Pills

Big Pharma, the FDA, & Problem Medicine

Written by Emily Gottlieb
Deputy Director for Law & Policy

Edited by Joanne Doroshow
Executive Director

November 2021

Center for Justice & Democracy at New York Law School
185 West Broadway, New York, NY 10013; centerjd@centerjd.org

Center for Justice & Democracy at New York Law School
185 West Broadway
New York, NY 10013
centerjd@centerjd.org
http://centerjd.org

"Fighting to protect the right to jury trial and an independent judiciary for all Americans."

© Copyright 2021 Center for Justice & Democracy. All rights reserved.

TABLE OF CONTENTS

INTRODUCTION

According to the most recent CDC data, close to half of the U.S. population has used at least one prescription drug in the past 30 days.[1] For those over age 57, more than 80 percent take at least one such pill *every day*.[2] Americans have clearly helped launch U.S. pharmaceutical industry finances into the stratosphere. In the United States, pharmaceutical spending exceeds $500 billion a year.[3] And U.S. companies dominate the world market, with six U.S. companies in the top 10 globally.[4] This wealth has helped lift the industry's global value to $1.27 trillion.[5]

But while everyday Americans have been very good to Big Pharma, Big Pharma has not been good to them. Despite its excessive wealth, the drug industry has maintained a cost-cutting business model that has created situations where many prescription drugs are of uncertain quality and potentially hazardous. When it comes to generic drugs, which represent 90 percent of all pills we ingest,[6] the safety concerns are particularly worrisome. The Food and Drug Administration (FDA), which is supposed to oversee and inspect the tens of thousands of drugs on the U.S. market, has neither the staff nor the resources to adequately protect the public. That is why the U.S. Supreme Court has said, when it comes to safety, "it is a central premise" of federal law that the manufacturer bears primary responsibility.[7]

People expect their medicine to be safe. This report shows two ways it may not be, and the ways the law protects the giant drug industry — not the American public — when it comes to one of its most important jobs: safety.

THE MEDICINE MANUFACTURING MESS

Many patients probably assume that any prescribed pill recommended by their doctor and obtained from their pharmacist has been made in a U.S. facility with high quality production standards and is manufactured safely. They would be wrong.

First, when it comes to manufacturing quality, no one should assume it to be particularly high. According to senior FDA officials who testified before Congress in June 2020,[8] "Some pharmaceutical firms have been slow to implement robust, mature quality systems and the accompanying quantitative measures of quality that have been the foundation of success in other industries, such as automotive and aerospace." *New York Times* editorial writer Farah Stockman recently put it bluntly:[9]

> [Some] companies with quality control issues simply opt to stop making a drug rather than invest in expensive upgrades to their aging facilities. The current system simply doesn't reward investments in quality.…
>
> The truth is, a pill is not just a pill. A pill that was made in a top-notch factory with a spotless track record is better than one that was made in a plant that barely passed inspection. A pill that was stored in a cool dark place is better than one left baking on an airport tarmac for weeks.

One example of a manufacturing quality problem is drug cross-contamination during the manufacturing process. As *Bloomberg Businessweek* reported in a July 26, 2021 article about "rampant" cross-contamination,[10] "Manufacturers stamp out pills for one condition on the same machines they use to stamp out pills for a different one, and while they're supposed to clean between production rounds, trace contamination is common and, some argue, inevitable." Some contaminants may be harmless but some may be dangerous, such as carcinogenic nitrosamines mentioned by *Bloomberg*.

Far-Off Factories

Once the FDA approves a drug, it can be manufactured anywhere in the world. Of course, foreign manufacturing does not necessarily mean pills are inferior or unsafe. But many companies have moved production to nations like China and India, where drug companies no longer have to follow basic public protection or labor laws, and they can make drugs on the cheap. Cut-rate production is the goal, not quality.

According to recent FDA estimates, "nearly 40 percent of finished drugs and approximately 80 percent of active pharmaceutical ingredients are manufactured in [FDA-]registered establishments in more than 150 countries."[11] Nineteen percent of active pharmaceutical ingredients come from India and 13 percent come from China.[12] A June 2021 White House report determined that about half of over 100 supercritical medications are made with ingredients produced outside the United States.[13] Moreover, a March 2021 Government Accountability Office (GAO) study found that "74 percent of establishments manufacturing active pharmaceutical ingredients and 54 percent of establishments manufacturing finished drugs for the U.S. market were located overseas."[14]

As far as generic drugs specifically, 40 percent come from India and "another sizable percentage comes from China."[15] Additionally, the White House reports that "of the top 100 generic medicines that Americans consume, 83 had no U.S. source of active pharmaceutical

ingredients. No American source existed for 97 percent of the most commonly prescribed antivirals and 92 percent of the most commonly prescribed antibiotics."[16]

Investigative journalist and pharmaceutical industry expert Katherine Eban told one publication:[17]

> [A] very common scenario is you'll have an Indian generic company buying active ingredients from a Chinese company, and then taking that active ingredient and formulating it into what is called a finished dose. The finished dose is what you get at the pharmacy. So that's a whole trail that occurs even before you get it in your hand.…
>
> As one FDA consultant explained to me, if you go out and you shop for cheddar cheese, there's different types of quality. There's Velveeta, there's Kraft and there's artisanal cheddar. But if you're a consumer going to a drugstore, what you probably don't know is that there are different levels of quality in different generics, even though the FDA has told us that all the generics are the same. That is simply not the case.

U.S. patients are kept in the dark about where specific drugs are manufactured and by whom. Such information is considered a "trade secret" preventing even the FDA from disclosing it. As NYT editorial writer Farah Stockman points out:[18]

> This secrecy, combined with the shift to low-wage countries, doesn't bode well for quality, according to John Gray, an Ohio State professor who studies the relationship between drug recalls and countries of origin. Because of the industry's lack of transparency, Professor Gray has to get creative to find data to crunch. "We know where our shirts are made, but not where our drugs are made, which is arguably more important," he told me. "If our shirts are shoddily made, we can tell and we are not going to buy them again." But we often don't know if our drugs are shoddily made, unless something terrible happens.

FDA Inspection Woes

As explained by GAO, "FDA's Office of Regulatory Affairs inspects both domestic and foreign establishments to ensure that drugs are produced in conformance with applicable laws of the United States, including current good manufacturing practice (CGMP) regulations."[19] Towards this end, facilities, both foreign and domestic, are typically inspected every two or three years.[20] Yet this even includes facilities the FDA deems "high-risk," *i.e.*, those that, "based on the characteristics of the drugs being manufactured, pose the greatest potential public health risk should they experience a manufacturing defect."[21]

COVID has made the state of inspections even more worrisome. In 2020 the FDA "largely paused" U.S. and foreign inspections, "unable to complete more than 1,000 of its planned inspections."[22] As of February 2021, domestic inspections were still limited and "the vast majority of foreign inspections continue to be postponed." The backlog means that even the highest priority inspections will continue to be delayed. In the words of NYT editorial writer Farah Stockman, this means "we don't know how close the house is to catching fire."[23] According to March 2021 testimony from GAO Health Care Director Mary Denigan-Macauley:[24]

> In January 2021, we reported that FDA used alternative tools to oversee drug manufacturing quality while inspections have been paused, including the use of inspections conducted by foreign regulators, requesting and reviewing records and other information, and sampling and testing drugs. These tools provide useful information, but are not all considered equivalent to an inspection conducted by FDA.

Other major long-standing problems with FDA inspections include language barriers[25] and training problems. For example, even when the FDA succeeds in hiring a new investigator, "it can take 1.5 to 2 years of training to bring them to a fully proficient level."[26]

Perhaps even more serious is the FDA's practice of tipping off foreign companies about upcoming inspections. U.S. Representative Rosa DeLauro (D-Conn.) explained the concern at a March 2021 hearing:[27]

> One of the main problems is that FDA gives foreign drug manufacturers, but not American ones, advanced notice of inspections. The twelve weeks of advanced notice has allowed foreign manufacturers to fabricate or shred data, use hidden laboratories, or secretly repeat tests before the FDA inspectors arrived.
>
> By contrast, in unannounced inspections, investigators have found issues the plants were unable to hide: important manufacturing records tossed in a trash bin, bird and insect infestations, even human urine puddled on the floor. Clearly, that is not a safe or sterile manufacturing area.
>
> These shoddy practices result in drugs with unapproved ingredients, toxic impurities, and dangerous particulates making their way into American medicine cabinets. In 2007 and 2008, hundreds of Americans died from contaminated heparin, an anticoagulant drug manufactured overseas. In 2018 and 2019 dozens of blood-pressure and anti-ulcer drugs were recalled because they contained more than 200 times the acceptable limit of a known carcinogen.

Senator Chuck Grassley (R-Iowa) put it this way at a June 2020 hearing: "[W]hy would we give manufacturers time to prepare their facility for inspection? They ought to be looking over their shoulder every day."[28]

And yet, it gets worse. Some drugs are altogether exempt from FDA inspection. Indeed, for over a decade, the FDA's failure to oversee the global pharmaceutical supply chain, especially its foreign drug inspections program, has been on GAO's high-risk list.[29] FDA officials testified,

> Drugs in this category typically include OTC monograph drugs [*e.g.*, aspirin, cold and cough medicine][30] and APIs [*i.e.*, active pharmaceutical ingredients] used in pharmacy compounding. FDA may be required to engage in more challenging and resource intensive efforts to identify and respond to any problems that arise subsequently; however, patients may have already been exposed to the drugs. For example, in 2019 we issued a warning letter to a discount retailer for receiving OTC drugs produced by foreign manufacturers with serious violations of CGMPs. The majority of the foreign facilities involved had distributed drugs to the U.S. prior to FDA inspections.[31]

Global pharmaceutical supply chain issues have started to get some attention in Washington, DC. In April 2021, U.S. Senators Elizabeth Warren (D-Mass.) and Marco Rubio (R-Fla.) introduced a bipartisan bill to "direct the Federal Trade Commission (FTC) and the Secretary of the Treasury, acting through the Committee on Foreign Investment in the United States (CFIUS), to conduct a study on the United States' overreliance on foreign countries and the impact of foreign direct investment on the U.S. pharmaceutical industry."[32] The bill's language is also in the original version of President Biden's Build Back Better bill.[33] However, it is not in the infrastructure bill that passed Congress on November 6, 2021. As of publication, its fate remains unclear.[34]

Conflicts and Incentives

There are more than 20,000 prescription drugs on the market.[35] The FDA does not have the resources to oversee their safety much less the incentive to do so given the agency's close ties with the industry it's supposed to regulate. The agency lost much of its independence in 1992 when Congress passed legislation that, among other things, allows drug manufacturers to pay the FDA "user fees" to review their products. These "user fees," paid to speed up the FDA's drug review process, constitute a huge portion of the agency's budget for regulating drugs, making the FDA financially beholden to the pharmaceutical industry.

For FY 2019, the FDA budget was $5.9 billion, with 45 percent (*i.e.*, $2.7 billion) paid for by industry user fees.[36] To put this in perspective, user fees accounted for over two-thirds of the

Center for Drug Evaluation and Research's budget that's dedicated to oversight of human drugs and more than one quarter of the Office of Regulatory Affairs' budget that's allocated to inspections, investigations and enforcement actions involving human drugs.[37] In FY 2020, user fees accounted for roughly 65 percent of the FDA's spending on human drugs.[38]

As a result of this "user fee" arrangement, drug companies and their trade associations have had a great deal of influence over FDA decision-making and policy. This leverage is evident from the extent to which patient and consumer advocacy groups, as well as safety experts, have been kept in the dark about the substance of recent meetings involving renegotiation of user-fee agreements. According to *MarketWatch*,[39]

> The industry "is incentivized to try to get the maximum it can for its user-fee contributions," [Dr. Aaron Kesselheim, a Harvard Medical School professor] says, and increased safety surveillance that could lead to more product recalls "doesn't financially benefit them."

In addition to exploiting the user fee system, the industry has other "incentives" at its disposal when it comes to influencing the FDA and Congress. The industry spends a huge amount of lobbying and political money in Washington, DC. For the past 15 years, the drug manufacturing industry, including its trade associations, has spent over $117 million annually lobbying Congress. For the past four years, spending has exceeded $160 million: $167.01 (2017), $168.86 (2018), $164.76 million (2019) and $160.16 million (2020).[40] In 2021 to date, drug manufacturers and their trade associations have spent over $123.5 million lobbying Congress.[41] During the 2020 election cycle, the drug manufacturing industry gave a total of nearly $20 million in contributions to U.S. congressional candidates.[42] One way or the other, this industry gets its way.

How Safety Can Suffer

While the odds may be against the FDA catching many industry safety problems, sometimes inspectors do end up at the right place at the right time. The following are a few recent examples of drug companies getting caught by the FDA, which illustrate how serious some safety problems can be.

Eli Lilly. In March 2021, the FDA cited Eli Lilly's Indianapolis "fill and finish" plant for multiple quality-control violations, including "staff failing to properly monitor environmental conditions where the finished drugs are made and failing to establish appropriate procedures to prevent contamination." For example:[43]

> FDA inspectors said they observed lapses in the manufacturing of the Glucagon kits [*i.e.*, therapy for diabetic patients in crisis] as well as in Lilly's COVID-19 antibody therapy bamlanivimab and several other drugs, according to the inspection records, dated March 16. They concluded that Lilly must take steps to remedy the lapses but did not recommend regulatory action on the part of the FDA.

The company also faces a federal criminal probe into alleged manufacturing irregularities and records-tampering at its Branchburg, NJ factory.[44] A former head of the FDA's Office of Manufacturing and Product Quality plus multiple industry and regulatory experts have characterized the probe as a "big deal" given that "the federal government rarely seeks criminal charges stemming from manufacturing violations unless those lapses are extremely serious and the company does little to fix them."[45]

A November 2019 FDA inspection of the facility found "quality control data had been deleted and not appropriately audited," causing the agency to issue its most serious category of violation, which if not fixed could result in the FDA blocking the sale of a blockbuster diabetes drug and several cancer medications made at the facility.[46] When inspectors came back eight months later, "they found several more problems. Among them: Batches of drugs had been discarded because of manufacturing mistakes and quality control problems were not being properly investigated by the company to prevent recurrence."[47]

The FDA's findings are consistent with serious manufacturing lapses alleged by a company whistleblower, who "repeatedly received complaints and raised concerns about everything from quality control to record-keeping with a host of Lilly managers and executives."[48] According to *Reuters*,

> [I]nternal Lilly documents portray a plant where a worker complained in capital letters about being "TIRED AND OVERBURDENED"; where substandard chemicals and ingredients were simply discarded and not reported as required; where safety hazards included the risk of electrocution from live wires; and where quality assurance records disappeared or were doctored. In one case, according to a 2018 email among managers, workers sifted through the garbage to find missing manufacturing records.

Mylan. Contamination has been a serious problem at multiple Mylan manufacturing sites. For example, in 2018, an FDA investigation of its Morgantown, WV factory revealed that the "cleaning validation and verification program for manufacturing equipment is inadequate to prevent cross contamination."[49] The FDA warning letter added, "Your firm has many recurring incidents in which visible drug residues were found on non-dedicated equipment after the equipment was deemed clean by multiple staff."[50]

Mylan received another warning letter over cross-contamination the following year, this time involving one of its plants in India.[51] Then in 2020, a different Mylan facility in India was the subject of an FDA warning letter, which alleged that the company failed "to have adequate cleaning procedures to prevent contamination or carry-over of a material that would alter the quality of the API"[52] and "did not do a sufficient job testing all incoming raw materials to ensure they are suitable for the manufacturing process, didn't have adequate procedures for detecting impurities, which, coupled with using non-dedicated equipment, created the risk of contaminating the ingredients that go into Mylan's medicines."[53] The 2020 letter stated:[54]

> These repeated failures at multiple sites manufacturing [active pharmaceutical ingredients] demonstrate that your company's oversight and control over the manufacture of drugs is inadequate. You should immediately and comprehensively assess your company's global manufacturing operations to ensure that systems and processes, and ultimately, the products manufactured, conform to FDA requirements at all your sites.

Teva. A July 2021 FDA inspection of the company's Irvine, CA production plant discovered unrepaired water damage "likely creating mold in the walls. Investigators also found that the company hadn't maintained procedures meant to keep factory workers from spreading mold and bacteria…."[55] More specifically,

> FDA inspectors said benches in the room where factory workers changed into their scrubs showed signs of excessive use and were visibly dirty and that the company's protocols didn't include any procedure for sanitizing them. In addition, factory workers would wear their scrubs outside to take out the trash or to the restroom and not change them when they reentered the building.
>
> FDA inspectors also said Teva hadn't made sure equipment used to ensure sterility and test for harmful organisms worked properly since it installed it 21 years ago, despite a change in how the test is performed, according to [inspection] documents.[56]

According to *Bloomberg*, such unsafe practices compromised the safety of over 2.5 million vials containing cancer, arthritis, schizophrenia and muscle relaxer drugs.[57]

Compounding Pharmacies: A Special Problem

Some patients who are allergic to certain ingredients or have trouble tolerating commercially-available drugs rely on compounding pharmacies for customized medications and dosages that meet their specific medical needs. Such facilities are regulated by the states, not the FDA, meaning that the drugs they manufacture aren't subject to federal requirements and policing

and "do not have to report adverse events to either the FDA or state regulatory authorities."[58] This makes oversight "less consistent … in fact, fewer than half of the states conduct routine inspections of compounding pharmacies."[59]

This lax system has resulted in countless compounded drugs "that are contaminated or made in excessive potency because of pharmacist error,"[60] causing serious injuries or death. Examples of dangerous compounded drugs include: contaminated steroid injections manufactured at a Massachusetts compounding facility, "which caused a fungal meningitis outbreak that sickened over 753 people and caused 64 deaths"; contaminated eye medications compounded by a Florida pharmacy "that caused fungal eye infections, vision loss, or both in 47 patients"; and contaminated IV fluids sold by an Alabama compounding pharmacy "that resulted in 19 cases of bacterial infections, 9 of which resulted in death."[61]

Recourse Complications

When patients are hurt or killed by defectively manufactured drugs, their legal rights are similar to those of any other victim injured by a defective product. Most U.S. drug manufacturing defect cases are brought under state products liability law, with consumers alleging strict liability for improper manufacturing or drug contamination during the production process that caused the harm.[62] Compensation may be available for injuries or wrongful death. Punitive damages are also possible. Damages laws vary from state to state.[63]

For example, some states cap noneconomic damages in products liability cases, stymieing manufacturing defect claims against culpable drugmakers whose products cause permanent disability, mutilation, trauma, loss of a limb, blindness, sexual or reproductive harm and other types of suffering and pain. Some states restrict punitive damages, which are awarded against wrongdoers whose conduct is grossly negligent or intentional and are meant to serve as a means for punishing bad actors and deterring others from committing similar dangerous behavior. Other state tort restrictions can limit victims' rights in varying ways. It all depends on the state where the case is filed.

While injured patients are able to turn to the U.S. civil justice system for legal and financial accountability against domestic drug companies, victims may have little recourse when foreign manufacturers are to blame. American University law professor Andrew Popper explained:

> It is both the current state of the law — and problematic — that a foreign producer cannot readily be held accountable in state courts even if (a) the product they design and manufacturer was unquestionably dangerous and defective, (b) the harm to the victim was foreseeable, and (c) the foreign producer has sold large numbers of these

> products in the U.S. in the past. Every U.S. manufacturer of any product is subject to the U.S. rule of law, the U.S. tort/civil justice system, and U.S. regulatory mandates. That foreign entities and individuals profit from the sale of defective goods and are outside this system is wrong.[64]

Some federal lawmakers have attempted to remedy this situation but so far have been unsuccessful.[65]

GENERIC DRUG ALARM BELLS

Good reasons exist as to why 90 percent of all drug prescriptions in the United State are filled by generic drugs today.[66] The biggest reason, of course, is that consumers usually have no choice in the matter. As most people know, health plans usually will not pay for brand medicines if generic versions are available.[67] According to a 2020 study, 19 states *require* pharmacists to dispense the generic cheaper version of a drug when available.[68] Theoretically that should be a good thing. But no one saves money if a generic drug is unsafe and they are medically harmed as a result.

In 1984, Congress passed the Hatch-Waxman Amendments[69] in order to get cheaper generic drugs into the marketplace.[70] Clearly, this is what happened. For example,

> Atorvastatin, a generic cholesterol medication, costs about $15 a month, while its brand-name equivalent, Lipitor, goes for between $450 and $500 a month. Abilify, an antipsychotic and antidepressant made by Bristol-Myers Squibb, costs between $700 and $900 a month; the generic version, aripiprazole, goes for around $8. And these aren't even extreme examples. Cuprimine, a brand-name drug made by Bausch Health to treat rheumatoid arthritis, retails for $26,000 a month; the generic version, penicillamine, costs $7,000.[71]

Generic drugs are cheaper because generic drug companies spend a fraction of what it costs to put brand-name drugs on the market.[72] Specifically, before the FDA approves a brand-name drug, it requires lengthy and expensive testing to ensure the safety and effectiveness of the drug. The process of inventing, testing, and marketing a new drug can run into the hundreds of millions of dollars.[73] After approval, the drug receives a patent, which means that, until the patent expires, no other company or manufacturer is allowed to make or sell the same drug. These patents typically last 20 years. But once they expire, the drug's ingredients become available to generic manufacturers, who then attempt to recreate the drug and sell it themselves for significantly less money.

In order to get a generic drug on the market, a drugmaker need only show that a generic drug is "bioequivalent" to an approved drug. Bioequivalent does not mean identical. Generic companies submit an Abbreviated New Drug Application (ANDA), which simply shows that their drugs are equivalent in "dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[74] But this still allows drugs to contain lower quality "inactive" ingredients, which can affect how drugs are absorbed, and even different concentrations of "active" ingredients, which can "vary in quantity by about 10% in either direction."[75] Unlike with brand-name drugs, data on hour-by-hour rate of absorption doesn't factor into agency decisions about which generics are approved. And the FDA does not independently test generics before allowing them on the market, relying primarily on the company's word before approving them for sale.

Others have pointed out:

> [Manufacturers] *don't* have to show therapeutic equivalency — that is, they don't have to prove that patients respond to the generic in the same way they respond to the brand name. It is instead assumed that the generic will produce the same effect because the active ingredient is supposed to be the same. Many ANDAs are aspirational, first filed before a manufacturer has figured out how exactly to produce a generic version of a brand-name drug. And since FDA approval can take as little as six months, an ANDA might be approved before a manufacturer has finalized a generic formulation.[76]

Indeed, the engineering process can be somewhat hit or miss. When the patent on the brand-name drug expires and generic drug manufacturers gain access to the ingredients in the brand-name drug, the patent does not explain how the drug is made or put together. Thus, the generic companies can't duplicate the original but instead have to figure out on their own how to create "copies" of brand-name drugs. As author and investigative journalist Katherine Eban pointed out:[77]

> [B]rand-name companies sort of build a citadel of patents around the generic drug. And so it's not like they hand over a formula or cookbook to the generic companies. They're fighting every step of the way to protect their patents. And what the reverse engineers who work for the generic drug companies need to do is try to break down the drug in a laboratory and reconstruct it under a different pathway so that they can essentially get around the patent.
>
> And then there are other elements of the drug that are protected by separate patents, like the time release mechanisms. And all of that has to be recreated, additionally using

possibly a new set of excipients, which is the additional ingredients. And then you've got to get the dissolution right.

Another important issue concerns the safety of generic drug labels. Under the FDA's "bioequivalence" regulatory structure, generic drug companies are responsible only for ensuring that their warning labels are identical to the brand-name labels. Generic drug companies are actually prohibited from independently modifying their warning labels on medicines, even if the manufacturer knows that label to be inaccurate and out-of-date.[78] This rule also creates immunity for generic drug companies — but not brand-name companies — if their label is unsafe. (See section below, "No Recourse.") Federal legislation to correct the situation was introduced in prior Congresses but failed to gain momentum.[79] During the Obama administration, the FDA tried to accomplish the same with a proposed rule establishing new safety responsibilities for generic drug companies to maintain safe labels.[80] However, the rule was never finalized.

Over the years, consumer website *The People's Pharmacy* — run by pharmacologist Joe Graedon and his wife Terry, who together host an NPR radio program[81] — has collected many stories from people who've experienced adverse effects after switching from brand-name drugs to generics or from one generic to another. For example:

> **Generic Celebrex.** As one victim explained, "Taking the generic initially didn't cause problems but then my mail-order drug company used another manufacturer. I have lupus. The generic celecoxib caused a flare to the point I could barely walk."[82]
>
> **Generic Lasix.** One user wrote, "I was on brand-name Lasix for over 30 years to treat lymphedema. Now that I can only get generic furosemide, I have found that the generic does nothing to reduce swelling. It only causes allergic skin outbreaks. The generic is not even close to the brand name based on how my body reacts."[83]
>
> **Generic Wellbutrin.** One patient, who took a "round small" generic version of the antidepressant for two years, "experienced a drastic improvement in my bipolar 2 depressive symptoms." Yet "[w]ithin the last 2-3 weeks of taking the same dosage, but a new manufacturer, I am having suicidal ideations. These thoughts are persistent. I have never considered thoughts such as these…ever! This manufacturer was just approved. It's an oblong, white pill."[84]
>
> **Generic Zoloft.** Said one victim, "A number of years ago my prescription for Zoloft was changed to generic sertraline. It simultaneously became ineffective. As a result, my [primary care provider] began adding other drugs to the generic sertraline to try to

achieve a response against depression. After several attempts at different add-ons, I was prescribed generic Budeprion XL 300. Three days later I suffered a grand mal seizure. I quit all depression medications then and have suffered through major depression since that time. That seems marginally better than dealing with the potentially life-threatening side effects of these generic drugs. I'm not willing to be a guinea pig!"[85]

No Recourse

Normally, if someone is harmed or killed by an unsafe product made by a negligent company, they or their family have the option to sue that company in court. The right to sue negligent drug manufacturers under state tort law has long existed, providing patients with both the ability to be compensated for harms and a means to hold irresponsible drug companies directly accountable for causing injuries, often forcing changes in the sale of unsafe drugs. Lawsuits also help uncover important information about dangerous drugs that the understaffed and under-resourced FDA misses and can create widespread publicity about them through the mass media and other means, alerting an unsuspecting public to drug dangers.[86]

The U.S. Supreme Court recognized the important role that lawsuits play to maintain drug safety when it confirmed that brand-name drug companies should be liable for injuring or killing patients in the 2009 case *Wyeth v. Levine*.[87] The Court said, "[S]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation,"[88] noting that "the FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."[89]

However, in 2011 and again in 2013, the U.S. Supreme Court immunized the generic drug industry for harm caused by a product's defective design or label.[90] Because the same immunity does not extend to brand-name drug companies, the result has been a two-tiered system of justice in America, which the Supreme Court suggested was a "bizarre" result.[91] This was succinctly described by Justice Sonia Sotomayor who wrote that generic drug immunity would result in "so many absurd consequences that I cannot fathom that Congress would have intended…." Specifically, "[a] drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings …. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue."[92]

While two recent state Supreme Court decisions did establish a state tort remedy for patients injured by generic drugs in those states,[93] such cases are the rare exception to the rule: Generic drug companies cannot independently change their warning labels on medicines, so even if the manufacturer knows that label to be inaccurate and out-of-date, they are immune from any liability for harm stemming from the drug's unsafe label or design.

Until Congress or FDA regulations change what the U.S. Supreme Court has done, the vast majority of those prescribed drugs in this country have no access to the courts if they are harmed.

NOTES

[1] National Center for Health Statistics, Centers for Disease Control and Prevention, "Therapeutic Drug Use" (page updated October 20, 2021), https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm, citing *Health, United States 2019* (Table 39), https://www.cdc.gov/nchs/data/hus/2019/039-508.pdf

[2] National Institute on Drug Abuse, *What is the scope of prescription drug misuse?* (June 2020), https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/what-scope-prescription-drug-misuse, citing Richard Miech et al., "Prescription Opioids in Adolescence and Future Opioid Misuse," *Pediatrics* (2015). *See also* Ashley Kirzinger et al., "Data Note: Prescription Drugs and Older Adults," August 9, 2019, https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/

[3] "Total nominal spending on medicines in the U.S. from 2002 to 2020*," *Statista*, https://www.statista.com/statistics/238689/us-total-expenditure-on-medicine/ (viewed November 9, 2021).

[4] Big Pharma and Medical Device Manufacturers, *Drug Watch*, https://www.drugwatch.com/manufacturers/ ("These include Johnson & Johnson, Pfizer, Merck, Gilead, Amgen and AbbVie.")

[5] "Revenue of the worldwide pharmaceutical market from 2001 to 2020," *Statista*, https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/ (viewed November 9, 2021).

[6] U.S. Food and Drug Administration, "Generic Drugs," February 5, 2021, https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs

[7] *Wyeth v. Levine*, 555 U.S. 555 (2009), https://www.supremecourt.gov/opinions/08pdf/06-1249.pdf

[8] Testimony of Office of Regulatory Affairs Associate Commissioner for Regulatory Affairs Judith A. McMeekin, Food and Drug Administration Associate Commissioner for Global Policy and Strategy Mark Abdoo and Center for Drug Evaluation and Research Deputy Director for Regulatory Programs Douglas Throckmorton on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process" before U.S. Senate Committee on Finance, June 2, 2020, https://www.finance.senate.gov/imo/media/doc/02JUN2020.FDAJNT.STMNT.pdf

[9] Farah Stockman, "Our Drug Supply Is Sick. How Can We Fix It?" *New York Times*, September 18, 2021, https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html

[10] Anna Edney, "Big Pharma's Little Secret: Drug Cross-Contamination Is Rampant," *Bloomberg Businessweek*, July 26, 2021, https://www.bloomberg.com/news/articles/2021-07-26/big-pharma-s-little-secret-drug-cross-contamination-is-rampant

[11] Office of Inspector General, U.S. Department of Health and Human Services, "Review of the Food and Drug Administration's Foreign Drug Inspection Process," https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000380.asp (viewed August 9, 2021).

[12] Prepared Opening Statement by U.S. Senator Chuck Grassley, Chairman, U.S. Senate Finance Committee Hearing on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process," June 2, 2020, https://www.grassley.senate.gov/news/news-releases/grassley-hearing-foreign-drug-manufacturing-inspection-oversight
[13] Farah Stockman, "Our Drug Supply Is Sick. How Can We Fix It?" *New York Times*, September 18, 2021, https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html
[14] Testimony of U.S. Government Accountability Office Health Care Director Mary Denigan-Macauley on "Drug Safety: FDA's Future Inspection Plans Need to Address Issues Presented by COVID-19 Backlog" before U.S. House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, March 4, 2021, https://www.gao.gov/assets/gao-21-409t.pdf
[15] Chia-Yi Hou, "Can you trust generic drugs?" *The Hill*, November 4, 2019, https://thehill.com/changing-america/well-being/466717-can-you-trust-generic-drugs
[16] Farah Stockman, "Our Drug Supply Is Sick. How Can We Fix It?" *New York Times*, September 18, 2021, https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html
[17] Chia-Yi Hou, "Can you trust generic drugs?" *The Hill*, November 4, 2019, https://thehill.com/changing-america/well-being/466717-can-you-trust-generic-drugs
[18] Farah Stockman, "Our Drug Supply Is Sick. How Can We Fix It?" *New York Times*, September 18, 2021, https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html
[19] Testimony of U.S. Government Accountability Office Health Care Director Mary Denigan-Macauley on "Drug Safety: FDA's Future Inspection Plans Need to Address Issues Presented by COVID-19 Backlog" before U.S. House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, March 4, 2021, https://www.gao.gov/assets/gao-21-409t.pdf
[20] Testimony of Office of Regulatory Affairs Associate Commissioner for Regulatory Affairs Judith A. McMeekin, Food and Drug Administration Associate Commissioner for Global Policy and Strategy Mark Abdoo and Center for Drug Evaluation and Research Deputy Director for Regulatory Programs Douglas Throckmorton on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process" before U.S. Senate Committee on Finance, June 2, 2020, https://www.finance.senate.gov/imo/media/doc/02JUN2020.FDAJNT.STMNT.pdf
[21] Testimony of U.S. Government Accountability Office Health Care Director Mary Denigan-Macauley on "Drug Safety: FDA's Future Inspection Plans Need to Address Issues Presented by COVID-19 Backlog" before U.S. House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, March 4, 2021, https://www.gao.gov/assets/gao-21-409t.pdf
[22] Ibid.
[23] Farah Stockman, "Our Drug Supply Is Sick. How Can We Fix It?" *New York Times*, September 18, 2021, https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html
[24] Testimony of U.S. Government Accountability Office Health Care Director Mary Denigan-Macauley on "Drug Safety: FDA's Future Inspection Plans Need to Address Issues Presented by COVID-19 Backlog" before U.S. House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, March 4, 2021, https://www.gao.gov/assets/gao-21-409t.pdf
[25] Ibid.
[26] Testimony of Office of Regulatory Affairs Associate Commissioner for Regulatory Affairs Judith A. McMeekin, Food and Drug Administration Associate Commissioner for Global Policy and Strategy Mark Abdoo and Center for Drug Evaluation and Research Deputy Director for Regulatory Programs Douglas Throckmorton on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process" before U.S. Senate Committee on Finance, June 2, 2020, https://www.finance.senate.gov/imo/media/doc/02JUN2020.FDAJNT.STMNT.pdf
[27] Statement of U.S. House Appropriations Committee Chair and Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee Chair Rosa DeLauro, hearing on "FDA's Foreign Drug Inspections Program," March 9, 2021, https://appropriations.house.gov/news/statements/chair-delauro-statement-at-fda-s-foreign-drug-inspections-program-hearing. *See also* Statement of U.S. House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee Chair Sanford Bishop, hearing on "FDA's Foreign Drug Inspections Program," March 9, 2021, https://appropriations.house.gov/news/statements/chairman-bishop-statement-at-fda-s-foreign-drug-inspections-program-hearing ("I have been troubled by recent news reports about the dangers of tainted drugs and unacceptable manufacturing practices coming from overseas. Instances of contaminants making their way into blood pressure medications, reports from inspectors who have observed

paper shredding campaigns, and descriptions of inspectors playing a cat and mouse game with foreign manufacturers intent on hiding problems paints a frightening picture of the global health of our drug supply. Inspections are some of our most valuable tools in the fight against fraud, and it sounds like we have to do better.")

[28] Prepared Opening Statement by U.S. Senator Chuck Grassley, Chairman, U.S. Senate Finance Committee Hearing on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process," June 2, 2020, https://www.grassley.senate.gov/news/news-releases/grassley-hearing-foreign-drug-manufacturing-inspection-oversight

[29] Statement of U.S. House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee Chair Sanford Bishop, hearing on "FDA's Foreign Drug Inspections Program," March 9, 2021, https://appropriations.house.gov/news/statements/chairman-bishop-statement-at-fda-s-foreign-drug-inspections-program-hearing

[30] U.S. Government Accountability Office, *Over-The-Counter Drugs: Information on FDA's Regulation of Most OTC Drugs* (July 2020), https://www.gao.gov/assets/gao-20-572.pdf

[31] Testimony of Office of Regulatory Affairs Associate Commissioner for Regulatory Affairs Judith A. McMeekin, Food and Drug Administration Associate Commissioner for Global Policy and Strategy Mark Abdoo and Center for Drug Evaluation and Research Deputy Director for Regulatory Programs Douglas Throckmorton on "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process" before U.S. Senate Committee on Finance, June 2, 2020, https://www.finance.senate.gov/hearings/covid-19-and-beyond-oversight-of-the-fdas-foreign-drug-manufacturing-inspection-process (citation omitted).

[32] *See* Office of U.S. Senator Elizabeth Warren press release, "Warren, Rubio Reintroduce Bill to Assess Effects of America's Overreliance on Foreign Countries in Pharmaceutical Supply Chain," April 22, 2021, https://www.warren.senate.gov/newsroom/press-releases/warren-rubio-reintroduce-bill-to-assess-effects-of-americas-overreliance-on-foreign-countries-in-pharmaceutical-supply-chain

[33] *See* H.R. 5376, Build Back Better Act, https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376RH-RCP117-17.pdf

[34] *See* H.R. 3684, Infrastructure Investment and Jobs Act, https://www.govtrack.us/congress/bills/117/hr3684/text

[35] U.S. Food and Drug Administration, "Fact Sheet: FDA at a Glance," November 18, 2020, https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance

[36] Ibid.

[37] Department of Health and Human Services, *FDA Fiscal Year 2021 Justification of Estimates for Appropriations Committees*, https://www.fda.gov/media/135078/download

[38] Eleanor Laise, "Drug-company-paid user fees under the microscope with beleaguered FDA in funding talks," *MarketWatch*, July 16, 2021, https://www.marketwatch.com/story/beleaguered-fda-in-talks-for-drug-company-funding-11626177049

[39] Ibid.

[40] Open Secrets, "Pharmaceutical Manufacturing: Lobbying, 2021," https://www.opensecrets.org/industries/lobbying.php?cycle=2020&ind=H4300 (viewed November 9, 2021).

[41] Ibid.

[42] Open Secrets, "Pharmaceutical Manufacturing: Money to Congress 2020," https://www.opensecrets.org/industries/summary.php?ind=H4300&recipdetail=A&sortorder=U&mem=Y&cycle=2020 (viewed August 29, 2021).

[43] Dan Levine and Marisa Taylor, "Exclusive: Eli Lilly's recalled emergency diabetes drug came from plant cited by FDA," *Reuters*, October 4, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-eli-lillys-recalled-emergency-diabetes-drug-came-plant-cited-by-fda-2021-10-04/

[44] Ibid.

[45] Marisa Taylor, Mike Spector and Dan Levine, "U.S. opens criminal probe into alleged lapses at Eli Lilly plant," *Reuters*, May 27, 2021, https://www.reuters.com/business/legal/exclusive-us-opens-criminal-probe-into-alleged-lapses-eli-lilly-plant-2021-05-27/

[46] Ibid.

[47] Ibid.

[48] Marisa Taylor and Dan Levine, "Special Report: Insider alleges Eli Lilly blocked her efforts to sound alarms about U.S. drug factory," *Reuters*, March 11, 2021, https://www.reuters.com/article/us-health-elililly-special-

report/special-report-insider-alleges-eli-lilly-blocked-her-efforts-to-sound-alarms-about-u-s-drug-factory-idUSKBN2B31K5

[49] U.S. Food and Drug Administration, "Warning Letter: Mylan Pharmaceuticals, Inc. MARCS-CMS 557903 — November 09, 2018," November 20, 2018, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mylan-pharmaceuticals-inc-557903-11092018

[50] Ibid.

[51] Patricia Sabatini, "Mylan hit with FDA warning letter over problems involving valsartan at plant in India," *Pittsburgh Post-Gazette*, November 15, 2019, https://www.post-gazette.com/business/healthcare-business/2019/11/15/Mylan-FDA-warning-letter-valsartan-India-losartan-irbesartan-high-blood-pressure-medication/stories/201911150141

[52] U.S. Food and Drug Administration, "Warning Letter: Mylan Laboratories Limited – Unit 7MARCS-CMS 607508 — AUGUST 20, 2020," September 1, 2020, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mylan-laboratories-limited-unit-7-607508-08202020

[53] Anya Litvak, "Mylan hit with warning letter from the FDA with echoes of a similar citation last fall," *Pittsburgh Post-Gazette*, September 20, 2020, https://www.post-gazette.com/business/healthcare-business/2020/09/02/Mylan-FDA-warning-letter-manufacturing-drug-process/stories/202009010139

[54] U.S. Food and Drug Administration, "Warning Letter: Mylan Laboratories Limited – Unit 7MARCS-CMS 607508 — AUGUST 20, 2020," September 1, 2020, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mylan-laboratories-limited-unit-7-607508-08202020

[55] Anna Edney, "Teva Recalls U.S.-Made Drugs Following Contamination Fears," *Bloomberg*, October 4, 2021, https://www.bloomberg.com/news/articles/2021-10-04/teva-recalls-u-s-made-drugs-following-contamination-fears

[56] Ibid.

[57] Ibid.

[58] Joanna Shepherd, "Regulatory Gaps in Drug Compounding: Implications for Patient Safety, Innovation, and Fraud Safety, Innovation, and Fraud," 68 *DePaul L. Rev.* 385 (2019), https://via.library.depaul.edu/cgi/viewcontent.cgi?article=4087&context=law-review

[59] Ibid.

[60] Ibid.

[61] Ibid.

[62] "This means that it does not matter how careful the manufacturer was when designing products, choosing materials, creating the assembly line, and issuing quality assurance guidelines. If a poorly manufactured product left the factory and caused injury when used for any of its intended purposes due to the defect in manufacturing, the manufacturer has to pay for any injuries." "Defects in Manufacturing," *FindLaw*, November 30, 2018, https://www.findlaw.com/injury/product-liability/defects-in-manufacturing.html

[63] *See* Ronen Avraham, "Database of State Tort Law Reforms (7.1)," October 27, 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=902711; Center for Justice and Democracy, "Fact Sheet: Caps On Compensatory Damages: A State Law Summary," August 20, 2020, https://centerjd.org/content/fact-sheet-caps-compensatory-damages-state-law-summary

[64] Andrew F. Popper, "The Two-Trillion Dollar Carve-Out: Foreign Manufacturers Of Defective Goods and the Death of H.R. 4678 in the 111th Congress," *Bloomberg Law*, February 17, 2011, https://news.bloomberglaw.com/product-liability-and-toxics-law/the-two-trillion-dollar-carve-out-foreign-manufacturers-of-defective-goods-and-the-death-of-hr-4678-in-the-111th-congress

[65] *See* H.R. 3737, Foreign Manufacturers Legal Accountability Act of 2019, https://www.congress.gov/bill/116th-congress/house-bill/3737; S. 1606, Foreign Manufacturers Legal Accountability Act of 2009, https://www.congress.gov/bill/111th-congress/senate-bill/1606?s=1&r=94

[66] U.S. Food and Drug Administration, "Generic Drugs," February 5, 2021, https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs

[67] "The Generic Drugs You're Taking May Not Be As Safe Or Effective As You Think," *Fresh Air*, May 16, 2019, https://www.npr.org/transcripts/723545864

[68] Lisa Rapaport, "Pharmacists Not Required to Substitute Generics for Brand-Name Drugs in Most U.S. States," *Reuters*, September 1, 2020, https://www.the-rheumatologist.org/article/pharmacists-not-required-to-substitute-generics-for-brand-name-drugs-in-most-u-s-states

[69] 21 U.S.C. Food and Drugs, Chapter 9 § 301 et seq.
[70] Brief of amici curiae U.S. Senator Tom Harkin and U.S. Representative Henry A. Waxman in Support of Respondent, *Mutual Pharmaceutical Company, Inc, v. Karen L. Bartlett*, No. 12-142 (February 2013), https://www.citizen.org/wp-content/uploads/mutual-pharmaceutical-v-bartlett-amicus.pdf
[71] Harriet Brown, "My Generic Medications Failed Me. I'm Not Alone," *Vice*, February 10, 2021, https://www.vice.com/en/article/v7mnm3/my-generic-medication-gave-me-constant-nosebleeds-im-not-alone
[72] Brief of amici curiae U.S. Senator Tom Harkin and U.S. Representative Henry A. Waxman in Support of Respondent, *Mutual Pharmaceutical Company, Inc, v. Karen L. Bartlett*, No. 12-142 (February 2013), https://www.citizen.org/wp-content/uploads/mutual-pharmaceutical-v-bartlett-amicus.pdf
[73] Ranit Mishori, "Why are generic drugs cheaper than brand-name ones?" *Washington Post*, July 11, 2011, http://articles.washingtonpost.com/2011-07-11/national/35267296_1_generic-drugs-manufacturers-of-brand-name-drugs-pharmaceutical-companies
[74] U.S. Food and Drug Administration, "Generic Drugs: Questions & Answers," March 16, 2021, https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers. Specifically, the drug must: contain the same active ingredients as the brand-name/innovator drug (inactive ingredients may vary); be identical in strength, dosage form and route of administration; have the same use indications; contain acceptable levels of inactive ingredients; last for at least the same amount of time; be manufactured under the same strict standards as the brand-name product; be shipped and sold in an appropriate container; have the same drug information label as the brand-name medicine's label; and have relevant patents or exclusivities addressed. U.S. Food and Drug Administration, "Generic Drugs: Questions & Answers," March 16, 2021, https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers
[75] Harriet Brown, "My Generic Medications Failed Me. I'm Not Alone," *Vice*, February 10, 2021, https://www.vice.com/en/article/v7mnm3/my-generic-medication-gave-me-constant-nosebleeds-im-not-alone
[76] Ibid.
[77] "The Generic Drugs You're Taking May Not Be As Safe Or Effective As You Think," *Fresh Air*, May 16, 2019, https://www.npr.org/transcripts/723545864
[78] *PLIVA, Inc. v. Mensing* 131 U.S. 2567 (2011), https://www.supremecourt.gov/opinions/10pdf/09-993.pdf. *See also Mutual Pharm. Co., Inc. v. Bartlett,* 133 U.S. 2466 (2013), https://www.supremecourt.gov/opinions/12pdf/12-142_8njq.pdf
[79] *See*, *e.g.*, S. 2295, the "Patient Safety and Generic Labeling Improvement Act" (112th. Cong.), https://www.congress.gov/112/bills/s2295/BILLS-112s2295is.pdf, sponsored by U.S. Senator Patrick Leahy and seven other Senators, which would permit generic drug companies to change the labeling of a drug. *See also* Office of U.S. Senator Patrick Leahy, "Leahy To Introduce Bill To Protect Consumers Who Take Generic Drugs," March 26, 2012, http://www.leahy.senate.gov/press/leahy-to-introduce-bill-to-protect-consumers-who-take-generic-drugs
[80] Under the rule, "when new information becomes available that causes information in labeling to be inaccurate," a generic company "must take steps to change the content of its labeling…." U.S. Food and Drug Administration, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," 78 F.R. 67985, November 13, 2013, http://www.gpo.gov/fdsys/pkg/FR-2013-11-13/pdf/2013-26799.pdf
[81] *See* "The People's Pharmacy Radio Program," https://www.npr.org/podcasts/381444414/the-people-s-pharmacy-radio-program
[82] Joe Graedon, "What Are Authorized Generic Drugs and Are They Better?" *People's Pharmacy*, May 18, 2021, https://www.peoplespharmacy.com/articles/what-are-authorized-generic-drugs-and-are-they-better
[83] Joe Graedon, "Generic Furosemide Disappoints | How to Afford Lasix?" *People's Pharmacy*, June 23, 2019, https://www.peoplespharmacy.com/articles/generic-furosemide-disappoints-how-to-afford-lasix
[84] Joe Graedon, "Problems with Generic Wellbutrin (Bupropion)? Not Again!" *People's Pharmacy*, July 6, 2021, https://www.peoplespharmacy.com/articles/problems-with-generic-wellbutrin-bupropion-not-again
[85] Terry Graedon, "Can You Overcome Trouble with Generic Antidepressants?" *People's Pharmacy*, August 26, 2019, https://www.peoplespharmacy.com/articles/can-you-overcome-trouble-with-generic-antidepressants
[86] The antipsychotic drug Risperdal is a good example of the role litigation plays in uncovering dangers that leads to public exposure and change. Johnson & Johnson/Janssen was pushing its salespeople to promote Risperdal illegally to children and the elderly knowing the drug had horrible hormonal side effects for children and could be lethal for the elderly. Some injured patients sued. During the first jury trial — brought by a 20-year-old autistic man who developed size 46DD breasts as a young teenager — it was revealed that Janssen had study data linking the drug's

use to breast development in boys but never published that information or shared it with the FDA. Chris Elkins, "Trial Evidence Indicates J&J Hid Risperdal Study Results From FDA," *Drugwatch*, September 3, 2015, https://www.drugwatch.com/news/2015/09/03/johnson-and-johnson-hide-risperdal-data/; David Sell, "Johnson & Johnson loses first Risperdal jury trial," *Philadelphia Inquirer*, February 25, 2015, https://www.inquirer.com/philly/business/20150225_Johnson___Johnson_loses_first_Risperdal_jury_trial.html; "Pennsylvania State Court Jury Awards $2.5M In Risperdal Gynecomastia Trial," 2015 *LexisNexis Jury Verdicts & Settlements* 117, February 24, 2015. J&J's misconduct would have remained largely hidden had it not been for the lawsuits brought against the company, which contributed to an explosive investigative series that received wide attention. *See* Steven Brill, "Americas Most Admired Lawbreaker," *Huffington Post/Highline*, September 15, 2015 https://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/. Had it been up to FDA oversight alone, this misconduct would never have been uncovered.

[87] *Wyeth v. Levine*, 555 U.S. 555 (2009), https://www.supremecourt.gov/opinions/08pdf/06-1249.pdf

[88] Id. at 579 (footnote omitted).

[89] Id. at 578-9 (footnote omitted).

[90] *PLIVA, Inc. v. Mensing*, 131 U.S. 2567 (2011), https://www.supremecourt.gov/opinions/10pdf/09-993.pdf. *See also Mutual Pharm. Co. v. Bartlett,* 133 U.S. 2466 (2013), https://www.supremecourt.gov/opinions/12pdf/12-142_8njq.pdf

[91] "We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated. But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581-2 (2011)(footnote omitted), https://www.supremecourt.gov/opinions/10pdf/09-993.pdf

[92] Id. at 2592 (Sotomayor, J. dissenting).

[93] In December 2017, in the case *T.H. v. Novartis*, 4 Cal. 5th 145 (2017), the California Supreme Court ruled that a brand-name drug company may be liable for injuries caused by an unsafe generic drug warning label. As explained by Leslie Brueckner, counsel for the plaintiffs, "Writing for a unanimous Court on this point, Justice Cuellar held that, because generic manufacturers are 'required to follow the brand-name manufacturer's label to the letter,' a brand-name manufacturer 'owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or its generic bioequivalent.'" In addition, the decision "gives consumers of generic drugs the right to seek justice for their injuries. It will also protect public health and safety, by giving brand-name manufacturers a strong incentive to update their labels when new risks emerge after their drugs go generic." Leslie Brueckner, "Public Justice Wins Huge Ruling on Behalf of Generic Drug Victims in California Supreme Court," December 21, 2017, https://www.publicjustice.net/public-justice-wins-huge-ruling-behalf-generic-drug-victims-california-supreme-court/. For decision, *see* https://casetext.com/case/th-v-novartis-pharm-corp. Similarly, in its March 2018 decision *Rafferty v. Merck*, 479 Mass. 141 (2018), the Massachusetts Supreme Court ruled that brand-name drug companies can be sued for recklessness from inadequate warning labels on generic versions of their drugs. The Court maintained that "public policy is not served if generic drug consumers have no remedy for the failure of a brand-name manufacturer to warn in cases where such failure exceeds ordinary negligence, and rises to the level of recklessness." According to the Court, "This recklessness standard strikes the most appropriate balance between competing public policy interests, limiting liability for brand-name manufacturers while also providing remedies for the most serious injuries and deterring the most dangerous forms of conduct." For decision, *see* https://case-law.vlex.com/vid/479-mass-141-2018-715365981