INNOVATOR LIABILITY AND PRESCRIPTION MEDICATION: A STOPGAP MEASURE PATIENTS DESERVE

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I. INTRODUCTION

Prescription medication has been a vital component of health care in the United States throughout the past decade.[1] Data from the National Center for Health Statistics highlighted that 48.6% of persons in the United States from 2015-2018 had used at least one prescription drug in the previous 30 days.[2] These statistics are not surprising due to the effectiveness of a wide variety of medications to treat a myriad of diseases and conditions.[3] However, prescription medications are not always safe and often result in side effects, which may be serious or minor in severity and which may not be disclosed on a medication's warning label.[4] In the event an individual suffers from a severe undisclosed side effect of a prescription medication, two factors currently pose tremendous consequences concerning potential recourse: (1) the jurisdiction in which the individual resides and (2) whether the individual ingested either the generic or brand-name version of the drug.

For instance, suppose Person A, like millions of other Americans, suffers from gastroesophageal reflux disease (GERD).[5] The person consults with his or her doctor and decides to seek treatment for GERD in the form of a prescription medication. To the relief of Person A, in 1983 the FDA approved the prescription drug ranitidine, under the brand-name Zantac, to help alleviate symptoms of GERD suffered by millions of Americans.[6] To Person A, the choice of whether or not to take Zantac seems clear based on the prominence and satisfaction with the drug; indeed, in 1988 Zantac became the world's best-selling drug and one of the first drugs to

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[1] *See* CRESCENT B. MARTIN ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS, NCHS DATA BRIEF NO. 334, PRESCRIPTION DRUG USE IN THE UNITED STATES, 2015-2016, at 4 (2019), https://www.cdc.gov/nchs/products/databriefs/db334.htm.

[2] U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2019, at xi (2019), https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm.

[3] *See* Sarah Lewis, *The Top 50 Drugs Prescribed in the United States*, HEALTHGRADES (Sept. 5, 2019), https://www.healthgrades.com/right-care/patient-advocate/the-top-50-drugs-prescribed-in-the-united-states.

[4] *See* Reuters Staff, *Timeline: Popular heartburn medicine Zantac pulled off store shelves*, REUTERS (Oct. 21, 2019), https://www.reuters.com/article/us-health-fda-heartburn-timeline/timeline-popular-heartburn-medicine-zantac-pulled-off-store-shelves-idUSKBN1X014E [hereinafter "Timeline"].

[5] *See* Linda Searing, *The Big Number: 60 Million Americans suffer from heartburn at least once a month*, WASHINGTON POST (Dec. 2, 2019), https://www.washingtonpost.com/health/the-big-number-60-million-americans-suffer-from-heartburn-at-least-once-month/2019/11/29/8f9f730a-106b-11ea-b0fc-62cc38411ebb_story.html.

[6] Timeline, *supra* note 4.

ever top $1 billion in annual sales.[7] In this hypothetical, suppose Person A began taking Zantac prior to the release of generic equivalents and continued to take brand-name Zantac after the release of generic equivalents. Tragically, Person A later develops cancer. Although Person A is not immediately aware, he or she has been ingesting a drug which potentially contains a dangerous level of NDMA, a probable human carcinogen.[8] On April 1, 2020, Person A reads the FDA's public announcement that the agency plans to recall Zantac and all generic ranitidine products after discovering an increased risk of cancer from taking the drug.[9]

Although nearly identical to the facts involving Person A, Person B also decided to begin taking ranitidine in order to alleviate the symptoms of GERD. However, unlike Person A, Person B received the generic version of the drug and never ingested brand-name Zantac. As with Person A, Person B later develops cancer. Despite the nearly identical factual scenarios of Person A and Person B, the two individuals will have drastically different abilities to recover damages under a products liability failure to warn claim. Person A, having ingested brand-name Zantac, will potentially have a viable tort claim against the brand-name drug manufacturer. However, in the vast majority of state jurisdictions, Person B will be completely without recourse involving a failure to warn theory of recovery against the generic drug manufacturer, even if Person B can allege a strong prima facie case. As later discussed in this Note, due to FDA regulations mandating that generic drugs use the same warning labels as the brand-name equivalent, generic manufacturers are shielded from liability involving failure to warn claims.[10]

Person B would only have potential recourse in a handful of jurisdictions. In these jurisdictions, despite still being unable to recover against the generic manufacturer, plaintiffs may sue the brand-name manufacturer for the harm caused from ingesting the generic version of the drug. This theory of recovery, termed "innovator liability," remains controversial throughout the United States.[11]

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[7] *Id.*

[8] *See* Gianna Melillo, *FDA Recalls All Ranitidine (Zantac) Products, Citing Increased Risk of Cancer*, AJMC (Apr. 1, 2020), https://www.ajmc.com/view/fda-recalls-all-ranitidine-products-zantac-citing-increased-risk-of-cancer.

[9] *See* FDA News Release, FDA Requests Removal of All Ranitidine Products (Zantac) from the Market: FDA Advises Consumers, Patients and Health Care Professionals After New FDA Studies Show Risk to Public Health (Apr. 1, 2020), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market.

[10] *See* 21 U.S.C. § 355 (2018); 21 C.F.R. § 314.94 (2020).

[11] *See*, *e.g.*, Huck v. Wyeth, 850 N.W.2d 353, 380 (Iowa 2014).

This Note argues that in the absence of an updated statute and FDA regulation, states should permit plaintiffs to recover under the theory of innovator liability. Despite the theory's arguable contravention of "traditional common law tort principles" and potentially unfair results against brand-name manufacturers, victims of defective drugs and inadequate warnings should have an avenue for recourse.[12] Forfeiting one's ability to recover potentially hundreds of thousands of dollars in damages in exchange for paying a cheaper price for medication is not a fair trade. Indeed, the Supreme Court in *PLIVA, Inc. v. Mensing* (discussed in Section II and arguably the most consequential case involving innovator liability) concedes that the opinion and pertinent federal regulations created an "unfortunate hand" for the plaintiffs and "others similarly situated."[13] However, this Note recognizes the substantial shortcomings and legal obstacles that innovator liability poses. Nevertheless, this Note argues that adopting innovator liability in more jurisdictions throughout the United States will exert greater pressure upon the federal government to rethink the current state of the law.

Thus, in the presence of statutory latitude, state courts should permit plaintiffs harmed by generic pharmaceuticals to recover under the theory of innovator liability against brand-name manufacturers due to the current federal legal framework. Alternatively, if a state's statutory code explicitly rejects innovator liability, thereby preventing the courts from adopting it in the common law, legislatures in those states should reverse their current approach. As discussed further below, adopting innovator liability would likely incentivize a change to the current federal framework. Ideally, the federal government should alter the current statutory and regulatory scheme involving prescription drugs in order to strike a better balance of providing recourse to generic prescription drug consumers, while also continuing to strive for the FDA's policy goals involving cost and safety.[14]

Section II of this Note provides the history and current background involving pharmaceutical failure-to-warn claims, innovator liability, and prescription medication law. The statutory and common law progression leading up to the current state of the law is further detailed in Section II. Section III of this Note analyzes two defenses raised by brand-name manufacturer defendants, including more typical arguments relating to the tort law, as well as

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[12] *Id.* at 370 (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013)).

[13] PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011).

[14] *See* Scott Gottlieb, M.D, *Looking ahead: Some of FDA's major policy goals for 2018,* USDA (Dec. 14, 2018), https://www.fda.gov/news-events/fda-voices/looking-ahead-some-fdas-major-policy-goals-2018.

the less-explored issue of personal jurisdiction as it relates to innovator liability. Specifically, Section III highlights recent case law involving personal jurisdiction serving as a useful threshold question if a jurisdiction decides to adopt innovator liability, as well as the obstacles of more rigid common law tort principles. Section IV presents this Note's primary proposal relating to innovator liability with the goal of attaining both short-term and long-term legal recourse for consumers involving pharmaceutical drug failure-to-warn claims. In summary, this Note argues that state governments should adopt innovator liability to accomplish two objectives: (1) provide injured plaintiffs with a more short-term stopgap avenue for recovery and (2) encourage the federal government to implement a more sustainable long-term solution involving pharmaceutical drug failure-to-warn claims.

II. HISTORY AND BACKGROUND OF PHARMACEUTICAL INNOVATOR LIABILITY

A. Pharmaceutical Drug Failure-to-Warn Claims

Because extensive warning labels are required to produce and distribute medication, plaintiffs often seek to recover against pharmaceutical companies for defective medications under a product liability theory involving "inadequate instructions or warnings."[15] The Restatement (Third) of Torts: Products Liability provides the following: "A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe."[16] Another torts text provides: "Strict liability for design defects or failure to warn does not apply to prescription drugs."[17] For instance, under the Restatement (Third) of Torts: Products Liability, prescription drugs are only defectively designed under a failure-to-warn claim "if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . "[18]

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[15] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW INST. 1998).
[16] *Id.* § 2.
[17] MEREDITH J. DUNCAN ET AL., TORTS: A CONTEMPORARY APPROACH 1102, 3rd ed. (2018) (citing RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998)).
[18] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW INST. 1998).

B. Federal Preemption Doctrine

As a result of the extensive federal statutory and regulatory framework involving prescription drugs, the federal preemption doctrine is pertinent to failure-to-warn prescription drug claims. Under the Supremacy Clause of the United States Constitution (Article VI Clause 2), federal law "shall be the supreme Law of the Land . . . [and] any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[19] In situations in which state law and federal law directly conflict, federal law controls.[20] Conflict occurs where it is "impossible for a private party to comply with both state and federal requirements."[21] In the context of prescription drug failure-to-warn claims, the preemption doctrine is the primary reason necessitating the adoption of innovator liability under the current state of the law, as discussed in the following subsections.

C. Statutory Background

i. Federal Food, Drug, and Cosmetic Act

The federal government has implemented substantial legislation regulating medication in order to protect U.S. consumers for nearly a century.[22] Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938 in order to "prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes."[23] Concerning drugs, the 1938 law served as a predecessor of later and more stringent rules for the drug approval process by requiring persons to file an application including "(1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug," in addition to various other requirements.[24]

While the 1938 version of the law served as an overall positive predecessor by focusing on safety, Congress later amended the Federal Food, Drug, and Cosmetic Act in 1962 to impose stricter standards on the drug industry concerning the effectiveness of

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[19] U.S. CONST., art. VI, cl. 2.
[20] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 486 (2013) (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).
[21] English v. General Elec. Co., 496 U.S. 72, 79 (1990) (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963)).
[22] *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
[23] *Id.*
[24] *Id.* at 1052.

medications before approval.[25] Signed into law by President John F. Kennedy on October 10, 1962, the amendment requires drug manufacturers seeking approval of a new drug from the government to engage in costly and lengthy studies to prove a drug's safety and effectiveness.[26] These drug studies can be very costly,[27] which is important to some of the policy arguments involving innovator liability. For example, studies published by the *Journal of Health Economics* and *JAMA* indicated that the average cost of bringing a new drug to market may range from $985 million to as high as $2.8 billion.[28]

ii. Hatch-Waxman Amendments (Drug Price Competition and Patent Term Restoration Act)

As an effort to lower the cost of prescription drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) permits generic drug manufacturers to submit an "abbreviated application" for a new drug which contains "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved [as a listed drug]."[29] In the context of innovator liability, the requirement of attaining approval of a drug's safety and effectiveness is relevant because the initial manufacturer of the drug bears the expensive cost of proving these characteristics.[30] In contrast, generic manufacturers may utilize the previous approval of a drug developed by the initial manufacturer when seeking an abbreviated application.[31] Of substantial importance in the context of innovator liability, the statutory requirements under the Hatch-Waxman Amendments require a generic drug application to "show that the [safety] labeling proposed for the new drug is the same as the labeling approved for the [brand-name] drug."[32] Implementing this language, FDA regulations likewise require companies submitting an abbreviated new drug

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[25] *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.
[26] *Id.* at 781.
[27] *See* Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 JOURNAL OF HEALTH ECONOMICS, 20 (2016), https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/12742/DiMasi-Grabowski-Hansen-RnD-JHE-2016.pdf; Oliver J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323(9) JAMA, 844, 855 (2020), https://jamanetwork.com/journals/jama/fullarticle/2762311.
[28] *Id.*
[29] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2018)).
[30] *See id.*
[31] *Id.*
[32] *Id.*

application (ANDA) to ensure the warning label is the same "as the labeling of the [brand-name drug]."[33]

Also of importance in the context of innovator liability is the FDA's current regulation permitting a brand-name drug manufacturer to change its warning labels prior to official approval from the FDA.[34] Under a process termed "changes-being-effected" (CBE), the FDA permits brand-name drug manufacturers to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."[35] For example, in the event that a brand-name drug manufacturer discovers an urgent need to update its drug label to reflect newly discovered information vital for patient health, the manufacturer "need not wait for preapproval by the FDA, which ordinarily is necessary to change a label."[36]

iii. Generic Substitution Laws

In an effort to further promote the goal of the Hatch-Waxman Amendments to make "available more low cost generic drugs by establishing a generic drug approval procedure,"[37] many state legislatures passed generic substitution laws that "require a pharmacist to substitute a therapeutically equivalent generic for a brand name drug, unless the physician specifies that a generic must not be substituted."[38] Although "[s]ome states impose an additional limitation that the pharmacist must get consent from the patient before substituting a generic,"[39] consumers are unlikely to object upon explanation that the generic version has the same active ingredients as the brand-name version for a substantially lower price. For example, in Minnesota, the jurisdiction in which the generic substitution law was implicated in *PLIVA, Incorporated v. Mensing*, a pharmacist must dispense the generic version of a drug in the absence of an explicit request for the brand-name version from a physician and after disclosing the substitution to the purchaser.[40] Additionally, in other states, patients who do not express a preference to their physician or pharmacist are nearly certain to

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[33] 21 C.F.R. § 314.94(a)(8) (2020).
[34] *See* 21 C.F.R. § 314.70(c)(6)(iii) (2020).
[35] *Id.*
[36] *PLIVA, Inc.*, 564 U.S. at 614.
[37] H.R. REP. NO. 98-857, pt.1, at 14-15 (1984).
[38] U.S. DEP. OF HEALTH AND HUMAN SERV., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS, 7-8 (Dec. 1, 2010), https://aspe.hhs.gov/system/files/pdf/76151/ib.pdf [hereinafter "ASPE ISSUE BRIEF"]. *See* MINN. STAT. 151.21 (2020).
[39] ASPE ISSUE BRIEF, *supra* note 38.
[40] MINN. STAT. 151.21 (2020).

receive the generic version because those states' statutes do not require the pharmacist to obtain consent from the patient if their prescription is being substituted with a generic equivalent.[41]

In the context of innovator liability, generic substitution laws are relevant because patients frequently receive the generic version of a drug, either with or without a disclosure from the pharmacist depending on state law.[42] Therefore, under the Hatch-Waxman Amendments and state generic substitution laws, patients often forfeit their ability to recover under a failure-to-warn theory against both the brand-name and generic drug manufacturers due to either a lack of disclosure from the pharmacist (in a state that permits this) or the patient's consent to the generic substitution without fully understanding the potential of forfeiting recovery rights.

iv. Case Law Background

Two U.S. Supreme Court cases gave rise to the disparate impact of one's ability to recover for a failure to warn by drug manufacturers. The first case, *Wyeth v. Levine*, presented the question of whether the FDA's approval of a new drug application and later approval of changes in a drug label provided the defendant manufacturer "with a complete defense to [the plaintiff's] tort claims."[43] In that case, Wyeth manufactured the drug Phenergan.[44] Tragically, doctors were forced to amputate a patient's arm after doctors injected the medication directly into the patient's vein, a dangerous procedure the plaintiff alleged was not warned against in the medication's warning label.[45]

After the patient sued Wyeth alleging a product liability failure-to-warn claim, the Supreme Court ultimately held that federal law did not preempt the plaintiff's state law claim.[46] The Court resolved two primary issues. First, the Court held that Wyeth was capable of complying with both federal and state law because an FDA regulation permits brand-name drug companies to add a stronger warning label to its preexisting label before receiving the FDA's approval.[47] Second, the Court held that Congress did not intend to preempt state law failure-to-warn claims and that approval from the FDA of a drug's warning label does not block a plaintiff's ability to pursue a failure-to-warn claim under state law.[48] Notably,

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[41] ASPE ISSUE BRIEF, *supra* note 38.
[42] ASPE ISSUE BRIEF, *supra* note 38, at 2, 7-8.
[43] Wyeth v. Levine, 555 U.S. 555, 558 (2009).
[44] *Id.* at 559.
[45] *Id.* at 559-60.
[46] *Id.* at 581.
[47] *Id.* at 568.
[48] *Id.* at 556.

and of great significance in the case discussed in the following paragraph, Wyeth manufactured the brand-name version of the drug involved.[49]

The second significant U.S. Supreme Court case in the context of innovator liability, *PLIVA, Inc. v. Mensing*, clarified that a patient's ability to recover against a drug manufacturer based on a state law failure-to-warn theory depends on whether the patient received the generic or brand-name version of a drug.[50] In *Mensing*, two different patients were prescribed the generic version of Reglan in order to treat digestive tract problems.[51] After both developed tardive dyskinesia, a severe neurological disorder, the two patients sued the manufacturers of their medication under state law failure to warn claims.[52] Contrasting from *Wyeth*, the Court in *Mensing* held that the generic manufacturer could not comply with both federal and state law, and thus the patients' failure-to-warn claims were preempted.[53] The Court distinguished the case from *Wyeth v. Levine* by emphasizing that the generic manufacturers in this case could not unilaterally update their warning labels under the Hatch-Waxman Amendments and corresponding FDA regulations without violating federal law.[54]

Under the Court's holding, if there is an intermediate step requiring FDA approval between a generic drug manufacturer wishing to change its label and being permitted to do so, the manufacturer "cannot independently satisfy those state duties for pre-emption purposes."[55] This is because brand-name and generic drug manufacturers have different "federal drug labeling duties."[56] "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval … is responsible for ensuring that its warning label is the same as the brand-name's."[57] This holding prompted a small number of states to adopt the theory of innovator liability in order to ensure plaintiffs asserting failure to warn claims have the ability to recover.[58] Despite the holding of *Mensing*, the Court's majority highlighted the blatant inequity resulting from the decision by stating, "We acknowledge the

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[49] *Id.* at 555.
[50] *See PLIVA, Inc.*, 564 U.S. at 604-06.
[51] *Id.* at 609.
[52] *Id.* at 610.
[53] *Id.* at 617-26.
[54] *Id.* at 612-13.
[55] *Id.* at 623-24.
[56] *Id.* at 613.
[57] *Id.* (citations omitted).
[58] *See* Rafferty v. Merck & Co., 479 Mass. 141 (2018).

unfortunate hand that federal drug regulation has dealt [the plaintiffs] and other similarly situated."[59]

v. Prior Proposed Changes to the Law

In response to the holding in *Mensing*, the FDA issued a proposed rule change in 2013, likely in an effort to alleviate the harsh effects from the holding of the case.[60] The proposed rule's primary change would have permitted generic manufacturers "to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug (RLD) upon submission to FDA of a 'changes being effected' (CBE-0) supplement."[61] Under the proposed rule, a generic manufacturer would be able to unilaterally change its warning label, effectively extending the holding of *Wyeth* to situations involving generic medication and eliminating the harsh ruling under *Mensing*. Consequently, under the proposed rule, plaintiffs would have had the option to bring a state failure-to-warn cause of action against generic manufacturers rather than being preempted by federal law.[62]

However, after five years of contemplation, the FDA withdrew the proposed rule on December 13, 2018.[63] Former FDA Commissioner Scott Gottlieb rationalized this decision based on the possibility of an increase in the price of generic medications, effectively ensuring the continued immunity of generic manufacturers from state failure-to-warn claims.[64] Additionally, the FDA voiced concern about the possibility that different generic manufacturers of the same drug would distribute medication with differing warning labels, potentially increasing uncertainty for consumers.[65] In contrast with generic-drug makers expressing satisfaction following the decision, consumer groups vehemently

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[59] *Mensing*, 564 U.S. at 625.
[60] *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (proposed November 13, 2013).
[61] *Id.*
[62] *See id.*
[63] Thomas M. Burton, *FDA Withdraws Proposed Rule That Would Have Exposed Generic-Drug Makers to Liability*, WALL STREET JOURNAL, (December 13, 2018), https://www.wsj.com/articles/fda-withdraws-proposed-rule-that-would-have-exposed-generic-drug-makers-to-liability-11544726478.
[64] *Id.*
[65] *See* FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D. and Director of FDA's Center for Drug Evaluation and Research Janet Woodcock, M.D., on efforts to modernize generic drug labels while maintaining the efficiency of generic development (December 13, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-director-fdas-center-drug-evaluation-and-research [hereinafter "FDA Statement"].

opposed the decision.[66] For example, "Sidney M. Wolfe, founder and senior advisor of the consumer-oriented Public Citizen Health Research Group, said the FDA, in withdrawing its proposed rule, 'has perpetuated a dangerous double standard. The winners are the generic companies, and the losers are the patients.'"[67] Despite the debate surrounding the issue, the FDA did not indicate a plan in its press release to propose a similar rule after rejecting the 2013 proposal.[68] Rather, the FDA stated that it planned to exert greater energy and time in working with the brand-name companies to update the warning labels of older medications.[69]

III. ANALYSIS OF BRAND-NAME MANUFACTURER DEFENSES INVOLVING INNOVATOR LIABILITY

Although the issue of innovator liability became significant following the Supreme Court's decision in *Mensing*,[70] various nuances involving viable defenses for brand-name manufacturers have continued to arise. For example, recent cases (discussed below) demonstrate brand-name manufacturers often object to personal jurisdiction in an effort to avoid potential liability.[71] In the event that more states throughout the country opt to adopt innovator liability, more recent case law demonstrates that personal jurisdiction may serve as an effective defense for brand-name manufacturers when holding the brand-name manufacturer liable for the harm caused by the generic version is especially unfair.[72] In contrast with personal jurisdiction, which involves unique facts on a case-by-case basis, tort law arguments provide courts with less flexibility: either courts will reconcile long-established tort law principles with innovator liability, or they will not.

A. Personal Jurisdiction

While courts have long recognized a wide range of justifications for rejecting innovator liability,[73] personal jurisdiction

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[66] *See* Burton, *supra* note 63.
[67] Burton, *supra* note 63.
[68] *See* FDA Statement, *supra* note 65.
[69] *See* FDA Statement, *supra* note 65.
[70] *PLIVA, Inc.*, 564 U.S. 604.
[71] *See*, *e.g.*, Quinn-White v. Novartis Pharms. Corp., 2018 U.S. Dist. LEXIS 227024, at *3 (C.D. Cal. Mar. 7, 2018).
[72] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, (E.D. Cal. Mar. 31, 2020).
[73] *See* Huck v. Wyeth, 850 N.W.2d 353, 370 (Iowa 2014) (quoting *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013)).

is a more recent argument advanced by brand-name defendants.[74] Like any other lawsuit, there may be instances in which a plaintiff's failure to warn claim will fail due to a court's lack of personal jurisdiction over the defendant. However, personal jurisdiction should not serve as an outright bar to all innovator liability claims. Instead, as demonstrated in the upcoming discussion of recent case law, personal jurisdiction may serve as a beneficial threshold question to potentially limit liability in cases with especially unfair scenarios for brand-name manufacturers. Therefore, if more states permit plaintiffs to proceed under innovator liability (as advocated for in Section IV), personal jurisdiction objections may provide brand-name defendants with an avenue to prevent innovator liability from resulting in widespread and excessively unfair outcomes. This would strike an ideal balance in the interim until federal regulatory changes are implemented: plaintiffs would have an avenue for recovery while brand-name defendants would possess a potentially effective defense in the most unfair fact patterns.

i. *Stirling v. Novartis Pharmaceuticals Corporation*

Depending on the factual and legal background of a case, various state courts have come to different conclusions regarding personal jurisdiction in cases involving the theory of innovator liability.[75] A relatively recent Idaho state court decision demonstrates an instance in which a brand-name manufacturer successfully objected to personal jurisdiction in a lawsuit with the requisite facts for a plaintiff to argue in favor of innovator liability.[76] In *Stirling v. Novartis Pharmaceuticals Corporation*, the plaintiffs brought, among a variety of claims, a negligent failure to warn claim against Novartis Pharmaceuticals Corporation ("Novartis").[77] Novartis owned the New Drug Application ("NDA") for Brethine (or terbutaline sulfate) and "developed, manufactured, packaged,

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[74] *See Henry*, 2020 WL 1532174.

[75] *Compare* Stirling v. Novartis Pharmaceuticals Corporation, No. CV01-18-04880, at *3-5 (4th Jud. Dist. Idaho July 13, 2020), https://www.druganddevicelawblog.com/wp-content/uploads/sites/30/2020/07/Stirling-II.pdf ("Memorandum Decision and Order Granting Dismissal of Novartis Pharmaceuticals Corporation from Second Amended Complaint" finding a lack of specific personal jurisdiction), *with* Quinn-White v. Novartis Pharms. Corp., 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016) (court finding specific personal jurisdiction).

[76] *See Stirling*, No. CV01-18-04880, at *3-5 (4th Jud. Dist. Idaho July 13, 2020); Stirling v. Novartis Pharmaceuticals Corporation, No. CV01-18-4880, at *2-4, *6-8 (4th Jud. Dist. Idaho Sept. 25, 2019), https://www.druganddevicelawblog.com/wp-content/uploads/sites/30/2019/10/Stirling.pdf ("Memorandum Decision Re: Novartis Pharmaceuticals Motion to Dismiss").

[77] *Stirling*, No. CV01-18-4880, at *1 (4th Jud. Dist. Idaho Sept. 25, 2019).

labeled, marketed, and distributed Brethine until around December 2001 when it sold the rights to the Brethine NDA to Alcami Carolinas Corporation."[78] In 2007, the plaintiff "was prescribed an injection of the generic drug terbutaline sulfate as a tocolytic – a drug to suppress premature labor in pregnant women."[79] The plaintiff alleged that because she used the generic version of Brethine, her child was later diagnosed with "cognitive and personality disorders."[80] Likely because FDA regulations and the Supreme Court decision in *Mensing* prevented the plaintiff from asserting a viable claim against the generic manufacturer, the plaintiff sued Novartis, the original brand-name manufacturer of the drug.[81] Ruling in favor of Novartis' on its motion to dismiss for failure to state a claim in 2019, the Idaho court in *Stirling* rejected the viability of innovator liability as it related to Idaho negligence principles.[82] However, later in 2020, the court addressed the issue of personal jurisdiction in an additional decision under the same case involving a second amended complaint that alleged fraud.[83]

Of importance, the plaintiff could not establish general personal jurisdiction over Novartis.[84] Therefore, the plaintiff needed to establish specific personal jurisdiction in order for the Idaho court to have authority over the defendant.[85] Regarding the Idaho standard for personal jurisdiction, the *Stirling* court provided the following:

> "[A] state [may] exercise personal jurisdiction over a non-resident defendant when that defendant has certain minimum contacts with the state such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice." *Profits Plus Capital Mgmt, LLC v. Podesta*, 156 Idaho 873, 883-84, 332 P.3d 785, 795-96 (2014) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). In determining the existence of minimum contacts, a court must focus on the relationship among the defendant, the forum, and the litigation. *Id.* (citing *Shaffer v. Heitner*, 433 U.S. 186, 205, 97 S. Ct. 2569, 2580, 53 L. Ed. 2d 683 (1977)). The minimum contacts required by *International Shoe's* minimum contacts requirement is satisfied if the defendant

[78] *Id.* at *2.
[79] *Id.*
[80] *Id.* at *3.
[81] *See id.* at *2.
[82] *Id.* at *6-8.
[83] *Stirling*, No. CV01-18-04880, at *1-3 (4th Jud. Dist. Idaho July 13, 2020).
[84] *See id.* at *5.
[85] *See id.* at *3-5.

> "purposefully directs his activities at residents of the forum state and the litigation arises out of or relates to those activities." *Id.* (quoting *Saint Alphonsus Reg'l Med. Ctr. v. State of Wash.*, 123 Idaho 739, 744, 852 P.2d 491, 496 (1993)); *Houghland Farms, Inc. v. Johnson*, 119 Idaho 72, 75, 803 P.2d 978, 981 (1990) ("It is not just any contacts by the defendant with Idaho that will sustain the exercise of specific personal jurisdiction, but only those out of which the suit arises or those that relate to the suit.").[86]

Concerning the "purposefully directs" requirement to qualify as sufficient minimum contacts, the *Stirling* court highlighted potential prior actions by the defendant that were "purposefully direct[ed] . . . at residents of the forum state . . . ."[87] Specifically, the court highlighted discovery cited by the plaintiffs which indicated Novartis, through an agent, called doctors in Idaho in 1999 for the purpose of promoting Brethine.[88] Additionally, the court highlighted discovery cited by the plaintiffs which indicated that Novartis was aware of marketing that took place for its benefit in Idaho in 1998.[89]

Nonetheless, the Idaho court held it did not possess personal jurisdiction over Novartis because the plaintiffs could not prove the litigation arose out of or related to Novartis' activities.[90] Explaining the lack of connection between Novartis' actions and the plaintiffs' cause of action, the court emphasized the importance of time as a factor by providing the following rationale:

> Important to the Court's decision is the lapse in time between the alleged contacts with Idaho (Horizon's marketing Brethine in calls in 1999) and Plaintiff Michelle's use of the generic form of Terbutaline Sulfate in 2007. This lapse in time, combined with the facts that Novartis sold the Brethine NDA in 2001 and then ceased marketing the product, support the Court finding this litigation does not arise out of the alleged marketing activities by Novartis.[91]

Additionally, the court acknowledged the need for overall reasonableness when analyzing specific personal jurisdiction: "It []

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[86] *Id.* at *3.
[87] *Id.* at *3-4.
[88] *Id.* at *4.
[89] *Id.*
[90] *Id.* at *5.
[91] *Id.*

is unreasonable that Novartis was on notice that it may be called into Idaho courts to answer for use of a generic form of Brethine as a tocolytic that was ingested six years after Novartis sold Brethine's NDA and seven years after its agent's direct marketing activity . . . ."[92]

ii. *Quinn-White v. Novartis Pharmaceuticals Corporation*

In contrast with the court in *Stirling*, in *Quinn-White v. Novartis Pharmaceuticals Corporation*, the U.S. District Court for the Central District of California held that the court did have specific personal jurisdiction over the brand-name drug manufacturer, despite the plaintiff ingesting the generic version of a drug.[93] In this case, the plaintiff experienced seizures and was "prescribed Tegretol, a brand-name, anti-epileptic drug manufactured and marketed by [Novartis]."[94] The plaintiff took the prescription to the pharmacy, "where the branded form of Tegretol was unilaterally substituted for a generic version called Epitol, which is manufactured and marketed by nonparty Teva Pharmaceuticals U.S.A., Inc."[95] The plaintiff later "experienced signs of conditions known as Stevens-Johnson syndrome ("SJS") and toxic epidermal necrolysis ("TEN")," resulting in the plaintiff becoming "blind in both eyes and with severe scarring over her body."[96] The plaintiff alleged causes of action for negligence, negligent misrepresentation, and fraud against Novartis.[97]

The court's initial holding determined that it had both general and specific jurisdiction over Novartis.[98] The court explained that Novartis was subject to specific personal jurisdiction because the plaintiff alleged that "her California-based physician reviewed and relied on Novartis's label and its warnings in California, where Novartis marketed its drugs."[99] In other words, without the California-based physician's review of Novartis's warning label and Novartis's marketing in California, the claim would not have arisen.[100]

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[92] *Id.*
[93] Quinn-White v. Novartis Pharms. Corp., 2018 U.S. Dist. LEXIS 227024, at *1-2, *13 (C.D. Cal. Mar. 7, 2018).
[94] *Id.* at *1.
[95] *Id.* at *1-2.
[96] *Id.* at *2.
[97] *Id.*
[98] Quinn-White v. Novartis Pharms. Corp., 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016).
[99] *Id.* (citations omitted).
[100] *See id.*

Following this determination, the court later agreed to reconsider the question of personal jurisdiction in light of two U.S. Supreme Court decisions: *Daimler AG v. Bauman* and *Bristol-Myers Squibb Co. v. Superior Court*.[101] The court in *Quinn-White* emphasized that its holding considered the Supreme Court's holding in *Bristol-Myers Squibb Co. v. Superior Court*, but was unconvinced with Novartis's argument that attempted to analogize the facts of *Quinn-White* to the facts in *Bristol-Myers*.[102] *Bristol-Myers Squibb* involved plaintiffs who were not domiciled in California and ingested the harmful drugs outside California,[103] whereas *Quinn-White* involved a California domiciliary who suffered an injury due to the defendant's contacts with the forum state.[104]

iii. *Henry v. Angelini Pharma, Inc.*

While the court in *Quinn-White* was willing to hold that the court had personal jurisdiction over a brand-name drug manufacturer in the context of innovator liability, a more recent case from the U.S. District Court for the Eastern District of California demonstrates the limits of innovator liability when confronted with a strong personal jurisdiction argument.[105] In *Henry v. Angelini Pharma, Inc.*, "a California resident[] consumed a generic intermediate release formulation of trazodone hydrochloride after his physician prescribed the drug for insomnia."[106] After taking the medication, the plaintiff developed a prolonged penile erection (known as a "priapism") that resulted in a permanent state of impotence.[107] Importantly, the plaintiff in this case sued the brand-name manufacturers of the extended-release formulation of the drug, despite ingesting a generic version of the intermediate-release formulation.[108] The court in this case dismissed the plaintiff's claim due to a lack of personal jurisdiction, demonstrating an avenue through which a brand-name drug manufacturer can avoid liability in a state which permits plaintiffs to recover under the theory of innovator liability.[109]

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[101] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *7. *See generally* Daimler AG v. Bauman, 571 U.S. 117 (2014); Bristol-Myers Squibb Co. v. Superior Court, 137 S. Ct. 1773 (2017).
[102] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *12-13.
[103] *Bristol-Myers Squibb Co.*, 137 S. Ct. at 1778-79.
[104] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *1, *12.
[105] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, at *3-4 (E.D. Cal. Mar. 31, 2020).
[106] *Id.* at *1.
[107] *Id.*
[108] *Id.* at *1-2.
[109] *See id.* at *3-4.

Explaining its decision, the court in *Henry* referenced the three requirements of specific personal jurisdiction in California: "(1) the nonresident defendant must have purposefully availed himself of the privilege of conducting activities in the forum by some affirmative act or conduct; (2) plaintiff's claim must arise out of or result from the defendant's forum-related activities; and (3) exercise of jurisdiction must be reasonable."[110] Mirroring the Idaho court in *Stirling*, the court in *Henry* dismissed the claim because the defendant's contacts failed to "ar[ise], result[] from, or . . . even relate[] to Defendants' forum related activities."[111] The contacts that the plaintiff argued satisfied the requirements of personal jurisdiction involved alleged misrepresentations made by a salesman of the brand-name medication, which the generic company later relied upon.[112] However, the court in *Henry* emphasized that even if the allegations were true, the plaintiff's claim did not arise out of or relate to the salesman's actions.[113] Just as in *Stirling*, the defendant's contacts in this instance were slim and simply too attenuated to the harm alleged by the plaintiff.[114] The court in *Henry* provided the following rationale for its decision: "[E]ven if [the salesman of the defendant] perpetuated misrepresentations about the side effects of trazodone during his year as an Oleptro salesman, there is no indication that [the salesman's] conduct had any effect on how Teva eventually labeled the trazodone product that allegedly harmed Plaintiff."[115] This case demonstrates that even in states permitting innovator liability, there are instances in which a defendant's contacts may be insufficient and result in a dismissal of the claim based on a lack of personal jurisdiction.

B. Tort Law: Duty

In addition to the issue of personal jurisdiction, the tort element of duty is often analyzed in the context of permitting or denying innovator liability.[116] In contrast with certain fact patterns involving personal jurisdiction, the tort element of duty should not serve as a barrier to an injured plaintiff's ability to recover in an innovator liability action. Creating an exception to the tort element of duty in the context of innovator liability is more black and white than a court's analysis involving personal jurisdiction. Either courts impose a duty on brand-name manufacturers in order to provide

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[110] *Id.* at *2 (quoting Roth v. Garcia Marquez, 942 F.2d 617, 620-21 (9th Cir. 1991)).
[111] *Id.* at *4.
[112] *Id.*
[113] *Id.*
[114] *See id.* at *1, *4.
[115] *Id.* at *4.
[116] *See, e.g.,* Huck v. Wyeth, 850 N.W.2d 353, 369 (Iowa 2014).

plaintiffs with a chance for recourse, or they do not. Because the FDA abandoned the proposed rule discussed in Section II,[117] a duty of care should be imposed as part of a stopgap measure to address the flaws in the current state of the law, as described later in Section IV.

i. *T.H. v. Novartis Pharmaceuticals Corporation*

A late-2017 case decided by the California Supreme Court illustrates how courts should create an exception to the tort element of duty by using the concept of foreseeability to provide injured plaintiffs with an avenue for recovery in the context of innovator liability.[118] In *T.H. v. Novartis Pharmaceuticals Corporation*, a father brought suit on behalf of his twin children against the brand-name manufacturers of the drug Brethine.[119] The mother of the children was prescribed Brethine's generic bioequivalent, terbutaline, during her pregnancy in order to suppress premature labor.[120] The court summarized the basis of the lawsuit by providing the following:

> Plaintiffs brought suit against defendant Novartis Pharmaceuticals Corporation (Novartis), which manufactured Brethine until December 2001, and aaiPharma Inc. (aaiPharma), which purchased the rights to and manufactured Brethine thereafter—using the same label Novartis had used—when plaintiffs' mother was prescribed the generic bioequivalent in 2007. Plaintiffs claim that Novartis knew or should have known that its warning label failed to alert pregnant women or their physicians to the risk Brethine posed to fetal brain development; that manufacturers of terbutaline were compelled by federal law to include Brethine's deficient label on their own products; that it was foreseeable Novartis's successor (aaiPharma) would not change or update Brethine's deficient label; and that in reliance on the deficient warning label, plaintiffs' mother was prescribed terbutaline, which adversely affected plaintiffs' developing brains in utero.[121]

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[117] *See* Burton, *supra* note 63.
[118] *See* T.H. Novartis Pharmaceuticals Corp., 4 Cal. 5th 145, 166 (2017).
[119] *Id.* at 155.
[120] *Id.* at 155.
[121] *Id.*

The primary question the court addressed was whether the brand-name manufacturer of a drug owes a duty to persons harmed by a generic bioequivalent due to an inadequate warning label created by the brand-name company.[122] Answering in the affirmative, the court in *T.H.* held that to "determin[e] whether to create an exception to the general statutory duty of care, the . . . 'most important'[] consideration under California law is the foreseeability of physical harm."[123] Here, the court held "it [wa]s entirely foreseeable that the warnings included (or not included) on the brand-name drug label would influence the dispensing of the generic drug . . . because the warning label on the generic drug is legally required to be identical to the label on the brand-name drug."[124]

California's rationale in this instance is not an anomaly in the United States. For example, the Supreme Judicial Court of Massachusetts circumvented the general rules of duty by adopting an identical rationale involving foreseeability in the context of innovator liability in *Rafferty v. Merck & Company*.[125] For example, the court in *Rafferty* provided the following rationale for imposing a duty of care on the brand-name manufacturer for the warning labels of generic bioequivalent medications: "With generic drugs, it is not merely foreseeable but *certain* that the warning label provided by the brand-name manufacturer will be identical to the warning label provided by the generic manufacturer, and moreover that it will be relied on . . . by users of the generic product."[126] The court emphasized that the context of prescription medication is markedly different than most other contexts; in most other cases, the manufacturer of a product and its corresponding warning label only involve that specific product, not the products of competitors.[127] Thus, because generic drug manufacturers are required to copy the warning label of the brand-name alternative, it should be foreseeable for every brand-name manufacturer that its warning label may cause harm to consumers of the generic equivalent, thereby justifying the creation of a duty.[128]

ii. *Huck v. Wyeth*

In contrast with the California Supreme Court in *T.H.*, the Iowa Supreme Court in *Huck v. Wyeth* declined to impose a duty of

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[122] *Id.* at 155-56.
[123] *Id.* at 166 (quoting Kesner v. Superior Court, 1 Cal. 5th 1132, 1145 (2016)).
[124] *Id.* at 166-67.
[125] *See* Rafferty v. Merck & Co., 479 Mass. 141, 150 (2018).
[126] *Id.* (emphasis in original).
[127] *Id.*
[128] *Id.* at 150-51.

care on the brand-name manufacturer for harm caused by the plaintiff ingesting a generic bioequivalent.[129] In *Huck*, similar to other cases involving innovator liability, a drug's warning label failed to warn of a serious side effect, resulting in harm to the plaintiff.[130] The plaintiff brought suit against both the brand-name and generic manufacturers.[131] Rejecting the theory of innovator liability, the Court in *Huck* reasoned that "[u]nder Iowa law, manufacturers owe duties to those harmed by use of *their* products."[132] Additionally, concerning foreseeability in the context of the duty, the Court further rejected the plaintiff's claim by agreeing with the notion adopted by other courts that "holding name brand manufacturers liable for harm cause by generic manufacturers 'stretches the concept of foreseeability too far.'"[133] The difference between the courts in *T.H.* and *Huck* illustrates the more black-and-white nature of the duty analysis in the context of innovator liability, differing from a personal jurisdiction analysis which offers a court more discretion to rule one way or the other.

By declining to impose a duty of care on the brand-name manufacturer, the court in *Huck* demonstrates the current problem with the law: many individuals are without recourse in states hesitant to adopt innovator liability due to the possibility of a future correction by the FDA. For example, as a reason to decline imposing a duty of care on the brand-name manufacturer, the court in *Huck* stated the following: "The FDA has responded to *Mensing* through a proposed rule to allow generic manufacturers to update their labeling on their own, regardless of the brand manufacturer labeling."[134] However, as described in Section II, the FDA later rejected the proposed rule change which would have permitted generic manufacturers to unilaterally change the warning labels on their products.[135] This inaction by the FDA necessitates the proposal advocated for in the following section.

IV. PROPOSED SOLUTION

Innovator liability undoubtedly contains substantial flaws. For instance, the Iowa Supreme Court in *Huck* cited to a few common objections to innovator liability such as the theory's arguable contravention of "traditional common law tort principles,"

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[129] Huck v. Wyeth, 850 N.W.2d 353, 369 (Iowa 2014).
[130] *Id.* at 357-61.
[131] *Id.* at 360.
[132] *Id.* at 369 (emphasis added).
[133] *Id.* (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1284-86 (10th Cir. 2013) (citing Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009))).
[134] *Id.* at 369.
[135] *See* Burton, *supra* note 63.

as well as the public policy consideration involving the large expense incurred by brand-name manufacturers to market a new drug.[136] Despite innovator liability's arguable contravention of tort law principles and arguably unfair results against brand-name manufacturers, state legislatures and courts should adopt innovator liability to accomplish two objectives: (1) provide injured plaintiffs with a short-term stopgap avenue for recovery and (2) encourage the federal government to implement a more sustainable long-term solution involving pharmaceutical drug failure-to-warn cases. Pharmaceutical drug consumers in states that reject innovator liability are likely unaware of the drastic difference in available recourse between ingesting the generic and brand-name versions of a drug. In contrast, brand-name manufacturers are likely well aware that a generic drug manufacturer is "responsible for ensuring that its warning label is the same as the brand-name's."[137]Weighing the fairness of both sides of the argument tilts in favor of providing plaintiffs with an avenue for recovery. To solve for cases with substantially unfair circumstances, brand-name manufacturers may still be able to successfully argue other defenses to avoid liability, such as personal jurisdiction as seen in *Henry*.[138]

An expansion of innovator liability would likely incentivize the federal government to promulgate a new framework permitting generic manufacturers to update their warning labels to contain differences from brand-name drug warning labels, all while providing injured plaintiffs with an avenue for recourse in the meantime. Some courts understandably have concluded that Congress and the FDA are in the best position to correct the ramifications of *Mensing*, and thus innovator liability should be rejected as a solution to provide patients with legal recourse.[139] For example, the Supreme Court of Iowa in *Huck* stated, "In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA."[140] However, under both the Obama administration and the Trump administration, which represent opposing sides of the political spectrum, Congress and the FDA have demonstrated their unwillingness to change the current state of the law.[141] Therefore, additional pressure must be exerted on

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[136] *Huck*, 850 N.W.2d at 369-71 (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013)).
[137] *PLIVA, Inc.*, 564 U.S. at 612 .
[138] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, at *3-4 (E.D. Cal. Mar. 31, 2020).
[139] *See Huck*, 850 N.W.2d at 380.
[140] *Id.*
[141] *See* FDA Statement, *supra* note 65.

Congress and the FDA in order to correct the unfair ramifications of the holding in *Mensing*.

Ignoring the debate of whether federal lobbying is a benefit or hindrance to the lawmaking process, the reality in the United States is that lobbying plays a significant role in political decisions.[142] In 2019 alone, over $280 million was spent on lobbying involving pharmaceutical drugs and health products.[143] In the context of innovator liability, the pharmaceutical drug lobby would naturally be concerned about any potential change to the law following the holding in *Mensing* and would likely lobby the federal government to support a position most beneficial to their particular interests.

Both the brand-name drug lobby and the generic drug lobby invest substantial amounts of money in their lobbying efforts.[144] Pharmaceutical Research and Manufacturers of America (PhRMA)[145], a trade group representing many prominent brand-name drug manufacturers, spent a record-high $29 million on lobbying in 2019.[146] In comparison, the Association for Accessible Medicines (AAM), a trade group representing manufacturers of generic medication[147], spent a total of $3.5 million on lobbying the federal government in 2017.[148] Based on a statement from FDA Commissioner Scott Gottlieb following the FDA decision to reject the 2013 proposed rule change, as discussed in Section II, the interests of the generic drug industry affected the FDA's choice to continue the harsh ramifications following *Mensing*.[149] In Gottlieb's official statement regarding the FDA's decision, he explained that a key basis for the outcome centered on the increased liability imposed on generic manufacturers: "Importantly, we heard important feedback that the proposed rule, if finalized, would have imposed significant burdens on the generic drug industry, and that

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[142] *See* Karl Evers-Hillstrom, *Lobbying spending reaches $3.4 billion in 2018, highest in 8 years*, OPENSECRETS (Jan. 25, 2019), https://www.opensecrets.org/news/2019/01/lobbying-spending-reaches-3-4-billion-in-18/.
[143] *Id.*
[144] *See A bitter pill: how big pharma lobbies to keep prescription drug prices high*, CREW (June 18, 2018), https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high/ [hereinafter "A bitter pill"]; Jessie Hellmann, *PhRMA spent a record-high $29 million on lobbying in 2019*, THE HILL (Jan. 22, 2020), https://thehill.com/policy/healthcare/479403-phrma-spent-record-high-29-million-lobbying-congress-trump-administration.
[145] *See generally* PHRMA, https://www.phrma.org.
[146] Hellmann, *supra* note 144.
[147] *See generally* AAM, https://accessiblemeds.org.
[148] A bitter pill, *supra* note 144.
[149] *See* FDA Statement, *supra* note 65.

it could have led to an increase in the cost of generic drugs or the market exit of certain products and manufacturers . . ."[150]

However, PhRMA's priorities in 2017, prior to the FDA's rejection of the proposed rule, likely would have been different if more courts across the country adopted innovator liability in the absence of an updated FDA regulation. For example, in 2017, PhRMA would have had a larger stake in the outcome of the proposed rule if innovator liability was adopted or appeared likely to be adopted in more states. While the FDA adopting the proposed rule in 2018 would have likely resulted in positive business ramifications for brand-name manufactures, such as the elimination of the need for plaintiffs to assert innovator liability in the small number of states it existed and an increase in the cost of generic medication, the relatively small number of states that permitted innovator liability did not make the stakes as high as the scenario described in the subsequent paragraph.

Contrasting with the circumstances around the time of the FDA rejected the proposed rule, if a larger number of states opted to permit innovator liability, the business interests of PhRMA would be substantially greater and would create a greater urgency in convincing the FDA to adopt a similar rule as proposed in 2013. For example, a wider adoption of innovator liability would naturally increase the potential liability facing brand-name manufacturers. Further, this additional liability imposed on the brand-name manufacturers would likely lead to an increase in the cost of prescription medication and temporarily hinder further innovation due to the added risk of the cost of litigation. In such a scenario, it is much more likely the FDA would reconsider its approach and remedy the harsh ruling for consumers following *Mensing*.

As previously mentioned in Section II of this note, the FDA stated it planned to exert greater energy and time in working with the brand-name manufacturers to update the warning labels of older medications.[151] This is not an ideal solution due to the inability to completely eliminate inadequate warning labels, despite a greater amount of energy and time being exerted to prevent mistakes from occurring. Even if the FDA is successful in updating warning labels to be more accurate, injured plaintiffs should have legal recourse in the event that a mistake does happen. With the current state of the law remaining flawed and the federal government seemingly remaining content with the status quo, there must be an impetus to encourage a change in the law. The adoption of innovator liability in more jurisdictions throughout the United States, despite the

[150] FDA Statement, *supra* note 65.
[151] FDA Statement, *supra* note 65.

theory's flaws, could serve as that impetus while also providing injured plaintiffs with an avenue for recourse.

VI. CONCLUSION

Admittedly, the proposed approach of this Note is not a perfect solution and is more difficult than other options, such as the FDA adopting a new rule without states adopting innovator liability. Nevertheless, this Note's proposal is a stopgap measure which would both encourage a change to the law and provide injured plaintiffs with an ability to recover until a change to the law is ultimately finalized. Although the Drug Price Competition and Patent Term Restoration Act of 1984 has been successful in promoting affordable generic drugs to consumers,[152] the current legal background involving pharmaceutical drugs is flawed due to the majority of the U.S. population currently ingesting generic drugs without proper recourse in the event of an inadequate warning. The purpose of generic drugs is to provide Americans with more affordable medication.[153] This purpose is greatly hindered if consumers are not adequately protected and provided with appropriate recourse in the event of tortious conduct by a generic drug manufacturer. Therefore, plaintiffs should be provided recourse in the interim before a more long-term solution is implemented. In addition to providing prescription drug consumers with a means to recover damages after suffering harm, adopting innovator liability would incentivize both the federal government to make a change to the current framework and the brand-name pharmaceutical drug lobby to exert influence in an effort to change the law.

[152] ASPE ISSUE BRIEF, *supra* note 38 at 3.
[153] *Id*.