Supreme Judicial Court

FOR THE COMMONWEALTH OF MASSACHUSETTS
No. SJC-12904

Norfolk, ss.

PATRICIA M. DUNN, Appellee

v.

GENZYME CORPORATION, -Appellant

On Appeal As A Certified Question From
The Order Of The Appeals Court
Case No. 2019-P-1140

BRIEF OF *AMICUS CURIAE*
MASSACHUSETTS DEFENSE LAWYERS ASSOCIATION
IN SUPPORT OF REVERSAL OF SUPERIOR COURT'S ORDER

Date: 08/21/2020

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STATEMENT OF INTEREST

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.

DECLARATION PURSUANT TO MASS. R. A. P. 17(c)5

Pursuant to Massachusetts Appellate Procedure Rule 17(c)5, *amicus curiae* hereby declares the following:

a. This brief was not authored in whole or in part by any party;

b. The preparation or submission of this brief was not funded by any party;

c. Final publishing of this brief was done with the assistance of Bateman & Slade, Inc., 263 Main Street, Stoneham, Massachusetts 02180 at no charge to the MassDLA. No other person or entity, other than the *amicus*

curiae, contributed money intended to fund the preparation or submission of this brief.

d. The *amicus curiae* does not represent and has not represented one of the parties to the present appeal in another proceeding involving similar issues, nor was the *amicus curiae* a party or represented a party in a proceeding or legal transaction that is at issue in the present appeal.

STATEMENT OF THE ISSUES PRESENTED

Whether Plaintiff's claims are preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act of 1938 or whether the plaintiff's "bare bones" allegations were sufficient to avoid federal preemption as so-called "parallel" state law claims pursuant to 21 U.S.C. § 360k(a) and Massachusetts law under Iannacchino v. Ford Motor Co., 451 Mass. 623 (2008).

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-Appellant Genzyme's Statement of the Facts.

INTRODUCTION

This case presents an issue that urgently merits review, namely, whether Plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 360c-1; 21 U.S.C. §§ 301 et seq., or whether the plaintiff's "bare bones" allegations were sufficient to avoid federal preemption as so-called "parallel" state law claims pursuant to 21 U.S.C. § 360k(a) and Massachusetts law under Iannacchino v. Ford Motor Co., 451 Mass. 623 (2008). Granting review of this case offers an important opportunity for this Court to uphold the intent of Congress with respect to express preemption of state claims under 21 U.S.C. § 360k, and to clarify the specific requirements that a plaintiff must meet to satisfy the narrow exception to preemption of a "parallel claim" under Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

SUMMARY OF THE ARGUMENT

Central to the Appellee's argument, and inherent in the Superior Court's decision, is that a pleading standard requiring facts to be pled that would demonstrate specific alleged violations of the MDA would somehow render a plaintiff's medical device claims impossible. The MassDLA is compelled to weigh in on the issue because Appellee's position would undermine Congress's clear intent of express preemption set forth in 21 U.S.C. § 360k(a). Allowing Appellee's factually deficient pleading to survive a motion to dismiss threatens to

erode the intent of Congress and would require medical device manufacturers to needlessly litigate cases that should otherwise be preempted. To assist with this inquiry, the MassDLA's brief will focus on three factors that are critical for the Court's analysis: (1) Congress's clear intent to provide broad preemption under the MDA, (2) the need for this Court to exercise judicial restraint and adhere to the express intent of the legislature, and (3) the importance of requiring a plaintiff to sufficiently plead facts that would allow a claim to survive under the narrow "parallel claims" exception articulated by the Supreme Court of the United States ("Supreme Court") in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

First, Article VI, Clause 2 of the Constitution of the United States of America, more commonly referred to as the "Supremacy Clause," establishes that "the Constitution, and the laws of the United States … shall be the supreme law of the land." U.S.C.S. CONST. ART. VI, CL. 2. It is a longstanding principle that state laws that conflict with federal laws are "without effect" and are therefore preempted. Altria Group v. Good, 555 U.S. 70 (2009) (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)). In enacting the MDA, Congress, by inclusion of a specific preemption clause, gave exclusive jurisdiction to regulate medical devices to the federal government, and more specifically the Food and Drug Administration ("FDA"). The Supreme Court carved out an explicit, albeit narrow, exception to federal preemption under the MDA, allowing state claims that

"parallel" federal requirements to survive. See Riegel, 552 U.S. at 316. Because Congress included an explicit preemption clause, plaintiffs must plead sufficient facts to show their state claims truly parallel, rather than add to or differ from, particular obligations set by the MDA and FDA regulations in order to overcome a presumption of preemption. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996). pp. 13-20.

Second, 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 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"). 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). In light of the clear intentionality of Congress to broadly preempt any claim "which is different from, or in addition to, any requirement applicable under this chapter to the device," this Court should not attempt to carve out exceptions where a statute's plain meaning grants broad and exclusive power to an administrative agency,

especially in cases where Congress explicitly created the few exemptions it intended to allow. pp. 21-25.

Third, it is essential that a plaintiff not only sufficiently plead the facts of the case, but also plead the specific provisions of the MDA which are allegedly paralleled by the state cause of action so that the Court may determine whether the plaintiff has satisfied the narrow exception to preemption. Allowing Appellee's "bare bones" claims to survive undercuts Congress's clear intent to preempt such claims, and threatens to waste resources during a lengthy discovery process in order to dispose of unmeritorious claims. Since the Appellee in the present case has failed to do so, the Court should dismiss this case. While it is unfortunate Appellee finds herself without a state remedy, sympathy alone is no justification for this Court to go against clear Congressional intent, fundamental Massachusetts law, and the many other courts who have decided this issue. Mut. Pharm. Co. Inc. v. Bartlett, 133 S. Ct. 2466, 2478 (2013) ("sympathy ... does not relieve us of the responsibility of following the law"). pp. 25-29.

ARGUMENT

I. THE EXPRESS LANGUAGE OF 21 U.S.C. § 360k(a) CONFERS A BROAD FEDERAL PREEMPTION POWER WHICH WAS INTENDED BY CONGRESS.

Preemption under the MDA derives its power directly from the Supremacy Clause of the Constitution, U.S.C.S. CONST. ART. VI, CL. 2. By including the Supremacy Clause, the Constitutional framers clearly established that when state

laws conflict with federal laws, they are to be preempted. U.S.C.S. CONST. ART. VI, CL. 2. Courts have generally held that there is an initial assumption that the police powers of the states are not to be superseded by a federal act unless "that was the clear and manifest purpose of Congress." Lohr, 518 U.S. at 485. With respect to the MDA, Congress's intention is made clear through the inclusion of an express preemption clause which states, in relevant part, that:

> [N]o State or political subdivision for a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (2000); FDCA § 521(a).

Congress could easily have limited the MDA's preemption power language, but it did not; instead, it chose to use expansive language when drafting § 360k(a). When Congress enacts a specific preemption provision, that provision determines the intent of Congress as to the preemptive effect of the statute." See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992). Here, Congress's broad preemption language was intentional and should be given the proper deference. Although some may find it hard to believe that Congress would remove judicial recourse for consumers injured by FDA-approved devices, "this is exactly what a preemption clause for medical devices does by its terms." Riegel, 552 U.S. at 326. As Justice

Neil Gorsuch pointed out in his opinion in Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1345 (10th Cir. 2015), the fact that Congress limited the first subcategory of section 2 in the MDA's preemption clause by subject matter ("safety or effectiveness"), the choice to use sweeping language ("or any other matter") for the second subcategory was deliberate and meaningful. Congress's use of "different language" for various parts within the same statute highlights the intentionality of each different phrase. See Roberts v. Sea-Land Servs., Inc., 566 U.S. 93, 102 (2012) (quoting Sosa v. Alvarez-Machain, 542 U.S. 692, 711 (2004)).

A. Congress intended to confer broad preemption power under the MDA to prevent divergent state requirements from unduly burdening interstate commerce.

Allowing state requirements to escape federal preemption and further restrict the medical device industry would add confusion, inconsistency, and inefficiency where Congress explicitly sought to preclude it. A closer look at the legislative history of § 360k further substantiates Congress's intent to create broad preemption power. In drafting the MDA, "the original objective was for FDA to have knowledge of all devices on the market so the Agency could prioritize and determine the appropriate classification and requirements." T. Wizemann, Institute of Medicine (US), *Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation* (2010). To this end, Congress rejected a Senate Bill that prohibited "requirements as to the performance,

composition, contents, design, finish, construction, packaging, or labeling of such products which are designed to deal with the same device" opting instead to adopt the current version, which prohibits "any requirement." Compare S.510, § 704; S. Rep. No. 94-33, at 33 (1975) with 21 U.S.C. § 360k. The choice shows Congress's intent to create a preemption power that does not mislead future litigants to believe there may be a loophole for certain uncontemplated possibilities for conflict between state and federal law.

If courts liberally find exceptions to preemption, state requirements will unduly burden device manufacturers, ultimately placing a strain on interstate commerce. Courts must be diligent in striking down state actions that directly or indirectly create obstacles to access or further expense for medical products placed in the chain of commerce. In addition to its effects on the availability of medical devices in various states, since expected costs of litigation are factored into the cost-benefit analyses for the research and manufacture of new products, liberal state tort litigation also increases the cost of medical devices for consumers. See Tomas Philipson & Eric Sun, *Is the Food and Drug Administration Safe and Effective?*, 22 J. ECON. PERSPECTIVES 1, 85-102 (Winter 2008). Congress's solution to problems like the inconsistency and cumulative effects of allowing states to impose such burdens are provisions like the MDA preemption provision,

which establishes an explicit hierarchy of authority, and courts should utilize the solutions Congress has provided for such issues.

B. Congress intended to confer broad preemption power under the MDA to discourage unnecessary restrictions that would stifle device innovation.

A second major goal underlying the adoption of the MDA was to encourage medical device development under strict federal oversight; to that end, Courts must prevent states from escaping preemption and placing additional and unnecessary restrictions on medical devices. See Ashley Abraham Williams, *Surviving Medical Device Preemption Under 21 U.S.C. 360k: Clarifying Pleading Standards for Parallel Claims in the Wake of Twombly and Iqbal*, 9 SETON HALL CIR. REV. 109, 112 (2013). Allowing states to impose restrictions beyond those set by the FDA introduces new hurdles, liability risks, and, consequently, expenses to manufacturers. Thus, heightened tort liability de-incentivizes investment into drugs that have both substantial benefits as well as significant side effects, which is typical of many drugs for serious illnesses such as cancer and multiple sclerosis. See Michael J. Moore & W. Kip Viscusi, *Product Liability Entering the Twenty-first Century: The U.S. Perspective*, 25-27 (2001).

Finding generous exceptions for state tort litigation of medical devices is also more likely than not a waste of the court's resources. The FDA already operates on an overly cautious basis. The FDA risks committing type I errors when

they wrongly approve a device, and type II errors when they wrongly reject a drug. See Michael D. Intriligator, *Drug Evaluations: Type I vs. Type II Errors*, UNIVERSITY OF CALIFORNIA (May 1, 1996). Economic investigation demonstrates the FDA errs on the side of committing type II errors, and over-rejecting, rather than over-approving. Id. Further, numerous studies show the FDA's hesitation in approving new devices negatively impacts benefits to new development while barely affecting device-related safety. Id. It follows that allowing state tort law to complicate and hinder the medical device regulatory process would have the same futile result in improving safety.

C. Congress intended to confer broad preemption power to keep regulation of medical devices in the well-equipped hands of the FDA rather than lay juries.

Congress also included the broad preemption clause in the MDA so that the FDA, and not lay juries, would maintain regulation over a complex subject matter. Congress recognized that the FDA is in the best position to effectively balance the intricacies of public health required in establishing and enforcing regulations on medical devices. After all, the FDA is an expert agency created for the sole purpose of protecting public health by both promptly approving beneficial drugs while also ensuring that drugs are safe. See U.S.C.S. §§ 393 b(1) and b(2) (2008). It is well-settled that any time Congress delegates authority to an agency, courts should show deference to the agency's interpretation of regulations and standards

within the agency's expertise. See Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 865 (1984).

The MDA established a regulatory scheme creating various levels of oversight, the most stringent of which applies to Class III medical devices such as those at issue in this case. The MDA mandates a rigorous Premarket Approval ("PMA") process for Class III devices which includes, *inter alia*, submission of a multivolume application by the device manufacturer which the FDA spends on average 1,200 hours reviewing. See Riegel, 552 U.S. at 318. The PMA ensures that thoughtful and carefully balanced decisions about medical devices are made. By the time a device has survived the PMA process, the federal government has "weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 929 (5th Cir. 2006) (citing Papike v. Tambrands, Inc., 107 F.3d 737, 741 (9th Cir. 1997)). There is no reason the federal government's conclusions in such cases should not have preemptive effect. See Gomez, 422 F.3d at 929.

In contrast to the FDA's unique position to make balanced judgments on these matters, lay juries often have difficulty remaining unprejudiced in medical

device cases. In fact, the Supreme Court has even recognized that juries are inherently biased toward plaintiffs in medical device cases because they have an injured plaintiff sitting in front of them, but they do not have patients who used the drug to their benefit in attendance to offset the perceived harm. See Riegel, 552 U.S. at 324. As the Riegel Court opined, it is implausible that the MDA was intended to confer greater power to set standards to any single state jury rather than to legislators, and this "perverse distinction is not required or even suggested by the broad language Congress chose in the MDA." Riegel, 552 U.S. at 325 citing Lohr, 518 U.S. at 504. Allowing lay juries to second-guess and disregard the FDA's conclusions on drug and device approvals and regulations undermines the very reasons the MDA was created and risks harming the public health system. See Howard L. Dorfman, Vivian M. Quinn, and Elizabeth A. Brophy, *Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate,* 61 FOOD & DRUG L.J. 585, 612 (2006). Because of this concern for bias inherent in lay juries, Congress unmistakably crafted the language of the MDA to delegate the power to regulate medical devices to the FDA, establishing a rigorous process for obtaining approval to market said devices. Congress expressly sought to preempt states from interfering in the process except under very limited circumstances, and this Court should refrain from doing so in this case.

II. CONGRESS INTENDED TO CONFER BROAD PREEMPTION POWER AND IT IS NOT THE ROLE OF THIS COURT TO UNDERMINE THE INTENT OF THE LEGISLATURE.

In light of the clear intentionality of Congress to broadly preempt any claim "which is different from, or in addition to, any requirement applicable under this chapter to the device," this Court should not attempt to carve out exceptions where a statute's plain meaning grants broad and exclusive power to an administrative agency, especially in cases where Congress explicitly created the few exemptions it intended to allow. See § 360k(a)-(b). The Supreme Court has held that it has "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341, 352 (2001). Ultimately, the only prerequisite to triggering preemption under the plain terms of § 360k is that "any" federal requirement be "applicable" to "the device." See Riegel, 552 U.S. at 322. Since this preemption power is plainly and explicitly stated in § 360k, the sole purpose of the Court "is to enforce it according to its terms." See Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6 (2000) (citing United States v. Ron Pair Enterprises, Inc., 489 U.S. 235, 241 (1989)).

This Court should not engage in judicial policymaking and disrupt the extensive legislative and regulatory framework contemplated by the MDA, and 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"). This Court has a strong history of recognizing the importance of judicial restraint, choosing to defer to legislative decision-making on numerous occasions and limiting the scope of its function 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, 100 NY.2d 893, 925 (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 MDA. 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).[1]

Recently, this Honorable Court rearticulated its obligation to strictly abide by statutory language and legislative intent when interpreting a statute. See

[1] In the rulemaking context, agencies are granted a substantial 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).

Stearns v. Metropolitan Life Ins. Co., et al., 481 Mass. 529 (2019). In Stearns, this Court addressed whether the six-year statute of repose set forth in G. L. c. 260, § 2B (§ 2B) operates to bar tort claims arising from diseases with extended latency periods. In reaching its decision, the Court explained its role with respect to interpreting a statute: "We interpret a statute according to the intent of the Legislature, which we ascertain from all its words, 'construed by the ordinary and approved usage of the language' and 'considered in connection with the cause of its enactment, the mischief or imperfection to be remedied and the main object to be accomplished.'" Stearns, 481 Mass. at 532 (quoting Harvard Crimson, Inc. v. President & Fellows of Harvard College, 445 Mass. 745, 749 (2006)). "Where, as here, the language is clear and unambiguous, it is conclusive as to the Legislature's intent." Id. (citing Sharris v. Commonwealth, 480 Mass. 586, 594 (2018)). This Court further noted that it "will not read into [the statute] any exception that the Legislature did not see fit to put there, whether by inadvertence or design. Id., citing Fernandes v. Attleboro Hous. Auth., 470 Mass. 117, 129 (2014). See Tze-Kit Mui v. Massachusetts Port Auth., 478 Mass. 710, 712 (2018) ("ordinarily we will not add language to a statute where the Legislature itself has not done so"), citing Dartt v. Browning–Ferris Indus., Inc. (Mass.), 427 Mass. 1, 9 (1998) (court will not add language to statute that Legislature could have, but did not, include). This is true even when strict interpretation of the statute "may

impose great hardship on a plaintiff." Stearns, 481 Mass. at 537 (quoting Klein v. Catalano, 386 Mass. 701, 713 (1982)). "Notwithstanding this harsh reality, we do not interpret statutes based on such concerns. Id., 481 Mass. at 538; see Bridgwood v. A.J. Wood Constr., Inc., 480 Mass. 349, 353 (2018).

In the case of the MDA, Congress intentionally drafted an uncompromising statute because they recognized the need for improvements and innovation with respect to medical devices. Although the requirements of the MDA may impose a hardship on plaintiffs by preempting their state law claims, the legislature, nonetheless, is within its right to impose those requirements. See Klein v. Catalano, 386 Mass. at 712 n.16 (Legislature may enact statute that abolishes common-law cause of action without providing substitute remedy if statute is rationally related to permissible legislative objective); see also Bridgwood v. A.J. Wood Constr., Inc., 480 Mass. at 353. As such, this Court should strictly interpret the MDA's preemption clause and dismiss Plaintiff's claims.

III. THE SUPREME COURT HAS CARVED OUT A CLEAR AND NARROW EXCEPTION TO FEDERAL PREEMPTION FOR PARALLEL CLAIMS.

Appellee contends that if claims like hers are preempted, it is impossible for plaintiffs to ever properly plead a state case for failure to comply with FDA regulations. The Supreme Court, however, has articulated the narrow circumstances under which plaintiffs can bring claims asserting violations of FDA regulations that caused injury to the plaintiff and may collect damages under state

law. See Riegel, 552 U.S. at 331. While §360k expressly preempts any state requirements that are "different from or in addition to" FDA requirements, the Supreme Court has held that § 360k does not prevent a State from providing a damages remedy for "parallel" claims premised on a violation of FDA regulations. Riegel, 552 U.S. at 324 citing Lohr, 518 U.S. at 495. A state claim is considered "parallel" if it does not add to or differ from requirements under the MDA or FDA regulations. Riegel, 552 U.S. at 324. To evade express preemption under the MDA, a plaintiff must plead specific facts and concrete allegations that the product failed to adhere to a particularized FDA requirement as, otherwise, the claims are not parallel. See Bryant v. Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010).

Given the narrow berth plaintiffs are allowed in making a parallel claim, it is therefore reasonable for plaintiffs to be expected to present more than a "bare bones" complaint. Under Massachusetts law, a plaintiff must plead "factual 'allegations plausibly suggesting (not merely consistent with)' an entitlement to relief, in order to 'reflect the threshold requirement of Federal Rule of Civil Procedure 8(a)(2) that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'" Iannacchino, 451 Mass. at 633 citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007). While courts must accept a plaintiffs' well-pleaded complaint and "indulge every reasonable inference hospitable to [her] case 'does not entitle [her] to rest on 'subjective characterizations' or conclusory

descriptions of a 'general scenario which could be dominated by unpleaded facts.'" See Schaer v. Brandeis Univ., 432 Mass. 474, 478 (2000) (citing Judge v. Lowell, 160 F.3d 67, 77 (1st Cir. 1998)). In the context of the MDA, at the very least, the plaintiff must plead facts that connect specific obligations under the MDA with parallel state claims. See Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (citing Parker v. Stryker Corp., 584 F.Supp. 2d 1298, 1301 (D. Colo. 2008)). "Plaintiffs cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." Morris v. Rotolo, No. 12-04046, 2014 Mass. Super. LEXIS 220 (Mass. Super. Jan. 15, 2014) at *5 (dismissing a plaintiff's complaint for failing to specify which FDA regulations had been violated).

Here, Appellee's claims do not allege *any* facts that demonstrate a failure to comply with *any* specific provision of the MDA or *any* specific FDA regulations. Instead, the Amended Complaint asks this Court to presume fault on the part of the defendant because the user experienced harm after using the device. However, this Court has already established that general conclusory accusations are not enough to defeat preemption. See Iannacchino, 451 Mass. at 636. Specifically, this Court held that the term "defect" is conclusory and subjective, so claiming that the manufacturer sold a "defective product" or a product that suffers from "safety-related defects" is not a viable claim that may prevail against preemption in the

state of Massachusetts. Iannacchino, 451 Mass. at 633. Without using the term, the Appellee has essentially brought a *res ipsa loquitur* claim against Appellant. However, *res ipsa loquitur* arguments cannot support a parallel claim because the PMA process under the MDA does not demand that a device be without risk to the user; instead it declares the product is not unreasonably dangerous in light of its possible benefits to the user. See Riegel, 552 U.S. at 318. As such, any attempt to confer liability under an argument of *res ipsa loquitur* necessarily imposes a requirement "which is different from, or in addition to, any requirement" under the MDA and cannot be deemed a parallel claim.

Numerous other United States Circuit Courts of Appeal have held that facts supporting parallel claims must be stated in the initial pleadings. See Wolicki-Gables, 634 F.3d at 1298 (holding "parallel claims must be specifically stated in the initial pleadings" and that the plaintiff must provide facts "pointing to specific PMA requirements that have been violated."); Caplinger, 784 F.3d at 1337 (dismissing plaintiff's complaint because she failed to "identify any legally viable federal requirement that might parallel and thus permit her claims."); Bryant, 623 F.3d at 1203 (dismissing design and manufacturing defect claims because they were merely conclusory allegations that the defendant violated the MDA).

In this case, Appellee has failed to allege sufficient facts to support her argument that her state claims are "parallel" to the requirements set forth under the

MDA as required under Riegel. Instead, the lower court's decision has left Appellant Genzyme in the inappropriate position to defend a case that, on its face, should be preempted under 21 U.S.C. § 360k(a). To allow for Appellee's Complaint to survive a motion to dismiss not only violates the pleading standard set forth by this Court in Iannachino, but it is also completely inapposite to Congress's intent to expressly preempt such claims. Moreover, to allow a plaintiff to survive a motion to dismiss without more than the type of 'bare bones' complaint filed by Appellee in this case would essentially render the express preemption clause of the MDA toothless, and would require defendants to needlessly litigate cases that have no basis to survive.

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. When enacting the MDA, Congress made clear it intended to confer broad federal preemption power. The Supreme Court has outlined a narrow exception to federal preemption in situations where the state law claims "parallel" federal requirements, but do not differ from or add to said requirements. This balance establishes a scheme that has the ability to fairly adjudicate conflicts between

injured plaintiffs and medical device manufacturers, and this Court should uphold that balance.

Here, Appellee Mrs. Dunn asks the Court to allow for her "bare bones" claims to survive and, in doing so, asks this Court to undermine Congress's clear intent in enacting the MDA. Existing Massachusetts case law does not support Appellee's position, and numerous courts considering this issue outside this jurisdiction have rejected her argument. While it is unfortunate Appellee finds herself without a remedy, sympathy alone is no justification for this Court to go against clear Congressional intent, fundamental Massachusetts law, and the many other courts who have decided this issue. Bartlett, 570 U.S. at 490 ("sympathy ... does not relieve us of the responsibility of following the law").

Therefore, the *amicus curiae*, MassDLA respectfully requests that this Court reverse the Superior Court's decision and dismiss Appellee's claims.

Respectfully submitted,
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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. 16(a), 18, and 20. This brief has been prepared using size 14 Times New Roman font and contains less than 7,500 words as calculated by the word counter on Microsoft Word 2016 word processor.

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CERTIFICATE OF SERVICE

I hereby certify that on August 21, 2020, I provided service of the Massachusetts Defense Lawyers Association's Brief of *Amicus Curiae* in the matter of Patricia Dunn v. Genzyme Corporation, Massachusetts Supreme Judicial Court No. SJC-12904 to all counsel of record via the Massachusetts electronic filing system, and served said document by electronic mail on the following counsel of record.

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