Supreme Judicial Court

FOR THE COMMONWEALTH OF MASSACHUSETTS

NO. SJC-12347

MIDDLESEX COUNTY

BRIAN RAFFERTY,
PLAINTIFF-APPELLANT,

v.

MERCK & CO., INC. & ANOTHER,
DEFENDANTS-APPELLEES.

ON APPEAL FROM A JUDGMENT OF THE SUPERIOR COURT

BRIEF OF *AMICUS CURIAE*
MASSACHUSETTS DEFENSE LAWYERS ASSOCIATION

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Dated: October 23, 2017

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STATEMENT OF THE INTEREST OF THE *AMICUS CURIAE*

The Massachusetts Defense Lawyers Association ("MassDLA"), *amicus curiae*, is a voluntary, non-profit, statewide professional association of trial lawyers who defend corporations, individuals and insurance companies in civil lawsuits. Members of the MassDLA do not include attorneys who, for the most part, represent claimants in personal injury litigation. The purpose of the MassDLA is to improve the administration of justice, legal education and professional standards, and to promote collegiality and civility among members of the Bar.

To promote its objectives, MassDLA participates as *amicus curiae* in cases raising issues of importance to its members, their clients and the judicial system. The MassDLA believes that this is such a case and that its perspective can assist the Court in resolving the important issues raised by this appeal.

STATEMENT OF THE ISSUES PRESENTED

Whether the manufacturer of a name-brand[1] pharmaceutical may be liable for its failure to warn users of a generic pharmaceutical manufactured and sold by a third-party.

STATEMENT OF THE CASE

The MassDLA, as *amicus curiae*, adopts the parties' statement of the case regarding the prior proceedings.

STATEMENT OF THE FACTS

The MassDLA, as *amicus curiae*, adopts defendant-appellee Merck & Co., Inc. ("Merck")'s statement of the facts.

ARGUMENT

The role of this Court is to interpret the law, not to create it. See Rosenbloom v. Kokofsky, 373 Mass. 778, 780 (1977) ("The scope of the authority of this court to interpret and apply statutes is limited by its constitutional role as a judicial, rather than a

[1] As used herein, the terms "name-brand pharmaceutical" and "name-brand drug" shall refer to those drugs subject to the provisions set forth in 21 U.S.C. § 355(b)(1)(A). The terms "generic pharmaceutical" and "generic drug" shall refer to those drugs subject to the provisions set forth in 21 U.S.C. § 355(j).

legislative, body"). See also School Comm. of Springfield v. Board of Ed., 362 Mass. 417, 458-59 (1972) ("although we will pass on questions of law related to the interpretation and the enforcement of the statute, it is not appropriate for us to enter directly into ... strictly administrative function[s] committed to agencies of the executive department of government").

In interpreting the law, this Court's "primary duty ... is to effectuate the intent of the Legislature in enacting" the law. Global NAPs, Inc. v. Awiszus, 457 Mass. 489, 496 (2010) (citation omitted).

"It is not the province of courts to add words to a statute that the Legislature did not choose to put there in the first instance," (Awiszus, 457 Mass. at 496), nor is it the place of the courts to create new statutory remedies or duties Congress never intended. Passatempo v. McMenimen, 461 Mass. 279, 287 (2012) (declining to interpret a statute as creating new remedies not intended by Congress). See also McGonagle v. United States, 155 F.Supp.3d 130, 136 (D. Mass. 2016) ("courts should not create new bases for liability"); Richard v. Dimonte, No. 09-2265, 2010 WL 4483739, at *1 (Mass. App. Ct. Nov. 10, 2010) ("the creation of new

duties ... should appropriately be reserved for the Legislature").

Appellant Brian Rafferty asks this Court to reverse the Superior Court's decision, (Rafferty v. Merck & Co., Inc., No. 13-04459, 2016 WL 3064255 (Mass. Super. Ct. May 23, 2016)), and hold Merck, as the manufacturer of a name-brand pharmaceutical, liable for its alleged failure to warn Mr. Rafferty of the alleged hazards and potential ill-effects of a similar generic drug neither manufactured nor sold by Merck. As set forth below, existing case law does not support Mr. Rafferty's position. Nor is there any indication Congress intended to create any duty on the part of name-brand manufacturers to warn about generic products they neither manufactured nor sold. See H.R. Rep. 98-857, 9-10 (1984) (setting forth Congress's intentions in enacting the Hatch-Waxman Act). To adopt Mr. Rafferty's position, this Court would therefore have to create a new duty which does not presently exist. The creation of new law, new duties, and new remedies is the function of the Legislature, not this Court.

The MassDLA respectfully urges, therefore, that the Court affirm the decision of the Superior Court, (Rafferty v. Merck & Co., Inc., No. 13-04459, 2016 WL

3064255 (Mass. Super. Ct. May 23, 2016)), and hold that, Merck may not be held liable for its alleged failure to warn Mr. Rafferty, the user of a generic pharmaceutical manufactured and sold by a third party.

I. CONGRESS' INTENTION IN ENACTING THE HATCH-WAXMAN ACT WAS TO ACCELERATE THE INTRODUCTION OF NEW DRUGS AND CHEAPER GENERIC DRUGS INTO THE MARKET.

In 1984, Congress enacted the Hatch-Waxman Act, an amendment to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, et seq. In enacting the Hatch-Waxman Act, Congress intended to expedite the introduction of new drugs into the market, and to "make available more low cost generic drugs by establishing a generic drug approval procedure." PLIVA, Inc. v. Mensing, 564 U.S. 604, 627-28 (2011) (quoting H.R. Rep. No. 98-857, pt. 1, p. 14 (1984)).

Before receiving approval from the Food and Drug Administration ("FDA"), a brand-name drug manufacturer must first submit a new-drug application ("NDA"), which includes, among various other information, "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." 21 U.S.C. § 355(b)(1)(A). The FDA requirements for an NDA are extensive, demonstrating the

rigorous nature of the application process. See 21 C.F.R. § 314.50. Statutory standards for NDAs also call for "specimens of the labeling propose[d] to be used for such drug." 21 U.S.C. § 355(b)(1)(F).

Many observers have criticized the approval process for new, brand-name drugs in this country as immensely time-consuming and resource-exhausting. See, e.g., David W. Jordan, International Regulatory Harmonization: A New Era in Prescription Drug Approval, 25 Vand. J. Transnat'l L. 471, 488-90 (1992) (analyzing the "drug approval lag" in the U.S. and the more rapid availability of new drugs in other countries); Kleinfeld et al., Human Drug Regulation: Comprehensiveness Breeds Complexity, ed., Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law 242 (Food and Drug Law Institute, 1984) (discussing the "pervasive" regulatory framework covering drug products); Henry Grabowski, Regulation and the International Diffusion of Pharmaceuticals, in The International Supply of Medicine 5, 7-8 (Robert Helm ed., 1980).

The Hatch-Waxman Act was Congress' effort to overcome the arduous nature of the approval of brand-name drugs and "to streamline the process." Wansheng Jerry Liu, Balancing Accessibility and Sustainability:

How to Achieve the Dual Objectives of the Hatch-Waxman Act, 18 Alb. L. J. Sci. & Tech. 441, 447 (2008). See Kimiya Sarayloo, A Poor Man's Tale of Patented Medicine: The 1962 Amendments, Hatch-Waxman, and the Lost Admonition to Promote Progress, 18 Quinnipiac Health L. J. 1, 17 (2015) (describing the marked increase in drug approval costliness under the previous framework); Elizabeth Stotland Weiswasser & Scott D. Danzis, The Hatch-Waxman Act: History, Structure, and Legacy, 71 Antitrust L.J. 585, 590 (2003) ("The Hatch-Waxman Act was enacted as compromise legislation between the competing interests in making available lower cost generic drugs and preserving incentives to develop new drugs").

The Hatch-Waxman Act established a system of abbreviated new drug applications ("ANDA"), 21 U.S.C. § 355(j), which accelerate the FDA's approval of generic drugs. Specifically, the Hatch-Waxman Act allows manufacturers of generic drugs to more quickly obtain FDA approval by demonstrating: (1) the generic drug is compositionally equivalent to a name-brand drug approved by the FDA; (2) the generic drug has the same method of administration, dosage, and strength as an approved name-brand drug; and (3) the labeling proposed for the

[generic] is the same as the labeling approved for the [brand-name] drug 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a)(8)(iii).

The United States Supreme Court recently discussed the Hatch-Waxman Act's impact on the relationship between brand-name and generic manufacturers, particularly as it relates to labeling requirements. See Mutual Pharmaceutical, Inc. v. Bartlett, 133 S. Ct. 2466 (2013); PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011). Specifically, the Court held that, because generic manufacturers, pursuant to statutory and regulatory mandate, must maintain identical warning labels as their brand-name counterparts, (Bartlett, 133 S. Ct. at 2470. Mensing, 564 U.S. at 617-18), generic drugs enjoy a "swifter rate for approval," while name-brand products must undergo the traditional "onerous and lengthy" application process set forth under the Food, Drug, and Cosmetic Act. Bartlett, at 2471.

In enacting the Hatch-Waxman Act, Congress struck a balance — it provided a means for generic drug manufacturers to introduce their products to the public at a faster rate than before, while still ensuring brand-name manufacturers are motivated to develop new drugs. See Weiswasser, supra, at 590.

II. MANUFACTURERS HAVE NO DUTY TO WARN INDIVIDUALS WHO DO NOT USE THEIR PRODUCT.

A. Manufacturers have no duty to warn users about potential defects in a third-party's products.

Under existing Massachusetts law, Mr. Rafferty cannot establish Merck owed him any duty, because Mr. Rafferty did not use, and was not harmed by, any Merck product. See Mitchell v. Sky Climber, Inc., 396 Mass. 629, 631 (1986) ("A manufacturer of a product has a duty to warn foreseeable users of dangers in the use of that product of which he knows or should have known ... We have never held a manufacturer liable, however, for failure to warn of risks created solely in the use or misuse of the product of another manufacturer.") (emphasis added); 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"); Garcia v. Kusan, Inc., 39 Mass. App. Ct. 322, 329 (Mass. App. Ct. 1995) (In the absence of special circumstances, [a plaintiff] may not recover for instructions and representations concerning the use of other manufacturers' [products] and may only recover if he can establish that some item traced to a specific

defendant caused his injury"); Freitas v. Emhart Corp., 715 F. Supp. 1149, 1152 (D. Mass. 1989) ("Defendant ... cannot be held liable unless there was a defect in the parts it sold or it was responsible for designing the [allegedly defective product] in question"); In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig., 756 F.3d 917, 938 (6th Cir. 2014) ("it is well-settled law that the threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury").

Not only have Massachusetts Courts generally declined to hold manufacturers liable for harm to users of products created by other manufacturers (Mitchell, 396 Mass. at 631), at least one Massachusetts Court has specifically declined to hold name-brand drug manufacturers liable to users of generic drugs they neither manufactured nor sold. See Kelly v. Wyeth, No. 03-03314, 2005 WL 4056740 (Mass. Super. Ct. May 6, 2005) (rejecting "innovator liability" theory, and holding name-brand drug manufacturer was not liable to user of generic drug). And, as set forth in Merck's Appellate Brief (pp. 11-18), most State and Federal Courts addressing this issue have also held that name-brand drug manufacturers may not be held liable for injuries

suffered by users of equivalent generic drugs manufactured and sold by third-parties.

B. The fact Merck created a label which the generic drug manufacturer later copied does not impose a duty to warn on Merck.

Although Mr. Rafferty admits Massachusetts Courts have never held a manufacturer of name-brand drugs owes a duty to users of a generic drug it neither manufactured nor sold (See Rafferty Brief, p. 5), Mr. Rafferty claims that such a duty should exist, and encourages this Court to create one. As set forth above, it is not the place of this Court to create new duties or to create new law. Awiszus, 457 Mass. at 496; Passatempo, 461 Mass. at 287; Richard, 2010 WL 4483739 at *1; McGonagle, 155 F.Supp.3d at 136.

Mr. Rafferty claims that the warning label for the generic drug he used was identical to a label Merck created for its equivalent name-brand drug, and that the label was defective. See Rafferty Brief, pp. 3-4, 7-23. Mr. Rafferty further claims that, because Merck created the warning label for its own name-brand product, Merck owed a duty to warn Mr. Rafferty of the generic drug's potential dangers, despite the fact Merck did not manufacture or sell the generic drug. Id.

Other plaintiffs have raised this argument in courts throughout the country, but have been largely unsuccessful in doing so. See, e.g., Foster v. Am. Home Prod. Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("We ... reject the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug ... there is 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, over whose production the name brand manufacturer had no control"); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 184 (5th Cir. 2012) ("[non]-viability of suits against generic manufacturers ... does not impose on name-brand manufacturers a duty of care to customers using generic products"); Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011) ("As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company"); In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig., 756 F.3d 917, 938 (6th Cir. 2014) ("we note that an overwhelming majority of courts, in at least fifty-five

decisions from twenty-two states, have rejected the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug"). See also Merck Brief, pp. 11-18.

Although the majority of courts addressing this issue have held manufacturers of name-brand drugs owe no duty to users of generic products, Mr. Rafferty urges the Court to follow the small minority of courts who have imposed a duty to warn on the part of name-brand manufacturers. See Rafferty Brief, pp. 31-32.

Even these cases, when more closely examined, do not actually support Mr. Rafferty's position. For example, in both Conte v. Wyeth and Kellogg v. Wyeth, (both cited by Mr. Rafferty in his Brief), the Court held there was some evidence Plaintiff's doctor relied on information provided by Wyeth (the name-brand drug manufacturer) about Reglan (the name-brand drug). Conte v. Wyeth, 168 Cal.App.4th 89, 98-99 (2008); Kellogg v. Wyeth, 762 F.Supp.2d 694, 701-02 (D. Vt. 2010). Accordingly, both Courts held Wyeth was not entitled to summary judgment on plaintiff's failure to warn claims. Conte, 168 Cal.App.4th at 98-99; Kellogg, 762 F.Supp.2d at 701-02.

Unlike in Conte and Kellogg, Mr. Rafferty's claims are not based on alleged defects in warnings or information provided by Merck in association with a Merck product. Rather, Mr. Rafferty claims that Merck is somehow responsible for the labeling of a generic drug neither manufactured nor sold by Merck. As set forth above, the majority of courts addressing this argument have rejected it, and the rulings in Conte and Kellogg should not persuade this Court to do otherwise.

III. THIS COURT SHOULD NOT INTERPRET THE HATCH-WAXMAN ACT AS CREATING NEW DUTIES NOT INTENDED BY CONGRESS.

This Court should not interpret the Hatch-Waxman Act as creating new duties never intended by Congress, particularly because such an interpretation would undermine Congress' intent in enacting the statute.

A. In enacting the Hatch-Waxman Act, Congress did not intend to introduce new duties on the part of name-brand drug manufacturers.

In enacting the Hatch-Waxman Act, Congress intended only to "make available more low cost generic drugs by establishing a generic drug approval procedure" (Mensing, 564 U.S. at 627-28), while encouraging brand-name manufacturers to develop new drugs. See H.R. Rep. 98-857, 9-10 (1984) ("In this case, Congress ...

balance[d] the need to stimulate innovation against the goal of furthering the public interest ... That is all this bill does")(emphasis added).

There is no indication in the Hatch-Waxman Act itself, the corresponding Congressional Reports, or the subsequent case law that Congress ever intended to require name-brand drug manufacturers to warn against the potential harms of generic products they neither manufactured nor sold. Nor does Mr. Rafferty cite any authority indicating Congress ever had such an intent.

Indeed, as set forth more fully in Merck's Brief to this Court (pp. 20-23) and the Amicus Brief of the Pharmaceutical Research Manufacturers (pp. 20-28), Mr. Rafferty's position, if adopted, would create disincentives for manufacturers of name-brand drugs from engaging in the "onerous and lengthy" application process set forth under the Food, Drug, and Cosmetics Act. See Bartlett, at 2471.

B. The Court must exercise judicial restraint in interpreting the Hatch-Waxman Act.

This Court should not engage in judicial policymaking and disrupt the extensive legislative and regulatory framework discussed above. It cannot create new duties not currently found in existing law, but must

instead exercise judicial restraint – a principle fundamental to the separation of powers within the Government. See, e.g., Knox v. Service Employees Int'l Union, Local 1000, 567 U.S. 298, 323 (2012) (Sotomayor, J., concurring) ("the majority breaks our own rules and, more importantly, disregards principles of judicial restraint that define the Court's proper role in our system of separated powers"); Joslyn v. Chang, 445 Mass. 344, 351 (2005) (referring to the "principle of judicial restraint embodied in art. 30 of the Massachusetts Declaration of Rights").

Massachusetts courts properly defer to legislative decision-making, recognizing the limited scope of their functions as a judicial actor. See Shell Oil Co. v. City of Revere, 383 Mass. 682, 687 (1981) ("Our deference to legislative judgments reflects neither an abdication of nor unwillingness to perform the judicial role; but rather a recognition of the separation of powers and the 'undesirability of the judiciary substituting its notion of correct policy for that of a popularly elected Legislature.'" (quoting Zayre Corp. v. Attorney General, 372 Mass. 423, 433 (1977)). See also Lunn v. Commonwealth, 477 Mass. 517, 534 (2017) ("The prudent course is not for this court to create, and attempt to

define, some new authority ... The better course is for us to defer to the Legislature to establish and carefully define that authority if the Legislature wishes that to be the law of this Commonwealth"); Public Emp. Retirement Admin. Comm'n v. Bettencourt, 474 Mass. 60, 78 (2016) ("These types of determinations are ones that fit squarely within the legislative, not the judicial, domain, and we believe that the more prudent approach is to defer to the Legislature for its resolution of such issues in the first instance"); Hancock v. Comm'r of Education, 443 Mass. 428, 456 (2005) ("'We are, of course, mindful ... of the responsibility ... to defer to the Legislature in matters of policymaking.'" (quoting Campaign for Fiscal Equity, Inc. v. State, 801 N.E.2d 326, 345 (N.Y. 2003))).

Not only must the Court defer to the Legislature, it also must defer to the FDA- as it is the administrative agency responsible for the implementation and enforcement of the Hatch-Waxman Act. See, e.g., Bd. of Health of Sturbridge v. Bd. of Health of Southbridge, 461 Mass. 548, 562 (2012); Seagram Distillers Co. v. Alcoholic Beverages Control Comm'n, 401 Mass. 713, 721 (1988); School Comm. of Wellesley v. Labor Relations Comm'n, 376 Mass. 112, 120 (1978); School Comm. of Boston

v. Bd. of Education, 363 Mass. 125, 128 (1973); Hickey v. Comm'r of Public Welfare, 38 Mass. App. Ct. 259, 262 (1995).[2]

IV. BRAND-NAME MANUFACTURERS SHOULD NOT BE HELD LIABLE FOR FAILURE TO WARN ABOUT GENERIC DRUGS WHICH ARE INHERENTLY DIFFERENT PRODUCTS.

In order to receive FDA approval, a proposed generic drug must demonstrate that the generic is "bioequivalent" to a reference-listed drug. Bioequivalence "may be demonstrated by several in vivo and in vitro methods," and is defined as "[t]he absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. §§ 320.1, 320.24(a).

[2] In the rulemaking context, agencies are granted a substantial amount of latitude in crafting standards pursuant to a statutory grant of power. See e.g., ENGIE Gas & LNG LLC v. Dep't of Public Utilities, 475 Mass. 191, 197 (2016); Massachusetts Teachers' Retirement System v. Contributory Retirement Appeal Bd., 466 Mass. 292, 297 (2013); Biogen IDEC MA, Inc. v. Treasurer and Receiver General, 454 Mass. 174, 187 (2009); Student No. 9 v. Bd. of Education, 440 Mass. 752, 762 (2004).

Two treatments are generally considered similar enough to one another, although not the same, after being analyzed with a confidence interval (CI) approach. See Food and Drug Administration, Draft Guidance for Industry on Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application (ANDA) (Dec. 2013). Bioequivalence is ultimately a comparison of similarity to a reference drug, and is limited to between eighty to one-hundred and twenty five percent (80 – 125%) for the ratio of product averages of peak concentration of a drug. See Guidance for Industry: Statistical Approaches to Establishing Bioequivalence, US Department of Health and Human Services, January 2001, p. 5. Bioequivalence studies compare the rate and extent of absorption of various drug formulations, and the result must be within a certain range (80 – 125% ratio of the product averages) in order for a given generic drug to be permitted to enter the market. See Bioavailability and Bioequivalence Requirements, 21 CFR 320.24; Food and Drug Administration, Guidance for Industry: Statistical Approaches to Establishing Bioequivalence, January 2001, pp. 2-7.

Although generic drugs must have certain similarities to their name brand equivalents, they are not identical. Omar Vesga, et al., Generic Vancomycin Products Fail In Vivo Despite Being Pharmaceutical Equivalents of the Innovator, 54 Antimicrob. Agents Chemother, 3271-79 (2010). Specifically, "Generic versions of intravenous [drugs] are not required to demonstrate therapeutic equivalence," because "it may be considered self-evident" that generics are similar enough to their brand-name counterparts. Id. However, studies have been done which demonstrate the differences between apparently identical drugs. For instance, one study noted that when examining two antimicrobial products which were indistinguishable from the brand-name drug in terms of concentration, potency, and protein binding, among numerous other criteria, but these generics were completely ineffective at killing the targeted bacteria. Id. The authors noted that some generic products were able to reach the levels of effectiveness of the brand-name drug, but only after buying manufacturing secrets from the original innovator. Id. Although this study did not address negative side effects, it does serve to demonstrate that

significant differences exist between generic and brand-name drugs, even when the two are seemingly identical.

In other contexts, there are concerns regarding substitution of generics for a brand-name drug. See Teun van Gelder, European Society for Organ Transplantation Advisory Committee Recommendations on Generic Substitution of Immunosuppressive Drugs, 24 Transplant International 1135-41 (2011) (considering the same bioequivalence standards as used by the US Food and Drug Administration). Some medical professionals doubt the safety of such substitutions in clinical settings where patients are especially sensitive to slight differences in their drug exposures. Id. This is particularly an issue where prescribers are unaware that pharmacists are dispensing alternate formulations. Id. Should generics be treated as identical to brand-name formulations, long-term outcomes for patients can be impacted. Id.

As discussed above, physicians have noted that brand-name and generic drugs are not necessarily interchangeable. This may result from the brand-name manufacturing secrets which, even once patents are lifted, are beyond the ability of generic manufacturers to reproduce. Any differences that may exist are beyond the power of the brand name manufacturer to control, and

the brand name manufacturer should not be held liable for failure to warn about products which are non-identical, and injuries which may be unforeseeable due to the inherent differences in generic and name-brand products. While generics serve a valuable public function, this value should not lead to pretending that two different drugs are the same simply for the cost-saving benefits.

V. THE INCLUSION OF TOO MANY WARNINGS ON A DRUG WOULD LEAD TO DILUTION OF WARNINGS AND WOULD DIMINISH THE EFFECT OF ALL WARNINGS

If a name-brand drug manufacturer failed to warn about a foreseeable side effect that might result from consumption of its own drugs, this failure to warn could be the basis of a lawsuit. Here, however, Mr. Rafferty accuses Merck of failing to include on its warning label side effects concerning a generic drug. As a matter of public policy, name-brand drug manufacturers should not be required to warn of every possible side effect of every possible alternate configuration of their drug. Not only is it impossible to anticipate every possibility, but drug warnings will cease to be useful if they are over-inclusive.

Courts have acknowledged that including too many warnings on a product "would decrease the effectiveness of all of the warnings." Broussard v. Cont'l Oil Co., 433 So.2d 354, 358 (La. Ct. App. 1983), writ denied, 440 So.2d 726 (La. 1983). The United States Supreme Court has held, "[m]eaningful disclosure does not mean *more* disclosure. Rather it describes a balance between "competing considerations of complete disclosure ... and the need to avoid ... [informational overload]." Ford Motor Credit Co. v. Milhollin, 444 U.S. 555, 568 (1980), citing S.Rep. 96-73, p. 3 (1979) (accompanying S. 108, Truth in Lending Simplification and Reform Act).

When Congress considered how to regulate the sale and distribution of packages of hazardous substances in 1960, it noted:

> If labeling were required to caution against the risk of even the most trifling indisposition, there would hardly be any substance going into the household which would not have to bear cautionary labeling, so that consumers would tend more and more to disregard label warning, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury.

1960 U.S.C.C.A.N. 2833, 2837.

For warnings on drugs to be valuable, they must only warn consumers of hazards which have some

reasonable degree of probability of occurring. Warnings should pertain only to the specific drug at issue in its exact formulation. Name-brand drug manufacturers should not be required to expand their labels to cover unforeseeable side effects which, under the brand name formulation, might even be impossible. Indeed, selecting the most important warnings to include improves the likelihood that those warnings which are most dire will be read, understood, and heeded, based on analysis of Restatement authors, judges, and Congress.

VI. THE COURT CANNOT CREATE NEW DUTIES SIMPLY BECAUSE MR. RAFFERTY WILL OTHERWISE BE WITHOUT A REMEDY.

Mr. Rafferty's brief to this Court focuses on the fact that, if the Court fails to create in name-brand drug manufacturers a new duty to warn, Mr. Rafferty will be left without remedy. See Brief of Plaintiff-Appellant Brian Rafferty, pp. 23-28.

Specifically, Mr. Rafferty claims that, because the United States Supreme Court has held failure to warn claims against generic drug manufacturers are pre-empted by the Hatch-Waxman Act (see Mensing, at 624), he should be able to proceed against the name-brand drug manufacturer Merck, despite Merck never having manufactured or sold the offending product.

It is unfortunate that those injured through their reliance upon the warning labels of generic drugs may be left without recourse. This does not justify, however, the abandonment of bedrock legal principles. See Bartlett, at 2478 ("sympathy ... does not relieve us of the responsibility of following the law").

To the extent the law must be changed to provide individuals like Mr. Rafferty a remedy, it is Congress which must change it. This Court, while properly tasked with interpreting laws like the Hatch-Waxman Act, is not equipped with the requisite expertise to take an active role in changing the law. See Huck v. Wyeth, Inc., 850 N.W.2d 353, 377 (Iowa 2014) ("courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals"); Dunham v. Ware Sav. Bank, 384 Mass. 63, 73 (1981) ("Although the question we decide today is a proper subject for judicial determination, the competing policies at issue in this case make it ideally suited to legislative resolution").

While it may seem unfair that Mr. Rafferty cannot sue either the generic or name-brand drug manufacturer for failure to warn, it is not this Court's role to

determine whether a piece of legislation like the Hatch-Waxman Act is unfair or unwise. See, e.g., Mensing, at 625-26 ("'[I]t is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" (quoting Cuomo v. Clearing House Ass'n, L.L.C., 557 U.S. 519, 556 (2009))); Suliveres v. Commonwealth, 449 Mass. 112, 116-17 (2007); Commonwealth v. Leno, 415 Mass. 835, 841 (1993) ("Whether a statute is wise or effective is not within the province of courts"); Mellor v. Berman, 390 Mass. 275, 283 (1983) ("It is not for this court to judge the wisdom of legislation or to seek to rewrite the clear intention expressed by the statute").

The importance of exercising judicial restraint under these circumstances is reflected in the FDA's efforts to rework the present regulations on drug labeling. See Supplemental Application Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314 and 601). The agency intends to alter the present legal framework in order to avoid the labeling and preemption issues raised in the instant case. See Bartlett, at 2470. The relevant text of the proposal reads:

> FDA is proposing to amend its regulations to revise and clarify procedures for application holders to change the labeling of an approved drug or biological product to reflect certain types of newly acquired information…The proposed rule would create parity among application holders with respect to these safety-related labeling changes by permitting [generic manufacturers] to distribute revised generic drug labeling that differs in certain respects ...

Supplemental Application Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985. This demonstrates the willingness of the FDA, which maintains the most advantageous and familiar position with regard to the labeling requirements, to craft real changes that would provide a more concrete solution than the one presently before this Court.

CONCLUSION

The role of this Court is to interpret the law in such a manner as will effectuate the intent of Congress in enacting it. See Rosenbloom, 373 Mass. at 780; School Comm. of Springfield, 362 Mass. at 458-59; Awiszus, 457 Mass. at 496.

Here, Mr. Rafferty not only asks the Court to create new law, he also asks the Court, in doing so, to undermine Congress' clear intent in enacting the Hatch-Waxman Act. Existing Massachusetts case law does not

support Mr. Rafferty's position. The majority of courts considering this issue have rejected Mr. Rafferty's argument.

While it is unfortunate Mr. Rafferty finds himself without a remedy, sympathy alone is no justification for this Court to go against clear Congressional intent, fundamental Massachusetts product liability law, and the majority of Courts who have decided this issue. Bartlett, 133 S. Ct. at 2478 ("sympathy ... does not relieve us of the responsibility of following the law").

Therefore, the *amicus curiae*, MassDLA respectfully requests that this Court affirm the Superior Court's decision and hold manufacturers of name-brand drugs like Merck may not be held liable for their failure to warn users of a generic pharmaceutical manufactured and sold by third parties.

Respectfully submitted,
MASSACHUSETTS DEFENSE LAWYERS ASSOCIATION

By its attorneys,

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Dated: October 23, 2017

MASS. R. A. P. 16(k) CERTIFICATION

I hereby certify that this brief complies with the rules of the court including but not limited to Mass. R.A.P. 16a 18 and 20.

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