SJC-12347

COMMONWEALTH OF MASSACHUSETTS
SUPREME JUDICIAL COURT

BRIAN RAFFERTY,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee,

and

SIDNEY RUBENSTEIN,

Defendant.

ON APPEAL FROM MIDDLESEX COUNTY SUPERIOR COURT

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE AMERICAN TORT REFORM ASSOCIATION, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF MERCK & CO., INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Judicial Court Rule 1:21(a), the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the American Tort Reform Association ("ATRA"), and the National Association of Manufacturers ("NAM") state that they are non-profit organizations with no parent corporations. No publicly held corporation has a 10% or greater ownership interest in PhRMA, ATRA, or NAM. A list of PhRMA's member companies can be found at http://www.phrma.org/about/member-companies.

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STATEMENT OF AMICI CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association comprised of the leading pharmaceutical research and technology companies. PhRMA members are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members alone have invested more than half a trillion dollars in R&D since 2000, and in 2016, PhRMA members invested $65.5 billion in discovering and developing new medicines. PhRMA, *Biopharmaceuticals in Perspective: Spring 2017*, at 30 (2017), http://phrma-docs.phrma.org/files/dmfile/Biopharmaceuticals-in-Perspective-2017.pdf.

Founded in 1986, the American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation.

The National Association of Manufacturers ("NAM") is the nation's largest manufacturing association, representing small and large manufacturers in every industrial sector and in all 50 states, including

pharmaceutical manufacturers. Manufacturing employs nearly 12 million men and women, contributes nearly $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private-sector research and development. NAM is a powerful voice for the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

PhRMA, ATRA, and NAM regularly file amicus briefs in cases of importance to their members, and the liability issue presented in this case is especially crucial to them. Nearly every brand-name medicine eventually faces generic competition. Indeed, ninety percent of 2016 prescriptions were filled with generics. *Id.* at 49. By expanding the already substantial litigation risks that brand-name companies face to encompass the risks created by their generic competitors' products in contravention of Massachusetts tort law, Plaintiff's outlier innovator liability theory would unfairly subject brand-name companies to unpredictable and potentially immense liability, stifling innovation and undermining public health.

SUMMARY OF ARGUMENT

Unable to recover from the manufacturer of the product that he claims injured him, Plaintiff instead seeks to hold another company liable for his injury. Specifically, he asks the Court to hold that Merck can be liable for its competitor's generic version of its innovative medicine, Proscar. In doing so, Plaintiff asks this Court to devise a tort duty that is contrary to Massachusetts law and that has been rejected by nearly every court to consider it. Pp. 4–11.

This Court should reject Plaintiff's innovator liability theory, which is inconsistent with Massachusetts social policy in two respects. *First*, by subjecting the companies engaged in innovation to liability for products they did not manufacture or profit from, Plaintiff's theory would substantially disrupt innovators' ability to invest in further innovation and their incentive to innovate in Massachusetts. Pp. 11–31.

Second, no notion of basic fairness tolerates making innovator companies serve as insurers for injuries caused by their generic competitors' products. This unfairness is especially pronounced in light of the Hatch-Waxman regime, which incentivizes innovators to

shoulder the enormous costs and risks of developing pioneering new treatments but allows generic competitors to capture almost all of their market share upon generic entry. Pp. 31–40.

The Superior Court's decision should be affirmed.

ARGUMENT

I. Brand-Name Companies Do Not Owe a Duty to Users of Generic Medicines

A. Innovator Liability Is Inconsistent with Massachusetts Tort Principles

Plaintiff asserts that "there is nothing analytically novel" about innovator liability. Reply Br. of Plaintiff-Appellant 1. To the contrary, Massachusetts follows the straightforward principle that "[t]he manufacturer of [a] product owes no duty of care to the user of another product." *Satchi v. Rheon U.S.A., Inc.*, No. CV 16-10521-WGY, 2017 WL 2541404, at *7 (D. Mass. June 12, 2017); *see also Carrier v. Riddell, Inc.*, 721 F.2d 867, 869 (1st Cir. 1983) (Breyer, J.) ("[A] duty of care runs to those who buy or use the product itself, not a different maker's product."); *Mathers v. Midland-Ross Corp.*, 403 Mass. 688, 691 (1989) ("A plaintiff who sues a particular manufacturer for product liability generally must be able to prove that the item which it is claimed caused the injury can be traced to

that specific manufacturer."). Indeed, while Plaintiff asserts that *Carrier* and *Payton v. Abbott Labs*, 386 Mass. 540 (1982), "permitted the possibility that there may exist situations in which a manufacturer's duty could extend beyond its own users," Opening Br. of Plaintiff-Appellant 21, Plaintiff points to no case applying Massachusetts law in which a manufacturer's duty was so extended. *See Carrier*, 721 F.2d at 869 ("[W]e have researched Massachusetts law and can find no case imposing liability upon a manufacturer (for failure to warn) in favor of one who uses the product of a different manufacturer."); *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629, 631 (1986) ("We have never held a manufacturer liable . . . for failure to warn of risks created solely in the use or misuse of the product of another manufacturer.").[1] Accordingly, earlier this month, a

[1] Nor is Plaintiff's theory supported by the lack of a privity requirement. The cases Plaintiff cites stand merely for the proposition that a manufacturer can be held liable for injuries sustained by a consumer while using *the manufacturer's own product*, notwithstanding a lack of contractual privity between the manufacturer and consumer. *See MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 135–39 (1985) (holding that pharmaceutical companies owe a duty to warn users of their oral contraceptives, notwithstanding that physicians act as middlemen); *Carter v. Yardley & Co.*, 319 Mass. 92, 96 (1946) (holding that a perfume manufacturer could be held liable for injuries sustained by a consumer while

federal district court rejected innovator liability under Massachusetts law. *In re Zofran (Ondansetron) Prod. Liab. Litig.*, No. 1:15-MD-2657-FDS, 2017 WL 3448548, at *12–13 (D. Mass. Aug. 4, 2017).

B. The Overwhelming Majority of Courts Have Rejected Innovator Liability

Plaintiff's theory has gained no more traction outside of Massachusetts. In his reply brief, Plaintiff engages in considerable gymnastics to sidestep the reams of cases rejecting innovator liability, somehow concluding that the majority of pertinent cases actually embrace his outlier theory. For instance, Plaintiff dismisses all federal cases as irrelevant, arguing that "federal courts [are] guided in part by the limitation on federal court authority to intrude upon state law absent clear guidance from the state appellate courts." Reply Br. of Plaintiff-Appellant 12. But the *Erie* doctrine does not allow federal judges to "simply throw up [their] hands" when there is no on-point opinion from a state's highest court. *Butler v. Balolia*, 736 F.3d

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using its perfume, even though the consumer had purchased the perfume from a third-party retailer). The abolition of the privity requirement in modern products liability law hardly supports the colossal leap forward that a manufacturer can be held liable for injuries sustained while using a *competitor's* product.

609, 613 (1st Cir. 2013). Rather it requires them to "endeavor to predict how that court would likely decide the question." *Id.* Here, federal courts have almost universally predicted that states would not find a duty among brand-name manufacturers toward users of their generic competitors' products.[2]

Plaintiff additionally asks the Court to ignore all cases that were decided before *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011), on the ground that many "rel[ied] in large part on the *Foster* decision, which in turn made a critical assumption that generic drug manufacturers had an independent right and obligation to provide adequate warnings to their consumers." Reply Br. of Plaintiff-Appellant 10. But *Mensing* hardly justifies casting aside earlier case law. Indeed, the very premise of Plaintiff's argument -- that because a plaintiff cannot recover from the manufacturer of the medicine he ingested, he should be able to turn a competitor into a

[2] That several courts expressed reluctance to "expand state tort doctrine in novel directions," *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013), or to "greatly expand[] liability," *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 937 (6th Cir. 2014), proves the point. Before declining to "expand" tort duties for brand-name manufacturers, each court necessarily predicted that the duties being sought would not be recognizable under existing state law.

guarantor of that product -- is contrary to basic fairness. *See* Part II.B. Moreover, although the court in *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), mentioned that a generic manufacturer could independently alter its labeling, *id.* at 169–70, the court did not rest its decision on that assumption.[3] Rather, the court held that brand-name companies owed no duty of care to generic users because there was "no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products." *Id.* at 170–71.

But even setting aside cases decided before *Mensing*, at least thirty six different courts -- including all six federal appellate courts to consider

[3] *Accord Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183-84 (5th Cir. 2012) ("We do not view *Mensing* as overruling *Foster* because the court in *Foster* did not reach its holding by relying on the ability of a plaintiff to sue generic manufacturers."); *Zofran*, 2017 WL 3448548, at *8 (although *Foster*'s statement "is no longer true . . . [,] the great majority of courts have continued to follow *Foster*"); *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1119 (D. Or. 2012) ("*Mensing does not overturn the central holding in Foster.*"); *Metz v. Wyeth, LLC*, 830 F. Supp. 2d 1291, 1293–94 (M.D. Fla. 2011) ("[T]he proposition (discussed in *dicta*) that consumers could recover from generic manufacturers for misrepresentations relating to their products . . . was by no means central to the ultimate holding in *Foster*.").

the issue and eight different state courts -- have rejected innovator liability in the time since *Mensing* was decided.[4] Indeed, many of those courts expressly

[4] *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 614–16 (5th Cir. 2014); *Darvocet*, 756 F.3d at 936–54; *Moretti v. Wyeth, Inc.*, 579 F. App'x 563, 564–65 (9th Cir. 2014); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 680–82 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–78 (5th Cir. 2014); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 401–06 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1281–86 (10th Cir. 2013); *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 743–44 (8th Cir. 2013); *Guarino*, 719 F.3d at 1250–53; *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092–94 (8th Cir. 2013); *Demahy*, 702 F.3d at 182-84; *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423-24 (6th Cir. 2011); *Zofran*, 2017 WL 3448548, at *9–15; *In re Mirapex Prod. Liab. Litig.*, No. 07-1836 (MJD/FLN), 2016 WL 4217758, at *5–6 (D. Minn. June 16, 2016), *report and recommendation adopted*, No. CV 15-3005 (MJD/FLN), 2016 WL 4203422 (D. Minn. Aug. 9, 2016); *Coleson v. Janssen Pharm., Inc.*, No. 1:15-CV-04792-RWS, 2017 WL 1745508, at *3–4 (S.D.N.Y. May 3, 2017); *Wells v. Wyeth Pharm., Inc.*, 233 F. Supp. 3d 534, 538-40 (W.D. Tex. 2017); *Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327, 1339–41 (S.D. Fla. 2016); *Neeley v. Wolters Kluwer Health, Inc.*, 311 F.R.D. 427, 432–34 (E.D. Ky. 2015); *McNair v. Johnson & Johnson*, No. CIV.A. 2:14-17463, 2015 WL 3935787, at *5–6 (S.D.W. Va. June 26, 2015); *Truddle v. Wyeth, LLC*, No. 2:11-CV-00207-GHD, 2015 WL 160696, at *2–4 (N.D. Miss. Jan. 12, 2015); *Chatman v. Pfizer, Inc.*, No. 5:11-CV-69 (DCB) (MTP), 2014 WL 4546042, at *1–3 (S.D. Miss. Sept. 11, 2014); *Willis v. Schwarz-Pharma, Inc.*, 62 F. Supp. 3d 560, 564–68 (E.D. Tex. 2014); *Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at *1–2 (N.D. Ill. June 13, 2014); *Hendricks v. Pharmacia Corp.*, No. 2:12-CV-00613, 2014 WL 2515478, at *5–6 (S.D. Ohio June 4, 2014), *report and recommendation adopted*, 2014 WL 4961550 (S.D. Ohio Oct. 2, 2014); *Stewart v. Sanofi Aventis U.S., LLC*, 15 F. Supp. 3d 1151, 1153–55 (N.D. Ala. 2014); *Tillman v. Woldenberg Vill., Inc.*, No. CIV.A. 13-4731, 2013 WL 6198864, at *4–5 (E.D. La. Nov. 27, 2013); *Neeley v. Wolters Kluwer Health, Inc.*, No.

rejected Plaintiffs' principal argument -- that it is "reasonably foreseeable to [brand-name companies] that the end users of both the drugs manufactured by [them] as well as bioequivalent generic drugs would rely on the contents of [their] label[s]," Opening Br. of Plaintiff-Appellant 14. *See, e.g.*, *Scott v. Elsevier Inc.*, No. 11-04445, slip op. at 5 (Mass. Super. Ct. Aug. 11, 2014)

4:11-CV-325 JAR, 2013 WL 3929059, at *20–23 (E.D. Mo. July 29, 2013); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 650 (S.D. Miss. 2013); *Wash. ex rel. Wash. v. Medicis Pharm. Corp.*, No. 3:12CV126-DPJ-FKB, 2013 WL 496063, at *2–4 (S.D. Miss. Feb. 7, 2013); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 601–04 (N.D. Miss. 2013); *Baymiller v. Ranbaxy Pharms. Inc.*, 894 F. Supp. 2d 1302, 1306–11 (D. Nev. 2012); *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 917–19 (S.D. Ohio 2012); *Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 843–46 (S.D. Tex. 2012), *reconsideration denied*, 2015 WL 12780637, at *4–5 (S.D. Tex. March 19, 2015); *Phelps*, 857 F. Supp. 2d at 1118-22; *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1344 (N.D. Ga. 2012); *Metz*, 830 F. Supp. 2d at 1294; *Morris v. Wyeth, Inc.*, No. 3:09-cv-854, 2011 WL 4975317, at *2-3 (W.D. La. Oct. 19, 2011); *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011); *PLIVA, Inc. v. Dement*, 780 S.E.2d 735, 743 (Ga. Ct. App. 2015), *cert. granted* (Sept. 6, 2016); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 369–81 (Iowa 2014); *Anselmo v. Sanofi-Aventis Inc. USA*, No. 10-CV-77, 2014 WL 8849464, at *1–4 (Kan. Dist. Ct. Oct. 13, 2014); *Cardinal v. Elsevier Inc.*, No. MICV201104442, 2014 WL 10937406, at *1 (Mass. Super. Ct. Aug. 11, 2014); *Franzman v. Wyeth LLC*, 451 S.W.3d 676, 689–92 (Mo. Ct. App. 2014); *Condouris v. Wyeth*, No. ATL-L-0257-11, 2012 WL 2401776 (N.J. Super. Ct. Law Div. June 26, 2012); *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993, at *1–3 (N.Y. Sup. Ct. Oct. 8, 2013); *Madden v. Teva Pharms., USA, Inc.*, No. 0087, 2012 WL 4757253 (Pa. Ct. C.P. Oct. 1, 2012).

(Ex. B to Br. of Defendant-Appellee) (finding "persuasive" the "rationale[] that the mere fact that state and federal laws require the Brand-Name Manufacturers to create the label does not satisfy the foreseeability element"); *Darvocet*, 756 F.3d at 945 ("[T]he generic consumers' injuries are not the foreseeable result of the Brand Manufacturers' conduct, but of the laws over which the Brand Manufacturers have no control. Using federal and . . . state laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far."); *Bell*, 716 F.3d at 1093; *Huck*, 850 N.W.2d at 370–71.

II. Holding Brand-Name Companies Liable for Injuries Allegedly Sustained from Their Generic Competitors' Products Is Bad Social Policy

In determining whether to fashion a new tort duty, Massachusetts courts look to "existing social values and customs and appropriate social policy." *Coombes v. Florio*, 450 Mass. 182, 187 (2007) (quoting *Cremins v. Clancy*, 415 Mass. 289, 292 (1993)). Though Plaintiff devotes much of his briefs to arguing that it is foreseeable that generic consumers will rely on information in the brand name label, "[f]oreseeability of harm is one, but only one, relevant factor in the

public policy assessment," *A.L. v. Commonwealth*, 402 Mass. 234, 253 (1988) (O'Connor, J., dissenting); *see also Bash v. Clark Univ.*, No. 06745A, 2006 WL 4114297, at *4 (Mass. Super. Ct. Nov. 20, 2006) (foreseeability "is not the linchpin for determining the existence of a common-law duty under Massachusetts tort law"). Because shifting liability to innovators for injuries allegedly sustained by individuals who ingest generic manufacturers' products will chill innovation and unfairly expose brand-name manufacturers to limitless liability, Plaintiff's innovator liability theory should be rejected.

A. Innovator Liability Will Harm Innovation

1. Innovator Companies Invest Immense Resources in Researching and Developing New Medicines

Bringing a new medicine to market is a lengthy and expensive process. Before studying a new medicine in humans, a pharmaceutical company must conduct a broad range of laboratory and animal studies to test how the medicine works and assess its safety. 21 C.F.R. § 312.23(a)(8). If the results are promising, the company submits an Investigational New Drug application ("IND") to the Food and Drug Administration ("FDA"), outlining the preclinical study results and offering a

plan for clinical trials in humans. 21 U.S.C. § 355(i)(2); 21 C.F.R. § 312.20(a)–(b). Only upon FDA approval of the IND can a company begin to study the prospective medicine in humans. Those human clinical trials generally occur in three phases, each of which must be completed successfully before the potential new medicine may undergo FDA review and approval. 21 C.F.R. § 312.21. On average, the clinical trial phase alone takes six to seven years to complete. PhRMA, *Modernizing Drug Discovery, Development and Approval* 1 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/proactive-policy-drug-discovery.pdf. If clinical trial results show that the medicine's benefits outweigh its risks, the sponsoring company can seek the FDA's approval to market the medicine by submitting a New Drug Application ("NDA"). 21 U.S.C. § 355(b)(1). The NDA, which must contain, among other things, the results of the clinical and pre-clinical testing, proposals for manufacturing, and proposed labeling for the new medicine, id., often exceeds 100,000 pages in length, PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines* 14 (2015), http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

Innovative companies undertake this process at tremendous expense. On average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion. PhRMA, *Biopharmaceuticals in Perspective: Spring 2017*, at 29 (2017), http://phrma-docs.phrma.org/files/dmfile/Biopharmaceuticals-in-Perspective-2017.pdf [hereinafter *Biopharmaceuticals in Perspective*]; *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016). PhRMA's member companies invest approximately one quarter of their total annual domestic sales on research and development -- an estimated $65.6 billion in 2016. *Biopharmaceuticals in Perspective*, *supra*, at 35.

These research efforts also involve tremendous risk, as most compounds invented never attain FDA approval. Just one out of every 5,000 to 10,000 compounds under development, and just one out of every eight medicines entering clinical trials, obtains FDA approval. Press Release, PhRMA, PhRMA Statement Regarding Benefits of New Medicines (Apr. 30, 2013), http://www.phrma.org/press-release/phrma-statement-regarding-benefits-of-new-medicines; *Biopharmaceuticals*

in Perspective, *supra*, at 29; *see also* PhRMA & Battelle, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies* 12 (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf (reporting that in 2013, pharmaceutical companies sponsored 6,199 clinical trials involving 1.1 million participants, including 1,577 clinical trials involving 33,346 participants in Massachusetts); *see also, e.g.*, Jared S. Hopkins & Michelle Cortez, *Lilly's Alzheimer's Disease Drug Fails in Final-Stage Trial* (Nov. 26, 2016), https://www.bloomberg.com/news/articles/2016-11-23/lilly-s-alzheimer-s-disease-drug-fails-in-final-stage-trial (discussing an innovator's $3 billion investment in an Alzheimer's treatment medication that failed at the final stage of clinical testing).

These costs do not end even when a medicine makes it through the rigorous approval process. Once a new medicine is brought to market, NDA holders are required to monitor, review, and report to the FDA all adverse events received from any source, "including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing

epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b); *see also* Food & Drug Admin., *Reports Received and Reports Entered into FAERS by Year* (2015), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm (stating that the FDA received over 1.2 million adverse event reports from pharmaceutical companies in 2014). NDA holders must also submit to the FDA annual reports summarizing all information received about their medicines, including adverse drug events and clinical trial results. 21 C.F.R. §§ 314.80(c), 314.81(b)(2)(vi).

Apart from adverse-event reporting, the FDA frequently requires NDA holders to undertake additional clinical studies after approval. *See* 21 U.S.C. § 355(o)(3)(A). According to one estimate, more than three quarters of all new medicine approvals are accompanied by a commitment from the sponsor to conduct one or more post-marketing, or "Phase IV," studies. Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 Food & Drug L.J. 295, 300 (2006). PhRMA's member companies spend more than $8.8

billion annually conducting these studies. PhRMA, *Annual Membership Survey* 6 tbl.4 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/annual-membership-survey-results.pdf.

2. The Duties Plaintiff Seeks to Fashion Would Expose Brand-Name Companies to Limitless Liability

Plaintiff's novel innovator liability theory would expose brand-name manufacturers to virtually unlimited liability for injuries allegedly caused by a generic competitor's version of their medicine. The scope of litigation against pharmaceutical companies is already immense and rapidly expanding. Last year alone, 21,517 product liability lawsuits were filed against pharmaceutical companies in federal courts alone, up from 6,791 lawsuits just five years ago and just 2,700 lawsuits in 2001. *See* Admin. Office of the U.S. Courts, Table C-2A: *U.S. District Courts--Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2012 Through 2016*, http://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf; Lisa Girion, *State Vioxx Trial Is Set as Drug Suits Boom*, L.A. Times, June 27, 2006, at C1. Today, out of seventy-three pending product liability multidistrict litigation proceedings, twenty-

eight involve pharmaceuticals. *See* U.S. Judicial Panel on Multidistrict Litig., MDL Statistics Report - Distribution of Pending MDL Dockets by District (Aug. 15, 2017), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2017.pdf. By comparison, between 1960 and 1999, there were only five MDL product liability actions involving FDA-approved medicines. *See* Deborah R. Hensler, *Has the Fat Lady Sung? The Future of Mass Toxic Torts*, 26 Rev. Litig. 883, 897–902 tbl.1 (2007).[5]

Lawsuits seeking to impose innovator liability on brand-name pharmaceutical companies already number in the thousands. *See Neeley*, 311 F.R.D. at 429 (noting that "thousands" of cases have been filed "against various generic and brand-name companies responsible for manufacturing Reglan®/metoclopramide"). Courts have ruled on this issue in lawsuits involving treatments for allergic reactions, asthma, bacterial infections, cardiac arrhythmias, depression, heartburn, insomnia,

[5] Similar increases have occurred in state courts. For example, nine of the nineteen consolidated multi-county litigation proceedings pending in New Jersey involve challenges to FDA-approved labeling for prescription medications. N.J. Courts, *Multicounty Litigation*, https://www.judiciary.state.nj.us/attorneys/mcl/index.html (last visited Aug. 22, 2017).

menopausal symptoms, migraine headaches, obesity, panic disorder, and schizophrenia, to name just a few.[6]

Should innovator liability gain acceptance, the number of lawsuits would multiply even further. A creative advocate can always sketch out a scenario where some action (or inaction) by the brand-name company years earlier could impact the subsequent generic labeling. Able lawyers can trace almost any safety issue back to the original innovator, essentially punishing it for the overwhelming amount of safety data it amasses over the decades of development and marketing of a medicine before generic entry. In this setting, lawyers have a nearly limitless ability to conceive of new or

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[6] *See, e.g.*, *Foster*, 29 F.3d at 168–71 (Phenergan (promethazine hydrochloride)); *Coleson*, 2017 WL 1745508, at *3–4 (Risperdal (risperdone)); *Tsavaris*, 154 F. Supp. 3d at 1339–41 (Activella (estradiol/norethindrone acetate)); *Neeley*, 311 F.R.D. at 432–34 (Reglan (metoclopramide)); *Anselmo*, 2014 WL 8849464, at *1 (Ambien (zolpidem)); *Barnhill v. Teva Pharm. USA, Inc.*, No. CIV A 06-0282-CB-M, 2007 WL 5787186, at *2 (S.D. Ala. Apr. 24, 2007) (Keflex (cephalexin)); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477(GLS/GJD), 2006 WL 2038436, at *3–8 (N.D.N.Y. July 19, 2006) (Prozac (fluoxetine)); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 539–43 (E.D. Pa. 2006) (Paxil (paroxetine)); *DaCosta v. Novartis AG*, No. CV 01-800-BR, 2002 WL 31957424, at *8–9 (D. Or. Mar. 1, 2002) (Migranal (ergot alkaloid)); *Stanley v. Wyeth, Inc.*, 991 So.2d 31, 33–35 (La. Ct. App. 2008) (Cordarone (amiodarone)); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350–52 (Minn. Ct. App. 2001) (Pondimin (fenfluramine)).

stronger warnings that they allege companies should have added to their labeling, or to claim in hindsight that existing warnings should have been added sooner. *See, e.g.*, Br. for the United States as Amicus Curiae Supporting Petitioner 25, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249), 2008 WL 2308908, at *25 (noting the "post hoc imagination of lawyers" in pursuing pharmaceutical lawsuits challenging safety labeling). And because nine out of every ten U.S. prescriptions are filled with generics, *Biopharmaceuticals in Perspective*, *supra*, at 49, the scope of potential liability is immense.

3. Litigation Risk Disincentivizes Innovator Companies from Investing in Research and Development of New Medicines

When a company is exposed to liability that bears no relationship to its products, sales, or revenue, it is both prevented from recapturing its research and development investment in that medicine and discouraged from making future investments. Such a result directly undermines the purposes of the Hatch-Waxman Amendments, which "careful[ly] balance" the interest in lower-cost medicines against the need to "encourag[e] research and innovation," 57 Fed. Reg. 17,950, 17,951 (Apr. 28,

1992); *see also* H.R. Rep. No. 98-857, pt. 1, at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647 ("The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."). It is also incompatible with Massachusetts' established "[p]ublic policy favor[ing] the development and marketing of new and more efficacious drugs." *Payton*, 386 Mass. at 573. This Court should decline to contort basic tort principles to reach such an unwise result.

Given the enormous costs associated with researching and developing a new medicine, the scope of litigation risk bears heavily on a company's decision to invest in innovation. *See Payton*, 386 Mass. at 573 (recognizing the "deleterious effect on the development and marketing of new drugs" caused by expansive tort liabilities); W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1419 (1994) ("[T]he net effect of the surge in liability costs ha[s] been to discourage innovation in the pharmaceutical industry."); Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 Cardozo L. Rev. 1139, 1153 (1987) ("If in

the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made.").

The anti-nausea drug Bendectin, used to treat severe morning sickness in pregnant women, illustrates why. After Bendectin was named as the cause of birth defects in thousands of lawsuits, its manufacturer withdrew the medicine from the market in 1983, only later to be vindicated by scientific studies showing that Bendectin posed no risks to either mothers or fetuses. *See* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1, 7 (1993); Robert Brent, *Medical, Social, and Legal Implications of Treating Nausea and Vomiting of Pregnancy*, 186 Am. J. Obstetrics & Gynecology S262, S262–63 (2002); *see also* David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 460 (1999); Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 371, 392 (2002). In 2013, after nearly thirty years off the market, Bendectin returned under a new name. *See* News Release, Food & Drug Admin., *FDA Approves Diclegis for Pregnant Women Experiencing Nausea and Vomiting* (Apr. 8, 2013). In the interim, however,

hospital admissions for excessive vomiting during pregnancy had doubled, costing the U.S. economy $1.7 billion annually in time lost from work, caregiver time, and hospital expenses. *See* Nina Nuangchamnong & Jennifer Niebyl, *Doxylamine Succinate–Pyridoxine Hydrochloride (Diclegis) for the Management of Nausea and Vomiting in Pregnancy: An Overview*, 6 Int'l J. Women's Health 401, 401–02 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3990370/pdf/ijwh-6-401.pdf.

Similarly, by 1990, eight of the nine major U.S. pharmaceutical companies that had been involved in researching and developing new contraceptives had abandoned their efforts. Nat'l Research Council, Comm. on Contraceptive Dev., & Inst. of Med., Div. of Int'l Health, *Developing New Contraceptives: Obstacles and Opportunities* 59 (Luidi Mastroianni et al. eds., 1990), https://www.nap.edu/read/1450. According to the National Research Council and the Institute of Medicine, "recent products liability litigation and the impact of that litigation on the cost and availability of liability insurance have contributed significantly to the climate of disincentives for the development of contraceptive products." *Id.* at 141. In 1989, the

inventor of the birth control pill, Carl Djerassi, recommended changes to the product liability regime, commenting that "the United States is the only country other than Iran in which the birth control clock has been set backward during the past decade." Carl Djerassi, *The Future of Birth Control*, Wash. Post (Sept. 10, 1989), https://www.washingtonpost.com/archive/opinions/1989/09/10/the-future-of-birth-control/7e25f2cc-ae35-4a79-8daf-031db02f81be/?utm_term=.dd4d8bbcf626. The executive director of the Society for the Advancement of Women's Health Research similarly testified before Congress that "the current liability climate is preventing women from receiving the full benefits that science and medicine can provide." S. Rep. No. 104-69, at 7 (1995).

The country's experience with vaccines is also illustrative. Lawsuits in the late 1970s alleging that the whooping-cough component of the DPT vaccine caused permanent brain damage led nearly all of its manufacturers to cease production, resulting in nationwide shortages. *See* Linda A. Willett, *Litigation as an Alternative to Regulation: Problems Created by Follow-on Lawsuits with Multiple Outcomes*, 18 Geo. J. Legal Ethics 1477, 1488 n.60 (2005). Although the

allegation that the DPT vaccine causes neurological harm was subsequently "discredited," Stephen D. Sugarman, *Cases in Vaccine Court – Legal Battles Over Vaccines and Autism*, 357 N. Eng. J. Med. 1275, 1276 (2007), by 1986, there was only one American manufacturer of the polio vaccine, one manufacturer of the measles, mumps, and rubella vaccine, and two manufacturers of the DPT vaccine, H.R. Rep. No. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344; *see also Payton*, 386 Mass. at 573 n.17 ("Manufacturer liability for vaccine-associated disability, regularly assigned by courts, threatens a predictable vaccine supply -- especially of oral polio vaccine -- and diminishes the chances of significant independent manufacturer-sponsored research and development of new biologics." (emphasis omitted) (quoting Assistant Surgeon General David Sencer)). Congress, realizing the "inadequacy -- from both the perspective of vaccine-injured persons as well as vaccine manufacturers -- of the current approach to compensating those who have been damaged by a vaccine," H.R. Rep. No. 99-908, at 7, passed the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, which removed many personal-injury cases involving vaccines from the state-law tort system. Congress hoped

that once "manufacturers ha[d] a better sense of their potential litigation obligations, a more stable childhood vaccine market w[ould] evolve." H.R. Rep. No. 99-908, at 7. And, in fact, the Act appears to have "succeeded in stabilizing prices and stemming further exit from the market" for listed vaccines. Noah, *supra*, at 393.

In short, the past 40 years have repeatedly demonstrated that dramatic increases in potential liability -- particularly unpredictable, long-enduring liability -- can drive biopharmaceutical companies to abandon the research and production of medicines, especially those used to treat populations like children and pregnant women where the liability risks are especially significant. Yet the unpredictable liability that would follow from Plaintiff's innovator liability theory is worse by an order of magnitude: all of the examples discussed above took place in a legal landscape where companies were potentially liable for injuries to plaintiffs who used medicines that they themselves manufactured. Under Plaintiff's theory, an innovator company could be subjected to decades of liability for a product manufactured by its competitor years after the innovative company's revenue trails off.

The impact of this unpredictable and potentially limitless liability on innovation, and correspondingly on public health, would be profound.[7] The

[7] *Accord Scott*, No. 11-04445, slip op. at 6 ("[T]his court agrees with the Sixth Circuit that 'there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs'" (quoting *Darvocet*, 756 F.3d at 945)); *Kelly v. Wyeth*, No. CIV.A.MICV200303314B, 2005 WL 4056740, at *4 (Mass. Super. Ct. May 6, 2005) (citing "social policy reasons" for not embracing innovator liability); *Huck*, 850 N.W.2d at 377 (plurality opinion) ("[E]xtending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks."); *Rossi v. Hoffmann-LaRoche*, No. ATL-L690-05, 2007 WL 7632318 (N.J. Sup. Ct. Jan. 3, 2007) (holding that innovator liability "could only act to stigmatize the ability of companies to develop new and innovative drugs"); *Sloan v. Wyeth*, No. MRS-L-1183-04, 2004 WL 5767103 (N.J. Sup. Ct. Oct. 13, 2004) ("Brand name manufacturers would be less likely to develop new products if liability were imposed upon these companies for injuries wrought by products of generic manufacturers."); Anna B. Laakmann, *The Hatch-Waxman Act's Side Effects: Precautions for Biosimilars*, 47 Loyola L.A. L. Rev. 917, 926 (2014) (innovator liability "could further dampen the incentives to create new drugs and thus reduce overall patient welfare"); Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 Tort Trial & Ins. Prac. L.J. 673, 688 n.69 (2010) (innovator liability "threatens to chill therapeutic product innovation"); Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1871 (2013) (innovator liability makes it "riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines"); Samantha Koopman, *Hidden*

biopharmaceutical industry provides the majority of funding to discover, develop, and manufacture transformative medicines. *Biopharmaceuticals in Perspective*, *supra*, at 30. Its investments have produced dozens of major scientific breakthroughs. For example, over the past two decades, innovative diagnostic techniques and treatments have reduced the death rate from cancer by 25 percent. *Id.* at 11. Innovations have reduced the death rate from heart disease by 35 percent since 2000. *Id.* at 14. And innovative treatments for HIV/AIDS have contributed to a nearly 87 percent decline in death rates since the mid-1990s, preventing over 862,000 premature deaths. *Id.* at 9. Without ongoing investments from pharmaceutical companies in research and development, none of these advances would have been possible.[8]

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, 140 (2014) ("Overall, innovator liability likely results in less new drug development.").

[8] Advances in medicine not only save lives, but also save money. According to one estimate, the development of a new medicine that could delay the onset of Alzheimer's disease by just five years would save the U.S. economy over $376 billion. PhRMA, *Prescription Medicines: International Costs in Context* 18 (2017), http://phrma-docs.phrma.org/download.cfm?objectid=1EB3F3B0-02B7-11E7-84190050569A4B6C.

4. Massachusetts Public Policy Favors the Research and Development of New Medicines *in Massachusetts*

A rule that chills the development and marketing of new and efficacious medicines in Massachusetts would also run counter to Massachusetts' policy goals. In June 2008, Massachusetts passed the Life Sciences Act, Mass Gen. Laws ch. 231, §§ 1–18, which had as its express purpose "expan[sion of] the life sciences activities in the Commonwealth." Deval L. Patrick, *FY2010 House 1 Budget Recommendation: Policy Brief: Life Sciences Initiative*, http://www.mass.gov/bb/h1/fy10h1/exec10/hbudbrief23.htm. The Act established a 10-year, $1 billion investment fund overseen by the Massachusetts Life Sciences Center, a new, state-sponsored non-profit organization. To date, the initiative has resulted in the creation of 1.4 million square feet of new life science facilities and commitments from biopharmaceutical companies to create more than 3,750 new, long-term life science jobs in Massachusetts. TEConomy Partners LLC, *Driving Innovation and Economic Growth for the 21st Century: State Efforts to Attract and Grow the Biopharmaceutical Industry* 6–7 (2017), http://phrma-docs.phrma.org/files/dmfile/PhRMA-Driving-Innovation_06_01.2017.pdf. Governor Charlie

Baker recently announced that he will ask lawmakers to extend the Act by five years and to provide an additional $500 million in funding. Jim O'Sullivan & Robert Weisman, *Baker to Unveil $500 Million Life Sciences Initiative*, Bos. Globe (June 19, 2017), https://www.bostonglobe.com/metro/2017/06/19/charlie-baker-unveil-new-million-life-sciences-initiative/SP8XvuilfFtSeRb1R4XOcJ/story.html.

There is good reason to seek expansion of Massachusetts' life science industry. Research shows that every direct biopharmaceutical sector job in Massachusetts is supported by nearly four additional jobs across the Massachusetts economy. *See* PhRMA, *Biopharmaceutical Sector Impact on Massachusetts' Economy*, http://phrma-docs.phrma.org/sites/default/files/pdf/economic-impact/massachusetts.pdf (noting that the biopharmaceutical industry supports more than 250,000 Massachusetts jobs). And the average compensation for a biopharmaceutical sector employee is more than double that of all Massachusetts workers. *Id.* Moreover, Massachusetts' biopharmaceutical industry generates $5 billion in annual tax revenue and $67.8 billion in economic output -- nearly three times more

output per employee than the Massachusetts' average. *Id.*

Creating a crippling increase in potential liability would strongly incentivize innovators to avoid the risk of having Massachusetts law apply when deciding where to locate operations. Doing so hardly amounts to good policy at a time when Massachusetts is actively attempting to stimulate the State's life sciences industry.

B. Innovator Liability Is Fundamentally Unfair

1. Generic Manufacturers Bear Almost None of the Costs of Researching and Developing Innovative Medicines

Prior to the passage of the Hatch-Waxman Amendments, virtually all companies were required to conduct pre-clinical and clinical trials as a prerequisite to obtaining the FDA's approval to market a medicine. Recognizing that this procedure was a hindrance to the availability of generic medicines, Congress amended the FDA approval process to "make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14.

The Hatch-Waxman Amendments left in place the multi-step approval process for innovative new medicines, but it streamlined that process for generic

versions of those medicines. Under Hatch-Waxman, a company may seek approval to market a generic medicine by filing an abbreviated new drug application ("ANDA") demonstrating that the generic version is biologically equivalent to an already-approved medicine. 21 U.S.C. § 355(j)(2)(A)(iv); 21 C.F.R. § 314.92(a)(1). An ANDA applicant need not independently perform extensive and costly studies to prove that the generic is safe and effective; instead, it can rely on "a prior agency finding of safety and effectiveness based on the evidence presented in [the] previously approved new drug application." 57 Fed. Reg. at 17,953.

Due to these streamlined procedures, researching and developing a generic version of an FDA-approved medicine costs under $2 million today -- less than one-tenth of one percent of the cost of developing the innovative medicine itself. U.S. Dep't of Health and Human Servs., *Expanding the Use of Generic Drugs* 4–5 (2010), https://aspe.hhs.gov/system/files/pdf/76151/ib.pdf; *Biopharmaceuticals in Perspective*, *supra*, at 29. Generic manufacturers pass these cost savings onto consumers. *See Biopharmaceuticals in Perspective*, *supra*, at 51. Consequently, immediately after generic entry, the market share of generic copies of medicines

dwarfs the brand's market share. *See, e.g.*, Henry G. Grabowski et al., *Updated Trends in US Brand-Name and Generic Drug Competition*, 19 J. Med. Econ. 836 (2016) (reporting that for brand medicines facing generic entry in 2013-2014, generics captured an average of 93 percent of the market (by volume) within the first year).[9]

2. Plaintiff's Innovator Liability Theory Would Unfairly Make Innovators Guarantors of Their Competitors' Products

Having paid nearly all of the costs associated with researching and developing a new medicine, only to lose nearly all of their market share to generic manufacturers upon generic entry, brand-name companies would nevertheless, under Plaintiff's innovator liability theory, have to pay for the harm allegedly caused by their generic competitors' products. If accepted, Plaintiff's theory would create an insurance scheme for generic companies, unfairly underwritten by pioneer pharmaceutical companies. Plaintiff cites no evidence that Congress intended to set up such a system, which would unfairly expose brand-name manufacturers to

[9] This result is virtually guaranteed in Massachusetts, where pharmacists are legally required to fill prescriptions using lower-priced generics unless the prescriber expressly writes the words "no substitution" below his signature. See 105 Mass. Code Regs. 720.200.

virtually unlimited liability and fundamentally disrupt the careful balance struck by the Hatch-Waxman Amendments.

This case starkly illustrates the unfairness of holding innovators liable for products that their competitors control, produce, and profit from. The first generic version of Proscar entered the market in July 2006. By March 2007, Proscar's share of the finasteride market had fallen by more than ninety percent and continued to decline. Natalia Shcherbakova et al., *The Role of Authorized Generics in the Prescription Drug Marketplace*, 8 J. Generic Medicines 28, 33 fig. 5 (2011). Plaintiff was not prescribed generic Proscar until June 2010 and did not bring suit until October 2013. Merck is thus being subjected to potential liability for a competitor's product, even when that product was manufactured years after Merck's market share (and corresponding revenue) dropped to miniscule levels.

Nor could Merck have foreseen that it could be held liable for injuries sustained at the hands of its generic competitors' products -- and thus factored that risk into its investment decision -- at the time that it chose to research and develop Proscar. Merck began developing

Proscar in 1975. Milt Freudenheim, *Keeping the Pipeline Filled at Merck*, N.Y. Times (Feb. 16, 1992), http://www.nytimes.com/1992/02/16/business/keeping-the-pipeline-filled-at-merck.html. Yet it was not until 2011, when the Supreme Court held that generic manufacturers were prohibited from submitting Changes Being Effected ("CBE") supplements, *Mensing*, 564 U.S. at 614, that (under Plaintiff's theory) Merck could have foreseen it "controlled the content of all finasteride labels, including the labels placed on generic versions," Opening Br. of Plaintiff-Appellant 1. To be sure, beginning with the passage of the Hatch-Waxman Amendments in 1984, ANDA applicants were required to "show that the labeling proposed for the drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(4)(G). But by 1984, Merck had already been working on Proscar for nearly a decade. And well after 1984, whether generic manufacturers could make labeling changes *after ANDA approval* remained an open question. In fact, prior to *Mensing*, multiple courts of appeals had held that generic manufacturers *could* make such changes through the CBE process. *See Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1232–34 (9th Cir. 2011); *Demahy v. Actavis, Inc.*, 593 F.3d 428, 439–44

(5th Cir. 2010); *Foster*, 29 F.3d at 170; *see also Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608 (8th Cir. 2009) (declining to decide the question). Indeed, when Plaintiff was prescribed Proscar in June 2010, the law in Massachusetts was that "[a] manufacturer of a generic drug may alter a drug's labeling." *Kelly*, 2005 WL 4056740, at *1 n.3.[10]

Plaintiff argues that innovator liability is not unfair because, although brand-name companies "do[] not profit directly from each separate sale of generic [medicine], [they do] profit from [Hatch-Waxman's] overall statutory scheme." Opening Br. of Plaintiff-Appellant 29. Specifically, Plaintiff points to the provision of the Hatch-Waxman Amendments that restores up to five years of the patent life lost during clinical testing and NDA review. *See* 35 U.S.C. § 156(a), (c), (g)(6)(A). Plaintiff's argument is divorced from today's reality, in which multiple brand-name companies

[10] Nor would it be sound policy to fashion a rule imposing liability on companies that decided to invest in innovative new medicines after *Mensing*. Given the protracted development cycle, it will be decades before any such medicines come to market, and even longer still before those medicines become generic. In light of the FDA's proposed generic labeling rule, 78 Fed. Reg. 67,985 (Nov. 13, 2013), it is hardly foreseeable to companies making investment decisions today that they will control generic labeling many years down the road.

are often simultaneously competing to research, develop, and secure FDA approval of first-in-class treatments. On average, a first-in-class medicine now faces competition within just 2.3 years of launch, down from 10.2 years several decades ago. *Biopharmaceuticals in Perspective*, *supra*, at 67. Correspondingly, the average lifetime revenue for a new medicine has declined by over forty percent since 2000, even as the costs of researching and developing new medicines have more than doubled over a similar timeframe. *See id.* at 36, 66. Thus, while the extended period of market exclusivity was intended to enable companies that bring innovative medicines to market to begin to earn back their up-front research and development costs, four out of every five medicines today never become profitable. *Biopharmaceuticals in Perspective*, *supra*, at 50. Innovator liability would shrink the number of profitable medicines even further.

Plaintiff alternatively argues that even if innovator liability is unfair for brand-name companies, it would be equally unfair to leave generic users without "recourse for harm resulting from inaccurate or erroneous warnings." Opening Br. of Plaintiff-Appellant 6. Plaintiff argues that this dichotomy is especially

problematic "at a time when, as a result of skyrocketing increase[s] in drug prices, the importance of generic drugs as a lower-cost alternative for public health is increasing." Opening Br. of Plaintiff-Appellant 25. But innovator liability would not increase consumer access to name-brand medicines. *See, e.g.*, *Sloan*, 2004 WL 5767103 (rejecting innovator liability because it would not "advance the affordably of drugs, one of the main policy foundations for the Hatch-Waxman amendments"); Schwartz, *supra*, at 1870 ("Saddling 10 percent of a market with 100 percent of its liability is certain to create new and significant financial pressures on brand-name drugs, the effects of which would harm health care consumers."). As the District of Massachusetts recently recognized:

> It is true that dismissal would appear to leave consumers injured by generic drugs without any form of remedy. But it is by no means obvious that [innovator liability] is correct or fair, or even that it is the outcome that best protects consumers. Just as it may be unfair to leave some injured consumers without a remedy, so too it may be unfair or unwise to require brand-name manufacturers to bear 100% of the liability, when they may have only 10%, or less, of the relevant market. A fair and rational system of tort liability must balance a variety of different factors, including not only providing compensation for injured persons, but also such factors as the appropriate allocation of risk. Congress has apparently decided, at least according to the

> Supreme Court, to exempt generic drug manufacturers from state-law tort liability. It does not clearly follow that brand-name manufacturers should bear all of the potential liability, particularly where it is unclear what the impact of such a potentially enormous shift in liability may have on the development of new drugs.

Zofran, 2017 WL 3448548, at *14.

Moreover, "[t]he brand-name manufacturer plays no role in the generic manufacturer's decision to enter the market, and it is not responsible for crafting the regulatory and legal framework within which the generic manufacturer chooses to do so." *Wyeth, Inc. v. Weeks*, 159 So.3d 649, 694 n.27 (Ala. 2014) (Murdock, J., dissenting). Instead, any perceived unfairness was "created by Congress and the Food and Drug Administration . . . in return for the perceived societal benefit of less expensive generic drugs, or perhaps instead by the manner in which the United States Supreme Court subsequently has applied the preemption doctrine to the legislative and regulatory scheme structured by those entities." *Id.* at 685.[11]

[11] Noting that judges "routinely decide cases involving complex scientific and economic factors," Plaintiff argues that courts are qualified to "decide the issues surrounding pharmaceutical labeling requirements." Opening Br. of Plaintiff-Appellant 30. Plaintiff misses the point. Balancing the need for injured persons to

Accordingly, the fact that "the consumer of a competitor's product is . . . blocked from imposing on that competitor the costs that would normally accompany the rewards attendant to the sale of that product" does not make it any less unfair to shift liability onto the brand-name company for injuries sustained from a product it never sold. *Id.* at 701 n.33.

CONCLUSION

For the foregoing reasons, the Superior Court's decision should be affirmed.

Respectfully submitted,

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recover monetary damages against the societal interest in promoting the development of life-saving new treatments is precisely the type of policymaking that is the province of legislators, not jurists. *Accord Zofran*, 2017 WL 3448548, at *16 ("[T]he balancing of the costs and benefits of different approaches should be left to the political branches, whether at the state or federal level . . . .").

ADDENDUM OF STATUTES AND REGULATIONS

21 U.S.C. § 355: New Drugs

. . .

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. . . .

* * *

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

. . .

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including--

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

* * *

(j) Abbreviated new drug applications

. . .

(2) (A) An abbreviated application for a new drug shall contain--

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

. . .

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

. . .

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the

listed drug are produced or distributed by different manufacturers;

* * *

(o) Postmarket studies and clinical trials; labeling

. . .

(3) Studies and clinical trials

(A) In general

For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

35 U.S.C. § 156: Extension of Patent Term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if--

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product

manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which--

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

* * *

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that--

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

* * *

(g) (6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

. . .

21 C.F.R. § 312.20: Requirement for an IND

(a) A sponsor shall submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to § 312.2(a).

(b) A sponsor shall not begin a clinical investigation subject to § 312.2(a) until the investigation is subject to an IND which is in effect in accordance with § 312.40.

. . .

21 C.F.R. § 312.21: Phases of an Investigation

An IND may be submitted for one or more phases of an investigation. The clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap. These three phases of an investigation are as follows:

(a) Phase 1.

(1) Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

(2) Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

(b) Phase 2. Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small

number of patients, usually involving no more than several hundred subjects.

(c) Phase 3. Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.

21 C.F.R. § 312.23: IND Content and Format

(a) A sponsor who intends to conduct a clinical investigation subject to this part shall submit an "Investigational New Drug Application" (IND) including, in the following order:

. . .

(8) Pharmacology and toxicology information. Adequate information about pharmacological and toxicological studies of the drug involving laboratory animals or in vitro, on the basis of which the sponsor has concluded that it is reasonably safe to conduct the proposed clinical investigations. The kind, duration, and scope of animal and other tests required varies with the duration and nature of the proposed clinical investigations. Guidance documents are available from FDA that describe ways in which these requirements may be met. Such information is required to include the identification and qualifications of the individuals who evaluated the results of such studies and concluded that it is reasonably safe to begin the proposed investigations and a statement of where the investigations were conducted and where the records are available for inspection. As drug development proceeds, the sponsor is required to submit informational amendments, as appropriate, with additional information pertinent to safety.

(i) Pharmacology and drug disposition. A section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known.

(ii) Toxicology.

(a) An integrated summary of the toxicological effects of the drug

in animals and in vitro. Depending on the nature of the drug and the phase of the investigation, the description is to include the results of acute, subacute, and chronic toxicity tests; tests of the drug's effects on reproduction and the developing fetus; any special toxicity test related to the drug's particular mode of administration or conditions of use (e.g., inhalation, dermal, or ocular toxicology); and any in vitro studies intended to evaluate drug toxicity.

(b) For each toxicology study that is intended primarily to support the safety of the proposed clinical investigation, a full tabulation of data suitable for detailed review.

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21 C.F.R. § 314.80:
Postmarketing Reporting of Adverse Drug Events

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(b) Review of adverse drug experiences. Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section must also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

(c) Reporting requirements. The applicant must submit to FDA adverse drug experience information as described in this section. Except as provided in paragraph (g)(2) of this section, these reports must be submitted to the Agency in electronic format as described in paragraph (g)(1) of this section.

(1) (i) Postmarketing 15–day “Alert reports”. The applicant must report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but no later than 15 calendar days from initial receipt of the information by the applicant.

(ii) Postmarketing 15–day “Alert reports”—followup. The applicant must promptly investigate all adverse drug

experiences that are the subject of these postmarketing 15–day Alert reports and must submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information.

. . .

(2) Periodic adverse drug experience reports.

(i) The applicant must report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals. The applicant must submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency may reestablish a quarterly reporting requirement following the approval of a major supplement. Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

(ii) Each periodic report is required to contain:

(A) Descriptive information.

(1) A narrative summary and analysis of the information in the report;

(2) An analysis of the 15–day Alert reports submitted during the reporting interval (all 15–day Alert reports being appropriately referenced by the applicant's patient identification code, adverse reaction term(s), and date of submission to FDA);

(3) A history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

(4) An index consisting of a line listing of the applicant's patient identification code, and adverse reaction term(s) for all ICSRs submitted under paragraph (c)(2)(ii)(B) of this section.

(B) ICSRs for serious, expected, and nonserious adverse drug experiences. An ICSR for each adverse drug experience not reported under paragraph (c)(1)(i) of this section (all serious, expected and nonserious adverse drug experiences). All such ICSRs must be submitted to FDA (either individually or in one or more batches) within the timeframe specified in paragraph (c)(2)(i) of this section. ICSRs must only be submitted to FDA once.

(iii) Periodic reporting, except for information regarding 15–day Alert reports, does not apply to adverse

drug experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience.

21 C.F.R. 314.81: Other Postmarketing Reports

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(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

. . .

(2) Annual report. The applicant shall submit each year within 60 days of the anniversary date of U.S. approval of the application, two copies of the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2252 (Transmittal of Periodic Reports for Drugs for Human Use), and must include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval that ends on the U.S. anniversary date. The report is required to contain in the order listed:

. . .

(vi) Clinical data.

(a) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in

which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(b) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

. . .

21 C.F.R. 314.92: Drug products for which abbreviated applications may be submitted

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A "listed drug" is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term "same as" means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered for sale by its manufacturer, a person who wishes to submit an abbreviated new drug application for the drug shall comply with § 314.122.

. . .

105 Mass. Code Regs. 720.200:
Massachusetts List of Interchangeable Drugs

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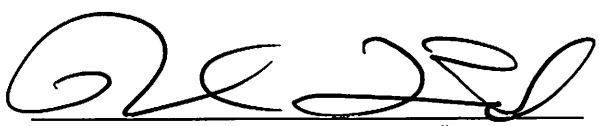
PRESCRIPTION FORM

M.G.L. c. 112, § 12D mandates prescription forms with one signature line. If the prescriber signs the prescription form and writes the words “no substitution” in his/her own handwriting in the space provided below the signature line, the pharmacist must fill the prescription exactly as indicated, with no interchange permitted. However, if the prescriber signs the prescription and does not write “no substitution” under his/her signature, the pharmacist is legally required to dispense a less expensive, equivalent interchangeable drug product listed in the Massachusetts List of Interchangeable Drugs if one is reasonably available.

. . .

RULE 16(k) CERTIFICATION

I, Paul W. Schmidt, counsel for *amici curiae* Pharmaceutical Research and Manufacturers of America, American Tort Reform Association, and National Association of Manufacturers in the foregoing action, hereby certify that the within brief complies with the rules of this Court that pertain to the filing of briefs, including, but not limited to: Mass. R.A.P. 16(a)(6) (pertinent findings or memorandum of decision); Mass. R.A.P. 16(e) (references to the record); Mass. R.A.P. 16(f) (reproduction of statutes, rules, regulations); Mass. R.A.P. 16(h) (length of briefs); Mass. R.A.P. 18 (appendix to the briefs); and Mass. R.A.P. 20 (form of briefs, appendices, and other papers).



Paul W. Schmidt, BBO #640488

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PROOF OF SERVICE

I, Paul W. Schmidt, hereby certify that, on August 25, I caused the foregoing to be served via first class mail upon the Clerk for the Commonwealth and the following counsel of record in this case:

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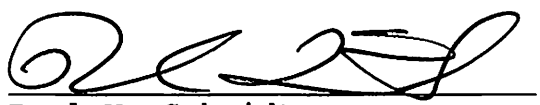
I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 25th day of August, 2017.



Paul W. Schmidt