

EXPANDING THE DOCTRINE OF INNOVATOR LIABILITY: USING TORT LIABILITY TO CREATE A VIABLE FOLLOW-ON BIOLOGIC REGIME

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I. INTRODUCTION

Historically, the pharmaceutical landscape has been dominated by traditional, chemical drugs, both brand-name and generic. And courts have categorically denied monetary compensation to plaintiffs who have been injured by the generic versions of brand-name chemical drugs. However, the rapidly advancing progress of DNA recombinant technology and biotechnology has ushered in a new class of medicines known as biologic drugs, and soon, their follow-on biologic counterparts, or, the “generic” versions of biologic drugs. Specifically, with the upcoming patent cliff whereby 2019, at least \$54 million worth of biologic drugs will be at risk for patent expiration, it is imperative that legislatures and policymakers prophylactically address the problem of how to compensate consumers who are injured by the follow-on biologic versions of brand-name biologic drugs. Under the Supreme Court’s current approach in the chemical context, generic drug manufacturers continue to collect colossal profits from the sales of its drugs, while leaving horrifically injured consumers wholly uncompensated. In order to solve the problem of the uncompensated consumer in a manner that promotes social welfare by ensuring the continued coexistence of brand-name biologic manufacturers and their follow-on biologic cousins, this Note argues for the straightforward application of tort doctrine in certain scenarios, and for the expansion of the doctrine of innovator liability into the biologics realm, in the more contentious scenarios.

After the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in 1984,¹ generic drugs were, for all practical purposes, the same as brand-name drugs,² except for the fact that they could be produced and sold at a fraction of the cost.³ The modern generic drug

1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, sec. 101, § 355(j), 98 Stat. 1585 [hereinafter Hatch-Waxman Amendments].

2. *Id.*; see also Erik Mogalian & Philip DeShong, *What’s the Difference Between Brand-Name and Generic Prescription Drugs?*, SCI. AM. (Dec. 13, 2004), <http://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-13/> (noting that in order to gain market entry approval as the generic version of a brand-name drug, under the Hatch-Waxman Act, a prospective generic drug manufacturer must show that its drug “contains the same active ingredient(s) as the brand-name product, in the same dosage form, at the same dose or concentration, and [that the drug has] the same route of administration (for example, amoxicillin 500 milligrams (oral) capsule)”). It is also worth emphasizing that Hatch-Waxman does permit the existence of impractical and trivial differences between generic drugs and brand-name drugs (i.e. differences in color, shape, taste, inactive ingredients, preservatives and packaging), to exist as bioequivalents as long as the generic drug manufacturers show that the generic drug is (1) manufactured under good manufacturing processes (GMPs), (2) has the same purity and stability as the brand-name drug, and (3) meets the pharmacokinetic parameters in the body (in other words, the generic drug dissolves to the same extent and at the same rate in a beaker as does the brand-name drug). *Id.*

3. *Generic Pharmaceuticals Saved \$734 Billion over Last Decade*, GENETIC PHARM. ASS’N (May 7, 2009), <http://www.gphaonline.org/gpha-media/press/generic-pharmaceuticals-saved-734-billion-over-last-decade>; see also Melissa Jeffries, *Generic Drugs, HOW STUFF WORKS* (Oct. 11, 2007), <http://health.howstuffworks.com/medicine/medication/generic-drug.htm> (reporting that the generic drug

industry thus had its genesis in an era of simpler and less subtle technology, when Congress passed the Hatch-Waxman Act, which effectively streamlined the FDA approval, marketing, and post-market surveillance process for generic drugs⁴ that had shown bioequivalence,⁵ by allowing them to free-ride off of the safety and efficacy trials that were already performed by the brand-name drug manufacturers.⁶ The only caveat was that under the Hatch-Waxman Act, the generic drug manufacturers had to comply with the “federal sameness requirement” by maintaining warning labels that were identical to their brand-name counterparts,⁷ for the twofold purposes of avoiding consumer confusion and garnering public confidence in the reliability and credibility of the generic drug regime.⁸

If the measure of a law’s success is its ability to live up to its statutory prescriptions, then Hatch-Waxman was a laudable success. The generic drug regime quickly gained traction among the general public, so much so that legislatures soon began to enact state substitution laws that required pharmacists to substitute all brand-name prescription drugs with the FDA-approved, generic versions.⁹

industry has saved American healthcare consumers an annual amount of \$10 billion).

4. Hatch-Waxman Amendments, *supra* note 1.

5. Lisa Barons Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, PRAC. L. 2, http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20pensabene_dgregory.pdf (last visited Oct. 27, 2014).

6. Hatch-Waxman Amendments, *supra* note 1; *see also* Don Jacob, *Hatch-Waxman Act and Exclusivities for Patent Holders and ANDA Applicant*, PHARMA TREASURES (Sept. 1, 2013, 11:38 PM), <http://pharmatreasures.blogspot.com/2013/09/hatch-waxman-act-and-exclusivities-for.html> (noting that under Hatch-Waxman, generic drug producers need to show that a drug is bioequivalent to a patented drug); Nebibe Varol et al., *Do International Launch Strategies of Pharmaceutical Corporations Respond to Changes in the Regulatory Environment?* 5 (LSE Health, Working Paper No. 19, 2010), available at <http://www.lse.ac.uk/LSEHealthAndSocialCare/pdf/LSEHealthworkingpaperseries/LSEHWP19.pdf> (“Generic imitations largely free-ride on the R&D efforts of originator firms, which enable them to compete solely based on price.”).

7. Hatch-Waxman Amendments, *supra* note 1.

8. *See* Janet Woodcock, *Label Confusion*, C-SPAN (June 19, 2014), <http://www.c-span.org/video/?c4501303/label-confusion> (noting that if the FDA did adopt a rule that allowed manufacturers of generic drugs to unilaterally change their labeling, deviating from the brand, the result would be mass consumer confusion because this success of the Hatch-Waxman Act has been possible because consumers and prescribers have confidence that generic drugs are deemed by the FDA to be the same as their brand-name counterparts, not only in terms of their chemical composition, but also in terms of their safety and effectiveness).

9. There are two types of state laws governing the substitution of generic versions of chemical drugs: permissive and mandatory. Erica Pascal, *Substitution Allowed? State Biosimilars Laws are Evolving*, JDSUPRA BUS. ADVISOR (Sept. 11, 2014), <http://www.jdsupra.com/legalnews/substitution-allowed-state-biosimilars-39691/>. Permissive regulations stipulate that a pharmacist has the discretion to substitute the generic versions for brand-name drugs. *Id.* Mandatory laws require the pharmacist to make a substitution, so long as the generic drug is available. *Id.* It is also worth noting that as of March 9, 2011, all fifty states and the District of Columbia had some type of generic substitution laws in place. Jessica S. Mazer, *Generic Substitution: The Science and Savings*, PCMA PHARMACEUTICAL CARE MGMT. ASS’N (Mar. 9, 2011), <http://amcp.org/WorkArea/DownloadAsset.aspx?id=10530>. Specifically, fifteen of those states had mandatory generic substitution laws, and 35 of those states and the District of Columbia had permissive substitution laws. *Id.* For a survey of the intricate details of state generic substitution laws as of 2009, *see* Wan-Chih Tom & Kayla Dotson, *State Regulations on Generic Substitution*, PHARMACISTS LETTER (Apr. 2009), <http://pharmacistsletter.therapeuticresearch.com/pl/ArticlePDF.aspx?dd=220901&segment=1186>; *see also* William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1383 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103121/> (“All states have adopted generic substitution laws, and many require step therapy or prior authorization prior to provide coverage for more expensive medications.”)

However, in July of 2013, the United States Supreme Court reminded us that the cost of this so called “affordable healthcare” was actually a modicum of corrective injustice.¹⁰ The recent *Bartlett v. Mutual Pharmaceuticals* decision to reverse a \$21 million verdict in favor of the injured plaintiff in light of the statutory conundrums implicated by the Hatch-Waxman Act is still reverberating across the pharmaceutical landscape, as scholars continue to speculate over what the implications will be for injured consumers of follow-on biologic drugs.¹¹ In *Bartlett*, the plaintiff Karen Bartlett suffered from toxic epidermal necrolysis after ingesting the generic version, Sulindac, of the brand-name drug Clinoril that her physician prescribed her for shoulder pain relief.¹² The generic drug manufacturer, Mutual Pharmaceuticals, knew that toxic epidermal necrolysis was a possible side effect, but in efforts to comply with federal law, omitted it from the drug’s warning label because the brand-name drug manufacturer at the time had omitted it from its own warning label.¹³ The disease caused the outer layer of Karen’s skin to deteriorate until it became an open wound, exposing over more than sixty-five percent of her body.¹⁴ She underwent twelve eye surgeries.¹⁵ She suffered lung damage and esophageal damage.¹⁶ She was induced into a medical coma and was tube-fed for a year.¹⁷ Today, she remains physically disfigured and legally blind.¹⁸ And to add salt to her wounds, the Supreme Court reversed the decision of the New Hampshire District Court and First Circuit to award her \$21.06 million in compensatory damages, leaving her wholly uncompensated.¹⁹

Because federal law under the Hatch-Waxman Act requires generic drug manufacturers to maintain warning labels that are identical to their brand-name counterparts,²⁰ the United States Supreme Court ruled that the Supremacy

10. See generally *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013) (holding that plaintiff’s tragic situation where she was permanently injured by a generic drug does not overcome Congressional intent to preclude state common-law tort liability).

11. *Infra* note 30 and accompanying text.

12. *Id.* at 2472.

13. See *id.* (“At the time respondent was prescribed Sulindac, the drug’s label did not specifically refer to Stevens-Johnson Syndrome or toxic epidermal necrolysis, but did warn that the drug could cause ‘sever skin reactions’ and ‘[f]atalities.’ However, Stevens-Johnson Syndrome and toxic epidermal necrolysis were listed as potential adverse reactions on the drug’s package insert.”); *id.* at 2470 (relying on *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) for the proposition that “federal law prohibits generic drug manufacturers from independently changing their drugs’ labels.”).

14. *Id.* at 2472.

15. *Id.*

16. *Nathan Taylor & Cristina Quinones-Betancourt, Mutual Pharmaceutical Co. v. Bartlett*, LEGAL INFO. INST., <http://www.law.cornell.edu/suptct/cert/12-142> (last visited Oct. 27, 2014).

17. *Bartlett*, 133 S. Ct. at 2472.

18. *Id.*

19. *Id.* at 2480. It is worth noting that both the United States District Court for the District of New Hampshire and the United States Court of Appeals for the First Circuit held that Bartlett’s state failure to warn claim was not preempted by federal law because generic drug manufacturers facing design-defect claims could comply with their federal duty of sameness and state tort law duty to warn by simply not making the drug at all. *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 248 (D. N.H. 2011), *aff’d*, 678 F.3d 30, 37 (1st Cir. 2012), *rev’d*, 133 S.Ct. 2466 (2013). This “stop selling” rationale was subsequently rejected by the Supreme Court as incoherent because of its ludicrous implication that under this theory, any regulated actor could and should avoid liability under both state and federal law by simply exiting the market. *Bartlett*, 133 S.Ct. at 2478.

20. *Bartlett*, 133 S.Ct. at 2470; Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Clause of the United States Constitution precluded Mutual Pharmaceuticals from complying with its state tort law duty to warn consumers of toxic epidermal necrolysis because it conflicted with Mutual's federal duty to maintain labels identical to its brand-name counterparts'.²¹ By refusing to speak in an area where in the court's opinion, Congress had already done so, the Supreme Court had for the second time, expressed cognizance of its political limitations by recognizing that "Congress and the FDA retain[ed] authority to change the law and regulations if they so desire[d]."²²

The resolution of these federal preemption cases can be difficult and controversial.²³ As a result, there has been a waxing and waning of scholarly interest in recent decades on the subject of how to compensate injured consumers such as Karen Bartlett in a manner that preserves fidelity between tort doctrine and congressional intent behind the Hatch-Waxman Act to promote affordable and accessible access to pharmaceuticals.²⁴ Recently, the saliency of *Bartlett* has re-sparked a politically charged institutional debate among scholars about whether the Supreme Court was correct in deferring to Congress or whether it was within the court's political jurisdiction to grant

21. *Bartlett*, 133 S.Ct. at 2480.

22. The first time the court refused to find liability where a consumer was injured by the generic version of a brand-name chemical drug was in *PLIVA v. Mensing*. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2571 (2011).

23. *Infra* note 24 and accompanying text.

24. See generally Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1525 (2014) (arguing that to remedy the issue of the injured and uncompensated plaintiff, the Food and Drug Administration (FDA) should use negotiated rulemaking to work with drug manufacturers, consumer representatives, healthcare providers, and other interested parties to create new drug regulations); Gregory J. Feeney, *PLIVA, Inc. v. Mensing: How Generic-Drug Manufacturers Avoided Liability for "Failure to Warn" Tort Claims*, 58 LOY. L. REV. 251, 252 (2012) (arguing that Congress should carefully consider the ramifications of altering the current pharmaceutical regulatory framework because any changes will render the purpose of the generic drug operating model to provide for safe, affordable, and effective drugs, nugatory); Samantha Koopman, *Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry*, 34 J. NAT'L ASS'N ADMIN. L. JUDICIARY 112, 114–15 (2014) (proposing various ways that the options for patients injured by prescription drugs can be improved); Stacey B. Lee, *PLIVA v. Mensing: Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y, L. & ETHICS 209, 213–14 (2012) (articulating a practical framework that would allow generic drug manufacturers to adequately warn consumers and the medical community with current and accurate labeling instructions for their products); Courtney A. Markey, *Implications of the Supreme Court's Decision in PLIVA, Inc. v. Mensing: Why Generic and Brand-Name Pharmaceuticals Must Be Treated Equally Under the Federal Food, Drug, and Cosmetic Act*, 15 MARQ. ELDER'S ADVISOR 135, 137 (2013) (arguing that the Supreme Court's interpretation of the FDCA in *PLIVA v. Mensing* results in the FDCA violating the Equal Protection component of the Fifth Amendment's Due Process Clause because of the FDCA's irrational differential treatment of generic and brand-name prescription drugs); Danielle L. Steele, *The "Duty of Sameness" As A Shield—Generic Drug Manufacturers' Tort Liability and the Need for Label Independence After PLIVA, Inc. v. Mensing*, 43 SETON HALL L. REV. 441, 444 (2013) (proposing that either legislative or regulatory changes should put generic drug manufacturers on par with brand-name drug manufacturers with respect to labeling responsibilities); Beatrice Skye Resendes, Note, *The Extinct Distinction of Privity: When a Generic Label Fails to Warn, the Drug's Pioneer Should be Liable as Component Part Supplier of the Warning Label*, 32 T. JEFFERSON L. REV. 95, 105–08 (2009) (arguing that brand-name drug manufacturers should be liable to plaintiffs who are injured by side effects of generic versions because the warning labels that they supply to generics are component parts); Wesley E. Weeks, Note, *Picking Up The Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257, 1259 (2012) (arguing that because of their sole ability to determine warning labels, brand-name manufacturers should be liable to plaintiffs who are injured by generic versions of their drug).

damages.²⁵ But with the fast and advanced development of modern biotechnology, especially recombinant DNA technology,²⁶ the academic conversation about *Bartlett* and its ancestral cases is becoming increasingly irrelevant, largely because it focuses on the tension between allocating liability among chemical brand-name and chemical generic drugs.²⁷ However, the recent expiration on a series of brand-name biologic drugs has teed up the market entry of follow-on biologic products.²⁸ Thus, it is only a matter of time before chemical drugs become an ancient relic of the past. With the upcoming biologic drug patent cliff, where by 2019, at least \$54 billion worth of biologics will be at risk for patent expiration, \$19.4 billion of which already expired in 2013,²⁹ thus opening the floodgates for follow-on biologic entry, the courts will soon be faced with the question of how to compensate the Karen Bartletts of the biologic drug world.³⁰

Because of the economic differences between chemical and biologic drugs driven by the complexities in their manufacturing and replication processes,³¹ and in their comparatively heightened regulatory standards as set out by the FDA in the Biologics Price Competition and Innovation Act of 2009,³² which is the regulatory pathway for follow-on biologic drugs, the market implications for biologic drugs and their follow-on counterparts will be especially sensitive to the torts regime that is imposed upon them. For these reasons, biologic drugs deserve to be examined through a unique lens when determining the appropriate allocation of tort liability among brand-name biologics and their follow-on biologic counterparts.

At its heart, tort law strives to calibrate a delicate balance between corrective justice, which is justice at the individual level for those who have

25. Weeks, *supra* note 24, at 1259.

26. Jun Wang & Shein-Chung Chow, *On the Regulatory Approval Pathway of Biosimilar Products*, PHARMACEUTICALS 353, 354 (Mar. 30, 2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3763644/>.

27. Weeks, *supra* note 24, at 1259; Resendes, *supra* note 24, at 105–08.

28. Wang & Chow, *supra* note 26, at 354.

29. *\$19 Bn Worth Biologics to go Off Patent in US This Year*, BUS. STANDARD (Feb. 1, 2013), http://www.business-standard.com/article/companies/-19-bn-worth-biologics-to-go-off-patent-in-us-this-year-113020100046_1.html; see also John Carroll, *Patent Cliff II: Nightmare on blockbuster street returns in 2015*, FIERCEPHARMA (Jan. 31, 2013), <http://www.fiercepharma.com/story/patent-cliff-ii-nightmare-blockbuster-street-returns-2015/2013-01-31> (noting that a significant number of drugs at risk for patent expiration are biologic drugs).

30. See generally J. Dominic Campodonico, *Innovator Liability for a Consumer's Use of Follow-On Biologics: the Combined Threat of Conte and New FDA Regulations*, DRI TODAY (July 21, 2011), <http://dritoday.org/feature.aspx?id=83> (“[P]ractitioners should prepare to . . . limit liability for innovator manufacturers of biopharmaceutical products.”).

31. See BIOSIMILARS — FDA GUIDANCE UPDATE, NOVATION 5 (2012), available at https://www.novationco.com/media/industryinfo/biosimilar_FDA_Guidance_Update_201205.pdf (citing the FDA’s view that it will be difficult for a prospective applicant to demonstrate interchangeability). See also Carroll, *supra* note 29 (noting that biosimilars’ future remains uncertain because it will not be “picked apart instantaneously the way small molecules are”); Doug Hornig, *Is the Patent Cliff a Lethal Blow to Big Pharma?*, CASEY RES. (May 23, 2013), <http://www.caseyresearch.com/cdd/is-the-patent-cliff-a-lethal-blow-to-big-pharma> (predicting that biologic drugs are not as simple to pick apart as chemical drugs, resulting in a not so robust follow-on biologic regime).

32. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119 (amending Public Health Service Act § 351, 42 U.S.C. § 262(i)(1) (2012)) [hereinafter Biologics Price Act].

been wronged,³³ and public welfare, which is justice at the collective level for society.³⁴ Frequently, the two policies lead to the same solution.³⁵ But, more often than not, they will point in diametrically opposing directions, and in such situations, it becomes necessary either for one of them to accede to the demands of the other, or for both of them to comprise.³⁶ This Note argues, as many judges and scholars do, for a primary commitment to corrective justice.³⁷ If, and only if, corrective justice does not unequivocally point to the right answer, this Note then argues that principles of social welfare should be deployed using (1) deterrence and (2) risk spreading as normative guideposts.³⁸

Part II provides an exposition of the conscious and articulated claims and policies of tort law. Part III provides a synoptic view of the Supreme Court's approach to allocating tort liability between chemical drug manufactures and their reference branded counterparts. Part IV surveys the four ways this problem can arise in the biologics context and articulates a narrowly tailored solution for each scenario based on the slightly nuanced normative concerns that each one implicates. Part V briefly concludes.

II. TORT LAW

A. *Introduction to Tort Law*

A tort is a conduct that “amounts to a legal wrong for which courts will impose civil liability.”³⁹ Tort law imposes liability where the defendant engages in conduct which is socially unreasonable.⁴⁰ It is primarily concerned with redressing legally recognized harms by rendering a judgment against the wrongdoer, usually through damages, restitution, or when necessary, injunctions.⁴¹ Particular aims of tort law are usually erected under one of two larger systems of thought: corrective justice and social welfare.⁴² Often times, corrective justice will point to the right

33. See DAN B. DOBBS, *THE LAW OF TORTS* 13 (2001) (noting that corrective justice entails ideals of “righting wrongs”, or “ideals about accountability or personal responsibility for harm-causing conduct” to “individual human beings”).

34. *Id.* at 12 (“The second large system of thought reverses the emphasis; it bases tort law on social policy or a good-for-all-of-us view. Social policy may coincide with justice in particular cases, but the dominant concern is not justice to the individual; it is to provide a system of rules that, overall, works toward the good of society.”).

35. *Id.* at 12–13 (“Although justice and policy often point to the same result, they do not always do so, and when they do not, one of these views must prevail or both must be compromised.”).

36. *Id.*

37. See *id.* at 18 (noting that fault is the most common basis for tort liability); PROSSER & KEETON ON TORTS § 1, at 5–6 (William Lloyd Prosser et al., eds., 5th ed. 1984) [hereinafter Prosser & Keeton] (“There remains a body of law which is directed toward the compensation of individuals, rather than the public, for losses which they have suffered within the scope of their legally recognized interests generally, rather than one interest only, where the law considers that compensation is required. This is the law of torts.”).

38. *Infra* note 138 and accompanying text.

39. See DOBBS, *supra* note 33, at 1 (noting that corrective justice entails ideals of righting wrongs, or ideals about accountability or personal responsibility for harm-causing conduct to individual human beings).

40. Prosser & Keeton, *supra* note 37 (“So far as there is one central idea, it would seem that it is that liability must be based upon conduct which is socially unreasonable.”).

41. DOBBS, *supra* note 33, at 2.

42. *Id.* at 12 (noting that particular aims of tort law are usually erected under corrective justice and

solution.⁴³ But while corrective justice has many lessons to teach tort scholarship, it fails to provide guidance in situations where there is no clear moral blame,⁴⁴ or in situations where the moral blame is grossly incommensurate with the severity of the resulting injury.⁴⁵ In such situations, it becomes necessary to invoke principles of social welfare using deterrence and risk distribution as normative guideposts.

B. Corrective Justice

Corrective justice embraces a rights-based approach to tort liability.⁴⁶ It is primarily concerned with ideals about righting wrongs, and about personal responsibility and accountability for conduct that causes harm.⁴⁷ In line with this reasoning, traditional tort liability requires the wrongdoer to compensate the plaintiff in some cognizable way for the harm it caused, in a manner that settles the accounts between the parties.⁴⁸ However, in spite of corrective justice's focus on the individual aspect of compensation,⁴⁹ it decries imposing liability upon a defendant who is not at fault in causing harm to the plaintiff, and thus will not condone forcing one innocent individual to compensate another just for the sake of making a wronged plaintiff whole.⁵⁰

social utility or policy).

43. See *id.* at 12–13 (“Although justice and policy often point to the same result, they do not always do so, and when they do not, one of these views must prevail or both must be compromised.”).

44. See Susan Randall, *Corrective Justice and the Torts Process*, 27 *IND. L. REV.* 1, 4 (1993) (arguing that corrective justice is “reasonable, but radically incomplete”). Specifically, Randall identifies a limitation of corrective justice as the sole metric for measuring the social effects of imposing tort liability because its tendency to assess “morality retrospectively at the point of injury causing action,” can be particularly problematic in the law of negligence because not all injuries in the negligence realm are grounded in moral fault. *Id.* at 8; see also John C.P. Goldberg & Benjamin C. Zipursky, *Torts as Wrongs*, 88 *TEX. L. REV.* 917, *passim* (2010) (arguing that corrective justice fails to capture the “fundamental structure and conceptual features of tort law” because, among other things, it fails to account for the diversity of interests that tort law strives to protect); Ernest J. Weinrib, *Corrective Justice*, 77 *IOWA L. REV.* 403, 413 (1992) (providing a synoptic critique of the Aristotelian view of corrective justice as “normatively empty” because it fails to account for the goals or functions of tort law). Finally, some scholars engender the view that despite corrective justice’s normative teeth, compensation in tort law can and should be justified on other grounds. IZHAK ENGLAND, *THE PHILOSOPHY OF TORT LAW* 11–16 (1992); Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 *TEX. L. REV.* 1801 (1997).

45. See Richard L. Abel, *A Critique of Torts*, 37 *UCLA L. REV.* 785, 791 (1990) (arguing that corrective justice violates basic principles of proportionality “between wrongfulness of the defendant’s conduct and the magnitude of the penalty imposed” resulting in “moral intuitions [that] lack a principled basis”).

46. DOBBS, *supra* note 33, at 18 (explaining the foundation of tort law as ideals of “righting wrongs, or ideals about accountability or personal responsibility for harm-causing conduct”).

47. *Id.* at 18. (“Tort law is at least partly rights-based. That is, it is at least partly based on ideals of corrective justice, ideals of righting wrongs, or (some-what relatedly) ideals about accountability or personal responsibility for harm-causing conduct.”).

48. *Id.* at 14–15.

49. See generally Eric Posner & Cass R. Sunstein, *Dollars and Death*, 72 *U. CHI. L. REV.* 537 (2005) (“[T]ort law seeks to ensure compensation . . . [and] has long focused on the compensation of those still living – a focus that leads to . . . an interest in a set of highly individuated awards.”).

50. DOBBS, *supra* note 33, at 15 (noting that corrective scheme emphasizes “individual accountability for fault” and that they do speak out against compensation by the faultless defendant).

C. Social Welfare

Despite tort law's primary focus on rectifying wrongs committed against the individual, to get to the right result, tort law, more often than not, must look beyond the individual and gauge the broader social consequences that would ensue as a result of imposing liability on the defendant.⁵¹ And oftentimes, the social implication will be a factor in determining whether or not the defendant truly engaged in conduct that was socially undesirable.⁵² Indeed, famous tort scholars, such as Prosser & Keeton, have recognized that even in disputes that are exclusively between two private parties, the interests of society may still be an important factor in determining the appropriate allocation, if any, of tort liability.⁵³

When assessing the social implications of imposing tort liability, decision makers will primarily examine the effects on: (1) a defendant's affinity to be deterred from engaging in the conduct that caused the harm and incurred the liability⁵⁴ and (2) the risk-spreading consequences to all members of society as a result of holding the defendant liable.⁵⁵

This Note further highlights how the economic differences between generic chemical drugs and follow-on biologic drugs implicate concerns for both corrective justice and social welfare that make the biologic drug regime worthy of observation through a fresh lens when assessing the best tort liability regime.

1. Deterrence

The first proxy for social welfare is deterrence.⁵⁶ Scholars have argued that tort law should advance social welfare by imposing liability in a manner that promotes systematic deterrence of harmful conduct or socially undesirable

51. See Prosser & Keeton, *supra* note 37, at 6 ("Often [the law] measures acts, and the harm an actor has done, by an objective, disinterested and social standard. It may consider that the actor's behavior, although entirely reasonable in itself or the point of view of anyone in the actor's position, has created risk or has resulted in harm to neighbors which is so far unreasonable that the actor should nevertheless pay for harm done. Sometimes it must range rather far afield, and look primarily to the social consequences which will follow.").

52. *Id.*

53. See *id.* at 15 ("But the twentieth century has brought an increasing realization of the fact that the interests of society in general may be involved in disputes in which the parties are private litigants.").

54. DOBBS, *supra* note 33, at 19 ("The idea of deterrence is . . . the idea that all persons, recognizing potential tort liability, would tend to avoid conduct that could lead to tort liability.").

55. *Id.* at 17.

[S]ome commentators have argued that tort liability should be strict or expansive in order to secure compensation for more injured persons. Some defendants if not all were seen as good 'risk distributors' who should be liable for any harms they cause regardless of fault because they can 'distribute' the costs of paying compensation. This means that some defendants, such as product manufacturers, could pay compensation for injuries they cause and then recoup some or all of those costs by raising the price of products. In this view, each individual purchaser of the products will pay a tiny fraction of the costs of injuries inflicted by those products and the injured person will not be compelled to bear the entire cost alone.

Id.

56. *Id.* at 19 ("Courts and writers almost always recognize that another aim of tort law is to deter certain kinds of conduct by imposing liability when that conduct causes harm."); see also DAN. B. DOBBS, THE LAW OF TORTS § 8 at 12 (2000).

behavior.⁵⁷ The idea behind deterrence is not that an individual, having been held liable for a tort, would subsequently conduct himself appropriately.⁵⁸ A deterrence school of thought holds that persons will account for the potential tort liability by avoiding or at least by engaging in less of the conduct that leads to the tort liability.⁵⁹ Under this view, decision makers and scholars argue that tort liability should not be imposed for conduct that society views as socially desirable.⁶⁰ Thus, in deciding whether and to what extent a defendant will be liable in tort damages, a deterrence analysis encourages decision makers to weigh the incremental cost of injuries against the social desirability and value of the enterprise.

2. *Risk Distribution*

A second commonly invoked metric for gauging the social welfare impacts of imposing tort liability is the risk distribution effects that could occur as a result of holding defendants financially liable.⁶¹ The idea here is that in some contexts, tort liability should be imposed without regard to fault because some defendants, are “seen as good ‘risk distributors’ who should be liable for any harms they cause regardless of fault because they can ‘distribute’ the costs of paying compensation.”⁶² This is a particularly palatable justification for imposing liability on defendants in the products liability context because they can absorb the costs of tort liability by paying out to the injured consumer, after which they can externalize those costs to their consumer base in the form of increased purchase prices.⁶³ The end result is that the defendant is not deterred from providing socially desirable services and the individual purchasers of the product collectively pay a fraction of the costs of injuries afflicted, minimizing the amount of social dislocation and the effect of negative externalities.⁶⁴

This next part of this Note argues that because these corrective justice and social welfare concerns are present, if not exacerbated in the biologic drugs context because of the economic differences implicated by follow-on biologics’ costly manufacturing processes, heightened regulatory hurdles, and regulatory uncertainties, any attempt to allocate tort liability among brand-name biologics and their follow-on cousins requires a critical reassessment of the Supreme Court’s current approach of categorically denying relief to injured plaintiffs.

57. *See id.* (“Some critics believe that tort law fails to provide systematic deterrence.”).

58. DOBBS, *supra* note 33, at 19.

59. *Id.* at 20.

60. *Id.* at 20 (noting that in determining whether a defendant committed a legal wrong such that he should be subject to tort liability, a deterrence expert would inquire as to whether it would be good for society as a whole to deter the builder’s conduct).

61. *Id.* at 17.

62. *Id.*

63. *Id.*

64. *Id.*

III. THE SUPREME COURT'S CURRENT APPROACH: FEDERAL PREEMPTION

A. *Bartlett v. Mutual Pharmaceuticals*

In 2013, the Supreme Court heard Karen Bartlett's case.⁶⁵ As mentioned above, the court was specifically tasked with how to compensate Karen Bartlett for her injuries suffered without transgressing its political limitations by awarding damages in tort liability where, in its opinion, Congress had already evinced an intent to pre-empt.⁶⁶

Karen Bartlett suffered from toxic epidermal necrolysis when her pharmacist substituted the brand-name drug Clinoril with the generic, FDA-approved version, Sulindac, manufactured by Mutual Pharmaceuticals.⁶⁷ The Supreme Court in a 5-4 majority reversed the decision of the United States Court of Appeals for the First Circuit, holding that Mutual Pharmaceuticals "was unable to change [its warning label] as a matter of federal law."⁶⁸ In ruling so, the Supreme Court remained faithful to its previous ruling in *PLIVA v. Mensing*,⁶⁹ which similarly held that federal law prohibited generic drug manufacturers from independently changing their warning labels.⁷⁰

The Bartlett court went through an introductory summary of the federal preemption enigma that it was tasked with solving,⁷¹ as well as an explication of the preemption analysis.⁷² Basically, as a result of the passage of the Hatch-Waxman Act in 1984, generic versions of patented brand-name drugs are permitted to enter the market by submitting an abbreviated new drug application (ANDA), rather than submitting an independent new drug application (NDA).⁷³ This means that instead of having to show de novo safety and efficacy like brand-name manufacturers, prospective generic drug

65. See generally *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013) (holding that the tragedy and sympathetic situation of plaintiff who was permanently injured by a generic drug did not overcome Congressional intent to preclude state common-law tort liability).

66. *Id.* at 2470.

67. *Id.* at 2472.

68. *Id.* at 2470.

69. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

70. *Bartlett*, 133 S. Ct. at 2476.

71. *Id.* at 2470–71 ("We must decide whether federal law pre-empts the New Hampshire design-defect claim under which respondent Karen Bartlett recovered damages from petitioner Mutual Pharmaceutical, the manufacturer of Sulindac, a generic nonsteroidal anti-inflammatory drug Under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. § 355(a). In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA) Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application. 21 C.F.R. § 314.70(b)(2)(i). Generic manufacturers are also prohibited from making any unilateral changes to a drug's label. See §§ 314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug's label 'is no longer consistent with that for [the brand-name] drug').").

72. *Id.* at 2473 ("In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on [S]ulindac's label and its federal-law duty not to alter [S]ulindac's label. Accordingly, the state law is pre-empted.").

73. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (1984).

manufactures only have to show that their drug is bioequivalent to the brand-name drug.⁷⁴ In order to satisfy the requirements for bioequivalence, generic drug manufactures have to demonstrate that their drugs' active ingredient is the same as the brand-name drug's active ingredient,⁷⁵ and that that active ingredient has the same level and rate of absorption in the bloodstream as does the active ingredient in the brand-name drug.⁷⁶

Thus, while the new drug applications for follow-on brand-name drugs require a de novo demonstration of safety and efficacy through relatively costly clinical trials, abbreviated new drug applications only require prospective generic drug manufacturer to demonstrate safety and efficacy to the extent that they have to show bioequivalence, a requirement which contemplates substantially less financial investments.⁷⁷ It is precisely this decreased financial investment in research and development that is intrinsic to a generic drug: a generic drug can essentially recreate the brand-name drug for a fraction of the cost, and can in turn, sell the drug to the public at a fraction of that already fractioned cost.⁷⁸ The only catch is that in an effort to avoid consumer confusion and garner the public's trust in the viability of the generic drug regime,⁷⁹ the Hatch-Waxman Act requires that generic drugs' warning

74. 21 U.S.C. § 355(j)(2)(A) (2012).

75. 21 U.S.C. § 355(j)(8)(B) (2012) (“A drug shall be considered to be bioequivalent to a listed drug if (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.”).

76. 21 U.S.C. § 355(j)(8)(B) (2012).

77. *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: Hearing on H.R. 1 and S. 1 Before the S. Comm. on the Judiciary, 108th Cong. 124–25 (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration) (noting that the second objective of the Hatch-Waxman Amendments are to ensure that “once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs.”).

78. *Id.* at 125 (“While the new rule will improve FDA’s implementation of the law, this is only one part of a set of FDA initiatives that will reduce drug costs by encouraging innovation and speeding up the drug development and approval process”); see also *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics> (last updated Sept. 18, 2014) (“Once [the Abbreviated New Drug Application is] approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public This Act expedites the availability of less costly generic drugs by permitting the FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials.”).

79. See *Examining Concerns Regarding FDA’s Proposed Changes to Generic Drug Labeling: hearing on Proposed Rule Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67,985 (Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601) Before the H. Subcomm. on Health of Comm. on Energy and Commerce, 113th Cong. (2014) (opening statement of Joseph R. Pitts, Chairman, Energy & Commerce Subcommittee on Health), available at <http://energycommerce.house.gov/hearing/examining-concerns-regarding-fdas-proposed-changes-generic-drug-labeling> (“[The] success [of the hatch-Waxman Act] has been possible because consumers and prescribers have confidence that generic drugs are approved by the FDA as the same as their brand-name counterparts, not only in terms of their chemical composition, but also with respect to their safety and

labels mirror their brand-name counterpart's, at all times.⁸⁰

Thus, the problem is born: under the Hatch-Waxman Act, generic drug manufacturers are precluded from updating their warning labels without the FDA's permission,⁸¹ even if they become privy to information about the drug's hazardous or even fatal side effects,⁸² as did Mutual Pharmaceuticals in the Bartlett case.⁸³

In writing the majority opinion Justice Alito also reasoned, "That federal law forbids Mutual to take actions required of it by state tort law evinces an intent to pre-empt."⁸⁴ Finally, the Supreme Court concluded the opinion by interpreting the Hatch-Waxman to mean that Congress had explicitly decided to regulate the manufacture and sale of generic drugs in a way that reduces their costs to patients.⁸⁵ More specifically, it was the Supreme Court's understanding that when Congress drafted the Hatch-Waxman Act, this problem of the uncompensated consumer was in the peripheral vision of the legislature, which had simply decided that, it would simply be one of the costs associated with an overall reduction in pharmaceutical prices.⁸⁶

This Note does not attempt to assess the merits and fallibilities of the Supreme Court's current approach in the chemical drug context, although it bears emphasis that the majority opinion elicited a strenuous sixteen-page dissent from Justices Sotomayor, Breyer, Kagan, and Ginsburg.⁸⁷ Instead, I argue that to the extent that scholars and commentators are correct in their

effectiveness.") (noting also that if the FDA did adopt a rule that allowed manufacturers of generic drugs to unilaterally change their labeling, deviating from the brand, the result would be mass [consumer] confusion).

80. 21 U.S.C. § 355(j)(2)(A)(v) (2012) ("An abbreviated application for a new drug shall contain . . . information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers.").

81. *Id.*

82. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) ("[T]he jury . . . was instructed to consider, whether Mutual had fulfilled its duty to label Sulindac adequately so as to render the drug not 'unreasonably dangerous.' In holding Mutual liable, the jury determined that Mutual had breached that duty . . . [F]ederal law prevents generic drug manufacturers from changing their labels Thus, federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law.").

83. *Id.*

84. *Id.* at 2480.

85. *Id.* ("[C]ongress' decision [was] 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.").

86. *See id.* ("[T]he FDCA's treatment of prescription drugs includes neither an express pre-emption clause . . . nor an express non-preemption clause In the absence of that sort of 'explicit' expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes. That federal law forbids Mutual to take actions required of it by state tort law evinces an intent to pre-empt [C]ongress' decision [was] 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.").

87. *See id.* at 2480–81 (Breyer, J., dissenting) (ascribing to the "stop selling" rationale as a solution to the generic drug manufacturer's Supremacy Clause predicament, where "a company can comply with [both state and federal law] by not doing business in the relevant State or by paying the state penalty, say damages, for falling to comply with, as here, a state-law tort standard"); *id.* at 2485 (Sotomayor, J., dissenting) (arguing that Congress's decision to not create a federal cause of action for damages signals its intent to preserve the state tort common law liability suit).

characterization of Bartlett as a fatal attack on bedrock principles of tort law,⁸⁸ there is an even stronger normative justification for why the Bartlett approach should not be transplanted to the biologic drug context.

B. Critique of *Bartlett v. Mutual Pharmaceuticals*

1. Corrective Justice Critique

It is abundantly clear that the Bartlett approach, which left a severely injured plaintiff uncompensated, subverts the fundamental foundation of corrective justice, which is to compensate individuals who have been wronged.⁸⁹ Indeed, if the cornerstone of the corrective justice theory is that the accounts between a wrongdoer and his victim should be settled such that the victim is made whole again,⁹⁰ then this is clearly an instance where tort law has utterly failed the plaintiff. More importantly, this attack on corrective justice does not disappear in the biologic drug context. Let us imagine that Karen Bartlett, for instance, was actually injured by the follow-on biologic version of the brand-name biologic drug that her physician prescribed her. Under a Bartlett approach, the end result would be a severely injured and uncompensated plaintiff.⁹¹ Regardless of the ongoing internal politics between the brand-name biologics and their follow-on counterparts,⁹² regardless of the inconsistencies between state and federal law,⁹³ and regardless of the social welfare implications of compensating her,⁹⁴ the fundamental foundations of tort law would be eviscerated if a plaintiff was injured by a drug with an

88. See Boyd, *supra* note 24, at 1525 (arguing that recent Supreme Court holdings, including Bartlett, have exposed a gap in the regulation of generic drugs in which no manufacturer is responsible for updating the warning label); Brittany Croom, *Buyer Beware: Mutual Pharmaceutical Co. v. Bartlett Continues to Alter the True Costs and Risks of Generic Drugs*, 15 N.C.J.L. & TECH. 1 (2014) (arguing that the Bartlett decision disincentivized generic drug manufacturers from conducting ongoing safety research); Koopman, *supra* note 24, at 140–41 (arguing that recent Supreme Court Hatch-Waxman jurisprudence, including the Bartlett decision, would result in decreased numbers of generic drug substitutions because physicians would stop selling them, pharmacists would stop making them, and patients would stop buying them); Markey, *supra* note 24, at 136 (arguing that the Supreme Court's interpretation of the Food, Drug and Cosmetic Act in *Pliva v. Mensing* results in the FDCA violating the Equal Protection component of the Fifth Amendment's Due Process Clause because it irrationally and differently treats generic and brand-name prescription drugs).

89. See DOBBS, *supra* note 33, at 12 (“[Tort law] attempts to hold defendants liable for harms they wrongfully caused and no others.”); *Id.* at 13 (“Tort law is . . . at least partly based on . . . ideals of righting wrongs . . . for harm-causing conduct.”); *Id.* at 14–15 (“Tort law imposes liability upon defendants for conduct the law treats as wrong . . . The defendant’s fault is a wrong that has harmed the plaintiff in some recognizable way; tort liability, by requiring the wrongdoer to compensate the plaintiff, can put the accounts right between the parties.”). It is worth emphasizing that even though corrective justice does not tell us who the wrongdoer necessarily is in the Bartlett context, it does tell us that the wrongdoer, whoever he is, owes plaintiff a duty of compensation. *Id.* at 12. Thus, the Bartlett approach, which left the plaintiff wholly uncompensated, is clearly an attack on principles of corrective justice. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2467 (2013).

90. DOBBS, *supra* note 33, at 15.

91. See *generally Bartlett*, 133 S. Ct. at 2466 (2013) (reversing a 21.06 million dollar verdict for the plaintiff).

92. See *Id.* at 2468–69 (going through a synoptic view of the federal preemption problem that Hatch-Waxman presents in tort litigation).

93. *Id.*

94. See Boyd, *supra* note 24; Feeney, *supra* note 24; Koopman, *supra* note 24; Lee, *supra* note 24; Steele, *supra* note 24 (and accompanying text for all).

effective warning label if no one later compensated her for her injury.⁹⁵

2. *Social Welfare Critique*

Apart from being problematic from a corrective justice perspective,⁹⁶ transplanting the Bartlett approach to the biologics realm implicates some disturbing deterrence concerns that would become particularly salient in the biologics context.

First of all, it would most undoubtedly deter prospective follow-on biologic manufacturers from producing less expensive, subsequent versions of life saving biological therapies, which is a socially valuable enterprise, because of these drugs' saving potentials. The whole premise of the Biologic Price Act's heightened standards in the form of extra steps to achieving substitution rights is that both a brand-name biologic and a follow-on biologic will produce the exact same immune response in the same patient.⁹⁷ Thus if, for example, the follow-on biologic drug A causes cancer in Patient X, then had Patient X ingested the brand-name version of the biologic drug, the patient still would have gotten the cancer. Patient X's prospects for recovery would then depend on which drug the patient took and under what regime he was in. If under a Bartlett regime, Patient X had taken the brand-name biologic, then he could sue the brand-name manufacturer under a design-defect, failure-to-warn claim, and would most likely recover in tort liability.⁹⁸ If, however, Patient X took the follow-on biologic version of the drug, then under a Bartlett regime, the follow-on biologic drug manufacturer would be insulated from any and all tort liability and the patient would be left uncompensated.⁹⁹ Thus, the Bartlett approach clearly presents a strategic incentives problem, one which is antithetical to a desirable social policy, and one which is exacerbated in the biologics context. Indeed, the academic literature in the chemical drug context is replete with concerns that a Bartlett regime deters prospective brand-name chemical drug manufacturers from entering the market, and incentivizes them to wait for other companies to obtain and exhaust their patent rights, after which they can enter the market as chemical generics, apparently insulated from tort liability.¹⁰⁰ And if the Bartlett approach is transplanted into the biologics realm, then this strategic incentives problem will be exacerbated because of the higher transaction costs imposed on prospective brand-name biologic drug manufacturers in the form of hurdles for achieving market entry

95. DOBBS, *supra* note 33, at 12–13, 15.

96. It would be problematic from a corrective justice point of view because the Bartlett approach would leave a severely injured consumer wholly uncompensated. *Id.* See generally *Bartlett*, 133 S. Ct. at 2466 (reversing a 21.06 million dollar verdict for the plaintiff).

97. Walter Jeske et al., *Update on the Safety and Bioequivalence of Biosimilars – Focus on Enoxaparin*, 7 DRUG, HEALTHCARE & PATIENT SAFETY 139, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684140/>.

98. See generally *Bartlett*, 133 S. Ct. at 2480 (holding that preemption law requires the plaintiff's judgment to be reversed).

99. *Id.*

100. *Id.*

approval.¹⁰¹ Biologic drugs, because they are uniquely derived from living organisms, are much more complex, and therefore notoriously expensive, to produce.¹⁰² The biologic drug manufacturing process requires a new breed of learned scientists and entirely new production facilities.¹⁰³ Also, although biological therapies have the potential to treat diseases that were never in the curable realm of chemical drugs, the population pool that suffers from those diseases is considerably smaller than the population pool that stands to benefit from the treatment of chemical drugs, and as such, it is harder for biologic drug companies to recoup their start-up and investment costs.¹⁰⁴

Additionally, biologic drugs usually consist of multiple patented organisms and technologies, making it more expensive for brand-name biologic drug manufactures to both keep up with their patent prosecution fees, patent maintenance fees, and their patent infringement fees¹⁰⁵ for attempted infringement by competitors, as compared to brand-name chemical drug manufacturers.¹⁰⁶ With all of these high transaction costs, biologic drugs already face so many premature disincentives to market entry. And a Supreme Court's blessing that it would never have to pay out in tort liability for failure-to-warn claims would just be the tip of the iceberg.

101. Ed Zimney, *Understanding Biologics: How they Differ from Drugs and Why They Cost More*, EVERYDAY HEALTH (Dec. 2, 2008), <http://www.everydayhealth.com/columns/zimney-health-and-medical-news-you-can-use/understanding-biologics-how-they-differ-from-drugs-and-why-they-cost-more>.

102. *Id.*

103. *Id.*

104. *Id.*

105. It is also worth noting that biotechnology executives suspect that because the essence of a biosimilar and interchangeable drug is its inability to be an exact copy or a "bioequivalent" of its brand-name biologic cousin, it will be much harder and more expensive for a brand-name biologic to prosecute firms for patent infringement, and it will be easier for competitors to persuasively show that their products do not infringe on the brand-name biologic's. Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, N.Y. TIMES (Jul. 21, 2009), <http://www.nytimes.com/2009/07/22/business/22biogenerics.html>. However, given the paucity of federal regulations surrounding the Biologics Price Act, it currently remains unclear whether a requirement for interchangeability with a brand-name drug will be an inability to survive a claim of patent infringement.

106. Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVIEWS DRUG DISCOVERY 479, 480 (2008), available at <https://fds.duke.edu/db/attachment-25-1301-view-503> ("[B]iologics typically have multiple patents on various elements of the active agent . . .").

IV. A FRESH LOOK AT THE PROBLEM: THE FOUR SCENARIOS

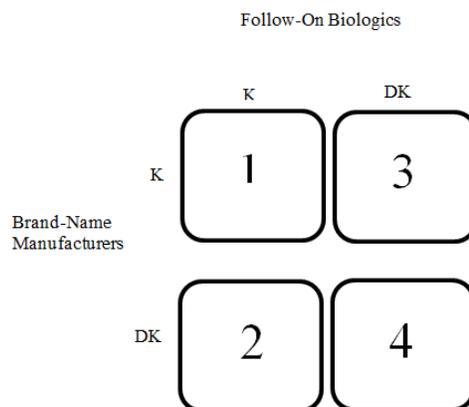


Figure 1

Part IV of this Note offers illustrative scenarios (as described in Figure 1) that capture the four pivotal ways a consumer can be injured by a follow-on biologic drug based on which market player (the brand-name biologic vs. the follow-on biologic) had the most information, and articulates a tailored solution for each scenario.¹⁰⁷ In doing so, I argue, as prominent tort scholars¹⁰⁸ and judges have,¹⁰⁹ for a firm commitment to principles of corrective justice and turn to the social welfare metrics of deterrence and risk distribution only when corrective justice fails to point to the correct solution.¹¹⁰

A. Scenario #1 and Scenario #2

The first way a plaintiff can be injured by a follow-on biologic drug is in

107. This Note does not explore the tort liability consequences to a biologic drug manufacturer whose product injures a consumer. In that situation, the plaintiff-consumer would have recourse via a traditional strict products liability suit pursuant to the common law of torts. See DOBBS, *supra* note 33, at 1010 (explaining that tort strict liability applies).

108. See DOBBS, *supra* note 33, at 16 (“[T]he great majority of tort cases turn on some kind of perception that the defendant is at fault in a significant way. At least for those cases, tort law begins with corrective justice ideals, even if those ideals [may later be] modified by pragmatic, process, or policy considerations in particular cases.”); see also Gregory C. Keating, *Distributive and Corrective Justice in the Tort Law of Accidents*, 74 S. CAL. L. REV. 193, 197 (2000) (“[M]ost of the prominent contemporary tort theorists who assert that the tort law of accidents is and should be a matter of justice—Jules Coleman, Richard Epstein, George Fletcher, Arthur Ripstein, and Ernes Weinrib among them—have concluded, in different ways, that tort law is and should be a matter of corrective justice.”).

109. See DOBBS, *supra* note 33, at 18 (arguing that judges feel “heavily committed to a system of corrective justice and turn to social policy only when they feel social policy and corrective justice coincide at least in part.”); see also Keating, *supra* note 108, at 197 (adopting “Jules Coleman’s conception of corrective justice as [his] touchstone”); Ernest J. Weinrib, *The Gains and Losses of Corrective Justice*, 44 DUKE L.J. 277, 277 (1994) (“According to Aristotle, liability is the law’s response to an unjust gain by the defendant that is correlative to the plaintiff’s unjust loss.”).

110. See DOBBS, *supra* note 33, at 19 (discussing the economic analysis of deterrence in a corrective justice system).

a situation where the follow-on biologic drug manufacturer knew of the side effect. This can happen in two ways: either the brand-name biologic can also be aware of the side effect, or the brand-name biologic can remain unaware of the side effect (scenario #1 and scenario #2 in Figure 1, respectively).¹¹¹

Now, to the extent that the Bartlett approach made any sense at all in the chemical context, it only did so because federal law (Hatch-Waxman) paralyzed a generic drug manufacturer's ability to update its warning label, even if it was aware of a side effect,¹¹² as was Mutual Pharmaceuticals in the Bartlett case.¹¹³ Thus, any solution that placed liability on the generic drug manufacturers would be a fundamental attack on corrective justice principles, since the generic drug manufacturer did not legally do anything wrong.¹¹⁴ Even though it might have technically caused the harm to the plaintiff, it was not at legal fault.¹¹⁵ In fact, the facts of *Bartlett* stipulated that Mutual Pharmaceuticals had actually listed toxic epidermal necrolysis as a possibility on the box label and on the insert, just not on the warning label.¹¹⁶ So even though Mutual obeyed federal law by failing to list toxic epidermal necrolysis as a side effect, it pushed the boundaries of federal law as safely as it could by listing toxic epidermal necrolysis as a possible side effect, only on the box label and on the insert. Thus even from a moral perspective, it is not entirely clear that Mutual Pharmaceuticals was at fault.

But, one key distinction between the Biologics Price Act and the Hatch-Waxman Act that deserves some attention is that even though the current FDA Draft guidelines are silent on the issue of labeling requirements for follow-on biologic drugs, it is most likely that the FDA will not only permit, but will require follow-on biologic drug manufacturers to maintain warning labels that are unique.¹¹⁷ What this means is that brand-name biologic drug

111. Brief for Amicus Curiae at 20, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-993, 09-1039, 09-1501) (“Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug.”). Common sense dictates that if the FDA regulations went out of its way to provide guidelines for generic drug manufacturers in the event they become aware of safety problems, then naturally, there will be situations in which generic drug manufacturers are unaware of latent design defects or adverse side effects. Although this regulation was issued in the context of chemical drugs, there is no reason why a follow-on biologic would also be ignorant of this possibility of an adverse side effect in the biologics context.

112. See Hatch-Waxman Act, 21 U.S.C. § 355(10)(A)(ii) (2012) (“[T]he labeling revision described under clause (i) does not include a change to the ‘Warnings’ section of the labeling . . .”).

113. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2488 (2013).

114. See 21 U.S.C. § 355 (2012) (precluding generic drug manufactures from unilaterally updating their warning labels without the FDA's approval).

115. *Id.*

116. *Bartlett*, 133 S. Ct. at 2472.

117. It is worth emphasizing that there is a normative debate amongst industry as to whether follow-on biologics should have unique names. See *Biosimilars: Intellectual Property Creation and Protection by Pioneer and by Biosimilar Manufacturers*, LEADERS IN PHARMACEUTICAL BUS. INTELLIGENCE, <http://pharmaceuticalintelligence.com/tag/BiologicsPriceAct/> (last visited Oct. 27, 2014) (“Having unique names will avoid unintended substitution, minimize risk of medication errors, allow for essential elements of pharmacovigilance such as traceability and follow-up of adverse drug reactions, as well as facilitate prescriber-patient decision making . . .”). However, the debate seems to be tipping in favor of requiring unique labeling as opposed to identical labeling. See *id.* (“[W]hile all biologics should be uniquely tracked, biosimilars should not require unique International Nonproprietary Names (INNs) from their reference products. Glaser said different INNS would impede market competition because it would likely require a different marketing campaign, thus raising costs, and would also complicate collection of global safety data and could increase

manufacturers will not hold the follow-on biologic manufacturer's warning labels hostage in the same manner that brand-name chemical drug manufacturers held generic chemical manufacturer labels hostage.¹¹⁸

Thus, since there is no legal barrier in the form of identical labeling requirements that would prevent a follow-on biologic drug manufacturer from changing a warning label, then if it is aware of a potential side effect that eventually injures a consumer and fails to report it on its warning label, it should pay out one-hundred percent of tort damages, regardless of whether scenario #1 or scenario #2 is in play, or in other words, regardless of the brand-name biologic's scienter.¹¹⁹

Whether the brand-name biologic knew of the side effect and alerted no one, or whether the brand-name biologic simply was unaware¹²⁰ is largely irrelevant in these two scenarios because corrective justice tells us that in a situation, where Defendant used its product to intentionally cause the harm to Plaintiff,¹²¹ Defendant should pay Plaintiff an amount commensurate to make him whole.¹²² Thus, in scenario #1 and in scenario #2, it is unnecessary to invoke principles of social welfare.

medical errors."); see also *Biosimilars: BIO Comments on Questions and Answers Regarding Implementation of BIOLOGICS PRICE ACT*, BIOTECHNOLOGY INDUSTRY ORG. (Apr. 16, 2012), <http://www.bio.org/advocacy/letters/biosimilars-bio-comments-questions-and-answers-regarding-implementation-Biologics-Price-Act> ("As stated in BIO's 2010 Comments to FDA, the labeling for a biosimilar should flow from the fundamental premise that biosimilars are not expected or required to be structurally the same as the reference product. The biosimilar product labeling must clearly identify the differences from the reference product to avoid being misleading to healthcare providers and patients, and to minimize potential safety risks. Clear, prominent labeling is necessary to inform healthcare providers and users of any important distinctions between the licensed uses or characteristics of the products.").

118. Hatch-Waxman Act, 21 U.S.C. § 355 (2012).

119. Scienter, as used in this Note, is defined as "A degree of knowledge that makes a person legally responsible for the consequences of his or her act or omission; the fact of an act's having been done knowingly, esp. as grounds for civil damages or criminal punishment." Scienter, BLACK'S LAW DICTIONARY (9th ed. 2009).

120. This is a commonality in the chemical drug context where often brand-name drug manufacturers are forced to exit the market after generic drug entry due to diminishing marginal returns on additional production of brand-name drugs. JULIE SOMERS, CONG. BUDGET OFFICE, PUB. NO. 4043, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING 8 (2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf> ("A brand-name drug is not always available because the manufacturer may choose to exit the market after generic entry.").

121. See DOBBS, *supra* note 33, at 52–53 ("The defendant is subject to liability for a simple battery when he intentionally causes bodily contact to the plaintiff in a way not justified by the plaintiff's apparent wishes or by a privilege, and the contact is in fact harmful or against the plaintiff's will."). Thus, if the interchangeable drug manufacturer knew of an adverse side effect, and if there was no legal barrier preventing it from alerting the plaintiff to this potential side effect, then it is guilty of the intentional tort of battery.

122. See Larry Alexander, *Foreword: Coleman and Corrective Justice*, 15 HARV. J.L. & PUB. POL'Y 621, 624 (1992) (arguing that the scope of corrective justice principles is limited to intentional torts); Jules L. Coleman, *Corrective Justice and Wrongful Gain*, 11 J. LEGAL STUD. 421, 436 (1982); Denise C. Morgan, *The New School Finance Litigation: Acknowledging That Race Discrimination in Public Education Is More Than Just A Tort*, 96 NW. U. L. REV. 99, 107 (2001) (citing Stephen R. Perry, *Comment on Coleman: Corrective Justice*, 67 IND. L.J. 381, 382 (1992) for the proposition that fault has traditionally been associated with corrective justice principles); Stephen R. Perry, *The Moral Foundations of Tort Law*, 77 IOWA L. REV. 449, 453–54 (1992) (applying the Aristotelian notion of corrective justice to intentional torts); see also Emily Sherwin, *Why Is Corrective Justice Just?*, 15 HARV. J.L. & PUB. POL'Y 839, 840 (1992) (noting that "remedies for intentional torts . . . fit the pattern of corrective justice.").

B. Scenario #3 and Scenario #4

Where it gets more contentious is in situations where a consumer was injured by the side effect of a follow-on biologic drug, a side effect which the follow-on biologic manufacturer remained ignorant of. Here once again, this can be further bifurcated into two scenarios, one where the brand-name biologic knew of the side effect, and one where the brand-name biologic did not, which respectively corresponds to scenario #3 and scenario #4 in Figure 1. In this next part, I begin by providing a primer on the doctrine of innovator liability and a brief exposition of its specific judicial application by various judges in different contexts. I then provide descriptive and normative justifications for resuscitating and expanding the doctrine of innovator liability into the biologic drug context, specifically, in the most contentious of all situations where a consumer was injured by the side effect that the follow-on biologic drug manufacturer was not aware of, regardless of the brand-name biologic's scienter, which pertains to scenarios #3 and #4, respectively. In this part, I concede that the doctrinal justifications for expanding innovator liability into the biologics realm are even weaker than the doctrinal justifications for its application in the chemical drug context. But I argue that the normative justifications for applying innovator liability in the biologic context are strong enough to compensate for this weaker doctrinal justification.

1. *Innovator Liability: A Primer*

Innovator liability is a common law cause of action that holds a brand-name drug manufacturer liable when a plaintiff is injured by the generic version of that drug.¹²³ To the minimal extent the innovator liability doctrine has been accepted by courts,¹²⁴ has only been applied in the chemical drug context.¹²⁵

The doctrine of innovator liability had its genesis in a 2008 California Court of Appeals decision, which held as a matter of first impression, that a manufacturer of a brand-name drug may be held liable for injuries suffered by a consumer who purchased the generic form of the drug if the consumer's injuries were foreseeably caused by negligence or of intentional misrepresentation by the brand-name manufacturer that developed the drug.¹²⁶

The California Appellate Court reasoned that the brand-name manufacturer knew or should have known "that a significant number of patients whose doctors rely on its product information for Reglan are likely to

123. See *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (holding a generic drug manufacturer not liable for failure to warn because federal law prohibits generic manufacturers from changing drug labels).

124. See *infra* notes 125–133 and accompanying text.

125. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010); *Wyeth v. Weeks*, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008); see J. Dominic Campdonico, *Innovator liability for a Consumer's Use of Follow-On Biologics: The Combine Threat of Conte and New FDA Regulations*, DRI TODAY (July 21, 2011), <http://dritoday.org/feature.aspx?id=83> ("[P]ractitioners should be knowledgeable and prepared for possible *Conte*-like arguments in the emerging legal field of follow-on biologics.").

126. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d at 315.

have generic metoclopramide prescribed or dispensed to them”¹²⁷ and that the brand-name manufacturer’s duty of care extends . . . “to those whose doctors foreseeably rely on the name-brand manufacturers’ product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug.”¹²⁸

Two years later, a Vermont District Court in *Kellogg v. Wyeth* held that a brand-name manufacturer of a drug has a duty of reasonable care to avoid causing injury to consumers who have been prescribed the generic bioequivalent of its drug, because “it is reasonably foreseeable that a physician will rely upon a brand-name manufacturer’s representations [. . .]—about the risk of side effects of its drug, regardless of whether the pharmacist fills the prescription with a generic form of the drug.”¹²⁹

The doctrine was resuscitated three years later by the Alabama Supreme Court in *Wyeth, Inc. v. Weeks*.¹³⁰ In *Wyeth*, the plaintiff Danny Weeks developed tardive dyskinesia, a neurological movement disorder, as a result of his prolonged use of metoclopramide, the generic equivalent of the drug Reglan.¹³¹ The Alabama Supreme Court held that because under the FDA’s regulatory scheme, brand manufacturers had the exclusive authority and obligation of their own labels and, in effect, monopolized control over the content of generic labels, a plaintiff injured by that generic drug could successfully sue a brand-name manufacturer for failure to warn claims that turned on the inadequacy of the brand-name drug manufacturer’s warning label.¹³²

In coming to its conclusion, the court in *Wyeth* heavily relied on the reality that a brand-name drug manufacturer “could reasonably foresee that a physician prescribing a brand-name drug or a generic drug to a patient would rely on the warning drafted by the brand-name manufacturer, even if the patient ultimately consumed the generic version of that drug.”¹³³

Furthermore, the court in *Wyeth* was largely motivated by equity concerns when it dismissed the argument that holding brand-name chemical drug manufacturers liable for injuries caused by its generic counterparts product (one that it did not produce) is fundamentally unfair, largely because the physical manufacturing process is irrelevant to theories based on informational deficiencies of a warning label, particularly when the deficiencies were created by the brand-name manufacturer and merely emulated by the generic manufacturer.¹³⁴

127. *Id.* at 315.

128. *Id.* at 304–05.

129. *Kellogg*, 762 F. Supp. 2d at 708–09.

130. *See generally* Weeks, 2013 WL 135753, *reargument granted* (June 13, 2013) (holding that a brand-name drug manufacturer could be held liable in an action brought by consumer who was allegedly injured by generic version of a drug).

131. *Id.* at *14.

132. *Id.* at *19.

133. *Id.* at *15.

134. *Id.* at *19.

2. *Normative Case for Expansion of Innovator Liability into the Biologics Context*

While judges¹³⁵ and academics¹³⁶ have historically resisted this strain of tort liability in the chemical drug context, the economic differences between biologic drugs and chemical drugs driven by the differences in their replication processes and regulatory pathways¹³⁷ call for an expansion of doctrine of innovator liability in the biologics drug context. The next part of this Note provides doctrinal and normative justifications for the expansion of innovator liability into the biologics realm. In doing so, I concede that the doctrinal justifications, while nevertheless present, are not as strong in the biologics context as they are in the chemical context. But I also argue that the normative justifications are stronger in the biologics context than they are in the chemical context, so much so that they compensate for the weaker doctrinal justification.

The common doctrinal vein that seems to be running through these handful of cases that have embraced innovator liability in the chemical drug context is “foreseeability.”¹³⁸ Although the foreseeability argument is less compelling in the biologics context than it is in the chemical context since in the former context, the federal laws will likely not impose identical labeling requirements upon the follow-on biologics,¹³⁹ the absence of the federal sameness requirement in the Biologics Price Act does not vitiate the foreseeability argument.¹⁴⁰

135. The Federal courts have consistently held that a brand-name drug manufacturer cannot be held liable under tort law claims for injuries done to a consumer who ingested a generic copy of their drug. See *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 543 (E.D. PA, 2006); *Block v. Wyeth, Inc.*, No. Civ.A 3-02-CV-1077, 2003 WL 203067, at *2–3 (N.D. Tex. Jan. 28, 2003); *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *3–5 (Fla. Cir. Ct. Feb. 17, 2006); *Kelly v. Wyeth, Inc.*, No. Civ.A.MICV2003-03314B, 2005 WL 4056740, at *4 (Mass.Super.Ct. May 6, 2005).

136. Lars Noah, *Adding Insult to the injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 694–95 (2009–2010) (invalidating the plausibility of the theory of innovator liability, despite its success in *Conte v. Wyeth*); Martin A. Ramey, *Conte v. Wyeth: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 PITT. J. ENV'T'L PUB. HEALTH L. 73, 113 (2010) (positing that the courts rejection of innovator liability in *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), emanated from a deep resentment of generic drugs because they were viewed by the court as plagiarists); Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 215 (2010) (arguing that the theory of innovator liability is fundamentally unjust); Weeks, *supra* note 24, at 1273 (perceiving scholars' and courts' reservations against the innovator liability doctrine as grounded in concepts of immorality and unfairness rather than on a judgment of the legal merits of its underlying rationales).

137. See *infra* notes 141–170 and accompanying text.

138. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705 (D. Vt. 2010) (“Whether there is a legal duty is primarily a question of law, dependent upon a variety of relevant factors . . . of which ‘foreseeability of the risk is a primary consideration’”); *Wyeth, Inc. v. Weeks*, 2013 WL 135753, at *20 (Ala. Jan. 11, 2013) (“We must focus on the role of ‘foreseeability’ in the creation of a duty to the exclusion of ‘relationship.’”); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 313 (Cal. Ct. App. 2008) (“[I]n this case our duty analysis must look primarily to the foreseeability of physical harm.”).

139. See *supra* note 117 and accompanying text.

140. But even if the foreseeability hook here had disappeared, this would not be the first time that tort doctrine has been stretched to accommodate the larger, overarching normative interests of society. One can draw a direct analogy between innovator liability and other unconventional yet pervasive theories of tort liability. For example, under the doctrine of market share liability, courts for reasons of justice or policy,

The truth of the matter is that even though scholars and courts have eschewed the adoption of innovator liability, their fundamental problem with the doctrine has never been with the doctrinal justifications. In other words, there has not been a strong push against the foreseeability argument. The real issue that judges and academics take with innovator liability is the normative parade of horrors that could emanate as a result of the doctrine's jurisdictional metastasis.¹⁴¹ In this next part, I provide normative justifications for the expansion of innovator liability in the biologics realm, and in doing so, I contend that these normative justifications are even stronger in the biologics context than they ever were in the chemical context. I start out by alluding to corrective justice rationales. Then, after demonstrating that corrective justice only partially answers the question of whether and to whom tort liability should be imposed upon, I invoke principles of social welfare to fill in the regulatory interstices.

In imposing tort liability upon a defendant, the law's primary function is to achieve corrective justice for the wronged plaintiff, usually by forcing the

impose liability upon defendants who are "not shown to have caused the plaintiffs' harm . . ." DOBBS, *supra* note 33, at 430. Coincidentally, market share liability had its origins in DES pregnancy cases. *Id.* Although market share liability is fundamentally distinct from innovator liability in that the former dispenses tort liability only for a percentage of plaintiffs' damages that are equal to that manufacturer's share of the market in the drug, the end result is that the court is still imposing tort liability upon defendants whom they know could not have caused the injury. *Id.* Under both doctrines of market share and innovator liability, "innocent" defendants are being held liable, the only difference being that under market share liability, courts don't know which defendant is guilty and which is innocent.

The second comparable doctrine is that of alternative liability, which essentially is an extension of joint and several liability. *Id.* at 426. In yet another famous tort case, *Summers v. Tice*, 199 P.2d 1 (Cal. 1948), the court imposed liability on two defendants, both of whom fired their guns negligently and independently; one of the bullets injured the plaintiff. *Id.* at 1-2. In holding both defendants liable under joint and several liability, the court once again knew that only one of the shots could have injured the plaintiff, and that it was necessarily placing liability upon an innocent defendant. *Id.* at 5. Again, the court simply did not know the identity of the innocent and the guilty defendant.

Still another example of the court imposing liability on defendants that it knew for a fact were innocent, is *Ybarra v. Spangard*, 25 Cal.2d 486, 154 P.2d 687 (Cal. 1944), a case that is usually taught to delineate the limitations of the doctrine of *res ipsa loquitur*. In *Ybarra*, when a plaintiff awoke from an operation with an injured appendage that was healthy prior to the operation, a California Court not only gave the jury a *res ipsa loquitur* instruction, permitting them to infer negligence, but it allowed them to infer negligence on the part of all of the defendants who were in the operating room, including doctors, nurses, and orderlies. *Id.* at 690. This was despite the court's recognized intuition that the likelihood that every one of the defendants was negligent was virtually nonexistent. DOBBS, *supra* note 33, at 430. But nevertheless, this court imposed tort liability upon defendants, at least some of whom it knew, were not guilty.

The point is that in each of the foregoing three contexts, courts were as a matter of first impression, relatively comfortable with imposing liability on defendants, notwithstanding the weak doctrinal justification, namely, that they were highly certain that they were holding innocent defendants liable. However, the courts hung their hats on broader, overarching social welfare justifications because in each of those cases, the existing informational asymmetries put the plaintiff in an especially vulnerable position in terms of being able to prove or disprove each of the defendant's guilt. Even though the normative justifications for imposing innovator liability into the present realm turn not on information asymmetries, but on economic differences between the operating models, which ultimately result in a vulnerable consumer, courts have shown in these three arenas that they are willing to turn to policy considerations as foundations for imposing tort liability. Thus even if in the biologics realm, the doctrinal reason (foreseeability) for imposing innovator liability is not as strong as they would be in the generic context, courts are sometimes willing to impose liability when the normative concerns in terms of consumer welfare and greater social welfare are at play.

141. Mark Wilson, *Dear Pharma GCs: Wyeth v. Weeks Isn't the End of the World*, FINDLAW (Aug. 29, 2014, 9:55 AM), http://blogs.findlaw.com/in_house/2014/08/dear-pharma-gcs-wyeth-v-weeks-isnt-the-end-of-the-world.html.

wrongdoer to compensate the victim with an amount commensurate to the amount of harm imposed.¹⁴² In Scenario #3 and Scenario #4, it is clear that a consumer was wrongfully injured by a follow-on biologic drug. The challenge lies in figuring out who wronged her. In scenario #3, was it the follow-on biologic drug manufacturer, whose drug technically injured the plaintiff, but who had no knowledge of the side effect? Or was it the brand-name biologic, who was aware of the side effect but who did not physically produce the defective drug? Even more puzzlingly, in scenario #4, who should be held responsible when the plaintiff is injured by the side effect of a follow-on drug that neither the follow-on biologic drug manufacturer nor the brand-name biologic drug manufacturer was aware of?

Invoking principles of corrective justice does not get us very far in terms of coming to an appropriate solution in either scenario #3 or in scenario #4; it simply tells us that if a plaintiff has been legally or morally harmed, then she deserves to be compensated.¹⁴³ Furthermore, corrective justice tells us that the wrongdoer, or the one who imposed the harm upon the victim should be responsible for paying her in tort damages.¹⁴⁴ But in scenario #3 and scenario #4, where the follow-on biologic manufacturer ignorantly injured the plaintiff and where the brand-name manufacturer knew of the defect but kept quiet, who is truly at moral fault? And in scenario #4, where neither the follow-on biologic drug manufacturer nor the brand-name manufacturer knew of the side effect, who is at fault? Apart from telling us that there is a wronged plaintiff who deserves to be compensated, corrective justice does not do a very good job of telling us who should be doing the compensating. To figure out the answer to this question in both scenario #3 and scenario #4, I turn to social welfare by invoking deterrence and risk spreading rationales as proxies for social welfare.

In deciding whether and to what extent tort liability should be imposed on a particular actor, social welfare can be measured by the effect on: deterrence and risk distribution.¹⁴⁵ Specifically, deterrence asks whether it would be good for society as a whole to deter the defendant's conduct. And risk distribution asks whether it would be good for society to force consumers to bear some of the cost of tort liability in the form of increased purchase prices. Corrective justice has already told us that the wronged consumer needs to be

142. DOBBS, *supra* note 33, at 14–15.

143. *Id.*

144. *Id.*

145. I have specifically chosen to use deterrence and risk distribution out of the many I could have chosen including, but not limited to, social policy, economic efficiency, compensation, etc. Indeed, scholars have argued that tort liability is understood as an “instrument aimed largely at the goal of deterrence, commonly explained within the framework of economics.” Schwartz, *supra* note 44, at 1801. Others have argued that deterrence is an apt metric for measuring social implications of products liability. See MARSHALL S. SHAPO, *SHAPO ON THE LAW OF PRODUCTS LIABILITY* xxv (2013) (arguing that courts use deterrence theory to justify the imposition of products liability, “pushing entrepreneurs toward safer design and great care in the processes of production and sale”). Secondly, I chose to focus on risk distribution, because learned scholars have also argued that risk distribution is an appropriate lens to view tort liability in the products context. DOBBS, *supra* note 33, at 17 (noting that “some defendants, such as products manufacturers, could pay compensation for injuries they cause and then recoup some or all of those costs by raising the price of products”).

compensated.¹⁴⁶ In order to understand the social policy implications of holding either the brand-name or the follow-on liable, a further dissection and critical comparison of the Biologics Price Act's regulatory pathways with the Hatch-Waxman Act's regulatory pathways is instructive.

While in ordinary contexts, and even in the chemical drug context, deterrence and risk distribution principles would weigh in favor of holding the generic drug manufacturer strictly liable for injuries caused by its products that it did not even know about, the complete opposite effect would be realized in the biologics realm. In fact, any additional costs to consumers in the form of increased purchase prices would render drugs officially unaffordable, and any deterrence effect on the follow on biologic drug manufacturers could render the market without any subsequent, less expensive versions of biologic drugs altogether.

In order to fully understand why the Bartlett approach would leave consumers permanently injured as a result of the cost spreading and the market without any follow-on drug products, it is imperative to understand the economic differences between follow-on biologics and generic chemicals that are driven by the differences in their replication processes and regulatory pathways. I analyze each in turn.

a. Differences in Replication Processes

Chemical drugs consist of small, known chemical compounds that can be easily identified and inexpensively replicated.¹⁴⁷ However, it is much more difficult and costly to recreate biologic drugs because the complex, larger proteins are derived from living organisms that are genetically modified.¹⁴⁸ This means that unlike the replication of a chemical drug where the process is only relevant insofar as the end result is the same chemical component, the successful creation of a follow-on biologic hinges exclusively on the replication process.¹⁴⁹ Although follow-on biologic drugs have the same molecular formula as their parent brand-name biologics, they are folded extremely differently, and as such, even minor changes in a prospective follow-on biologic drug's manufacturing process such as the temperature of the laboratory setting can result in a drug with structures and stabilities that are totally different than the original brand-name biologic's.¹⁵⁰ This in turn could affect the subsequent, replicated drug's safety and efficacy, essentially creating a brand new biologic drug instead of a follow-on biologic.¹⁵¹

Thus, because each step in the production of a biologic drug is "intricate,

146. DOBBS, *supra* note 33, at 14–15.

147. *How do Drugs and Biologics Differ?*, BIOTECHNOLOGY INDUS. ORG. (Nov. 10, 2010), <http://www.bio.org/articles/how-do-drugs-and-biologics-differ>.

148. *Id.*; *see also*, Goran Mijuk, *Generics Companies Weigh in on Biological Drugs*, WALL ST. J. (Jan. 31, 2011, 3:46 AM), <http://online.wsj.com/articles/SB10001424052748703833204576113863804531534> (pointing out that the head of Sandoz, Jeff George, estimates that large-molecule drugs will cost firms as much as \$250 million to replicate).

149. BIOTECHNOLOGY INDUS. ORG., *supra* note 147.

150. *Id.*

151. *Id.*

sensitive[,] and often specific to a particular medicine, requiring . . . significant experience [and] expertise,”¹⁵² developing a follow-on biologic drug will require a more robust financial investment at the outset.

b. Differences in Regulatory Pathways

The first difference between the Hatch-Waxman Act and the Biologics Price Act, which are the respective regulatory pathways for generic chemicals and follow-on biologics, lies in the requirements for market entry approval.¹⁵³ In order to gain market entry approval rights, a potential generic chemical manufacturer must demonstrate bioequivalence.¹⁵⁴ This means that the prospective generic manufacturer must demonstrate that (1) it has the same active ingredient as does the brand-name chemical drug, and that (2) that active ingredient in the generic chemical drug has the same rate and amount of absorption in the bloodstream as does that active ingredient in the brand-name chemical drug.¹⁵⁵ And a prospective generic chemical manufacturer must do this by presenting a minimal amount of clinical trial data.¹⁵⁶

In contrast, in order for a prospective follow-on biologic to gain market entry approval rights, it must demonstrate “biosimilarity” to the brand-name biologic drug.¹⁵⁷ Biosimilarity is to biologic drugs, as bioequivalence is to chemical drugs, but only in nomenclature.¹⁵⁸ Biologic drugs products, unlike chemical drugs that have clearly and well-defined composition structure, are

152. *Biologics and Biosimilars: An Overview*, AMGEN 6 (Mar. 2014), http://www.amgen.com/pdfs/misc/Biologics_and_Biosimilars_Overview.pdf.

153. See *infra* notes 157, 160 (discussing the differences between the Hatch-Waxman Act and the Biologics Price Act).

154. Hatch-Waxman Amendments, *supra* note 1.

155. *Id.*

156. See Scott Gavura, *Generic Drugs: Are they Equivalent?*, SCIENCE-BASED MEDICINE (JAN. 5, 2012), www.sciencebasedmedicine.org/generic-drugs-are-they-equivalent (noting that, “[w]e also don’t need to do clinical trials with the generic drug. If we can demonstrate that the API is absorbed at the same rate and extent as the brand drug, then we can declare two products to be bioequivalent.”).

157. Biologics Price Act, *supra* note 29; *Biosimilars*, FDA, www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm (last updated Sept. 9, 2014).

(“The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be ‘biosimilar’ to or ‘interchangeable’ with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be ‘biosimilar if data show that, among other things, the product is ‘highly similar’ to an already-approved biological product.”)

The Biologics Price Competition and Innovation Act has adopted the European approach by using the term “biosimilar” to refer to subsequent, less expensive versions of biologic products. Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 818 n.1 (2010). However, other synonyms used by stakeholders include “generic biologics” or “follow-on biologics” or “comparable biological products” or “follow-on protein products” or “biobetters.” *Id.*

158. Dr. Joseph P. Fuhr Jr., *Biosimilars Can Save Lives and Cost Less*, FORBES (Aug. 8, 2014), <http://www.forbes.com/sites/realspin/2014/08/08/biosimilars-can-save-lives-and-cost-less> (“Biosimilars are to biologics as generics are to name brand chemical drugs.”). The European Medicines Agency and the United States Food and Drug Administration refer to generic versions of biologic products as follow-on biologics, and Health Canada refers to them as “subsequent entered biologics.” *Id.*

made from living systems and have much more structural complexity.¹⁵⁹ As such, the FDA has determined that the standard assessment for assessing bioequivalence cannot be an appropriate method for assessing biosimilarity, which requires more specified regulation and approval tracks.¹⁶⁰ Biosimilars, unlike bioequivalents which are exact replicas of their brand-name chemical cousins, are not exact replicas of the innovator biologics; they are merely “highly similar,”¹⁶¹ largely because it is impossible to recreate those exact living manufacturing conditions.¹⁶² Because the limitations of current science and the inherent complexities in biologic drugs’ manufacturing processes preclude a manufacturer from being able to replicate the exact same drug,¹⁶³ the FDA requires biosimilar manufacturers to demonstrate biosimilarity first through data derived from analytical studies, animal studies, clinical studies, including the assessment of immunogenicity,¹⁶⁴ and secondly through independent, de novo demonstration of safety and efficacy through these burdensome data requirements,¹⁶⁵ a requirement which is present in the Hatch-Waxman act only to the extent that generic drug manufacturers have to show bioequivalence.¹⁶⁶ In other words, in the Hatch-Waxman context, the requirement of showing safety and efficacy is subsumed by the bioequivalence requirement, whereas in the Biologics Price Act, in addition to showing biosimilarity, prospective follow-on biologic manufacturers have to show de novo safety and efficacy, both through rigorous clinical trials.

The second important distinction between the two regulatory pathways for generic and follow-on biologic drugs lies in the requirements for achieving automatic substitution rights: the Hatch-Waxman Act allowed states to enact mandatory substitution laws at the pharmacy retail level, upon a successful demonstration of bioequivalence,¹⁶⁷ an advantage which states have taken advantage of.¹⁶⁸ However, the Biologics Price Act does not grant follow-on biologics substitution rights at the pharmacy retail level upon a showing of biosimilarity. This is because the Hatch-Waxman Act’s designation of

159. *Frequently Asked Questions About Therapeutic Biological Products*, FDA, www.fda.gov/DevelopmentApprovalProcess/20HowDrugsareDevelopedandApproved/ApprovalsApplications/TherapeuticBiologicApplications/ucm113522.htm (last updated Dec. 4, 2009).

160. Jun Wang & Shein-Chung Chow, *On the Regulatory Approval Pathway of Biosimilar Products*, 5 PHARMACEUTICALS 353, 354 (2012).

161. Letter from Ann Palmer, President & CEO, Arthritis Found., to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (Aug. 22, 2014), available at www.arthritis.org/files/sections/advocacy/Biosimilars-AF-Letter-to-FDA-8-21-14.pdf.

162. *Id.*

163. See Pollack, *supra* note 105 (characterizing biologic drugs as “hard to copy”).

164. AMGEN, *supra* note 152, at 6.

165. *Id.*

166. Hatch-Waxman Amendments, *supra* note 1.

167. Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013)

(“Because the FDA-published list included drug products designated as therapeutically equivalent to an original drug product, it became possible for health care providers to substitute a generic equivalent for a brand product. This allowed the creation of a substitution system where state legislation would allow or mandate the substitution of generic equivalents, where they exist, for prescriptions written for brand products. . . . [P]hysicians need not know that a generic exists or that it will [even] be taken by their patients.”).

168. See *infra* note 173 (discussing states that have enacted biosimilar substitution laws).

bioequivalence as a proxy for assessing a drugs' safety and efficacy is predicated on the assumption that if two chemical drugs are equivalent in their bioavailability averages, then they will have the same therapeutic effect and can hence be used interchangeably.¹⁶⁹ But because of the fact that biologics have much more structural complexity and are much more sensitive to even minor changes in the manufacturing processes,¹⁷⁰ a showing of biosimilarity will not be sufficient to merit substitution rights at the pharmacy retail level.¹⁷¹ In order to gain substitution rights, follow-on biologic manufacturers have to show, in addition to biosimilarity, interchangeability, which requires even more clinical data proving that when the biological product is administered more than once to an individual, the "risk in terms of safety or efficacy of alternating or switching between the biological product and the reference product is not greater than the risk of using the reference product without such alteration or switch."¹⁷² Make no mistake, achieving interchangeability is no easy task.¹⁷³ Doctors will not want to prescribe and consumers will not want to pay for biologic drugs that are not interchangeable with their reference biological products.¹⁷⁴ Thus, a follow-on biologic's commercial success hinges exclusively on whether or not it achieved interchangeability.¹⁷⁵ This Note does not address the appropriate assignment of tort liability in the event a consumer is injured by a follow-on biologic drug that has attained biosimilarity but not interchangeability. This is because, as mentioned, non-interchangeable, biosimilar follow-on biologic drugs and their brand-name biologic counterpart drugs are expected to produce different side effects in different patients. Therefore, any previous or subsequent reference to follow-on biologics or to interchangeable biologics refers exclusively to the class of follow-on biologics that have achieved interchangeability designation by the

169. See Boehm et al., *supra* note 167 (discussing the effects of the Hatch-Waxman Act on the generic drug industry).

170. See Bhupinder Singh Sekhon & Vikrant Saluta, *Biosimilars: An Overview*, BIOSIMILARS (Mar. 14, 2011), <http://www.dovepress.com/getfile.php?fileID=9251> (noting that biologic drugs are "[h]ighly susceptible to slight changes in production process and environment").

171. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119 (amending Public Health Service Act § 351, 42 U.S.C. § 262(i)(1) (2012)).

172. *Id.*; see also David R. Holmes Jr. et al., *ACCF/AHA 2011 Health Policy Statement on Therapeutic Interchange and Substitution*, CIRCULATION (Aug. 15, 2011), <http://circ.ahajournals.org/content/124/11/1290.full> ("Interchangeability can occur only when the biologic product: 1) is considered a biosimilar to the reference product; and 2) can be expected to produce the same clinical results as the reference product in any given patient. Additionally, for a product that requires multiple administrations in the same individual, 'the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and reference product is not greater than the risk of using the reference product without such alternation or switch.") (citing to U.S. Food and Drug Administration, *Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments*, 75 Fed. Reg. 61497-501).

173. See Erica Pascal, *supra* note 9 (noting that while all states have biosimilar substitution laws, the laws differ from state-to-state).

174. John Carroll, *Is the FDA Writing a Recipe for the Failure of Biosimilars in the U.S.?*, FIERCE BIOTECH (Aug. 8, 2011), <http://www.fiercebiotech.com/story/fda-writing-recipe-failure-biosimilars-us/2011-08-08>.

175. See *Interchangeable Biosimilars: The Future of Affordable Medicine*, GENERIC PHARMACEUTICAL ASS'N, http://www.gphaonline.org/media/cms/General_Fact_Sheet_for_Biosimilars_FINAL.80913.pdf (last visited Oct. 27, 2014) (arguing that substitutability spawned the growth of the chemical generic drug industry and will be indispensable to fostering competition in the follow-on biologic market because the competition will spur innovation, improve consumer choice, and decrease medical costs).

FDA.

Finally, the third difference between the respective regulatory pathways of generic and follow-on biologic drugs is simply the resulting uncertainty that lurks in the regulatory approval processes for follow-on biologics.¹⁷⁶ Even though the FDA has created two classes of follow-on biologic producers and has heightened the clinical trial requirements for demonstrating interchangeability, it has yet to specify what quantity, level, or amount will satisfy.¹⁷⁷ Thus, prospective follow-on biologic manufacturers are left to make ex-post guesses about what level of investment will satisfy the FDA's demands, necessarily running the risk of systemic under estimation or over estimation, either of which can result in substantially unrecoverable sunk costs. This lack of clear standards to obtain biosimilarity and interchangeability designation results in a strikingly idiosyncratic approach for regulatory approval.

The point is that the complex replication process, the FDA regulatory compliance costs, and colossal uncertainty facing prospective follow-on biologic manufactures could result in extremely expensive follow-on biologic prices for producers and for consumers,¹⁷⁸ a result which seems to be perverse given that unlike cheaper chemical generic drugs, they treat some of society's most serious and life threatening diseases.¹⁷⁹

This rationale can be explained by turning to a simple economic model. In the chemical generic context, there existed multiple, simultaneous generic manufactures producing the counterpart for the same exact chemical brand-name drug. This concentrated market had two positive implications for consumers: (1) first the existence of multiple simultaneous generic competitors drove down the price of the average generic drug¹⁸⁰ and; (2) second, even if imposing tort liability upon one particular generic manufacturer would result in its deterrence from continuing to produce generic drugs, there would be no social dislocation because there were still plenty of other generic firms producing the subsequent, less expensive version of the drug.¹⁸¹

176. Fuhr, *supra* note 158.

177. *A Comparison of US and EU Biosimilars Regimes*, FENWICK & WEST LLP 1 (Mar. 16, 2014), http://www.fenwick.com/fenwickdocuments/01-06-12_comparison_us_eu_biosimilars_regimes.pdf.

178. *See infra*, note 180 and accompanying text.

179. Fuhr, *supra* note 158.

180. *Why Generics Prescriptions Drugs Cost Less*, STAYSMARTSTAYHEALTHY, http://www.staysmartstayhealthy.com/generic_drug_costs.

181. *Id.* Congress also faced a similar problem in 2006, when it created the Vaccine Injury Compensation Fund (VICF) to provide compensation to people found to be injured by certain vaccinations. 26 USC § 9510 (2012). And indeed, junior scholars have argued that there should be a similar paradigm in place for consumers who are injured by chemical generic drugs with deficient warning labels. Duncan, *supra* note 136, at 185. I do not similarly argue for the creation of a compensation trust fund for consumers who are injured by follow-on biologic drugs. Rather, I believe that the rationale behind the creation of the VICF is pertinent to the biologic drugs context. By creating the VICF to compensate plaintiffs instead of imposing liability on the vaccine manufacturers, Congress essentially created a "no-fault" alternative by shifting the burden of liability from the manufacturer to the public. And it did so primarily for three reasons: (1) to prevent the likelihood of a vaccine market shortage; (2) to perpetuate competition among vaccine manufacturers to ensure that prices remained affordable; and (3) to improve the general public health by encouraging the widespread use of vaccinations. H.R. Rep. 99-908 (articulating these three rationales for creating the VICF). And indeed, Congress recognized that placing liability on vaccine manufacturers would drive these goals

The biosimilars market, in contrast, can be considered as somewhat of an economic market failure. Because of the costs associated with biologic drug replication, heightened FDA regulatory requirements, and regulatory uncertainty that accompanies those heightened regulations, the cost of market entry for prospective follow-on biologic manufacturers has increased, simply resulting in fewer firms who are willing to invest in the biosimilar market, translating to higher purchase prices for consumers.¹⁸² It is worth emphasizing that experts such as the Federal Trade Commission expect the follow-on biologic regime to bring only a 10% to 40% decline in the cost of biologic drugs,¹⁸³ while evidence confirms that the Hatch-Waxman Act and the entry of generic chemical drugs brought down the average price of generic drugs by 60% to 80%.¹⁸⁴ Thus, in the chemical drug context, market forces were able to cure the problem of perceived high costs of healthcare by perpetuating competition among multiple generics to drive down the prices of drugs.¹⁸⁵

further and further away. *Id.* While I do not argue for a no-fault public compensation fund, I do argue that just as Congress did in 2006, policymakers in 2014 should also adopt a liability shifting mechanism, in this case, innovator liability, for compensating consumers who are injured by follow-on biologic drugs, mainly for the reasons that the goals between the passage of the Act that created the VICF are so strikingly similar to the goals of the Biologics Price Act. Compare H.R. Rep. 99-908 (“[A] greater number of manufacturers will enter the vaccine market and that a greater number of vaccine products will become available to prevent disease, reduce reactions and otherwise improve public health . . . The purpose of this program is to provide needed focus and direction at the Federal level on the development of both new and improved vaccines that can be used in this country and around the world . . . Current economic conditions have resulted in an unstable and unpredictable childhood vaccine market, making the threat of vaccine shortages a real possibility.”); with 158 Cong. Rec. 54668-03 (“The legislation also contains provisions to incentivize development of pediatric drugs and devices, spur innovation of new drug therapies for life-threatening medical conditions, mitigate drug shortages, and improve agency accountability and transparency in the drug and device approval process.”), 158 Cong. Rec. E1147-04 (“This bipartisan legislation enables FDA to . . . reduce[] cost . . . and takes important steps to prevent and mitigate critical drug shortages.”), 158 Cong. Rec. S4610-03 (“[T]his legislation will ensure that . . . patients have access to less expensive medications . . . These resources are vital to patients who need both access to drugs and devices . . .”).

Now that I have demonstrated the similarity of the policy prescriptions undergirding the creation of the VICF and the Biologics Price Act, I turn to arguing that in the biologics case, policymakers should adopt a slightly modified liability shifting approach in that instead of shifting the liability from the market actor (biologic drug manufacturer) to the public (in the form of a public trust fund), they should shift liability from the market actor (biologic brand-name manufacturer) to market actor (the follow-on biologic manufacturer). The rationalization for this is simply what I alluded to in this Note. See *supra* notes 147-189 and accompanying text. The heightened regulatory scrutiny that follow-on biologics face translates to an expensive manufacturing process, which further translates to increased purchase prices for consumers. This effect makes the biologic consumer way more financially vulnerable than the vaccine consumer, and for that reason externalizing the cost to the public through a public trust fund would be inapposite. Thus, liability should be shifted to the brand-name biologic manufacturer, through the innovator liability doctrine.

182. See Pollack, *supra* note 1f05 (“The likelihood that biosimilar competition might be somewhat muted means that sales and profits of the originals may not necessarily dry up.”); see also STAYSMARTSTAYHEALTHY, *supra* note 180 (“Because it is harder and costlier to make biologic drugs than it is to copy pills, fewer generic competitors are likely to enter the fray.”); JOHN R. THOMAS, CONG. RESEARCH SERV., R41483, FOLLOW-ON BIOLOGICS: THE LAW AND INTELLECTUAL PROPERTY ISSUES 2 (Jan. 15, 2014) (“[I]n contrast to the generic drugs available in traditional pharmaceutical markets, few ‘follow-on’ biologics compete with the original, brand-name product. The lack of competition in the biologics markets is perceived to be a consequence of the complexity of biologics in comparison with small-molecule, chemical-based pharmaceuticals.”).

183. Pollack, *supra* note 105.

184. Brue Japsen, *Law Change Allows Cheaper Generic Versions of Biotech Drugs*, CHI. TRIB. (May 24, 2011), http://articles.chicagotribune.com/2011-05-24/business/ct-biz-0525-humira-biogenics-20110524_1_way-for-genetic-engineering-biotech-drugs-abbott-s-humira.

185. This is in fact because generic drugs are substantially cheaper to produce—cheaper than brand-

Therefore, in the chemical context, risk distribution principles would weigh in favor of placing tort liability upon the generic drug manufacturer, because the generic drug manufacturer could simply pass those costs on to the consumers in the form of increased purchase prices.¹⁸⁶ However, the prices for chemical generic drugs were already so cheap¹⁸⁷ that it would not be a significant increase for the consumer; certainly not high enough to preclude affordability to the average generic drug consumer. And given that biologic follow-ons are already proving to be unaffordable for the average consumer,¹⁸⁸ it would be socially irresponsible to impose liability upon the interchangeable drug manufacturer, because it would then just pass those prices on to consumers in the form of increased purchase prices.¹⁸⁹ Consumers can barely afford interchangeable drugs at the price they are retailed, and forcing them to internalize the cost of tort liability pursuant to risk distribution principles could result in consumers no longer being able to afford follow-on biologics, assuming that they ever could in the first place.

As many scholars and courts have recognized, one of the fundamental goals of imposing tort liability is to deter a defendant from engaging in the activity that causes the harm.¹⁹⁰ And even though courts use tort liability to incentivize deterrence, defendants will often continue to engage in the activity in question, while running the risk of tort liability because they stand to gain more in profits than they stand to lose in tort liability payouts.¹⁹¹ However, generally courts will only impose tort liability to deter conduct that they view as socially undesirable.¹⁹² And indeed, as already explained above, given that the increased regulatory scrutiny for follow-on biologic drug market already

name chemical drugs, and definitely cheaper than follow-on biologic drugs. See STAYSMARTSTAYHEALTHY, *supra*, note 180. And this is because generic drug manufacturers don't have the same investment costs as brand-name drugs, and even as follow-on biologic drugs. *Id.* All they have to do is literally copy the brand-name chemical drug in their lab, and then sell that drug. *Id.* Indeed, one study concluded that while it takes approximately \$800 million to develop a new chemical drug, it costs only between 5 and 20 cents to produce a generic chemical pill. *Id.* Thus, the big expenses, for chemical drugs, lies not in the production of the drug itself, but in the actual act of bringing the new drug to the market. *Id.* See also Elizabeth Rosenthal, *The Soaring Cost of a Simple Breath*, N.Y. TIMES (Oct. 12, 2013), <http://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html> (pointing out that brand-name chemical drugs have been replaced by "cheap generics in a very competitive market."); JULIE SOMERS, A CONG. BUDGET OFFICE, PUB NO. 4043, : EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING 8 (Sept. 2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/11838/09-15-prescriptionsdrugs.pdf>

("As a result of the abbreviated regulatory process, several manufacturers of generic drugs typically enter the market when the law allows them to do so. As the number of manufacturers grows, price competition among them increases, and the average price of the generic drug relative to that of the brand-name drug declines. On average, the retail price of a generic drug is 75% lower than the retail price of a brand-name drug.")

186. Dobbs, *supra* note 33, at 17.

187. *Id.*

188. See Pollack, *supra* note 105 (highlighting that even though the follow-on biologic operating model is expected to produce substantial savings for the overall healthcare systems, a "\$35,000 copycat version of a \$50,000 cancer drug would still be unaffordable" for a lot of consumers).

189. See Frank Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 915-920 (1996) (arguing that much of the costs of regulation "will be passed on to consumers in the form of higher prices.")

190. DOBBS, *supra* note 33, at 19.

191. *Id.*

192. *Id.* at 20.

disincentivizes or at least cautions prospective follow-on biologic manufacturers from investing in the development of biosimilars and more specifically, interchangeable, anymore economic strain placed on them in the form of tort liability could result in a complete refusal to enter the market. Where the deterrent effect of imposing tort liability upon generic drug manufacturers would not be so strong in the chemical context given that society would still be gaining socially useful services from the rest of the competitive generic firms, the threat of tort liability hanging over interchangeable manufacturers like the Sword of Damocles could eviscerate the follow-on biologic operating model¹⁹³ before it even gets introduced into the market, creating a biopharmaceutical regime that is strongly and dangerously reminiscent of the pre-1984 paradigm. This is an especially salient concern, given that historically, drug manufacturers in the chemical context are already prone to systematic over-deterrence.¹⁹⁴

c. Preventing the Reversion to the Pre-1984 Paradigm

Before 1984, chemical drug manufacturers did not have the option of taking advantage of an abbreviated new drug application.¹⁹⁵ Hence, the concept of the “generic” drug was completely foreign.¹⁹⁶ In fact, all of the chemical generic companies seeking market approval had to perform their own safety and efficacy studies on the proposed drug even though it was duplicative and grossly inefficient.¹⁹⁷ As a result, empirical evidence confirms that the pre-1984 paradigm deterred prospective generic drug manufacturers who, but for the costly and expensive clinical trial requirements of having to show de novo safety and efficacy, would have entered the market.¹⁹⁸ This political atmosphere was a slightly awkward fit from a social welfare standpoint because it left consumers without access to what could have easily been affordable, lifesaving medical treatment.¹⁹⁹ In fact, the legislative history

193. *Id.*

194. See Richard C. Ausness, *When Warnings Alone Won't Do: A Reply to Professor Phillips*, 26 N. KY. L. REV. 627 (underscoring examples of situations where in response to the threat of tort liability, drug manufacturers have either redacted their products from the market or dramatically raised prices); see also *Enright v. Eli Lilly & Co.*, 570 N.E.2d 198 (N.Y. 1991) (exhibiting general concern over the over-deterrent effect on drug companies in holding the defendant companies liable).

195. See Gerald Mosinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, FOOD & DRUG L.J. 54, 187–94 (1999) (finding empirically that between the years of 1962 and 1984, approximately 150 drugs were off-patent but had no generic counterpart because prior to Hatch-Waxman, prospective generic companies were deterred from expending the time and money in completing clinical trials to gain market entry approval from the FDA); see also Pensabene & Gregory, *supra* note 5, at 2 (“Before [the adoption of the Hatch-Waxman Act], no streamlined Food and Drug Administration (FDA) approval process existed for generic drugs. Rather, generic drugs companies were required to conduct the same kinds of expensive, time consuming clinical trials that drug companies conducted for new brand-name drugs.”).

196. Mosinghoff, *supra* note 195, at 187–94.

197. *Id.*

198. *Id.*

199. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, U. MICH. J.L. REFORM. 461, 466–67

(“[T]ort law results in overdeterrence, which in the drug context has several undesirable aspects:
(1) Manufacturers are deterred from research and development of new and effective drugs, the

makes clear that Congress passed the Hatch-Waxman Act in response to this unpleasant social climate.²⁰⁰

Notwithstanding that biochemical necessity of a biologic drug justifies this difference in replication processes and relative heightened regulatory burdens for follow-on biologic drug manufacturers in the form of demonstrating biosimilarity and achieving interchangeability,²⁰¹ it remains that the paradigm as contemplated by the Biologics Price Act foreshadows a dangerously proximate return to the pre-1984 paradigm when prospective generic drug manufacturers were deterred from entering the market. And unless the extensive clinical trials that biologic generic drug manufacturers will be forced to conduct are in reality, abbreviated and less comprehensive than the ones that the brand-name biologics will have to conduct, the Biologics Price Act would be completely nugatory, and modern society would be well on its way to reverting to the pre-1984 paradigm.

Thus, even though the Biologics Price Act has formally carved out a name and unique category for subsequent, less expensive versions of original brand-name biologics, i.e., follow-on biologics,²⁰² this might be nothing more than an illusion. As it currently stands, follow-on biologics are already closer in semblance to branded biologics than generics are to chemical brand-names because their expensive manufacturing and regulatory processes will result in retail prices that are not meaningfully cheaper than brand-name biologic drugs.²⁰³ And if we place any more economic strain on follow-on biologic manufacturers by hanging the threat of tort liability over their heads, there is a

benefits of which are lost to society; (2) Manufacturers who do develop new drugs will test them longer and more carefully, thereby delaying the availability of the drug and its therapeutic advantages to society; (3) Beneficial drugs are withdrawn from the market; (4) Shortages in supplies and suppliers of pharmaceuticals will occur, as has been most notable in the vaccine area; (5) Dual systems overlap, which results in duplicative administrative costs; unnecessary administrative costs are a concern especially in light of the substantial administrative costs of the tort system.”)

200. See 130 Cong. Rec. E3840-41 (daily ed. Sept. 13, 1984) (“However, the savings to consumers under this bill remain intact. Senior citizens and others who are currently burdened by excessive drug costs will experience a considerable reduction in these costs in the near future.”); see also 130 Cong. Rec. H9105-51 (daily ed. Sept. 6, 1984) (“But on balance, what we have is a total bill that I think is very good. It provides low-cost, generic drugs for millions of Americans, saving maybe a billion dollars over a several-year period. There is going to be a significant savings to people who purchase drugs.”); *id.*

(“This bill will accomplish two objectives. First, it will make available almost immediately nearly twice as many low-cost, generic drugs as are now available. Second, it will create new incentives for research and development by restoring the patent time lost by a development of a new drug while waiting for approval by the Federal Food and Drug Administration. H.R. 3605 will make hundreds of new low-cost, generic drugs available by speeding up the approval process for these drugs. As the current law stands, all drugs approved after 1952 can only be made available in generic form through a long and involved testing process. This process is unnecessary because the active ingredient in the generic drug is identical to that in the name-brand drug. Under H.R. 3605, this testing process would be speeded up tremendously without endangering the safety to the consumer. As well as making more generic drugs available to the public, this bill will create new incentives for R&D in the pharmaceutical industry.”)

201. FENWICK & WEST LLP, *supra* note 177, at 1 (“‘Biochemical necessity’ refers to the fact that biologic medicines . . . are developed using ‘unique biological systems, living cells, and cell lines that are unique to each manufacturer,’ making it virtually impossible to recreate exactly the active ingredient.”); AMGEN, *supra* note 152, at 5.

202. Biologics Price Act, *supra* note 32.

203. See Fuhr *supra* note 158 and accompanying text.

good chance that prospective follow-on biologic manufacturers will call it quits even before they start. And needless to say, societal deprivation of the opportunity to access cheaper, lifesaving biotechnological drugs would be an anathema to social welfare.²⁰⁴

Thus, given the dangerous proximity of follow-on biologic drugs to brand-name biologic drugs (or in other words, given how reminiscent the Biologics Price Act is of the pre-1984 paradigm), placing anymore economic strain in the form of tort liability on the interchangeable manufacturers could result in their deterrence from entering the market. Corrective justice tells us that in scenarios #3 and #4, the plaintiff should be compensated, but not who should be doing the compensating. And principles of risk spreading and deterrence fill in that regulatory interstice by telling us that it should be the brand-name biologic manufacturer.

V. CONCLUSION

Advances in biotechnology and in recombinant DNA technology have revolutionized medicine with the introduction of biologic drugs to treat diseases that were previously excluded from the curable realm of chemical drugs. And although the fate, or even the existence of follow-on biologic drugs remains uncertain, it is abundantly clear that given their high production costs associated with replication, regulatory compliance, and regulatory uncertainty, any threat of tort liability could have an undesirable social welfare effect. To solve the problem of the uncompensated consumer in the biologics drug context, this Note proposes a straightforward application of tort principles in certain scenarios, and an expansion of the doctrine of innovator liability in the more contentious scenarios, a combination approach which will assuage the unique normative concerns that are the byproducts of the biologic drug revolution.

204. See Green, *supra* note 199 and accompanying text.