

A GENERIC A DAY KEEPS THE LAWYER AWAY

Cara Brumfield*

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* Cara Brumfield earned her undergraduate degree from the University of West Florida, and her Juris Doctor from the University of Nevada, Las Vegas, William S. Boyd School of Law. Her experience with mass torts and product liability law were her inspiration to attend law school. She would like to thank her husband for all of his support, as well as her many colleagues who encouraged her to write about her passion.

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INTRODUCTION

“In Supreme Court Ruling, Drugmakers Win and Consumers Lose.”¹ In June 2013, headlines around the country proclaimed their disbelief when the United State Supreme Court stripped a woman of a \$21 million jury award she received for being burned, blinded, and permanently disfigured after ingesting a generic prescription drug.² The woman, Karen Bartlett, was diagnosed with Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN),³ after

¹ Ed Silverman, *In Supreme Court Ruling, Drugmakers Win and Consumers Lose*, FORBES (June 24, 2013, 5:25 PM), <http://www.forbes.com/sites/edsilverman/2013/06/24/in-supreme-court-ruling-drugmakers-win-and-consumers-lose/#721804473770> [https://perma.cc/W5WG-9AXD].

² Katie Moisse, *Woman Disfigured by Generic Drug Loses \$21 Million Award*, ABC NEWS (June 29, 2013), <http://abcnews.go.com/Health/woman-disfigured-generic-drug-loses-21-million-award/story?id=19520506> [https://perma.cc/A687-5Z5L].

³ “Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are [severe reactions to prescription drugs] characterized by peeling of skin along with hemorrhagic crusting of lips and erosions of oral and genital mucosa.” G. K. Singh et al., *Cyclosporine in Stevens Johnson Syndrome and Toxic Epidermal Necrolysis and Retrospective Comparison with Sys-*

ingesting a generic prescription drug for shoulder pain.⁴ However, if Ms. Bartlett had taken the brand-name version of her prescription, the verdict would have been upheld.

In the wake of the Supreme Court's decision in *Mutual Pharmaceutical Co. v. Bartlett*, reporters and consumers began to demand that the United States Food and Drug Administration (FDA) alter its regulations in order to make generic drug companies liable for any injuries their products cause.⁵ The question left unanswered was how it could be possible for companies to make products but not be responsible when those products hurt innocent consumers.

This article examines the evolution of product liability for pharmaceutical drug manufacturers, as well as proposed regulations and the current effects of the United States (U.S.) health care system on consumer rights. Part I discusses the background of the FDA and the agency's current rules for gaining approval to bring prescription drugs to market. Part II reviews landmark legislation in the field of products liability, including the recent decisions, which stripped consumers of a remedy for side effects suffered after ingesting generic drugs. Finally, Part III discusses current proposed regulations that would make generic drug manufacturers independently responsible for the safety of their products.

I. BACKGROUND OF THE U.S. FOOD AND DRUG ADMINISTRATION AND RULES FOR GAINING APPROVAL TO MARKET PRESCRIPTION DRUGS

The U.S. Food and Drug Administration is responsible for protecting the public health by ensuring the safety and efficacy of all food, drugs, medical devices, and other medical products.⁶ In the field of pharmaceutical drug manufacturing, the FDA has issued strict guidelines which require manufacturers seeking to gain market approval for new pharmaceutical drugs to demonstrate that the "drug is safe for use and . . . effective,"⁷ and that the benefits outweigh the risks.⁸

Throughout much of the twentieth century, the FDA has enacted numerous regulations to achieve the goal of ensuring the safety of prescription drugs. However, the FDA has different requirements for granting market approval of brand-name drugs than it does for generic equivalents.

temic Corticosteroid, 79 INDIAN J. DERMATOLOGY, VENEREOLOGY, & LEPROLOGY 686, 686 (2013). The mortality rate is around "5% for SJS and 30% for TEN." *Id.*

⁴ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013).

⁵ See, e.g., Editorial, *A Damaging Decision on Generic Drugs*, N.Y. TIMES (June 28, 2013), <http://www.nytimes.com/2013/06/29/opinion/a-damaging-decision-on-generic-drugs.html> [<https://perma.cc/HW3Q-YB68>].

⁶ *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/> [<https://perma.cc/9Y6M-JQ9H>] (last updated Oct. 24, 2016).

⁷ 21 U.S.C. § 355(b)(1) (2012).

⁸ *Id.* § 355(d).

A. *Creating the U.S. Food and Drug Administration*

The modern day Food and Drug Administration began in 1862 when President Abraham Lincoln appointed a single chemist to serve in the newly-formed U.S. Department of Agriculture's Division of Chemistry.⁹ The Division of Chemistry was responsible for overseeing and investigating the purity and safety of ingredients in the nation's foods and drugs.¹⁰ The Division of Chemistry changed its name to the Bureau of Chemistry (the Bureau) with passage of the Pure Food and Drugs Act in 1906, and finally received the name "United States Food and Drug Administration" in July 1930.¹¹

1. *The Pure Food and Drug Act*

In 1880, Peter Collier, a chemist for the U.S. Department of Agriculture recommended a national food and drug law, but it was rejected by Congress.¹² Afterwards, several other bills were introduced to Congress to regulate food and drugs, but only one, the Meat Inspection Act of 1891, passed before the Pure Food and Drug Act.¹³ In 1906, the Pure Food and Drug Act was signed into law,¹⁴ adding a regulatory function to the Bureau's list of responsibilities.¹⁵ Initially, the Bureau was charged with regulating the interstate transportation of food and drugs, focusing primarily on regulating product labels.¹⁶ Under the new regulations, manufacturers had to list the product ingredients and refrain from labeling products in a way that was false or could mislead consumers.¹⁷ For example, drugs could be sold only in accordance with the standards set forth in the *United States Pharmacopoeia* and the *National Formulary* unless the specific variations were "plainly stated on the label."¹⁸ In contrast, foods

⁹ *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> [https://perma.cc/2FBF-9R9X] (last updated Dec. 19, 2014).

¹⁰ John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> [https://perma.cc/KM8Z-EBWQ] (last updated June 23, 2014).

¹¹ Charles Warren, *When the Feds Have Taken the Field: Federal Field Preemption of Claims Against Manufacturers Whose Medical Devices Have Received Premarket Approval by the FDA*, 9 OKLA. J.L. & TECH. 65, at 7 (2013), <https://www.law.ou.edu/sites/default/files/files/FACULTY/warren%20final.pdf> [https://perma.cc/8JZS-9KUE].

¹² *Significant Dates in U.S. Food and Drug Law History*, *supra* note 9.

¹³ Thomas F. McGuire, Note, *Food, Drug or Both?: Dual Classification Under the Federal Food, Drug, and Cosmetic Act*, 1984 U. ILL. L. REV. 987, 990 & n.19 (1984).

¹⁴ Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

¹⁵ Swann, *supra* note 10.

¹⁶ Priya Brandes, Comment, *Regulation of Drugs: A Death Sentence for the Terminally Ill?*, 46 U.S.F. L. REV. 1149, 1151 (2012).

¹⁷ McGuire, *supra* note 13, at 991.

¹⁸ *FDA History—Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> [https://perma.cc/ME4F-E7PK] (last updated June 18, 2009).

were not subject to “analogous standards, but the law prohibited the addition of any ingredients” that would constitute a food substitute or could pose a health hazard.¹⁹ Congress’s intent was for consumers to be able to ascertain from the label a product’s ingredients and its intended use.²⁰

2. *The Federal Food, Drug, and Cosmetic Act*

Public concern over the lack of product testing for safety and efficacy prior to introduction to the market led to the 1938 passage of the Food, Drug, and Cosmetic Act (“FDCA”), thus replacing the Pure Food and Drug Act.²¹ The FDCA created new requirements for a drug to gain pre-market approval, including proof of the drug’s safety and inclusion of directions for safe use on the drug’s label.²² The FDCA also increased the FDA’s ability to ensure quality manufacturing processes by allowing the FDA to perform factory inspections.²³

3. *Notable Amendments to the FDCA*

The Durham-Humphrey Amendment of 1951 created the requirement that certain drugs be dispensed only by prescription.²⁴ The main reason behind this new requirement was that the usage of these drugs, without thorough explanation of their labels, posed the potential for harm to consumers.²⁵ The Durham-Humphrey Amendment, therefore, ensured that a physician would inform the patient of the risks and benefits of the prescription-only drugs.²⁶

The Kefauver-Harris Amendment of 1962 included new requirements, which mandated that drug manufacturers prove their products were both safe and effective.²⁷ Furthermore, manufacturers were now required to report to the FDA any adverse side effects discovered after a drug was approved and introduced on the market.²⁸ Most notably, the amendments required express FDA approval before a drug could enter the market.²⁹ Previously, manufacturers could introduce a drug to the market provided that the FDA had not objected

¹⁹ *Id.*

²⁰ *See id.*

²¹ Brandes, *supra* note 16, at 1149, 1152.

²² *Id.* at 1152.

²³ 21 U.S.C. § 374(a)(1) (2012).

²⁴ Durham-Humphrey Amendment of 1951, Pub. L. No. 82-215, sec. 1, § 503(b), 65 Stat. 648, 648–49 (codified as amended at 21 U.S.C. §§ 352–355 (2012)).

²⁵ *See FDA History—Part III: Drugs and Foods Under the 1938 Act and Its Amendments*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055118.htm> [https://perma.cc/Q92K-G9KW] (last updated June 18, 2009).

²⁶ Durham-Humphrey Amendment, sec. 1, § 503(b), 65 Stat. at 648–49.

²⁷ *See* Kefauver-Harris Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780; *see also* Brandes, *supra* note 16, at 1152–53.

²⁸ 21 U.S.C. § 355(k)(4)(D)(i)(II)(bb) (amended 2016).

²⁹ *Id.* § 355(a).

within sixty days of the manufacturer first seeking approval.³⁰ After the adoption of the Amendments of 1962, a drug manufacturer had to conduct pre-marketing trials to prove the safety and efficacy of its drugs, present its findings to the FDA, and wait for the FDA to review and affirmatively approve those findings before bringing a new drug to market.³¹ All manufacturers seeking to market a generic drug not only had to conduct pre-marketing trials to prove that their versions of the product were safe and effective, they also had to wait until the expiration of the original patent on the brand-name drug before marketing their drug.³²

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) eliminated the requirement for generic drug manufacturers to independently prove drug safety and efficacy,³³ instead requiring them only to prove bioequivalency to a previously approved brand-name drug.³⁴

Most recently, the Food and Drug Administration Amendments Act of 2007 required manufacturers to immediately implement changes to drug labels without waiting for FDA approval.³⁵ Previously, when drug manufacturers learned new safety information after a drug had already received FDA approval, the FDA had to review any proposed label changes before the manufacturer could update the label.³⁶ This meant that manufacturers were responsible for warning consumers of risks discovered by new data or by new analysis of old data.

³⁰ See Suzanne White Junod, *FDA and Clinical Drug Trials: A Short History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History//ucm304485.htm> [<https://perma.cc/5R8U-EFRN>] (last updated Apr. 11, 2016).

³¹ *Id.*; see also Chris Woolston, *History of Generic Drugs*, HEALTHDAY, <http://consumer.healthday.com/encyclopedia/drug-center-16/misc-drugs-news-218/history-of-generic-drugs-646390.html> [<https://perma.cc/XMF5-VKZZ>] (last updated Jan. 20, 2017).

³² Woolston, *supra* note 31.

³³ See generally Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act was intended to strike a balance between providing consumers with low-cost generic drugs while also providing brand-name manufacturers with time to recoup their investment costs from developing innovative drugs. See *The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. On the Judiciary* 108th Cong. (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration), <https://www.judiciary.senate.gov/imo/media/doc/Troy%20Testimony%20061703.pdf> [<https://perma.cc/QCV8-SN5P>]. Among its key provisions was the creation of an abbreviated drug approval process for generic drugs, lessening the expense and time necessary to bring generic drugs to market. *Id.*

³⁴ CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY*, at xii (1998).

³⁵ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; see also *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

³⁶ *Wyeth*, 555 U.S. at 567.

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B. Brand Name Manufacturer Requirements for Drug Approval

The FDCA requires a new drug application be approved by the FDA before a manufacturer may introduce the drug into interstate commerce.³⁷ The drug application content requirements are listed in the FDCA and include reporting the safety and the effectiveness of the drug, a listing of the drug components, and proposed labeling for the drug.³⁸ The applicant, or manufacturer, is referred to as a “new drug application (NDA) holder.”³⁹

However, a pioneer, or brand-name, drug manufacturer may have to complete additional steps before submitting an NDA for FDA approval.⁴⁰ The process often begins with an Investigational New Drug Application, reporting the early results of animal testing, and a proposal for human testing.⁴¹

Once the FDA determines it is reasonably safe to begin human trials, the manufacturer begins testing the product on healthy volunteers to learn the drug’s most frequent side effects.⁴² The manufacturer may then conduct additional tests to determine if the drug performs as intended on patients suffering from the targeted medical conditions.⁴³ This includes comparing the drug’s efficacy with a placebo drug and evaluating short-term side effects.⁴⁴ The FDA and the manufacturer then determine if large-scale testing should occur, where the drug will be tested on patients with other illnesses and in combination with other drugs.⁴⁵ Once all clinical trials have concluded, the manufacturer submits its NDA for FDA approval.⁴⁶ Only an average of one in five new drugs to survive this process makes it to market.⁴⁷

1. Period of Exclusivity for Brand-Name Drugs

Clinical trials can be both expensive and time-consuming. It can cost upwards of \$1.3 billion and take an average of twelve years to obtain market ap-

³⁷ 21 U.S.C. § 355(a) (2012).

³⁸ *Id.* § 355(b)(1).

³⁹ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

⁴⁰ See generally *FDA Ensures Equivalence of Generic Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134444.htm> [<https://perma.cc/GW6F-G3VP>] (last updated Aug. 21, 2015).

⁴¹ *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> [<https://perma.cc/S73P-2YS7>] (last updated Nov. 6, 2014).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Jane Larkindale, *Why Does it Take so Long to Go From Mouse to Man?*, QUEST (Jan. 1, 2012, 3:11 PM), <http://quest.mda.org/article/why-does-it-take-so-long-go-mouse-man> [<https://perma.cc/E6XS-XV54>].

proval for one new drug.⁴⁸ “To balance the interests of generic drug manufacturers and those of [brand-name] drug manufacturers, Congress provided [brand-name manufacturers] with varying periods of exclusivity prior to FDA approval of a competing generic drug.”⁴⁹ Exclusivity periods prohibit generic versions of new drugs from gaining FDA approval within a certain period of time from the brand-name drug’s NDA approval.⁵⁰ These periods vary depending on the type of drug and the year the drug was approved.⁵¹ These periods of exclusivity serve to reward manufacturers of pioneer drugs “while protecting consumers from . . . high prices by refusing to give a long period of market exclusivity to drugs which required no new research effort.”⁵² This period of exclusivity gives brand-name drug manufacturers the exclusive right to market and sell their product before competing companies can sell generic equivalents, allowing brand name manufacturers to recover some of the costs expended in their initial research and development efforts before facing competition from less expensive generics.

2. *Labeling Revisions for Brand-Name Drugs*

When a manufacturer learns new information about its drug, such as an increased risk of an adverse reaction, it must update the drug’s label to reflect that new information.⁵³ In the absence of these revisions, the drug may be “misbranded” due to false or misleading labeling.⁵⁴ The FDA explicitly prohibits the manufacture or sale of misbranded drugs, meaning that a failure to update a drug’s label can lead to a revocation of FDA approval to sell the drug.⁵⁵

Generally, in order for a manufacturer to change its label, it must once again obtain FDA approval.⁵⁶ However, in limited circumstances, manufacturers may implement label changes simultaneously with asking the FDA for per-

⁴⁸ *Id.*; see also Avik Roy, *How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials*, FORBES (Apr. 24, 2012, 5:19 PM), <http://www.forbes.com/sites/aroy/2012/04/24/how-the-fda-stifles-new-cures-part-i-the-rising-cost-of-clinical-trials/> [https://perma.cc/9YFR-6ZD3].

⁴⁹ *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 221–22 (D.D.C. 1996) (citing *Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988)).

⁵⁰ See 21 U.S.C. § 355(c)(3)(E) (2012).

⁵¹ *Id.*

⁵² *Abbott Labs. v. Young*, 920 F.2d 984, 986 (D.C. Cir. 1990).

⁵³ See 21 C.F.R. §§ 314.70, 314.97, 601.12 (2016).

⁵⁴ See 21 U.S.C. § 352(a) (amended 2016).

⁵⁵ See *id.* § 331(a), (b).

⁵⁶ See 21 C.F.R. § 314.70(b); see also *id.* § 601.12(f)(1).

mission for their implementation.⁵⁷ These changes are referred to as “CBE-0 supplements,” or “changes being effected supplements.”⁵⁸

C. *Generic Drug Manufacturers Requirements for Drug Approval*

Generic drugs come in three general categories: (1) “Pharmaceutical Equivalents,” which contain the same active ingredients and dosage form of a brand-name drug; (2) “Pharmaceutical Alternatives,” which contain the same therapeutic components, but a different dosage of a brand-name drug; and (3) “Therapeutic Equivalents,” pharmaceutical equivalents that are “expected to have the same clinical effect and safety profile when administered to patients” as brand-name drugs.⁵⁹

In 1984, the Hatch-Waxman Act (“the Act”) revolutionized the pharmaceutical industry by allowing manufacturers to submit abbreviated drug applications, thus shortening the time for FDA approval and introduction into the market.⁶⁰ Furthermore, the Act provided a ten-year period of exclusivity for drugs containing an active ingredient that had been approved between January 1, 1982 and September 24, 1984,⁶¹ and a seven-and-one-half year period of exclusivity for those approved *after* September 24, 1984.⁶²

Shortly after the implementation of the abbreviated processes, brand-name drug manufacturers began to experience increased competition by generic equivalents.⁶³ The new processes allowed generic drugs to be introduced onto the market only three months after the expiration of the name-brand drug’s exclusivity period, which had previously taken an average of three years.⁶⁴

1. *Gaining Market Approval for Generic Drugs*

The FDA considers a generic manufacturer an “abbreviated new drug [applicant],”⁶⁵ and requires it to submit an “abbreviated new drug application[]” (“ANDA”) in order to gain FDA approval to market a generic version of a pre-

⁵⁷ See *id.* § 314.70(c)(6)(iii)(A) (to add or strengthen an instruction or warning, contraindication, or adverse reaction); *id.* § 601.12(f)(2).

⁵⁸ See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,987 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

⁵⁹ U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at vii (36th ed. 2016).

⁶⁰ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

⁶¹ See 21 U.S.C. § 355 (c)(3)(E)(i) (2012).

⁶² See *id.* § 355 (j)(5)(F)(ii).

⁶³ CONG. BUDGET OFFICE, *supra* note 34, at xii.

⁶⁴ *Id.*

⁶⁵ See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

scription drug.⁶⁶ The requirements for an ANDA include proof of prior approval of the brand-name drug equivalent, proof of identical active ingredients and dosage to that of the brand-name drug, and proof that the label will mirror the brand-name drug's approved label.⁶⁷

2. *Period of Exclusivity for Generic Drugs*

Although generic drug manufacturers must wait until the expiration of the period of exclusivity for the brand-name drug before submitting an ANDA to market an equivalent drug, the generic drug manufacturer who submits the *first* ANDA gains its own period of exclusivity for 180 days, meaning that no other generic drug manufacturers may market their versions of the drug until after that first generic drug manufacturer has had the exclusive opportunity to do so for 180 days.⁶⁸ There are a few exceptions to this 180-day period of exclusivity, such as when the manufacturer seeking to market a second generic form of a drug is the brand name manufacturer of that drug.⁶⁹

3. *Labeling Revisions for Generic Drugs*

As previously discussed, generic drugs can gain FDA market approval only if their labels exactly match those of their brand-name equivalent drugs.⁷⁰ This requirement is subject to certain limited exceptions, such as differences in manufacturer names.⁷¹ In contrast to a brand name manufacturer's ability to revise drug labels to reflect new information, generic drug manufacturers are required to maintain labels that mirror that of the brand-name drug throughout the product's lifetime.⁷² If at any time the labeling for the generic drug is "no longer consistent with that for the [brand-name drug equivalent]," the FDA may withdraw approval of the generic drug.⁷³

However, "[i]f an ANDA applicant believes new safety information should be added to a product's labeling, it should contact [the] FDA, and [the] FDA

⁶⁶ 21 U.S.C. § 355(j).

⁶⁷ *See id.* § 355(j)(2).

⁶⁸ *See id.* § 355 (j)(5)(B)(iv).

⁶⁹ *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).

⁷⁰ *See Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585; *see also* *Abbreviated New Drug Application Regulations*, 57 Fed. Reg. 17,950-01, 17,953 (proposed Apr. 28, 1992) (to be codified at 21 C.F.R. pts. 2, 5, 10, 310, 314, 320, 433).

⁷¹ *See Drug Price Competition and Patent Term Restoration Act*, 98 Stat. at 1585; *see also* *Abbreviated New Drug Application Regulations*, 57 Fed. Reg. at 17,953.

⁷² *See* 21 C.F.R. § 314.150(b)(10) (2016); *see also* *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67,985, 67,988 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

⁷³ 21 C.F.R. § 314.150(b)(10).

will determine whether the labeling for the generic and listed drugs should be revised.”⁷⁴

D. Prevalence of Generic Drugs in the Market

As more brand-name drugs lose their period of exclusivity, an increasing number of generic drugs become available to consumers. In 1983, just before the Act was passed, “only 35 percent of the top-selling drugs with expired patents . . . had generic versions available.”⁷⁵ In the years since the Act, however, the opposite trend began to emerge—the percentage of brand-name drugs being dispensed in comparison to generic drugs shrunk dramatically.⁷⁶ In 1995, 59.8 percent of all drugs dispensed were name brands, while generics accounted for only 40.2 percent.⁷⁷ By 2010, brand-name drugs accounted for only 28.8 percent of all drugs dispensed, with generics leading the way with 71.2 percent of all sales.⁷⁸

Paradoxically, although generic drugs control a larger share of the pharmaceutical market, the disparity in prices between brand-name and generic drugs is decreasing. In other words, although generic drugs are still less expensive, they no longer save consumers as much money as they did in the past. For example, in 1995, the price difference between a generic drug and a brand-name drug was 36.89 percent, but in 2010, that difference shrunk to 26.49 percent.⁷⁹

Furthermore, despite the increased prevalence of generic drugs on the market, some consumers remain dubious about their safety.⁸⁰ Consumers are not alone: even in the medical community, physicians have reported skepticism about the quality and efficacy of generic medications.⁸¹ However, the FDA maintains that “[h]ealth care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the [brand-name] drug.”⁸² Although generic drugs may be as *safe* as their brand name counterparts, there is a large disparity in their treatment within the U.S. legal system.

⁷⁴ Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,961.

⁷⁵ CONG. BUDGET OFFICE, *supra* note 34, at xii.

⁷⁶ See U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2012, at 113 (131st ed. 2012), <https://www.census.gov/prod/2011pubs/12statab/health.pdf> [<https://perma.cc/E5D6-JDFP>].

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *What Are Generic Drugs and Are They Safe?*, CONSUMER REPS. (Aug. 2012), <http://www.consumerreports.org/cro/2012/08/are-generic-drugs-safe/index.htm> [<https://perma.cc/T9DX-PF9T>].

⁸¹ William H. Shrank et al., *Physician Perceptions About Generic Drugs*, 45 ANNALS PHARMACOTHERAPY 31, 34 (2011).

⁸² *Understanding Generic Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm> [<https://perma.cc/V88H-S2P8>] (last updated Oct. 17, 2016).

II. LANDMARK LEGISLATION IN PRODUCTS LIABILITY

There are three main theories which establish manufacturer liability in U.S. courts: manufacturing defect, defective design, and inadequate warnings.⁸³ However, two recent U.S. Supreme Court decisions have essentially led to completely exempting generic drug manufacturers from liability for injuries caused by their products.

A. *Establishing Strict Products Liability for Drug Manufacturers*

In the legal community, the terms “product liability” and “strict liability” are frequently combined to create the phrase “strict products liability.” In a tort claim, strict liability means that “it is immaterial whether the manufacturer was negligent in creating the design or exercised all reasonable care in the creation of the design. If a defect appears in the product in spite of all reasonable care exercised by the manufacturer, he is liable just the same.”⁸⁴ Said another way, strict products liability is imposed in order to “relieve the plaintiff of the burden of proving that the defect in design or manufacture resulted from the negligence of the defendant.”⁸⁵

Certain products are “inherently dangerous” because “the danger of injury stems from the product itself”⁸⁶ Some products found to be inherently dangerous include furniture polish,⁸⁷ pesticides,⁸⁸ “highly toxic materials, second hand guns[,] and [illegal] drugs.”⁸⁹ Establishing liability for injuries arising out of the use of such inherently dangerous products is difficult because these products present obvious risks to the consumer. For these products, “[t]he obviousness of a danger and adequacy of a [manufacturer’s] warning are determined by a ‘reasonable person’ standard, rather than [an individual] plaintiff’s subjective appreciation of the danger.”⁹⁰ For example, it would be difficult for a plaintiff to bring a claim for being cut by a saw, because the saw itself is obviously dangerous due to its sharp teeth and it was designed to cut through things.⁹¹

Unlike products whose risks may seem obvious, there are others which pose dangers that may not be as apparent. Therefore, when a product is not in-

⁸³ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(b) (AM. LAW INST. 1998).

⁸⁴ Ritter v. Narragansett Elec. Co., 283 A.2d 255, 262 (R.I. 1971).

⁸⁵ *Id.*

⁸⁶ Gen. Bronze Corp. v. Kostopulos, 122 S.E.2d 548, 551 (Va. 1961).

⁸⁷ Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 83, 84 (4th Cir. 1962).

⁸⁸ Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402, 404 (1st Cir. 1965).

⁸⁹ O’Connor v. Kawasaki Motors Corp., 699 F. Supp. 1538, 1542 (S.D. Fla. 1988).

⁹⁰ Byrnes v. Honda Motor Co., 887 F. Supp. 279, 281 (S.D. Fla. 1994).

⁹¹ See Hagans v. Oliver Mach. Co., 576 F.2d 97, 102 (5th Cir. 1978) (noting “the dangerous nature” of a commercial table saw).

herently dangerous, a manufacturer may still have a duty to warn about known dangers that might not be immediately apparent to consumers.⁹²

1. *Liability for Products Which Are Not “Inherently Dangerous”*⁹³

Many claims for products liability arise out of negligence on the part of the product’s manufacturer. The traditional elements necessary to prove a claim for negligence include duty, breach, proximate cause, and damages.⁹⁴ Generally, a manufacturer has a duty to consumers to “exercise reasonable care in designing and manufacturing” a product.⁹⁵ Furthermore, manufacturers have a duty to warn consumers upon becoming aware of a defect in a product.⁹⁶ Prior to 1916, courts primarily considered negligence claims for inherently dangerous products, such as poisons and explosives.⁹⁷

However, in 1916, *MacPherson v. Buick Motor Co.* became one of the first cases to apply negligence to products liability for products that were *not* inherently dangerous.⁹⁸ In *MacPherson*, the plaintiff was thrown from a vehicle after it collapsed due to a defective wheel, which had been installed by the vehicle manufacturer.⁹⁹ There, the court explained that the manufacturer (Buick Motor Co.) had a strict duty to inspect the finished product to ensure that it was not negligently made, thus imposing a new duty on manufacturers to ensure safety, regardless of the quality of the product’s components.¹⁰⁰

Beginning in the 1960s, courts began to apply strict liability to the manufacture of non-food items, such as power tools, automobiles, vaccines, and hair dyes.¹⁰¹ For example, in *Greenman v. Yuba Power Products, Inc.*, where the plaintiff was injured as a result of the malfunction of a power tool, the court imposed a strict duty for manufacturers to inspect its products for defects by holding that “[a] manufacturer is strictly liable in tort when an article he places on the market . . . proves to have a defect that causes injury to a human being.”¹⁰²

Now that manufacturers may be held strictly liable for injuries caused by their products, there is no longer a need to prove the traditional elements of

⁹² See *Byrnes*, 887 F. Supp. at 280–81 (citing *Cohen v. Gen. Motors Corp.*, 427 So. 2d 389, 390 (Fla. Dist. Ct. App. 1983)).

⁹³ This section only addresses the various duties imposed on a product manufacturer.

⁹⁴ *Parker v. Allentown, Inc.*, 891 F. Supp. 2d 773, 780 (D. Md. 2012).

⁹⁵ *C & S Fuel, Inc. v. Clark Equip. Co.*, 524 F. Supp. 949, 953 (E.D. Ky. 1981); see also *Fischbach & Moore Int’l Corp. v. Crane Barge R-14*, 632 F.2d 1123, 1127 (4th Cir. 1980).

⁹⁶ *Smith v. FMC Corp.*, 754 F.2d 873, 877 (10th Cir. 1985).

⁹⁷ *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1051–52 (N.Y. 1916).

⁹⁸ *Id.* at 1053.

⁹⁹ *Id.* at 1051.

¹⁰⁰ *Id.* at 1055.

¹⁰¹ *Greenman v. Yuba Power Prods.*, 377 P.2d 897, 900–01 (Cal. 1963).

¹⁰² *Id.* at 900.

negligence. Instead, to establish a prima facie case for strict products liability, the plaintiff must prove three things:

(1) [T]hat he was injured by the product; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user.¹⁰³

Over the years, the courts have set forth various ways of proving these essential elements.

2. *Bases of Strict Products Liability for Drug Manufacturers*

Manufacturers are generally held liable for injuries caused by products that are “defective” or “unreasonably dangerous” to consumers.¹⁰⁴ A product is “defective” when it “does not meet the reasonable [safety] expectations of the ordinary consumer”¹⁰⁵ A product is “unreasonably dangerous” if it is more dangerous than the ordinary consumer with generally available knowledge would expect.¹⁰⁶

A prescription drug is defective if, at the time of sale, the drug (1) contained a manufacturing defect; (2) was not safe due to defective design; or (3) was not safe due to inadequate warnings or instructions.¹⁰⁷ These three bases for strict products liability are commonly referred to as “manufacturing defect,” “defective design,” or “failure to warn” claims.¹⁰⁸ However, a manufacturer is *not* subject to strict liability if the drug was “properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.”¹⁰⁹

a. *Manufacturing Defect*

The first way a product can be defective is when it contains a manufacturing defect. A manufacturing defect exists “when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.”¹¹⁰ To establish a claim for a manufacturing defect, the plaintiff must prove that (1) the manufacturer sold the product; (2) the manufacturer regularly sold the product; (3) the product “contained a manufacturing defect that departed from its intended design” when it left the manufac-

¹⁰³ *Madden v. Cox*, 328 S.E.2d 108, 112 (S.C. Ct. App. 1985).

¹⁰⁴ RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965).

¹⁰⁵ *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 789 (6th Cir. 2005) (citing *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. Ct. App. 1999)).

¹⁰⁶ RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (AM. LAW INST. 1965).

¹⁰⁷ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(b) (AM. LAW INST. 1998).

¹⁰⁸ *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 (2011) (Sotomayor, J., dissenting).

¹⁰⁹ *Brown v. Superior Court*, 751 P.2d 470, 482–83 (Cal. 1988).

¹¹⁰ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB § 2(a) (AM. LAW INST. 1998).

turer's control; (4) "[t]he manufacturing defect was a proximate cause of plaintiff's damages;" and (5) plaintiff sustained actual damages.¹¹¹

Put another way, "a manufacturing defect exists in a product when it leaves the hands of the manufacturer in a defective condition because it was not manufactured or assembled in accordance with its specifications" and that defective condition made the product unreasonably dangerous to the consumer.¹¹² This does not mean that the plaintiff must prove *fault* on the part of the manufacturer,¹¹³ only that the manufacturer's *negligence* in producing the product must have been "a substantial factor in [causing the] plaintiff's harm."¹¹⁴

b. Defective Design

In contrast, the second category of strict products liability defects governs when the product itself was defectively designed. A drug is defectively designed when "the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits . . ." ¹¹⁵ A plaintiff may bring a case for design defect by demonstrating that the manufacturer "marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing [the] plaintiff's injury."¹¹⁶ If a product is defectively designed, it is considered unreasonably dangerous and the manufacturer may be held liable for injuries caused by the product, regardless of whether it was manufactured as intended.¹¹⁷ Courts employ different tests, as explored in the following subsections, to determine whether a product is unreasonably dangerous.

i. The Reasonable Care Balancing Test

Some jurisdictions use the reasonable care balancing test, which focuses on whether the manufacturer has exercised "that degree of care in [the] plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used . . ." ¹¹⁸ In performing the rea-

¹¹¹ Estate of Thompson v. Kawasaki Heavy Indus., Ltd., 922 F. Supp. 2d 780, 789–90 (N.D. Iowa 2013).

¹¹² Greene v. B.F. Goodrich Avionics Sys., Inc., 409 F.3d 784, 788 (6th Cir. 2005) (citing Montgomery Elevator Co. v. McCullough, 676 S.W.2d 776, 780 (Ky. 1984)).

¹¹³ *Id.*

¹¹⁴ *Id.* (citing King v. Ford Motor Co., 209 F.3d 886, 893 (6th Cir. 2000)).

¹¹⁵ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(c) (AM. LAW INST. 1998).

¹¹⁶ Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 208 (N.Y. 1983).

¹¹⁷ Reyes v. Wyeth Labs., 498 F.2d 1264, 1272–73 (5th Cir. 1974); *see, e.g.*, Pree v. Brunswick Corp., 983 F.2d 863, 868 (8th Cir. 1993) (holding that unguarded propellers are not unreasonably dangerous); Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 655, 659 (1st Cir. 1981) (noting that "the absence of proper warnings itself renders a product unreasonably dangerous" and holding that some drugs can be unreasonably dangerous).

¹¹⁸ Kruszka v. Novartis Pharm. Corp., 19 F. Supp. 3d 875, 896–97 (D. Minn. 2014) (citation omitted).

sonable care balancing test, “evidence of the existence of a feasible, alternative safer design,” is relevant, but not necessary.¹¹⁹ The reasonable care balancing test weighs the relative costs and benefits of an allegedly defective design against the relative costs and benefits of either a proposed alternative design, or the removal of the challenged product from the market.¹²⁰ In effect, the reasonable care balancing test requires that the plaintiff demonstrate that “the world would be a better place if the product were either designed differently or taken off the market.”¹²¹

ii. *The Risk-Benefit Test*

Other jurisdictions use the “risk-benefit” test, which considers the risks associated with using a product in the intended and reasonable manner and compares them with the benefits associated with the product’s design.¹²² If the risks of using a product outweigh the expected benefits, it may be unreasonably dangerous.

Some relevant factors to consider when determining whether the risks outweigh the benefits of a product include: (1) the usefulness of the product, both to the user and the public as a whole; (2) the likelihood that the product will cause injury, and how serious those injuries may be; (3) the availability of safer substitute products; (4) the ability of the manufacturer to make the product safer without impairing its usefulness or making it or too expensive; (5) the consumer’s ability to avoid danger by exercising care when using the product; (6) the consumer’s awareness of the product’s inherent danger due to general public knowledge about the product or the availability of suitable warnings or instructions; and (7) the feasibility of the manufacturer “spreading the loss by setting the price of the product or carrying liability insurance.”¹²³

iii. *The Consumer Expectation Test*

The “consumer expectation test” is used to prove design defects by demonstrating that “the product failed to perform as safely as an ordinary consumer

¹¹⁹ *Id.* at 897 (citing *Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 96 (Minn. 1987)); *see, e.g.*, *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1161 (D. Minn. 2011).

¹²⁰ *Kapps*, 813 F. Supp. 2d at 1161.

¹²¹ *Id.*

¹²² *Gumnitsky v. Delta Int’l Mach. Corp.*, 411 F. Supp. 2d 756, 762–63 (N.D. Ohio 2005) (citing *Clay v. Ford Motor Co.*, 215 F.3d 663, 669–70 (6th Cir. 2000)).

¹²³ *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 537 (Colo. 1997) (citing *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 414 (Colo. 1986), *overruled by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992)); *see, e.g.*, *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1109 (D. Colo. 2000) (holding that the risk-benefit test is applicable to all products, not just complex products like vehicles or drugs); *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010) (explaining that the “risk-benefits test” requires the plaintiff to “allege that the risks of the design outweigh the benefits,” and then explain how that design caused the plaintiff harm).

would expect when used in an intended or reasonably foreseeable manner.”¹²⁴ Consequently, the jury must determine if they believe “the product meets ordinary expectations as to its safety under the circumstances presented [to the plaintiff].”¹²⁵ Generally, the plaintiff needs only to provide evidence of his use of the product, the circumstances surrounding his injury, and the objective product features relevant to an evaluation of its safety.¹²⁶

c. Failure to Warn

The third and final category of strict products liability defects is known as “failure to warn,” or those claims that arise from inadequate instructions or warnings. Although most consumers believe a manufacturer’s “duty to warn” means providing notice of the known risks and side effects to the consumer, the manufacturer’s duty extends much further. A prescription drug is not reasonably safe

if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows . . . that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.¹²⁷

Therefore, the prescribing physician, not the consumer, is the primary party the manufacturer must warn about known risks and side effects in order to avoid liability under a “failure to warn” theory. Thus, in a claim for inadequate warnings, “the issue . . . is whether the warning, if any, that was given to the *prescribing physicians* was proper and adequate.”¹²⁸ Most claimants bring their claim for failure to warn by invoking the learned intermediary rule. The claimants either allege that the manufacturer gave inadequate warnings to the prescribing physician or allege fraud against the manufacturer for making misleading statements to the consumer.

¹²⁴ *Mariscal v. Graco, Inc.*, 52 F. Supp. 3d 973, 985 (N.D. Cal. 2014) (citing *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 452 (Cal. 1978)).

¹²⁵ *Id.* at 985 (citing *McCabe v. Am. Honda Motor Co.*, 123 Cal. Rptr. 2d 303 (Cal. Ct. App. 2002)).

¹²⁶ *Id.* (citing *Campbell v. Gen. Motors Corp.*, 649 P.2d 224, 233 (Cal. 1982)); *see, e.g.*, *Papike v. Tambrands Inc.*, 107 F.3d 737, 743 (9th Cir. 1997) (applying the consumer expectation test to hold that a consumer is not “entitled to expect a product to perform more safely than its government-mandated warnings indicate”); *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1314 (11th Cir. 2005) (requiring a jury instruction regarding the consumer expectation test to all cases involving products where “an ordinary consumer could form expectations” as to its safety, such as seatbelts).

¹²⁷ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d) (AM. LAW INST. 1998).

¹²⁸ *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990) (emphasis added) (citations omitted) (quoting *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987)).

i. Learned Intermediary Rule

The manufacturer has a duty to provide warnings to the prescribing physician because the prescribing physician has a duty “to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking.”¹²⁹ The prescribing physician also has the duty “to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.”¹³⁰

This duty to warn the prescribing physician is commonly referred to as the “learned intermediary rule.”¹³¹ “Warnings and instructions with regard to [prescription] drugs . . . are, under the ‘learned intermediary’ rule, directed to health-care providers.”¹³²

Drug manufacturers frequently invoke the learned intermediary rule as an exception to their duty to provide adequate warnings and instructions, emphasizing that their duty is “to warn physicians about the risks associated with use of the drug, and not the consumers of the drug.”¹³³ For example, in *Doe v. Solvay Pharmaceuticals, Inc.*, a failure-to-warn claim was dismissed under the learned intermediary rule after finding the warnings to the plaintiff’s prescribing doctor were adequate.¹³⁴ The rationale is that the prescribing physician acts as an intermediary between the manufacturer and consumer and is “generally in the best position to evaluate the potential risks and benefits” of taking a drug “and to advise the patient accordingly.”¹³⁵

ii. Fraud

Another, less common way to bring a claim for failure to warn or inadequate instructions or warnings is to plead fraud as a natural extension of the learned intermediary rule. However, this can often be a challenge because a claim for fraud must be pleaded with particularity.¹³⁶

For example, in *Gainer v. Mylan Bertek Pharmaceuticals, Inc.*, the court noted that to bring a claim for fraud, a plaintiff has to show:

- (1) a representation (or concealment where there is a duty to disclose); (2) which is material to the transaction; (3) made falsely, with knowledge of or reckless disregard as to its falsity; (4) with the intent of misleading another into relying

¹²⁹ *Hahn v. Richter*, 628 A.2d 860, 866 (Pa. Super. Ct. 1993) (quoting *Makripodis*, 523 A.2d at 378).

¹³⁰ *Id.*

¹³¹ See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (AM. LAW INST. 1998).

¹³² *Id.* § 6 cmt. e.

¹³³ *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 700 (D. Vt. 2010).

¹³⁴ *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 274 (D. Me. 2004), *aff’d*, 153 F. App’x 1 (1st Cir. 2005).

¹³⁵ *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

¹³⁶ See FED. R. CIV. P. 9(b).

on it; (5) justifiable reliance on the misrepresentation or concealment; and (6) resulting injury proximately caused by the reliance.¹³⁷

There, the plaintiff took the generic prescription drug Phenytoin and subsequently developed SJS and TEN.¹³⁸ In claiming fraud, the plaintiff alleged that the manufacturer was aware of the connection between Phenytoin and SJS or TEN but that it continued to represent that Phenytoin was safe and failed to disclose the connection to the plaintiff's prescribing physician.¹³⁹ The plaintiff further stated that the failure to disclose the connection resulted in the prescribing physician's inability "to fully assess the risks when making the decision to prescribe" Phenytoin, and that the plaintiff "would not have taken Phenytoin if she had been warned that it might result in SJS or TEN."¹⁴⁰ The court reasoned that:

A duty to disclose exists if a "party fails to exercise reasonable care to disclose a material fact which may justifiably induce another party to act or refrain from acting, and the non-disclosing party knows that the failure to disclose such information to the other party will render a prior statement or representation untrue or misleading."¹⁴¹

The court held that the plaintiff's allegations sufficiently identified the essential elements of fraud and ultimately denied the manufacturer's motion to dismiss.¹⁴²

These cases exemplify that courts spent the majority of the twentieth century developing and defining the bases of liability available to consumers of defective products. Manufacturer liability expanded from simple negligence to strict products liability, with three alternative paths, in which consumers could prove that a product was defective. As a result, consumers now have a variety of ways to bring their claims, and they have a more direct path of imposing liability on a manufacturer than was available to previous generations.

B. Abolishing Liability for Generic Drug Manufacturers

In the early part of the twenty-first century, drug manufacturers began seeking ways to excuse themselves from liability for drug-induced injuries. Many manufacturers rested their attempts on claims of preemption due to the plethora of state and federal regulations governing the manufacture and sale of drugs. The U.S. Supreme Court validated the manufacturer's arguments in two groundbreaking decisions in 2009 and 2011. The effects of the Court's decisions meant an endorsement of preemption as a shield for manufacturer liability

¹³⁷ *Gainer v. Mylan Bertek Pharm., Inc.*, No. 09–690 (JNE/JSM), 2010 WL 2519988, at *2 (D. Minn. June 15, 2010) (quoting *Rose v. Zaring Homes, Inc.*, 702 N.E.2d 952, 955 (Ohio Ct. App. 1997)).

¹³⁸ *Id.* at *1.

¹³⁹ *Id.* at *2.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* (quoting *Miles v. McSwegin*, 388 N.E.2d 1367, 1369 (Ohio 1979)).

¹⁴² *Id.*

and still affect injured consumers nationwide, many of whom have lost the right to seek recovery for their injuries in a court of law.

1. *The Slippery Slope of Preemption*

The U.S. Constitution's Supremacy Clause invalidates state laws that "interfere with, or are contrary to," federal law.¹⁴³ The Supremacy Clause led to the creation of the preemption doctrine, under which federal statutes may preempt state law.¹⁴⁴ More specifically, the doctrine applies in three instances: (1) by an express statement from Congress; (2) where the scheme of federal regulation creates an inference that Congress did not intend for supplementary state regulations; or (3) where the federal interest is so dominant that preemption of state laws is assumed.¹⁴⁵

Some courts have expressed concern that permitting preemption in some cases could "[expand] the scope of preemption to areas of traditional state control where Congress has not expressed its 'clear and manifest' intent to preempt."¹⁴⁶ However, even in the absence of express intent by Congress, it is assumed that Congress does not intend to take the place of state law,¹⁴⁷ and that state law is naturally preempted when it conflicts with federal law.¹⁴⁸

In the realm of prescription drugs, preemption means that if a state law imposes stricter requirements on a manufacturer than federal law, the manufacturer is shielded from liability so long as they are not in violation of applicable federal laws. Consequently, drug manufacturers frequently invoke "conflict-preemption" as a means to escape liability.¹⁴⁹

2. *Two Cases Leading to Preemption of All Claims Against Generic Drug Manufacturers*

In 2008, the U.S. Supreme Court reviewed a case in which a drug manufacturer claimed conflict preemption as a means to escape liability.¹⁵⁰ This single

¹⁴³ U.S. CONST. art. VI, cl. 2; *see also* *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824)).

¹⁴⁴ *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1030 (S.D. Ill. 2001).

¹⁴⁵ *Hillsborough*, 471 U.S. at 713.

¹⁴⁶ *Californians for Safe & Competitive Dump Truck Transp. v. Mendonca*, 957 F. Supp. 1121, 1130 (N.D. Cal. 1997), *aff'd*, 152 F.3d 1184 (9th Cir. 1998).

¹⁴⁷ *Caraker*, 172 F. Supp. 2d at 1032; *see also* *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) ("Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law.").

¹⁴⁸ *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

¹⁴⁹ *See, e.g., Caraker*, 172 F. Supp. 2d at 1031 (dismissing the manufacturer's claim that it was impossible to comply with both the state and federal warning requirements); *Gaeta v. Perrigo Pharm. Co.*, 562 F. Supp. 2d 1091, 1098 (N.D. Cal. 2008) (dismissing a claim due to preemption of over-the-counter drugs in a failure to warn claim); *Morris v. Wyeth, Inc.*, 582 F. Supp. 2d 861, 868–69 (W.D. Ky. 2008) (dismissing a failure to warn claim under conflict preemption against generic drug manufacturer).

¹⁵⁰ *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

case, when combined with a later case, resulted in a pivotal win for the pharmaceutical industry and took the Court down a slippery slope, which resulted in complete insulation from liability for generic manufacturers.

a. Case One: Wyeth v. Levine (2009)

In April, 2000, Diana Levine received a direct IV-push injection of Wyeth's anti-nausea medication Phenergan, which accidentally entered her artery due to an unknown reason.¹⁵¹ Levine subsequently developed gangrene and had to have her forearm amputated.¹⁵² She brought a claim against Wyeth for defective labeling because it failed to instruct physicians to administer Phenergan through an IV-drip administration as opposed to a direct IV-push method of administration.¹⁵³ Wyeth's defense rested on a claim of conflict pre-emption, and the trial court found for the plaintiff because Wyeth did not present sufficient evidence that it "earnestly attempted" to strengthen its label to warn about the increased risks associated with intra-arterial injections.¹⁵⁴ The trial court also found there was no indication that the FDA had "specifically disallowed" stronger language warning that the drug had a serious risk of substantial side effects.¹⁵⁵ At trial, the jury found that Wyeth was negligent, Phenergan was a defective product due to inadequate warnings and instructions, and total damages were awarded in excess of \$7.4 million.¹⁵⁶ The Vermont Supreme Court affirmed, holding that the jury's verdict "did not conflict with FDA's labeling requirements for Phenergan because [Wyeth] could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation."¹⁵⁷

On appeal to the United States Supreme Court, the issue became whether the FDA's drug labeling judgments "preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use."¹⁵⁸ Wyeth argued that the federal laws prohibited it from making stricter label warnings in order to comply with the state warning requirements because a unilateral label change would have subjected it to sanctions for misbranding.¹⁵⁹ The Supreme Court ultimately held that manufacturer compliance with federal law, but not state laws requiring stricter label warnings, does not insulate a manufacturer from liability.¹⁶⁰ In short: it was not

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 1191–92.

¹⁵⁴ *Id.* at 1192.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 1193.

¹⁵⁷ *Levine v. Wyeth*, 944 A.2d 179, 184 (Vt. 2006).

¹⁵⁸ *Wyeth*, 129 S. Ct. at 1193.

¹⁵⁹ *Id.* at 1197.

¹⁶⁰ *Id.* at 1202–03.

impossible for the manufacturer (Wyeth) to comply with both the federal and state labeling requirements.¹⁶¹

b. Case Two: Pliva v. Mensing (2011)

Mensing involved two plaintiffs who were prescribed Reglan to treat digestive tract problems, however both received the generic version, metoclopramide, from their respective pharmacies.¹⁶² “After taking the drug as prescribed for several years, both [plaintiffs] developed tardive dyskinesia[.]” a severe neurological disorder, which causes involuntary body movements.¹⁶³ Both plaintiffs sued the generic manufacturers, claiming failure to provide adequate warnings, as the manufacturers were aware of the mounting evidence of a significant risk of tardive dyskinesia from ingesting metoclopramide yet failed to increase the drug’s warning labels.¹⁶⁴ The manufacturers raised a preemption defense and insisted that compliance with both the FDA’s requirement to have a label identical to that of the brand name manufacturer and the increased warnings required by state law was impossible.¹⁶⁵

The U.S. Supreme Court agreed with the manufacturers:

Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA’s help—is not a matter of state-law concern. [The plaintiffs’] tort claims are pre-empted.¹⁶⁶

The plaintiffs argued that the manufacturers could have utilized “Dear Doctor” letters to independently warn prescribing physicians of the increased risk of tardive dyskinesia.¹⁶⁷ This argument also failed, as the Court deferred to the FDA’s assertion that “Dear Doctor” letters are treated the same as labels, so the generic manufacturers could not issue their own letters.¹⁶⁸

The combined decisions of *Wyeth* and *Pliva* shook the foundation of the products liability world, resulting in near immunity for generic drug manufacturers and making “access to the courts . . . dependent on whether an individual

¹⁶¹ *Id.* at 1204.

¹⁶² *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011).

¹⁶³ *Id.*; see also *Tardive Dyskinesia*, NAT’L ALLIANCE MENTAL ILLNESS, <http://www.nami.org/Learn-More/Mental-Health-Conditions/Related-Conditions/Tardive-Dyskinesia> [http://perma.cc/3EZC-7WD5] (last visited Mar. 13, 2017).

¹⁶⁴ *Pliva*, 131 S. Ct. at 2573.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 2581.

¹⁶⁷ *Pliva*, 131 S. Ct. at 2576. “A “Dear Doctor” letter is a common name for a Dear Health Care Professional (DHCP) letter, which is “intended to alert physicians and other health care providers about important new or updated information” about a drug. U.S. DEP’T HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., DEAR HEALTH CARE PROVIDER LETTERS 1 (2014). The FDA recommends that manufacturers issue DHCP letters when an important safety concern “could affect the decision to use a drug or require some change in behavior by health care providers . . . to reduce the potential for harm from a drug.” *Id.* at 3.

¹⁶⁸ *Pliva*, 131 S. Ct. at 2576.

is dispensed a brand name or generic drug.”¹⁶⁹ The FDA has even remarked that the *Mensing* decision lessens the incentive for generic drug manufacturers to comply with FDA requirements to conduct post-marketing surveillance, evaluation, and reporting, and to provide current and accurate drug labels.¹⁷⁰

3. *Mensing applied: Mutual Pharmaceutical Co., Inc. v. Bartlett* (2013)

Before the U.S. Supreme Court’s decision in *Mensing*, generic drug manufacturers were just as susceptible to products liability claims as their brand name counterparts.¹⁷¹ However, since *Mensing* in 2011, federal preemption has insulated generic drug manufacturers from virtually all products liability claims. This new wave of federal preemption claims manifested in the 2013 case, *Mutual Pharmaceutical Co., Inc. v. Bartlett*.¹⁷²

Karen Bartlett was prescribed the prescription drug Cinoril for shoulder pain, but the pharmacist dispensed her the generic version, Sulindac.¹⁷³ After using Sulindac, Ms. Bartlett developed toxic epidermal necrolysis, with burns covering over 60 percent of her body.¹⁷⁴ “[Ms. Bartlett] spent months in a medically induced coma, underwent [twelve] eye surgeries, and was tube-fed for a year.”¹⁷⁵

When Bartlett ingested Sulindac, the label warned only about “severe skin reactions and fatalities.”¹⁷⁶ The next year, the FDA recommended that the Cinoril label change to explicitly warn about toxic epidermal necrolysis.¹⁷⁷ Ms. Bartlett brought suit under the theories of failure-to-warn and design defect, ultimately receiving a jury award of over \$21 million in damages for her design

¹⁶⁹ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

¹⁷⁰ *Id.* at 67,989.

¹⁷¹ *See, e.g.*, *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299, 1303 (N.D. Fla. 2009) (noting that “[n]othing in federal law . . . suggests that a generic manufacturer should be exempt from the same liability that the brand manufacturer faces for any design defect or failure to warn.”); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1265 (W.D. Okla. 2009), *aff’d*, 727 F.3d 1273 (10th Cir. 2013) (denying generic drug manufacturer’s motion to dismiss failure-to-warn claims on federal preemption grounds); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 436 (D. Vt. 2008) (same).

¹⁷² *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

¹⁷³ *Id.* at 2472.

¹⁷⁴ *Id.* at 2472. Toxic Epidermal Necrolysis (TEN) is

an especially severe form of Stevens Johnson Syndrome (SJS), a rare but life-threatening disease that causes severe blistering and sloughing off of skin, together with serious damage to the mouth, eyes, throat, and esophagus. Treatment for the disease is similar to that given burn victims, as the separation of the top layer of skin from the deeper layers of skin, is akin to a second-degree or partial-thickness burn.

Maya v. Johnson & Johnson, 97 A.3d 1203, 1209–10 (Pa. Super. Ct. 2014).

¹⁷⁵ *Bartlett*, 133 S. Ct. at 2472.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

defect claim.¹⁷⁸ The appellate court affirmed the verdict, holding that the manufacturer could comply with both state and federal law by choosing not to produce the drug.¹⁷⁹ The U.S. Supreme Court rejected this approach, relying on “a straightforward application of preemption law” and reversed the jury award, leaving Ms. Bartlett without recourse, simply because she ingested the generic version of Cinoril.¹⁸⁰ In the Court’s closing remarks, Justice Alito lamented “Congress’ decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs’ compositions or their warnings.”¹⁸¹

In contrast, claims against brand name manufacturers may still proceed. For example, in *Maya v. Johnson & Johnson*, the Superior Court of Pennsylvania affirmed a \$10-million verdict for a young girl who suffered from toxic epidermal necrolysis after ingesting two brand-name over-the-counter drugs.¹⁸² Three days after three-year old Brianna Maya’s mother gave her doses of Children’s Motrin and Children’s Tylenol to fight a fever, Brianna was diagnosed with TEN, requiring a sixteen day stay in a children’s burn unit, and suffered severe eye damage.¹⁸³ As a result of her injuries, Brianna had to endure sixteen eye surgeries and make lifestyle changes such as avoiding strenuous activity “due to her inability to perspire normally, pulmonary fibrosis, and . . . scarring in the lungs which [made] respiration difficult and increase[d] the risk of asthmatic attacks and upper respiratory infections.”¹⁸⁴ Additionally, she suffered so much damage to her reproductive system that she may never be able to naturally bear children.¹⁸⁵ Following a nine-week jury trial, the jury awarded a \$10-million verdict against McNeil, the manufacturer of Children’s Motrin, for negligent failure to warn under applicable state law.¹⁸⁶

III. PROPOSED REGULATIONS FOR CHANGE

Following the Supreme Court’s ruling in *Mensing*, the legal community began to contemplate how to fix this new gap in manufacturer liability. They

¹⁷⁸ *Id.*

¹⁷⁹ *Bartlett v. Mut. Pharm. Co. Inc.*, 678 F.3d 30, 44 (1st Cir. 2012).

¹⁸⁰ *Bartlett*, 133 S. Ct. at 2480.

¹⁸¹ *Id.*

¹⁸² *Maya v. Johnson & Johnson*, 97 A.3d 1203, 1211, 1225 (Pa. Super. Ct. 2014).

¹⁸³ *Id.* at 1208–10.

¹⁸⁴ *Id.* at 1210.

¹⁸⁵ *Id.* at 1211.

¹⁸⁶ *Id.*; see also *Rowland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 556, 579 (W.D. Pa. 2014) (denying brand name manufacturer’s motion for summary judgment and allowing case to proceed for failure to warn claim); *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 170 (W.D.N.Y. 2014) (denying brand name manufacturer’s motion to dismiss and allowing case to proceed for strict liability for negligent failure to warn); *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1303 (N.D. Ga. 2012) (denying brand name manufacturer’s motion to dismiss and allowing case to proceed under bases of failure to warn and strict liability for defective design).

focused on those FDA regulations which allow generic drug manufacturers to assume minimal liability as compared to the brand name manufacturers.¹⁸⁷ The current state of the U.S. health care system, where insurance companies control which prescriptions may be filled and where pharmacies fill generic prescriptions by default, has created a sense of urgency to once again hold generic drug manufacturers liable for injuries caused by their products. Requiring all manufacturers, generic and brand-name, to adequately warn consumers of potential adverse events, would ensure they are held liable. Should the FDA change its current regulations to allow generic manufacturers to make label changes with increased warnings without waiting for brand name manufacturer approval, generic manufacturers would no longer be able to hide in the shadows of their brand name counterparts.¹⁸⁸ Without such a change in the FDA's regulations, injured consumers are left to the mercy of their insurance companies and pharmacies to dictate whether or not they have a right to relief in a court of law.

A. *Changes within the Food and Drug Administration*

The FDA has the ability to amend its regulations to either strengthen or weaken requirements for drug manufacturers. However, before doing so, the FDA must engage in formal rulemaking, receive comments from interested parties and provide the opportunity for an oral hearing.¹⁸⁹

1. *Petitions for Rulemaking*

On August 29, 2011, Public Citizen submitted a petition for formal rulemaking, urging the FDA to allow generic drug manufacturers to independently revise their prescription labels.¹⁹⁰ The petition also requested that the FDA allow generic drug manufacturers' labels to differ from the labels of the brand name equivalents without withdrawing ANDA approval.¹⁹¹ Finally, the petition

¹⁸⁷ See, e.g., James M. Beck, *Two Firsts in Post-Mensing Litigation*, LAW360 (Dec. 9, 2011, 3:34 PM), <http://www.law360.com/articles/291541/two-firsts-in-post-mensing-litigation> [<https://perma.cc/KRF6-T9PJ>]; Kelly Savage Day & Michael Healy, *From the Experts: Brave New (Post-Mensing) World* (Aug. 10, 2011), http://files.sedgwicklaw.com/Publication/422361e1-88c4-4c3d-b392-e5385d8f3c0b/Presentation/PublicationAttachment/ad00cf42-8113-40d9-ba64-f0c0a50e6ddd/Corporate%20Counsel_8-10-11.pdf [<https://perma.cc/6L86-XW4M>].

¹⁸⁸ See generally Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Sidney M. Wolfe, Dir., Pub. Citizen Health Research Grp., Allison M. Zieve, Dir., Pub. Citizen Litig. Grp., & Brian Wolfman, Co-Director, Inst. of Pub. Representation, (Nov. 7, 2013), <http://www.citizen.org/documents/2169.pdf> [<https://perma.cc/Q92T-8YGB>].

¹⁸⁹ 21 U.S.C. § 360j(f)(1)(B) (2012).

¹⁹⁰ Petition from Pub. Citizen to U.S. Food & Drug Admin. (Aug. 29, 2011), <http://www.citizen.org/documents/1965.pdf> [<https://perma.cc/C9MM-EYAQ>] [hereinafter Public Citizen Petition]. Public Citizen is a non-profit advocacy group which represents citizen's interests in Washington D.C. See *About Us*, PUB. CITIZEN, <http://www.citizen.org/Page.aspx?pid=2306> [<https://perma.cc/R8MD-RL5X>] (last visited Mar. 13, 2017).

¹⁹¹ Public Citizen Petition, *supra* note 190.

requested that the FDA make *all* manufacturers independently responsible for reporting safety concerns to the FDA.¹⁹²

2. *The Food and Drug Administration's Response*

As courts continued to shield generic manufacturers from liability, the FDA received several notices from concerned organizations like Public Citizen and was reminded of the Supreme Court's prompting that the "FDA retain[s] the authority to change the law and regulations if they so desire."¹⁹³ On November 8, 2013, the FDA granted the numerous petitions for formal rulemaking and opened the subject for public notice and comments.¹⁹⁴ Specifically, the FDA announced a proposed rule, which would allow generic drug manufacturers to independently change their prescription labels to reflect "newly acquired safety-related information in advance of FDA's review of the change."¹⁹⁵

Furthermore, the proposed regulation would make new labels immediately available online for the public to view and would also establish a procedure whereby all generic manufacturers must change their labels to mirror the change of another manufacturer within thirty days, even if that other manufacturer is not the brand name manufacturer.¹⁹⁶ The time for the FDA to receive comments to its proposed rule expired on March 13, 2014.¹⁹⁷ Now, the nation waits to see if the FDA will enact the rule and allow generic manufacturers to be liable for injuries caused by its drugs.

B. *Effects of the United States Health Care System on Consumer Rights*

Currently, the law only bars consumers from bringing claims against generic drug manufacturers. However, the number of Americans affected by this constraint is rapidly growing due to federal legislation mandating health insurance, insurance companies restricting which drugs consumers can take, and state laws requiring pharmacies to fill prescriptions with generics when available.

¹⁹² *Id.*

¹⁹³ *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2568 (2011).

¹⁹⁴ Letter from Janet Woodcock, *supra* note 188.

¹⁹⁵ *Id.* (citation omitted); *see also* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,986 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

¹⁹⁶ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,986.

¹⁹⁷ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Correction and Extension of Comment Period, 78 Fed. Reg. 78,796, 78,796 (proposed Dec. 27, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

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1. *The Affordable Care Act Requires All Americans to Carry Health Insurance*

The Patient Protection and Affordable Care Act (“Affordable Care Act”) requires that all Americans maintain minimum essential health insurance coverage.¹⁹⁸ Part of the Affordable Care Act’s requirement for minimum coverage is “essential health benefits,” including coverage for prescription drugs.¹⁹⁹ The penalty for not enrolling in a qualified health insurance plan is to pay a percentage of income equaling 1 percent for 2014, 2 percent for 2015, and 2.5 percent for all years after 2015.²⁰⁰ The percentage of uninsured Americans had dropped from approximately 18 percent at the end of 2013 just before the Affordable Care Act went into effect to 11.9 percent after the first quarter of 2015.²⁰¹

Despite the penalty for not enrolling in a qualified plan, some Americans are choosing that option.²⁰² This is due in part to the high cost of premiums and deductibles when compared to the income of individuals.²⁰³ Without insurance coverage, some facilities will not see patients, and patients have to pay all costs out of their own pockets, yet even these out-of-pocket costs are less than the cost of coverage for many Americans.²⁰⁴ Indeed, some consumers have indicated they would be more likely to sign up for a qualified plan if the penalty were higher.²⁰⁵

2. *Most Insurance Companies Force Patients to Take Generic Prescriptions*

Even among those with insurance plans, more and more Americans are finding that many of their prescriptions are not covered by their insurance plans leaving the consumers to pay for their prescriptions out of their own pockets.²⁰⁶ Insurance plans vary: while some may not provide coverage for a particular drug, others may, and different plans may require different co-pays for the

¹⁹⁸ Patient Protection and Affordable Care Act § 1501, 42 U.S.C. § 18091 (2012).

¹⁹⁹ 42 U.S.C. § 18022(b)(1)(F) (2012).

²⁰⁰ 26 U.S.C. § 5000A(c)(2)(B) (2012).

²⁰¹ Jenna Levy, *In U.S., Uninsured Rate Dips to 11.9% in First Quarter*, GALLUP (Apr. 13, 2015), <http://www.gallup.com/poll/182348/uninsured-rate-dips-first-quarter.aspx> [https://perma.cc/5LSD-F4AT].

²⁰² See, e.g., Carl Gibson, *Why I’m Choosing to Pay \$300 to Stay Uninsured*, READER SUPPORTED NEWS (Dec. 24, 2013), <http://readersupportednews.org/opinion2/272-39/21144-why-im-choosing-to-pay-300-to-stay-uninsured> [https://perma.cc/6C55-NP8Y].

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Charlie Richter & Stafford Nichols, *Higher Fines Compel Uninsured Americans to Sign Up*, GALLUP (Apr. 16, 2014), <http://www.gallup.com/poll/168542/higher-fines-compel-uninsured-americans-sign.aspx> [https://perma.cc/228B-UQ2P].

²⁰⁶ See Scott Gottlieb, *No, You Can’t Keep Your Drugs Either Under Obamacare*, FORBES (Dec. 9, 2013, 7:22 AM), <http://www.forbes.com/sites/scottgottlieb/2013/12/09/no-you-cant-keep-your-drugs-either-under-obamacare/> [https://perma.cc/T4EK-GRAX].

same prescription.²⁰⁷ Due to the disparity in out-of-pocket costs for brand name versus generic drugs (30 to 80 percent savings), many consumers have no choice but to purchase the generic versions, especially because their insurance companies will only allow them to purchase generics.²⁰⁸

3. *Pharmacies Are Required by Law to Fill Prescriptions with Generic Equivalents*

Additionally, many states have enacted laws “requir[ing] pharmacists to automatically substitute the generic version [of a drug] when available, unless the doctor has specifically noted otherwise.”²⁰⁹ Some states provide that the pharmacist does not have to notify the consumer when substituting a generic drug for the brand name, though some states do require that the pharmacist ask permission first.²¹⁰

For example, in Nevada, pharmacists have the discretion to substitute a less expensive generic drug for a brand name prescription unless the prescribing physician prohibits substitution or the consumer refuses the substitution.²¹¹ In contrast, California pharmacists have this same discretion unless the prescription bears the words “do not substitute,” but they do not have to notify the consumer.²¹²

Thus, the current set up of the U.S. health care system provides an overall scheme, which has curtailed the rights of many Americans. Americans are now required to carry health insurance, or face a monetary penalty. Insurance companies restrict which prescriptions consumers can purchase, and pharmacies automatically fill prescriptions with generics. As a result, many Americans have no choice but to take generic drugs, and thereby lose their rights to redress in a court of law when they suffer injuries because of those drugs.

CONCLUSION

The scope of the FDA’s authority has expanded greatly over the past century, allowing it to promulgate regulations to ensure the safety, efficacy, and honest labeling of all prescription drugs. Similarly, the FDA has also provided a way to allow consumers to have access to less-expensive versions of pharmaceuticals, while also providing a time period for manufacturers to recoup their investment costs for developing new drugs. Just as the FDA’s scope of authority has expanded, the courts have also broadened the ways manufacturers can be

²⁰⁷ *Id.*

²⁰⁸ Chris Woolston & Stephen Levine, *Generic Drugs*, HEALTHDAY, <http://consumer.healthday.com/encyclopedia/drug-center-16/misc-drugs-news-218/generic-drugs-646396.html> [<https://perma.cc/5V3Q-2B3V>] (last updated Jan. 20, 2016).

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ NEV. REV. STAT. § 639.2583 (1), (3) (2016).

²¹² CAL. BUS. & PROF. CODE § 4073 (West 2016).

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held liable when their products harm consumers. However, the current regulatory scheme is vulnerable to claims of preemption, resulting in generic drug manufacturers being virtually immune from suit.

Current proposed regulations would change this regulatory scheme by allowing generic manufacturers to increase warnings on their drug labels without waiting for approval from their brand-name counterparts. Should the FDA fail to adopt the proposed regulations, countless Americans would be stripped of their rights to pursue litigation for claims of negligence against generic drug manufacturers who introduce their drugs to market but fail to provide adequate warnings of safety concerns. This danger is amplified further because of the amount of control and discretion insurance companies and pharmacies have over which drugs are covered and dispensed to consumers. The legal landscape needs to continue to evolve so that consumers are able to make informed choices about their prescriptions, and that all manufacturers are held responsible for the harms their products cause.

