Commonwealth of Massachusetts
Supreme Judicial Court

No. SJC-12904

PATRICIA M. DUNN,

Plaintiff-Appellee,

v.

GENZYME CORPORATION,

Defendant-Appellant

On Appeal From a Decision of the Norfolk County Superior Court Denying Genzyme's Motion to Dismiss

BRIEF FOR *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF APPELLANT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Judicial Court Rule 1:21(a), the Chamber of Commerce of the United States of America ("the Chamber") and the Pharmaceutical Research and Manufacturers of America (PhRMA) state that they are non-profit organizations with no parent corporations. No publicly held corporation has a 10% or greater ownership in the Chamber or PhRMA.

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ISSUE PRESENTED

Amici Curiae address the issue presented by the Court in its February 2020 amicus announcement: "Whether the Superior Court erred in denying defendant's motion to dismiss the plaintiff's complaint alleging injury from a Class III medical device subject to the Federal Food and Drug Administration's premarket approval process; including, whether the plaintiff's allegations were sufficient to avoid Federal preemption of the plaintiff's so-called 'parallel' State law claims pursuant to 21 U.S.C. § 360k(a)."

INTEREST OF *AMICI CURIAE*[1]

Amici are the Chamber of Commerce of the United States of America ("the Chamber") and the Pharmaceutical Research and Manufacturers of America (PhRMA).

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of

[1] *Amici* declare that: (1) no party, nor any party's counsel, has authored this brief in whole or in part; (2) no party, nor any party's counsel, has contributed money that was intended to fund preparing or submitting this brief; (3) no person or entity—other than *Amici*, their members, or their counsel—has contributed money that was intended to fund preparing or submitting this brief; and (4) neither *Amici* nor their counsel represents or has represented one of the parties to this case in another proceeding involving similar issues, or was a party or represented a party in a proceeding or legal transaction that is at issue in the present appeal. *See* Mass. R. App. P. 17(c)(5),

more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of their members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the business community in Massachusetts.

PhRMA represents leading pharmaceutical and biotechnology companies. Its members develop cutting-edge medicines, treatments and vaccines that save and improve the lives of countless individuals. Since 2000, PhRMA members have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. PhRMA regularly files *amicus* briefs in cases that raise issues of vital concern to the pharmaceutical and biotechnology communities.

This is such a case. *Amici*'s members include medical-device manufacturers that comply with an extensive federal premarket approval process before selling a medical device and with post-marketing reporting and other safety requirements for the life of their products—a process required by the Medical Device Amendments to the Food, Drug and Cosmetic Act (MDA). When Congress passed the MDA, it swept back state oversight schemes, expressly providing that the federal scheme would preempt any state-law requirements that were different from or additional to

the federal requirements. Medical-device manufacturers, including *Amici*'s members, depend on the pleading standard adopted by the U.S. Supreme Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007), and by this Court in *Iannacchino v. Ford Motor Co.*, 451 Mass. 623 (2008), as protection against meritless suits that are plainly preempted by the MDA and suits that seek to extort settlements given burdensome discovery costs. *Amici*'s members have a strong interest in ensuring that courts in Massachusetts evaluate state-law claims involving federally regulated medical devices under a clear and uniform pleading standard—and one that accords with this Court's precedent.

INTRODUCTION AND SUMMARY OF ARGUMENT

Patricia M. Dunn's allegations in this case are as bare-bones as they come. Dunn alleges, in essence, that she was treated with Genzyme's Synvisc-One® product, a federally regulated Class III medical device; that Synvisc-One® was "defective" because it "violates" one or more unspecified "FDA regulations"; that she was injured; and that the defect "proximately caused" her injury. Under the *Twombly* pleading standard adopted by this Court in *Iannacchino*, 451 Mass. 623, a plaintiff must plead "factual 'allegations plausibly suggesting (not merely consistent with)' an entitlement to relief." *Id.* at 636 (quoting *Twombly*, 550 U.S. at 545). These conclusory allegations are plainly insufficient to meet that standard. Indeed, their obviously conclusory nature seems *designed* to evade dismissal on the basis of

express or implied preemption, which as a matter of law bars many claims involving Class III medical devices like Synvisc-One® pursuant to the Medical Device Amendments to the Food Drug and Cosmetic Act (MDA). As discussed below, the MDA expressly preempts any state law claim that rests on an obligation that is greater to or in addition to those imposed by the MDA itself (*e.g.*, a claim alleging that the FDA-approved warnings accompanying the device were inadequate under state law), and impliedly preempts claims that a defendant violated state law *because* the conduct violates federal law (*e.g.*, claims based on a violation of a federal regulation that has no parallel basis in state law).

The Superior Court should have granted Genzyme's motion to dismiss for failure to state a viable state-law claim. Instead, the court held that Dunn had done enough "*given the amount of information to which she had access*." App. 13. Not only is this holding incorrect under *Iannacchino*, it also imposes unfair burdens on the medical-device industry in Massachusetts, which, under the Superior Court's decision, will be drawn into costly and burdensome discovery by even the most speculative allegations of unspecified wrongdoing. And it does so for no good reason; contrary to the Superior Court's concern, there are various ways in which plaintiffs alleging injury from a Class III medical device can—and do—provide factual support for viable claims. The lower pleading standard the Superior Court

adopted in this case is therefore not only contrary to *Iannacchino*'s uniform standard, but wholly unnecessary, and harmful to this state's medical innovation economy.

ARGUMENT

I. ADHERENCE TO *IANNACCHINO*'S PLEADING STANDARD IS PARTICULARLY IMPORTANT IN THE MEDICAL-DEVICE CONTEXT, WHERE FEDERAL PREEMPTION IS AT PLAY.

A. Congress Left Only A "Narrow Gap" For Private Parties To Sue Under State Law For Harm From Class III Medical Devices.

Regulation of medical devices is governed by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq.*, to the Federal Food Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. The MDA separates devices into three categories. Class I and Class II devices—things like bandages and mercury thermometers—are subject to regulatory standards and controls, but do not require premarket approval. Class III devices "presen[t] a potential unreasonable risk of illness or injury" or are used to sustain or support human life or to prevent impairment of human health, and therefore are subject to the FDA's strictest regulation. 21 U.S.C. § 360c(a)(1)(C). The device at issue here—Synvisc One®—is a Class III device.

Class III devices like Synvisc-One® must complete a premarket approval process ("PMA") that requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C.

§ 360e(d)(2)(A). The process is "a rigorous one," in which manufacturers submit "detailed information regarding the safety and efficacy of their devices." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). A manufacturer must submit: full reports of all studies and investigations regarding the device's safety and effectiveness; a full statement of the components, ingredients, and properties of the device; a full description of the methods used in, and facilities and controls used for, the manufacture, processing, packing, and installation of the device; a reference to any performance standard that would apply if the device were a Class II device, and information showing that the device satisfies the standard or justifying any deviation from it; any sample of the device requested by the FDA; and the proposed labeling. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The FDA may request additional information from the manufacturer and also may consult with a scientific advisory committee composed of outside experts. *See* 21 C.F.R. §§ 814.44, 814.20. The agency conducts an in-depth review of requests for premarket approval, devoting an average of 1,200 hours to each application. *See Lohr*, 518 U.S. at 477.

The FDA's regulation of Class III medical devices does not end when the agency grants premarket approval. A manufacturer must file supplemental information and obtain FDA approval for any change that may affect the safety or

effectiveness of the device.[2] 21 U.S.C. § 360e(d)(5)(A)(i); 21 C.F.R. § 814.39(a). Manufacturers are also required to collect and report to the FDA information on certain adverse events after the device has been approved, including any incident in which the device may have caused or contributed to death or serious injury. 21 U.S.C. § 360i(a); 21 C.F.R. §§ 803.10(c)(1), 803.50(a)(1). The manufacturer must provide annual reports to the FDA that identify, among other things, any scientific literature or clinical studies about the device. 21 C.F.R. § 803.55(b). The FDA may withdraw premarket approval if it determines that the device no longer satisfies the standards for premarket approval. 21 U.S.C. § 360e(e)(1).

Congress expressly provided, in 21 U.S.C. § 360k(a), that this detailed regime of ongoing federal oversight preempts any state-law claim that would impose safety or effectiveness requirements beyond those imposed by the FDA. The U.S. Supreme Court has on two occasions examined and defined the contours of preemption under the MDA. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court, addressing express preemption, held that "[s]tate [law requirements and related causes of action]

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[2] These changes can seem minor, yet the FDA requires their preapproval nonetheless. For example, Genzyme filed a supplement for Synvisc-One® in 2011 when it added a "syringe assembly machine to the packaging department," and again in 2020 to get FDA approval for "modifications to the washing process of a component used [in] manufacture." *See* Synvisc-One® Supplement 022 (2011), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P940015S022; Synvisc-One® Supplement 045 (2020), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P940015S045.

are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Id.* at 330 (quoting 21 U.S.C. § 360k(a)(1)). As such, the Court held, the MDA "does not prevent a State from providing a damages remedy for claims premised on the violation of FDA regulations" where "the state duties in such a case parallel, rather than add to, federal requirements." *Id.* In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court addressed the different issue of implied preemption and held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based *solely* on a violation of the FDCA rather than on some independent state law duty. *Id.* at 352-53.

Federal courts have interpreted *Riegel* and *Buckman* together as "creat[ing] a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA ([as] such a claim would be impliedly preempted under *Buckman*)." *Id.* Put slightly differently, "the plaintiff's state-law claim must 'parallel[] a federal-law duty under the MDA' but also exist [in state law] 'independent[ly]' of the MDA."

A.F. v. Sorin Grp. USA, Inc., 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (quoting *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013)).

The FDA approved Genzyme's Synvisc-One® under its rigorous PMA process in 2009. As a result, suits challenging Synvisc-One's® design or FDA-approved warnings will often be preempted under federal law. To avoid preemption, a plaintiff like Dunn must plead a claim that fits through the "narrow gap" left by Congress: she must allege conduct that violates the FDCA but also independently violates a duty created by Massachusetts law. As explained next, conclusory allegations are never permissible in any civil suit, but they are particularly problematic in a suit involving a Class III medical device, where vague and conclusory pleadings often represent a plaintiff's effort to evade dismissal of a clearly preempted claim and force defendants into expensive discovery in the hopes of obtaining an extortionate settlement.

B. A Plaintiff In A Class III Medical Device Suit Must Plausibly Allege A State-Law Claim That Is Not Preempted By The MDA.

In *Iannacchino*, this Court adopted the pleading standard articulated by the U.S. Supreme Court in *Twombly*. To survive a motion to dismiss under Massachusetts Rule of Civil Procedure 12(b)(6), the Court held, a complaint must contain "factual allegations" that are "enough to raise a right to relief above the speculative level." *Iannacchino*, 451 Mass. at 635-36 (quoting *Twombly*, 550 U.S. at 545). In other words, (1) legal conclusions are ignored, *Iannacchino*, 451 Mass.

at 636; *Twombly*, 550 U.S. at 555 ("a formulaic recitation of the elements of a cause of action will not do"); *see also Aschroft v. Iqbal*, 556 U.S. 662 (2009) ("[A] complaint [will not] suffice if it tenders naked assertions devoid of further factual enhancements." (quotations omitted)), and (2) any remaining factual allegations must cross "the line between possibility and plausibility," *Twombly*, 550 U.S. at 545, *i.e.*, they must "plausibly suggest[] (not merely [be]consistent with) an entitlement to relief," *Iannacchino*, 451 Mass. at 636 (quotations omitted).

This pleading standard applies in all civil cases, but it is particularly salient in the context of Class III medical devices. As noted above, for a plaintiff's product-liability claim to avoid preemption, it must fit through the narrow gap Congress left for state-law claims that are premised on violations of federal regulations but based on a state-law obligation that exists independently of those regulations. *See* pp. 11-13, *supra*. *Iannacchino* requires that a plaintiff do so *plausibly—i.e.*, it is not enough that a plaintiff allege, in conclusory fashion and with no supporting factual allegations, that the manufacture of a device "violated federal regulations." Rather, "the majority of courts who have addressed the pleading standards in this context" have rightly held that "Plaintiffs cannot simply incant the magic words [defendant] violated FDA regulations in order to avoid [express] preemption." *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010).

Nor can a Plaintiff simply incant the magic words "the defendant violated state law" in order to avoid implied preemption. A claim that a manufacturer was negligent under Massachusetts law requires plausible factual allegations that the defendant owed the plaintiff a duty of care, that the defendant did not exercise reasonable care, and that the manufacturer's negligence caused the plaintiff's injury. *See Jupin v. Kask*, 447 Mass. 141, 146 (2006) (elements of negligence). The mere assertion that the violation and the injury are linked is not sufficient. *See, e.g.*, *Rassias v. M.B.T.A.*, 27 Mass. L. Rptr. 25 (Sup. Ct. 2010) (claim dismissed where plaintiff failed to allege "how the MBTA agent was negligent" or "how such negligence caused her injury"). After all, the PMA requirements cover a wide range of things, some very minor, including, for example, requiring the device label to include the zip code where the device was packaged, 21 C.F.R. § 801.1(d). A plaintiff cannot bring a state-law claim by simply asserting that *some* regulation among the thousands of technical requirements in the MDA and FDA regulations—most of which have no state-law counterpart—was violated; rather, the plaintiff must plausibly allege that the violation contravened the duty of care imposed by state law and caused the plaintiff's injury.

C. Dunn's Conclusory Allegations Are Insufficient Under Iannacchino, And Evade Any Preemption Analysis.

Dunn's complaint is so lacking in factual allegations that whether her claims survive a motion to dismiss is not a close call. Her claims should have been dismissed.

First, Dunn concedes that she must allege some violation of federal law to avoid dismissal based on federal preemption. Dunn Response Br. 42. To do so, Dunn simply asserts, in the broadest possible fashion, that Genzyme "failed to comply with the [FDA's] premarket approval requirements in the continued manufacture, distribution and sale of Synvisc-One®" and "did not comport with the [FDA's] 'Good Manufacturing Practices' in the manufacture, distribution and sale of Synvisc-One®." App. 29.[3] These allegations are incredibly broad, and amount to no more than "the product violates federal law." Indeed, the speculative and conclusory nature of the complaint is evident on pages 5-6, where Dunn surmises the ways in which Genzyme may have violated its "duty of reasonable care," which "included, but were not limited to, some or all of the following acts and/or omissions":

> a. Negligently manufacturing adulterated Synvisc-One® and/or carelessly placing it into the stream of commerce;
>
> b. Negligently failing to ensure that Synvisc-One® was manufactured and distributed pursuant to appropriate

[3] Cites to "App." are to Genzyme's Appendix.

governmental and industry practices and standards, thereby resulting in a defective product;

c. Negligently failing to provide proper instructions and/or warnings regarding the appropriate method of injection or use of Synvisc-One®

d. Negligently failing to properly warn or instruct intended users of the dangers and side-effects of Synvisc-One®; and/or

e. Negligently failing to comply with FDA and other applicable Massachusetts rules and regulations.

App. 31-32. These general allegations are barely more detailed than the blanket statement, "the defendant violated federal regulations" and "the defendant committed a tort." Dunn has not pleaded any facts linking Genzyme's conduct to the violation of any law or regulation, let alone facts giving rise to a plausible inference of such a violation.

Dunn's allegations are not unlike those rejected in *Iannacchino* itself. In *Iannacchino*, the plaintiffs alleged that defendant Ford violated M.G.L. Chapter 93A when it sold vehicles that purportedly complied with federal safety standards but in fact did not. 451 Mass. at 629. The Court agreed that if the plaintiffs adequately alleged that their vehicles failed to comply with federal standards, then they had stated a claim under Chapter 93A. *Id.* at 630-31. But it held that the plaintiffs had failed to allege that key fact, because their only "factual assertion of noncompliance" did not show noncompliance: the complaint alleged that Ford had used a "GM test" to test the safety of the vehicles, but plaintiffs acknowledged that the GM test was federally approved. *Id.* at 631. Elsewhere in the complaint, the plaintiffs asserted

"noncompliance in broad fashion" and alleged that the vehicles were "defective." *Id.* at 630-31. This Court held that, even under the pleading standard applicable at the time (which is more plaintiff-friendly than the pleading standard the Court went on to adopt in *Iannacchino* and which applies to this case), the broad allegations of "defect" were not sufficient to plausibly allege that the vehicles violated federal safety standards, because "the term 'defect,' is conclusory." *Id.* at 631. So, too, here. Dunn's general allegation that the Synvisc-One® she received was "defective," is insufficient to plausibly allege that Genzyme violated federal law—a necessary element of her purportedly parallel state-law tort claims.

Second, Dunn's allegations regarding Genzyme's supposed violation of *Massachusetts* law—which are necessary both to avoid implied preemption and also to state a plausible state-law tort claim—are also pleaded in the broadest possible manner. Dunn alleges, for example, that the drug carried "dangers" that were "reasonably foreseeable." App. 29-30. She also claims that Genzyme manufactured and marketed its product "negligently," *see* list, *supra*. Her allegations regarding causation—a necessary element of her state law claims—are devoid of any factual content or color. Dunn states that "[i]mmediately after, and as a direct and proximate result of the injection of the adulterated doses of Synvisc-One®, Dunn began to suffer adverse side-effects from it," and "[a]s a directly [sic] and proximate cause of aforementioned physical conditions caused by the Synvisc-One® injections, Dunn

fell several times which resulted in, among other injuries, her tearing her meniscus and breaking her neck," and "[t]hese damages would not have occurred but for the defective nature of the product injected into Dunn and/or Genzyme's otherwise wrongful conduct." App. 29. These are effectively legal conclusions; Dunn might as well have written, "Synvisc-One® proximately caused my injury." Under *Iannacchino*, this is not enough.

D. Courts Have Overwhelmingly Dismissed Claims Involving Class III Medical Devices Alleged In Similar Fashion To Those Here.

The Superior Court's decision is contrary to the overwhelming authority from federal district courts, which have almost uniformly dismissed allegations against Class III medical device manufacturers that are as conclusory as Dunn's allegations in this case. There is no reason for Massachusetts courts to reach a different conclusion than these federal courts, because the *Iannacchino* pleading standard is taken directly from *Twombly*.

For example, in *Zeman v. Williams*, 2014 WL 3058298 (D. Mass. 2014), the plaintiff alleged that Neurologix had designed and manufactured medical equipment used to treat Parkinson's Disease in violation of federal regulations and Massachusetts common law of negligence. *Id.* at *1. The district court dismissed the claim as implausible:

> The allegations are . . . entirely general and conclusory. For example, it is alleged that the ABID System "was manufactured in violation of the Federal Food, Drug and Cosmetic Act ('Act') and regulations

> promulgated pursuant to said Act," but there are no specifics about which provisions of the Act or regulations were violated or how. The plaintiffs similarly allege that Neurologix "negligently manufactured and/or designed the ABID system," but no details are alleged. Instead, there is a catalog of summary and conclusory allegations, such as the allegation that Neurologix was negligent by "designing, manufacturing, and/or distributing a product in a defective condition." Such generalities do not come close to satisfying the *Twombly-Iqbal* standard.

Id. at *4. So, too, here. Dunn's complaint alleges only generalities. This includes her negligent manufacture claim; for that claim, Dunn alleges that Genzyme "[n]egligently fail[ed] to ensure that Synvisc-One® was manufactured and distributed pursuant to appropriate governmental and industry practice and standards" and "negligently fail[ed] to comply with FDA and other applicable Massachusetts rules and regulations." App. 32. As in *Zeman*, these generalities are insufficient to state a claim for negligence, and that claim, along with the others, should have been dismissed.

Zeman is not an outlier; courts across the country overwhelmingly dismiss state-law tort claims where the plaintiff fails to allege in more than conclusory fashion that a medical device was manufactured in violation of federal regulations and that the violation caused the plaintiff's injury. A recent example is *D'Addario v. Johnson & Johnson*, 2020 WL 3546750 (D.N.J. Jun. 30, 2020), which dismissed a manufacturing defect claim brought pursuant to Connecticut law for two reasons. First, the "federal requirement [was] not properly identified, [therefore] the Court

[was] unable to determine whether Plaintiffs' state-law claim based upon Connecticut requirements" was preempted. *Id.* at *4. Second, the plaintiffs failed to plausibly allege that violations of "numerous federal specifications . . . *resulted in* the presence of lymphocytes in [the] implants or any other injury." *Id.* (emphasis added).[4]

[4] *See also, e.g.*, *Webb v. Mentor Worldwide LLC*, -- F. Supp. 3d --, 2020 WL 1685323, *5 (N.D.N.Y. 2020) (dismissing claim because "the complaint's generic allegations of a defective manufacturing claim do not demonstrate that they are based on Defendants' violation of federal regulations"); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 249 (S.D.N.Y. 2013) (claims dismissed where plaintiff failed to "allege[] facts supporting an inference that he was implanted with [a medical device] . . . manufactured in contravention of the FDA's premarket approval"); *Cohen v. Guidant Corp.*, 2011 WL 637472, *2 (C.D. Cal. 2011) (claims dismissed where plaintiff merely "list[ed] boilerplate FDA regulations without linking any of those regulations to a defect in his specific pacemaker that was caused by Defendants violating FDA regulations"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (claims dismissed where "plaintiff has done nothing more than recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged"); *Dawson v. Medtronic, Inc.*, 2013 WL 4048850, *7 (D.S.C. Aug. 9, 2013) (claims dismissed where complaint "merely contain[ed] a formulaic recitation of the elements, which is insufficient to survive a motion to dismiss under *Twombly*"); *Maness v. Boston Sci*., 751 F. Supp. 2d 962, 969-70 (E.D. Tenn. 2010) (claims dismissed where plaintiff alleged in conclusory fashion that the medical device was "defective and therefore caused the plaintiff harm" and failed to "allege facts regarding how an alleged defect . . . caused her injuries"); *Ali v. Allergan USA, Inc.*, 2012 WL 3692396, *13 (E.D. Va. Aug. 23, 2012) ("without factual enhancement," a "series of conclusory allegations that [defendant] violated federal law in the manufacture and marketing of" medical device were "insufficient to plead plausible federal violations"). *Steiden v. Genzyme Biosurgery*, 2012 WL 2923225 (W.D. Ken. 2012), upon which Dunn relies (at 33), is an outlier.

Notably, some of these cases involved allegations that were *more detailed* than Dunn's allegations in this case, yet the allegations were still dismissed. For example, Stryker Corporation was sued in several jurisdictions for manufacturing an allegedly defective hip replacement device. The allegations in the Stryker cases were similar to those here; the plaintiffs alleged in conclusory fashion that the hip devices did not comply with FDA regulations and that the defect caused them injury. But the plaintiffs also included facts notably absent from Dunn's complaint. To support the allegation that the device violated federal regulations, the plaintiffs in those cases alleged that Stryker had been issued warning letters by the FDA. And to support the allegation that the violation caused injury, the plaintiffs alleged that they had heard a noise emanating from the device's location in their body immediately before the injury. *See Gelber*, 752 F. Supp. 2d at 333-34; *Covert v. Stryker Corp.*, 2009 WL 2424559, *15 (M.D.N.C. Aug. 5, 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). Despite this detail, the claims were dismissed. Dunn has pleaded even fewer facts than the plaintiffs in the Stryker cases, and her claims, too, should have been dismissed as implausible.

In sum, Dunn has not stated a plausible claim for relief under *Twombly/Iannacchino*. If her claims were sufficient, then *any plaintiff* in a Class III medical device case could avoid dismissal and obtain discovery by alleging that "the

defendant violated FDA regulations," she "was injured," and "the violation caused the injury." This cannot be what this Court meant when it held that "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions." *Iannacchino*, 451 Mass. at 636 (quotation marks and brackets omitted). Dunn is wrong when she suggests (at 11, 12, 35, 39, 41) that Genzyme is attempting to hold medical-device plaintiffs to a heightened pleading standard or require them to invoke magic words or cite chapter and verse of the subsection of the Code of Federal Regulations that was violated. What is required in this context, as in all contexts, are *facts* plausibly suggesting a viable state-law claim. And facts are precisely what is missing from Dunn's complaint.

II. THE SUPERIOR COURT'S DECISION WILL BURDEN THE MASSACHUSETTS MEDICAL-DEVICE INDUSTRY AND MASSACHUSETTS COURTS.

The *Iannacchino* pleading standard, which this Court imported directly from *Twombly*, has vital practical significance: without it, a plaintiff with "a largely groundless claim" may "be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 550 U.S. at 558 (quotation marks omitted). Weeding out largely groundless claims must be done *before* discovery because "the success of judicial supervision in checking discovery abuse has been on the modest side." *Id.* at 559. Nor can courts expect summary judgment and trial to protect defendants from strike

suits, since "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings." *Id.* Accordingly, the only way to "avoid the potentially enormous expense of discovery" and the consequent pressure it places on defendants to settle groundless claims is to require the allegations in a complaint to raise a plausible claim for relief. *Id.* That is a very modest requirement, especially considering the consequences of permitting meritless suits to proceed to discovery.

This practical concern—that a too-low pleading standard leads to burdensome discovery and, with it, the pressure to settle even the most meritless of cases—is particularly salient in cases involving medical devices, and especially so in medical-device suits brought in Massachusetts courts, for several reasons.

First, the costs of discovery in medical-device suits can be staggering. Discovery usually involves deposing a manufacturer's employees, numerous experts, and damages witnesses. *See* Report of Advisory Committee on Civil Rules, Statement of Donald H. Slavik, AAJ Products Liability, https://www.uscourts.gov/sites/default/files/fr_import/CV05-2014.pdf. It also often involves dozens of interrogatories on a range of topics, from the identity of the employees responsible for design, assembly, and manufacture, to design history, computer modeling, field performance, and alternative designs. *See id*., Statement of Larry E. Coben for the

Attorneys Information Exchange Group.[5] Discovery costs in medical-device suits in Massachusetts are particularly high, because Massachusetts has not adopted a rule like the federal rule requiring discovery to be "proportional to the needs of the case." Fed. R. Civ. P. 26(b). Instead, the Massachusetts rules allow broad discovery of any matter that is "relevant to the subject matter involved in the pending action." Mass. R. Civ. P. 26(b)(1).

The proper enforcement of pleading standards ensures that discovery will be limited to the factual and legal issues that are plausibly alleged in a case. Casting those standards aside, as the Superior Court did here, encourages litigants to be as vague and broad in their allegations as possible and thereby ensure a correspondingly expansive fishing expedition during discovery. This case presents a prime example: Dunn alleges that the Synvisc-One® she received was "adulterated," "negligently manufactured, designed, distributed, and sold," and "failed to contain appropriate and significant warnings." App. 27. But these allegations cover *everything* about Synvisc-One®, from its development and design by doctors, researchers, and

[5] The high costs of litigating a medical-device case continue long after discovery. The cases are not often resolved on summary judgment because they often involve a "predominance of factual issues—design defect, warning inadequacy, and causation—that generally preclude the resolution of disputes on motion for summary judgment." Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 Harv. L. Rev. 773, 782 (1990) (discussing similar concern in pharmaceutical context).

engineers, to storage and facility controls, to packing and distribution and warnings. Discovery in this case would therefore be far-reaching and without any meaningful limit; anything that is part of the design, manufacture, distribution, and sale of Synvisc-One® is "relevant" to Dunn's claims and therefore could be deemed fair game.

Second, in the medical-device context, losing one significant case is likely to trigger "an avalanche" of others, placing even more pressure on a manufacturer to settle a case that proceeds beyond a motion to dismiss. *See* David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 463 (1999). And that "avalanche" can come all at once—through a mass tort action—particularly when the plaintiffs' bar finds a plaintiff-friendly forum.

Third, a lower pleading standard that allows more medical-device cases to proceed to burdensome discovery and forced settlement will be felt acutely in Massachusetts, where the medical-device industry makes up a substantial portion of the state's economy. Massachusetts is home to over 400 medical-device companies (including Genzyme), which are responsible for $6.1 billion in exports—almost a quarter of the state's total exports, and the highest in the nation. *See* Grant Thornton & MassMEDIC, *Medical Devices in Massachusetts: State of the Industry*, at 2 (July 2019), https://www.massmedic.com/wp-content/uploads/2019/07/grantthorntonmedicaldevicesinMassachusettsStateoftheIndustryjuly2019.pdf ("MassMEDIC,

Medical Devices in Massachusetts"); Chris Newmarker, *Massachusetts' medical device hub: What you need to know*, Medical Design & Outsourcing (May 15, 2019), https://www.medicaldesignandoutsourcing.com/massachusetts-medical-device-hub-what-you-need-to-know/. The medical-device industry is also a vital source of employment in Massachusetts, which ranks third among states for total number of medical-device employees, with almost 25,000 workers in the field. MassMEDIC, *Medical Devices in Massachusetts*, at 2. These companies and individuals are responsible for developing and manufacturing a large portion of Class III medical devices. In 2019, Massachusetts ranked second in the nation (to California) in devices that go through the FDA's stringent PMA process, and second in the nation (to Minnesota) in devices that go through the more streamlined "510(k)" process for devices that are substantially similar to existing devices. *See id.* at 6-7.

Whether these Massachusetts companies settle or litigate when faced with lawsuits like this one, the attendant costs are necessarily reflected in the price of the device and other products they make. *Cf.* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203, 227 (1997) (finding "a substantial premium exists in U.S. pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in Canadian prices"). And an increased risk of liability for new products will deter manufacturers from developing new technologies, contrary to public policy. *See, e.g.*, Alberto

Galasso & Hong Luo, *When does product liability risk affect innovation? Evidence from Medical Implants* (July 31, 2018), https://www.hbs.edu/faculty/Publication%20Files/19-002_7ddf96de-ece1-4b20-aea1-a97626f5e3a5.pdf; *see also Payton v. Abbott Labs*, 386 Mass. 540, 573 (1982) (recognizing that "[p]ublic policy favors the development and marketing of new and more efficacious drugs" and that expansive tort liabilities have a "deleterious effect on the development and marketing of new drugs"); Am. Med. Ass'n, *Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988) (certain older technologies have been removed from the market because product liability suits have exposed manufacturers to unacceptable financial risks); *see also* Am. Med. Ass'n, House of Delegates: Proceedings 59 (1991) ("The AMA has adopted policy supporting . . . efforts to prevent product liability suits from slowing the development and utilization of medical technologies.").[6] The rule announced by the Superior Court could therefore further increase the already escalating cost of health care, limit access to medical technology that the FDA has found beneficial to

[6] *Cf.* W. Kip Viscusi et al., *A Statistical Profile of the 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 public health, and disincentivize production of new, life-saving technologies in Massachusetts.

The Superior Court's pleading standard could also result in an increased burden on Massachusetts courts by drawing more products liability cases to Massachusetts, as plaintiff-friendly rules tend to do. California, which has several rules that favor plaintiffs in products liability cases—including a low standard for the admissibility of expert testimony and no cap on punitive damages—is inundated with mass torts involving pharmaceuticals and medical devices, a large number of which involve non-resident plaintiffs. California's judiciary has experienced severe budget crises as a result.[7] Likewise, when a judge in Philadelphia instituted various procedural mechanisms to attract plaintiff filings, out-of-state filings ballooned to 47% of the court's docket. The court reversed course three years later.[8] The Superior Court's decision in this case risks exposing Massachusetts courts to a similar inundation of products-liability suits.

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[7] *See* Tabitha Fleming, "California attracts 'litigation tourists,' study finds," Legal Newsline (Feb. 3, 2017), https://legalnewsline.com/stories/511079169-california-attracts-litigation-tourists-study-finds#; California Judicial Branch, "In Focus: Judicial Branch Budget Crisis," http://www.courts.ca.go/partners/1494.htm.

[8] *See* Chris Mondics, "Philadelphia court changes address a backlog of cases," *The Philadelphia Inquirer* (Mar. 9, 2012); Ashby Jones, "Philly Regrets Flood of Cases," *The Wall Street Journal* (Sept. 23, 2012), https://www.wsj.com/articles/SB10000872396390444083304578014400849363158.

III. THE SUPERIOR COURT'S CONCERN THAT A PLAINTIFF IN DUNN'S POSITION CANNOT PLEAD WITH GREATER SPECIFICITY IS UNFOUNDED.

The Superior Court justified its decision on the ground that "there is nothing to indicate that Dunn had access to any publicly available information which would have permitted her to plead with greater specificity." App. 13. "[G]iven the amount of information to which she had access," the Court held, "Dunn has provided sufficient allegations to avoid preemption and survive Genzyme's motion." *Id.* This reasoning is flawed, for at least two reasons.

First, neither this Court in *Iannacchino* nor the U.S. Supreme Court in *Twombly* suggested that the pleading standard is subject to adjustment based on the amount of information available to the plaintiff in a particular case, or that conclusory pleadings suffice where there is "nothing to indicate" that the plaintiff has access to any public information that would support conclusory claims. To the contrary, the law is clear that the pleading rules "do[] not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678-79.

The law is also clear that the standard articulated in *Twombly* and adopted by this Court in *Iannacchino* applies to *all claims* subject to the pleading standards in Massachusetts Rule of Civil Procedure 8(a), which parallels Federal Rule of Civil Procedure 8(a). In *Iqbal*, a case alleging that federal officials subjected Arab Muslim

men to unconstitutional conditions of confinement because of their race, religion, or national origin, the plaintiff argued that "*Twombly* should be limited to pleadings made in the context of an antitrust dispute." 556 U.S. at 684. The U.S. Supreme Court squarely rejected that argument, holding that it was "not supported by *Twombly* and . . . incompatible with the Federal Rules of Civil Procedure." *Id.* The Court held that "[o]ur decision in *Twombly* expounded the pleading standard for 'all civil actions.'" *Id.* (quoting Fed. R. Civ. P. 1).

Consistent with *Iqbal*'s understanding of *Twombly*, this Court has applied the *Twombly/Iannacchino* standard without regard to the type of claim at issue. *See, e.g.*, *UBS Fin. Servs., Inc. v. Aliberti*, 483 Mass. 396, 405 (2019) (fiduciary breach); *Edwards v. Commonwealth*, 477 Mass. 254, 260 (2017) (defamation); *Polay v. McMahon*, 468 Mass. 379, 382 (2014) (invasion of privacy and intentional infliction of emotional distress). *Iannacchino* itself involved a claim for breach of warranty and violation of Chapter 93A—two of the five claims in this case. *See* 451 Mass. at 634-45; App. 29-34. And courts in Massachusetts have likewise applied *Iannacchino* to negligence claims, like those Dunn asserts here. *See, e.g.*, *LeBlanc v. Commonwealth*, 75 Mass. App. Ct. 419 (2009) (negligence); App. 29-34. There

is no support in the case law for applying a different, more liberal standard to a lawsuit that involves federally regulated Class III medical devices.[9]

Second, and in any event, the Superior Court's apparent concern that plaintiffs in cases involving federally regulated medical devices are *incapable* of pleading more than bare-bones legal conclusions is unfounded. There is certainly more Dunn and her counsel could have done with the information that was available to them. For example, Dunn alleges in Count I that Genzyme "failed to comply with [the] FDA's regulations that address a manufacturer's duty to warn" of the "dangerous propensities" of a product. App. 29-30. But what warnings were missing, exactly? Dunn could have specified, by comparing the warnings to her injuries or even simply asking her doctor what dangers she was not warned of. In Counts II-IV, Dunn alleges that Synvisc-One had a "defect" in its "manufacturing." App. 31-33. Here, too, she could have done more. Dunn could have asked her physician what was defective about the product, and she could include the doctor's statements in her complaint. In Count V, Dunn alleges that Genzyme committed certain "unfair and deceptive acts or practices" in violation of Chapter 93A. App. 33-34. But on what falsity did

[9] Even putting aside that this case-specific rule is not supported by this Court's precedent, it is hard to see how the Superior Court's rule would work in practice—would the plaintiff be responsible for proving a negative, *i.e.*, that there was no public source of information to support her claims? Or would the defendant be charged with bolstering the plaintiff's complaint by identifying information that the plaintiff did not but could have included?

Dunn rely? At the very least, she should have an idea of how she supposedly was deceived, and how the deception caused her harm. She alleges none of these things.

Indeed, these are just some of the ways in which plaintiffs can and do allege facts to support otherwise conclusory allegations that a Class III medical device violated FDA regulations and the violation caused harm, without subjecting the defendant to costly and burdensome discovery. Individuals and their counsel have access to their treating physicians, their medical history and medical records, and myriad public FDA and product documents (which include product warnings, FDA product approval summaries, warning letters or "483 notices," adverse event reports, recall notices, and other agency actions).[10] Basic pre-suit diligence by a plaintiff and her counsel would reveal ample sources to obtain facts to support a viable claim, if there was one.

For example, in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), *see* App. 12, the plaintiff alleged that she was injured by the defendant's defective hip replacement device. In support of that otherwise conclusory allegation, she alleged

[10] *See* U.S. FDA, Medical Devices Databases, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases; U.S. FDA, Inspection Classification Database, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database; U.S. FDA, CDRH Transparency: Compliance and Enforcement Database, https://www.fda.gov/about-fda/cdrh-transparency/cdrh-transparency-compliance-enforcement.

that the device was implanted in her body six days after the FDA issued a warning letter to the manufacturer notifying it that the device did not comply with federal regulations, and that the device she received bore the same catalogue number as the device in the letter. *Id.* at 546. The plaintiff also alleged that the manufacturer had received complaints that the device was failing after it was implemented, that a batch of the device's components were recalled, and that the FDA had issued an inspection report noting deficiencies at the device's manufacturing site. *Id.* at 559. These types of allegations are precisely what nudges claims from speculative to plausible, but there are no similar allegations in this case.

Similarly, in *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012), *see* App. 12, the plaintiff alleged he was injured by manufacturing defects in the same hip replacement device at issue in *Bausch*, and he supported that claim with allegations that the defendant manufacturer had received warning letters from the FDA and had initiated a recall of the device following an investigation, and that the recall concerned a defect that is known to cause the injury the plaintiff suffered. *Id.* at 510. Dunn alleges nothing close to these facts.

Finally, in *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014), *see* App. 12, the court held that the plaintiff had satisfied the *Twombly* pleading standard in part because the plaintiff had "provided factual support" for his allegation that the defendant violated the applicable PMAs and GMPs. *Id.* at 181.

That factual support came "in the form of Dear Doctor letters and FDA actions, as well as a recall." *Id.* The court also noted, in deeming the allegations plausible, that the plaintiff had provided factual support for the allegation that the violations caused her injury, by alleging "that insulation abrasion led to externalization and/or fracturing of her [device], which her physician determined had occurred when the [device] was surgically extracted." *Id.* at 181. There are no similar allegations in this case.[11]

These cases make clear that the Superior Court's concern that a plaintiff in Dunn's position is *incapable* of alleging more is unfounded. Where plaintiffs like Dunn include nothing but conclusory statements that a device was "adulterated" in violation of FDA regulations and the adulteration "proximately caused" their harm—vague pleading that appears to be designed to avoid dismissal on preemption grounds—the correct approach is not to give them discovery in the hopes they *may* find something to render their speculative lawsuit plausible. Rather, the appropriate step is to dismiss the action as insufficient under *Iannacchino*: "[A] wholly

[11] *See also Phillips v. Medtronic*, 2012 WL 3641487, *1 (Mass. Super. July 10, 2012) (plaintiffs stated plausible parallel claims because they were contextualized with facts, including statements by physician, Dear Doctor letter, recall, and FDA warning letter); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156-58 (S.D.N.Y. 2011) (plaintiff stated plausible parallel state-law claims where she provided supporting evidence in the form of FDA warning letter and subsequent voluntary recall).

conclusory statement of claim" is not sufficient to survive a motion to dismiss merely because it "[leaves] open the possibility that a plaintiff might later establish some set of undisclosed facts to support recovery." 451 Mass. at 636 (internal quotation marks and brackets omitted).

CONCLUSION

The Court should reverse.

Dated: August 21, 2020

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I, Sarah K. Frederick, counsel for *Amici Curiae*, certify pursuant to Rule 17(c)(9) of the Massachusetts Rules of Appellate Procedure, that this brief complies with the rules of court that pertain to the filing of briefs, including but not limited to Mass. R. App. P. 17 and 20. This brief contains 7,463 words, excluding the parts of the brief exempted by Mass. R. App. P. 20(a)(2)(D). The brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman font, using Microsoft Word 2010.

/s/Sarah K. Frederick
Sarah K. Frederick

CERTIFICATE OF SERVICE

I, Sarah K. Frederick, hereby certify this 21st day of August, 2020, that I have served a copy of the foregoing **Brief for *Amici Curiae* the Chamber of Commerce of the United States of America and Pharmaceutical Research and Manufacturers of America in Support of Appellant**, in *Patricia M. Dunn v. Genzyme Corporation*, Case No. SJC-12904, on behalf of *Amici Curiae* the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America, by causing it to be delivered by eFileMA.com to counsel of record for Appellees, Matthew J. Dunn and Meghan Hall, and by causing it to be sent by electronic mail to counsel for Appellant, John Dougherty, at jdougherty@haugpartners.com.

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