11] The mutual recognition route involves a medication in one EU Member State receiving authorization by being recognized by another EU Member State. The "centralized" procedure allows a drug to be marketed after it has successfully undergone EU-wide evaluation. Within the EMA, the Name Review Group is responsible for assessing PNPs. In 2021, the EMA released a seventh revised version of its guidelines on the acceptability of PNPs for drugs (EMA 2021). Originally published in 2007, the 2021 version introduces several new requirements based on the FDA's recommendations. The EMA regulations are generally still not as far-reaching as those used by the FDA.

## Conclusion: How Big Pharmaceutical Companies Use PNPs to Connect Brand Identity and Consumer Identity

As indicated in section four, today, the FDA reviews and approves new medicines at record pace, despite regulations for the approval of a PNP being still rather stringent. However, obtaining FDA approval is not the only hurdle drug companies face when devising new names for their products. In the United States and New Zealand, pharmaceutical companies are allowed to use broadcast advertising to extol the merits of their prescription drugs. This strategy is called "direct-to-consumer advertising" (DTCA). This "mixed" marketing strategy must not only effectively reach doctors, but also patients. Ferrier (2001) has this to say about the use of large-scale DTCA to promote prescription purchasing:

> [t]he permitted use … has dramatically changed the landscape of brands, in terms of their levels of consumer awareness and the claimed level of prescriptions that have been made out by doctors as a result of branded consumer requests.
>
> (Ferrier 2001: 69)

In recent years, potential effectiveness of DTCA has been increased by the incorporation of internet-based ads. This medium has provided another powerful (often unregulated) means of advertising prescriptions directly to consumers. To reach e-audiences, some pharmaceutical companies have begun to target patient advocacy groups to help promote their medications to treat their diseases. The rationale behind developing campaigns to reach this new consumer group is that patients are now more actively engaged in their care. This phenomenon of "patient

[11] European Commission, https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/authorisation-procedures-centralised-procedure.

empowerment" is defined by the WHO as "a process through which people gain greater control over decisions and actions affecting their health."[12] Such empowered patients, when targeted by DTCA campaigns, may ask their doctors for particular brands. To help ensure that these patients ask for their product when they speak with their healthcare providers, pharmaceutical companies work very hard to attract consumers via effective logos, slogans, and packaging to make a brand unique. An integral part of this strategizing is devising names that are memorable and positive. The ultimate goal is to create a unique name that will avoid the regulatory and safety pitfalls of the government guidelines, while still appealing to both practitioners and patients. According to Scutti (2016), names are crafted as per four distinct dimensions: visual distinctiveness, melodic contrast, verbal velocity, and language neutrality (the absence of negative or offensive connotations in foreign languages). Government-sanctioned PNPs that successfully meet each one of these criteria have an optimal chance of not only attracting consumer attention, but also creating a strong bond between a brand identity and the consumer's identity. When this match occurs, the resulting relationship can be enormously profitable and remarkably long-lasting.

## References

Angell, Marcia. 2004. "Excess in the Pharmaceutical Industry." *Canadian Medical Association Journal 171*, no. *12*: 1451–1453. doi:10.1503/cmaj.1041594.

Blackett, Tom and Rebecca Robins. 2001. *Brand Medicine, the Role of Branding in the Pharmaceutical Industry*. New York: Palgrave.

Brown, Kevin. "Alexander Fleming." *Encyclopedia Britannica*. https://www.britannica.com/biography/Alexander-Fleming. Accessed 26 January 2023.

Dachez, Roger. 2012. *Histoire de la médecine* [History of Medicine]. Paris: Taillandier.

Donohue, Julie. 2006. "A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection." *Milbank Quarterly 84*, no. *4*: 659–699. doi:10.1111/j.1468-0009.2006.00464.x.

Dutchen, Stephanie. 2009. "A Drug By Any Other Name." *Scope*. http://classic.scopeweb.mit.edu/articles/a-drug-by-any-other-name/. Accessed 15 February 2018.

European Medicines Agency. 2021. *Guideline on the Acceptability of Names for Human Medicinal Products Processed Through the Centralised Procedure*.

[12] World Health Organization, https://www.who.int/teams/health-promotion/enhanced-wellbeing/seventh-global-conference/community-empowerment.

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf.

Faure, Pascaline. 2014. “Du sildénafil citrate au Viagra® ou l’art délicat de nommer les médicaments. [From Sildenafil Citrate to Viagra® or The Delicate Art of Naming Drugs].” *Terminology 20*, no. *1*: 74–91. doi: https://doi.org/10.1075/term.20.1.04fau.

Faure, Pascaline. 2018. “Natesto®. What Else? New Trends in Drug Naming.” *Names: A Journal of Onomastics 66*, no. *2*: 65–74. doi:10.1080/00277738.2017.1415532.

Faure, Pascaline. 2022. “Le marketing des médicaments ou l’art de transformer les bien-portants en malades: analyse multimodale des noms et des logos de dix médicaments de marque sur ordonnance.” [Drug Marketing Or The Art of Turning the Healthy Into The Sick: A Multimodal Analysis of the Names And Logos Of Ten Branded Prescription Drugs]. *ELAD-SILDA*. doi:10.35562/elad-silda.1182.

FDA. 2014. *Guidance for Industry. Best Practices in Developing Proprietary Names for Drugs*. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf.

FDA. 2016. *Contents of a Complete Submission for the Evaluation of Proprietary Names. Guidance for Industry*. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf.

FDA. 2020. *Best Practices in Developing Proprietary Names for Human Prescription Drug Products, Guidance for Industry*. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry.

Ferrier, Hugh. 2001. “Successful Switch Strategies.” In *Brand Medicine, the Role of Branding in the Pharmaceutical Industry*. Edited by Tom Blackett and Rebecca Robins, 61–81. New York: Palgrave.

Gangwal, Amit and Ankit Gangwal. 2011. “Naming of Drug Molecules and Pharmaceutical Brands.” *Journal of Current Pharmaceutical Research 7*, no. *1*: 1–5. https://lawpunditsglobal.com/media/uploads/2013/10/Branding-of-Pharma-Products.pdf.

Gupta, Himanshu, Suresh Kumar, Saroj Kumar Roy, and R. S. Gaud. 2010. “Patent Protection Strategies.” *Journal of Pharmacy & Bioallied Sciences 2*, no. *1*: 2–7. doi:10.4103/0975-7406.62694.

Hoffman, James M., and Susan M. Proulx. 2003. “Medication Errors Caused By Confusion Of Drug Names.” *Drug Safety 26*, no. *7*: 445–452. doi:10.2165/00002018-200326070-00001.

Hosztafi, Sandor. 1997. “The Discovery of Alkaloids.” *Die Pharmazie 52*, no. *7*: 546–550.

Institute for Safe Medicine Practices. 2017. *List of Confused Drug Names*. https://www.ismp.org/sites/default/files/attachments/2017-11/confuseddrugnames%2802.2015%29.pdf.

Jones, Alan. 2011. “Early Drug Discovery and The Rise of Pharmaceutical Chemistry.” *Drug Test and Analysis 3*, no. *6*: 337–344. doi:10.1002/dta.301.

Karet, Gail. 2019. “How Do Drugs Get Named?” *AMA Journal of Ethics 21*, no. *8*: 686–696. doi:10.1001/amajethics.2019.686.

Keller, Kevin, Susan Heckler, and Michael Houston. 1998. “The Effects of Brand Name Suggestiveness on Advertising Recall.” *Journal of Marketing 62*, no. *1*: 48–57. https://doi.org/10.1177/002224299806200105.

Lowrey, Tina M., L. J. Shrum, and Tony M. Dubitsky. 2003. “The Relation between Brand-Name Linguistic Characteristics and Brand-Name Memory.” *Journal of Advertising 32*, no. *3*: 7–17. https://doi.org/10.1080/00913367.2003.10639137.

MarketWatch. 2023, January 5. “Warfarin Market Insights 2023: Key Dynamics, Significant Growth Rate, Revenue Expectations, and Size Forecasts.” https://www.marketwatch.com/press-release/warfarin-market-insights-2023-key-dynamics-significant-growth-rate-revenue-expectations-and-size-forecast-to-2027-2023-01-05.

Paling, Mike. 2001. “The Role of Advertising in Branding Pharmaceuticals.” In *Brand Medicine: The Role of Branding in the Pharmaceutical Industry*. Edited by Tom Blackett and Rebecca Robins, 113–129. New York: Palgrave, 2001.

Room, Adrian. 1982. *Dictionary of Trade Name Origins*. London: Routledge and Kegan Paul Ltd.

Scheindlin, Stanley. 2010. “Our Man in Dorpat: Rudolf Buchheim and the Birth of Pharmacology.” *Molecular Interventions 10*, no. *6*: 331–335. doi:10.1124/mi.10.6.1.

Scutti, Susan. 2016. “‘Creation Engineering’: The Art and Science of Naming Drugs.” *CNN*. Accessed May 14, 2020. https://edition.cnn.com/2016/11/25/health/art-of-drug-naming.

Stepney, Rob. 2010. “A Dose by any Other Name would not Sell as Sweet.” *The British Medical Journal 341*, no. *7786*. doi: https://doi.org/10.1136/bmj.c6895.

Wardrop, Douglas and David Keeling. 2008. “The Story of the Discovery of Heparin and Warfarin.” *British Journal of Hematology 141*, no. *6*: 757–763. doi:10.1111/j.1365-2141.2008.07119.x..

Wilkinson, Ian. 2002. “History of Clinical Chemistry.” *The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine 13*, no. *4*: 114–118. PMCID: PMC6208063.

Tetsumori, Yamashima. 2016. “Jokichi Takamine (1854–1922): The Samurai Chemist and His Work on Adrenalin.” *Journal of Medical Biography 11*, no. *2*: 95–102. doi:10.1177/096777200301100211.