COMMONWEALTH OF MASSACHUSETTS

Supreme Judicial Court

FOR THE COMMONWEALTH OF MASSACHUSETTS

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 OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION IN SUPPORT OF APPELLANT AND REVERSAL

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Corporate Disclosure Statement

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Statement Of Interest Of *Amicus Curiae*[1]

Washington Legal Foundation ("WLF") is a public-interest law firm and policy center, headquartered in Washington, D.C., with supporters nationwide, including many in Massachusetts. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It believes that the American economy and the public health both suffer when state law, including state tort law, conflicts or interferes with federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act ("FDCA"). WLF often appears as *amicus curiae*, including in state supreme courts across the country, to advance this view. *See, e.g.*, *Burningham v. Wright Med. Grp.*, 448 P.3d 1283 (Utah 2019); *McNair v. Johnson & Johnson*, 818 S.E.2d 852 (W. Va. 2018); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012).

In addition, WLF's Legal Studies division, the publishing arm of WLF, has published papers emphasizing Congress's intent to preempt most product liability claims against manufacturers of FDA-approved medical devices. *See, e.g.*, James M. Beck, *Recent Rulings Establish Beachheads for Preemption in Drug and Device Product-Liability Litigation* (Jan. 11, 2019) WLF Legal Backgrounder;

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[1] WLF submits this brief under Mass. R. App. P. 17(a) (allowing the filing of amicus briefs when solicited by an appellate court) and the Court's February 26, 2020 amicus announcement in this case.

Edward J. Fanning, Jr., et al., *New Jersey High Court Fortifies "FDA Defense" in Failure-to-Warn Litigation* (Dec. 6, 2018) WLF Legal Opinion Letter.

By including an express preemption clause in the FDCA's medical device provisions, Congress intended to foster economic efficiency, and thus innovation, by subjecting medical devices to one set, rather than fifty-one sets, of legal requirements. Likewise, *Iannacchino v. Ford Motor Co.*, 451 Mass. 623 (2008), requires that a complaint, to survive a motion to dismiss, must allege sufficient facts plausibly supporting an entitlement to relief *before* the economic burdens of full-blown litigation, including discovery, may be imposed on a defendant. The Superior Court's decision here, which refused to dismiss a complaint involving an FDA-approved medical device where plaintiff asserted no plausible basis either to assert a claim under state product liability law or to avoid preemption, greatly concerns WLF.

Declaration Under Mass. R. App. P. 17(c)(5)

No party, party's counsel, or person or entity other than *amicus curiae* and its counsel, authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. Neither *amicus curiae* nor its counsel has either represented any party to this appeal in another proceeding involving similar issues, or been or represented a party in a proceeding or legal transaction at issue in the present appeal.

Introduction and Summary of Argument

This case concerns what a plaintiff is required to plead to overcome a broad express preemption provision intended to protect medical device manufacturers from facing legal requirements that may vary in every state. Because plaintiff's complaint fails as a matter of both state product liability and federal preemption law, the Superior Court's order should be reversed.

The Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA") expressly preempt state law requirements that are "different from, or in addition to," any "requirement" under the FDCA. The U.S. Supreme Court has held that a medical device's premarket approval ("PMA") imposes FDCA "requirements" under this provision but that the Food and Drug Administration ("FDA")'s generic "current Good Manufacturing Practices" regulations ("cGMPs") do not. Thus, to avoid preemption of a manufacturing-defect claim involving a device subject to a PMA, a plaintiff must prove a violation not only of state product liability law but also of a PMA requirement, such as the specifications in the device's approved label, that is "parallel" to—*i.e.*, either identical to or at least includes—the state law requirement. Similarly, to avoid preemption of a failure-to-warn claim, plaintiff must prove a violation of product liability law that deviates from the device's approved labeling. (*See* pp. 11–16.)

Under Mass. R. Civ. P. 8(a) and this Court's holding in *Iannacchino v. Ford Motor Co.*, a plaintiff, to adequately plead *any* type of claim, must include facts that plausibly support an entitlement to relief before she may impose on the defendant the burdens of discovery. This requirement is also vital to ensuring the "just, speedy, and inexpensive" resolution of every action that lies at the heart of the civil rules. Mass. R. Civ. P. 1. These pleading requirements are particularly important in the medical device context, where discovery is especially burdensome and FDA regulations require manufacturers to maintain voluminous records of all sorts. What's more, imposing excessive costs on manufacturers will invariably impede their development of valuable medical devices. (*See* pp. 17–20.)

At bottom, to state a claim involving an FDA-approved medical device, a plaintiff must allege sufficient facts to plausibly support violation of both a state product liability law requirement *and* a "parallel" federal "requirement" under the FDCA. Here, plaintiff's claims are a textbook example of inadequate pleading. Her conclusory assertion that her dose of Synvisc-One was "adulterated" contains no facts making plausible a manufacturing defect in the product, as it fails to identify what the purported adulterant was or why there is reason to believe it was introduced into Genzyme's manufacturing process. Moreover, the claim impermissibly relies on an alleged violation of the cGMPs, which are not a federal

"requirement" sufficient to avoid preemption, and fails to allege any facts supporting a violation of the device's PMA specifications. (*See* pp. 20–25.)

Similarly, her failure-to-warn claim is inadequate on state law grounds because she fails to identify the particular risk that Genzyme allegedly fail to warn of. Indeed, the FDA-approved label warns of the adverse effects she now claims. Nor does plaintiff plead facts plausibly showing what Synvisc-One's label failed to disclose (or even what it actually disclosed), that Genzyme knew or should have known of the unidentified risk, or that her physician, to whom under the "learned intermediary" doctrine any warning should have been directed, did not know of the unidentified risk. She also fails to allege any facts to make plausible a deviation from the FDA-approved labeling, which is necessary to avoid preemption. (*See* pp. 25–27.)

This Court should reverse the Superior Court's order and dismiss plaintiff's Complaint.

Argument

I. THE FDCA PREEMPTS PRODUCT LIABILITY CLAIMS INVOLVING AN FDA-APPROVED MEDICAL DEVICE UNLESS A PLAINTIFF PROVES PARALLEL VIOLATIONS OF BOTH STATE AND FEDERAL REQUIREMENTS FOR THE DEVICE.

A. The Supremacy Clause And The FDCA Prohibit States From Imposing Requirements On Approved Medical Devices That Are Different From Or In Addition To Those Imposed By The FDCA.

Plaintiff alleges injury from the Synvisc-One, a Class III medical device that received premarket approval ("PMA") in 2009.[2] Under the Food, Drug, and Cosmetic Act (the "FDCA"), the Food and Drug Administration ("FDA") grants PMA only to Class III medical devices it has judged safe and effective. 21 U.S.C. § 360e(d)(2). The FDCA makes it illegal to sell Class III devices that have not received PMA, and such devices must be labeled consistent with their PMA. 21 U.S.C. §§ 331(a), 351(f); 21 C.F.R. § 814.80.

The FDCA's Medical Device Amendments ("MDA") also include an express preemption clause, which Congress enacted pursuant to its authority under

[2] The FDA posts PMA-related information on its website, which users can search. *See* Premarket Approval (PMA) Search Tool, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm (last accessed Aug. 24, 2020). In addition to allegations included in a complaint, courts may consider such matters of public record on a motion to dismiss for failure to state a claim. *Schaer v. Brandeis Univ.*, 432 Mass. 474, 477 (2000).

the Supremacy Clause. *See* U.S. Const. art. 6. The express preemption clause prohibits states from imposing on any medical device (1) "any requirement" that is (2) "different from, or in addition to" (3) "any requirement" under the FDCA, and which (4) "relate[s] to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). Federal preemption reflects "solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel v. Medtronic, Inc*., 552 U.S. 312, 326 (2008); *see also Caplinger v. Medtronic, Inc*., 784 F.3d 1335, 1336 (10th Cir. 2015) (Gorsuch, J.) (medical device preemption prevents manufacturers from having to abide by "fifty-one sets of requirements, a prospect that could deter or delay access to innovative devices and wind up hurting more patients than it helps").

Generally, only the second prong is a live issue in product liability cases involving an approved device. The first and fourth prongs are always satisfied, as state product liability law inherently establishes "requirements" that "relate[] to the safety or effectiveness of the device." *Riegel*, 552 U.S. at 323-325. The third prong is also always satisfied because a PMA, as a matter of law, "imposes 'requirements' under the MDA." *Id*. at 322.

As for the second prong, a state requirement is preempted as "different from, or in addition to" a federal requirement unless the two requirements are "parallel." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). *See also Riegel*, 552 U.S. at

330 (reaffirming the "parallel" analysis). A state requirement is parallel to a federal one only if it is either identical, or "narrower, not broader," *i.e.*, if it imposes only a subset of the federal requirements. *Lohr*, 518 U.S. at 495. Thus, to avoid preemption on a claim for a medical device that has received a PMA, plaintiff must identify federal requirements that impose duties "at least as broad as those she seeks to vindicate through state law." *Caplinger*, 784 F.3d at 1340.

B. Manufacturing Defect And Failure-To-Warn Claims Are Preempted Unless Plaintiff Proves Defendant Violated A Device-Specific FDCA Manufacturing Or Labeling Requirement.

All of plaintiff's allegations are based on either an alleged "adulteration" of Synvisc-One, *i.e.*, a manufacturing defect, or Genzyme's alleged failure to warn of the product's risks.

Plaintiff identifies the FDA's "current good manufacturing practices" ("cGMPs") as the federal "requirement" that is purportedly parallel to her manufacturing defect claims. The cGMPs, however, are generic—*i.e.*, not device-specific—regulations that broadly "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). Because the regulation is not device-specific, it "does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring

that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device." Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 F.R. 52602, 52603 (Oct. 7, 1996). Thus, for example, while the cGMPs require manufacturers to "develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications," 21 C.F.R. § 820.70(a), they do not prescribe what those processes must be.

The cGMPs are not parallel federal "requirements" that can avoid preemption because they are not "requirements" under § 360k(a) at all. In *Lohr*, the Supreme Court held that the cGMPs are too generic to constitute a federal "requirement" that could preempt an arguably different or additional state law requirement. *Lohr*, 518 U.S. at 501. By the same logic, they are too generic to constitute a parallel "requirement" that could save a state law claim from preemption.

For this reason, numerous courts have held that a product liability claim premised on cGMP violations do not rely on a parallel federal "requirement" and are expressly preempted. *E.g.*, *Kubicki v. Medtronic*, Inc., 293 F. Supp. 3d 129, 180 (D.D.C. 2018) (claims preempted because cGMPs consist only of "overarching guidelines" rather than any "specifically established" "federal-

requirement baseline"). *See also Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (affirming district court preemption holding that a particular cGMP regulation was not a "specific federal requirement in the PMA approval"); *Gross v. Stryker Corp*., 858 F. Supp. 2d 466, 495, 497 (W.D. Pa. 2012) ("[a]llowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel*," and the cGMPs are not specific so as to constitute relevant requirements).

Moreover, counting the cGMPs as parallel federal requirements would conflict with a primary Congressional purpose behind the FDCA's express preemption provision: to establish one set—rather than fifty-one different sets—of rules to ensure a device's safety and effectiveness, and thereby to facilitate manufacturers' ability to innovate. *See Riegel*, 522 U.S. at 326; *Caplinger*, 784 F.3d at 1336. For example, if the cGMP requiring manufacturers to implement unspecified "production processes" to ensure that manufactured devices conform to their specifications was a parallel federal "requirement," then each state could require manufacturers to adhere to a different production process. Given the cGMP's high level of generality, fifty-one sets of laws would potentially be parallel to it, undoing the very national uniformity and economic efficiency that preemption seeks to secure.

As for a failure-to-warn claim involving a device subject to a PMA, any claim that the manufacturer should have provided warnings other than those in the approved labeling is expressly preempted. As already noted, manufacturers of such devices generally must follow the approved labeling. 21 U.S.C. §§ 331(a), 351(f); 21 C.F.R. § 814.80. Thus, under *Riegel*, the labeling establishes federal requirements to which additional state-law warning requirements would not be parallel, so that claims under such a requirement are preempted. *E.g.*, *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993) ("The MDA forecloses these claims because [defendant] cannot be forced to change [the product's] packaging and labeling by virtue of these state law damage claims."); *Bryant*, 623 F.3d at 1205 ("Even if federal law *allowed* [defendant] to provide additional warnings, as Plaintiffs alleged, any state law imposing an additional requirement is preempted by § 360k.").

Still, not all manufacturing defect and failure-to-warn claims are expressly preempted. As already noted, *Riegel* held that a PMA *does* impose federal requirements within the meaning of § 360k(a). *Riegel*, 552 U.S. at 322. Thus a manufacturing defect claim that a device did not conform to its composition as specified in the approved label, or a failure-to-warn claim that the manufacturer did not provide the PMA-required warning, would not be expressly preempted, as such claims would impose no requirements in addition to those imposed by the PMA.

II. RULE 8 ESTABLISHES A PLAUSIBILITY PLEADING STANDARD THAT IS PARTICULARLY IMPORTANT IN CASES INVOLVING FDA-APPROVED MEDICAL DEVICES.

To adequately state a claim under Mass. R. Civ. P. 8(a), a plaintiff must plead "*factual* allegations *plausibly suggesting* (not merely consistent with) an entitlement to relief." *Iannacchino*, 451 Mass. at 636 (emphasis added); *see* Mass. R. Civ. P. 8(a) (complaint "shall contain . . . a short and plain statement of the claim *showing that the pleader is entitled to relief*") (emphasis added). Under this standard, a plaintiff cannot rely on mere "labels and conclusions," but must both *acquire* and *plead* sufficient facts to justify relief before discovery may proceed. *Iannacchino*, 451 Mass. at 636; *Flagg v. AliMed, Inc.*, 466 Mass. 23, 38 (2013) ("a plaintiff must allege facts that demonstrate he has a cause of action, and cannot ignore well-recognized pleading standards because he has not yet acquired sufficient information to do so").

Beyond the requirements of Rule 8, *Iannacchino*'s pleading standard is critical to "secur[ing] the just, speedy, and inexpensive determination of every action" that lies at the heart of the civil rules. Mass. R. Civ. P. 1. As the United States Supreme Court recognized in *Twombly* (which *Iannacchino* adopted), allowing a conclusory pleading to open the gates to full-blown litigation would expose defendants to burdensome discovery and "push cost-conscious defendants to settle even anemic cases." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559

(2007). This concern about costly and unproductive discovery is well founded. More than ten years ago, survey data found that discovery costs can run into the millions of dollars and account for 70% of total litigation costs in cases that do not go to trial, and costs are only likely to be far higher today. Lawyers for Civil Justice *et al.*, "Litigation Cost Survey of Major Companies" (May 2010), *available at* https://tinyurl.com/yy4s7ohw ("for the period 2006-2008, the average company paid average discovery costs per case of $621,880 to $2,993,567"); ABA Section of Litigation Member Survey on Civil Practice: Detailed Report at 9 (Dec. 11, 2009), *available at* https://tinyurl.com/y3nga2l5 (attorneys estimate discovery accounts for 70% of litigation costs in cases not tried).

Conclusory complaints only compound the problem. Because the scope of discovery potentially includes anything that "relates to the claim or defense of the party seeking discovery or . . . of any other party," Mass. R. Civ. P. 26(b)(1), an overly general complaint readily invites a fishing expedition by plaintiff into all areas that might belatedly unearth facts to support her up-to-that-point unspecified "claims."

Applying *Iannacchino*'s plausibility standard is particularly important for claims involving FDA-approved medical devices. Importantly, because preemption stems from the Supremacy Clause, a defendant's protections against such claims have a constitutional dimension. *Gade v. Natl. Solid Wastes Mgmt. Assn.*, 505 U.S.

88, 108 (1992) ("pre-emption doctrine is derived" from the Supremacy Clause). These constitutional protections would be severely diminished if they could not meaningfully be enforced at the motion-to-dismiss stage, and a defendant who succumbs to an *in terrorem* settlement because of discovery costs, *see Twombly*, 550 U.S. at 558, would end up with no protection at all.

Moreover, under Mass. R. Civ. P. 26(b)(1), bare-bones pleading in a medical device case could make virtually anything about the device discoverable, including information about defendant's design, engineering, testing, manufacturing, sales, marketing, and regulatory compliance—not to mention the defendant's medical and scientific knowledge. This would be particularly burdensome for medical device manufacturers, who must maintain voluminous records for regulatory compliance and other reasons. *See, e.g.*, 21 C.F.R. § 820.160 ("manufacturer shall maintain distribution records"); 21 C.F.R. § 820.181 ("manufacturer shall maintain device master records").

In addition, the economic burdens of excessive discovery, with the accompanying risk of liability or nuisance settlements, would harm the public health by either discouraging medical device development in the first instance, or diverting resources from it. That would be contrary to Congress's intent in enacting the MDA. *Riegel*, 552 U.S. at 326 (MDA preemption clause shows Congress's "solicitude for those who would suffer without new medical devices if

juries were allowed to apply the tort law of 50 States to all innovations"); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) (MDA intended to "spur[] innovation by ensuring that device manufacturers are subject to uniform, nationwide standards"). Such economic burdens are also contrary to the objectives of Massachusetts product liability law. *See Payton v. Abbott Labs*, 386 Mass. 540, 573 (1982) (increasing costs by expanding tort liability "could have a deleterious effect on the development and marketing of new drugs").

III. PLAINTIFF'S COMPLAINT FAILS ADEQUATELY TO PLEAD A NON-PREEMPTED CLAIM.

By marrying the substantive law of product liability and preemption to *Iannacchino*'s procedural requirements for pleading, Massachusetts law requires a complaint involving an FDA-approved medical device to plead sufficient facts that plausibly suggest a violation of both state product liability law and a parallel federal "requirement" under § 360k(a). Plaintiff's Complaint is a textbook example of a failure to meet these standards. While she asserts counts for negligence, breach of the implied warranty of merchantability, breach of express warranty, strict product liability, and violation of Mass. G. L. ch. 93A, all are based on theories of manufacturing defect (*i.e.*, an alleged "adulteration") or failure to warn, RA29-34, and plaintiff failed adequately to plead a claim under either theory.

A. Plaintiff Failed to State a Manufacturing Defect Claim Under Both State and Federal Law.

Plaintiff failed adequately to plead a manufacturing defect claim under Massachusetts product liability law because her repeated allegation that she received "adulterated" Synvisc-One injections, RA28, RA29, RA31, RA32, RA33, is a bare legal conclusion devoid of facts and that fails to make her claim plausible. *See Iannacchino*, 451 Mass. at 636 (plausibility "requires more than labels and conclusions"); 21 U.S.C. § 351 (legal definition of "adulterated"); Plaintiff-Appellee's Brief at 8 n. 3 ("The word 'adulterated' is a term of art. *See* 21 U.S.C. § 351(h)."). She alleges no facts to make plausible that the product "was manufactured differently, or deviated in any respect from its intended design," in a way that made it unreasonably dangerous. *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 313 (2016) (citing *Carter v. Yardley & Co.*, 319 Mass. 92, 96 (1946), and *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978)). She fails to identify any adulterant, how it affected the device, or any reason to think the adulteration occurred before the product left Genzyme's hands. *See Laporte v. Vlad,* 97 Mass. App. Ct. 1121 (2020) (Rule 1:28 Decision) (manufacturing defect claim requires plaintiff to show "the [device] at issue had a defect, which was created during the manufacturing process before it left [manufacturer's] hands").

This is not the rare case where the injury itself supports an inference of a claim. Plaintiff alleges that she was injected with Synvisc-One separately in each

of her knees and "[i]mmediately" experienced "adverse side-effects" that included "pain and swelling in her knees" and "difficulty walking," which in turn caused several falls leading to injuries including a broken neck. RA29. But Synvisc-One's approved labeling expressly warned of "arthralgia" (joint pain), "arthritis," "injection site pain," "joint effusion" (accumulation of fluids), "joint swelling," and "[g]ait disturbance," FDA, Synvisc-One Approved Labeling, 39-40, https://www.accessdata.fda.gov/cdrh_docs/pdf/P940015S012C.pdf (last accessed Aug. 16, 2020), so the occurrence of the symptoms alone could not support an inference that the product deviated from its approved specifications. *See Twombly*, 550 U.S. at 557 (antitrust claim must be dismissed where allegations of parallel conduct "could just as well be independent action" as conspiracy); *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009) (dismissing religious discrimination claim where there were "more likely explanations" for FBI conduct than "purposeful, invidious discrimination").

Beyond its deficiencies under state law, the Complaint lacks any facts alleging what parallel federal "requirement" was violated, as is necessary to avoid preemption. *Caplinger*, 784 F.3d at 1340 (to avoid preemption in a case involving a device subject to a PMA, a plaintiff must also adequately plead how "federal requirements impose duties that are at least as broad as those she seeks to vindicate through state law") (citing *Riegel*, 552 U.S. at 322-24); *see also Wolicki-Gables v.*

Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) ("To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated."). Plaintiff vaguely gestures to entire bodies of requirements—FDA's "premarket approval requirements" or "Good Manufacturing Practices" (at times termed "FDA's regulations"), RA29, RA30, RA32, but never specifies a particular PMA or other FDCA requirement that Genzyme violated. And, as noted above, the "overarching guidelines" of the cGMPs are too general to constitute a parallel federal requirement. *Kubicki*, 293 F. Supp. 3d at 180. Thus, without identifying any PMA requirement that Genzyme violated, plaintiff fails to plead a non-preempted claim.

Nor is it relevant whether plaintiff might learn facts in discovery to bolster her claim. Under *Iannacchino*'s standard, she must both *acquire* and *plead* sufficient facts to plausibly support relief; she "cannot ignore well-recognized pleading standards because [s]he has not yet acquired sufficient information to do so." *Flagg*, 466 Mass. at 38. To hold otherwise would return to the pre-*Iannacchino* era, when conclusory statements survived on "the possibility that a plaintiff might later establish some 'set of [undisclosed] facts' to support recovery." *Iannacchino*, 451 Mass. at 636 (brackets in original; quoting *Twombly*, 550 U.S. at 561). Instead, plaintiff must state a plausible non-preempted claim *before* she can impose on Genzyme the burdens of discovery.

Plaintiff's belated citation in a brief to a recall of one or more Synvisc-One lots that occurred two years *after* her injections, *see* RA88, not only fails to make her claim plausible but also underscores her failure even to *try* through any number of ways to try to "acquire[] sufficient information" to adequately plead a claim before filing suit. *Flagg*, 466 Mass. at 38. The FDA's website contains searchable databases for Warning Letters, results of FDA inspections, reports of adverse events, recalls, and PMA supplements for all Class III medical devices.[3] She could have requested information not posted on the website through Freedom of Information Act requests, including the "device history record" for the specific Synvisc-One injections she received. *See* 21 C.F.R. § 820.182. She also could have asked her doctor to advise her about potential contamination or lack of sterility, to preserve a sample of the product for testing, or to test her knee for potential infection or foreign material. And she could have asked an expert to opine on these issues.

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[3] *See* "Warning Letters," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters; "Inspection Classification Database Search," https://www.accessdata.fda.gov/scripts/inspsearch/; "MAUDE - Manufacturer and User Facility Device Experience," https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm; "Medical Device Recalls," https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm; "Premarket Approval (PMA)," https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

Judging by her Complaint, plaintiff either attempted none of this, or did so but to no avail. Regardless, under *Iannacchino*, *Flagg*, and similar cases, plaintiff could not adequately plead a plausible claim that the Synvisc-One injection she she received suffered from a manufacturing defect without pleading some facts plausibly identifying a particular "adulterant" in the product that deviated from the specifications listed in its FDA-approved labeling.

B. Plaintiff Failed to State a Failure-To-Warn Claim Under Both State Product Liability and Federal Preemption Law.

Plaintiff's Complaint fails to state a failure-to-warn claim as a matter of Massachusetts product liability law because she makes only conclusory allegations that the product was "not accompanied by proper warnings," RA28, that plaintiff was not "adequately warned," RA30, and that defendant "fail[ed] to properly warn," RA33, without identifying the risk that Genzyme failed to disclose and allege facts showing that it knew or should have known of that risk. *See Vassallo v. Baxter Healthcare Corp.*, 428 Mass. 1, 23 (1998) (defendant may be liable only for failing to warn of risks that were "reasonably foreseeable at the time of sale" or discoverable through "reasonable testing prior to marketing the product"); *see also Hoffman v. Houghton Chem. Corp.*, 434 Mass. 624, 637 (2001) (liability turns on "the reasonableness of the defendant's actions in the circumstances").

Indeed, as discussed at p. 22 above, Synvisc-One's approved labeling expressly warns of the very adverse effects that plaintiff alleges. Lacking any

factual allegations about an undisclosed risk, plaintiff also naturally fails to allege facts that plausibly show Genzyme should have known of this unidentified risk.

Nor is that all. Massachusetts also applies the "learned intermediary" doctrine, so "in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient." *Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, 120 n.2 (1st Cir. 1991); *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 136 (1985). Plaintiff says nothing—not even in vague or conclusory fashion—about the warning Genzyme gave to her treating physician, much less how that warning was defective. *See Acevedo v. Johnson & Johnson*, No. 16-CV-11977-DLC, 2018 U.S. Dist. LEXIS 168910, at *10-11 (D. Mass. Sep. 30, 2018) (dismissing action where "[t]he amended complaint fails to identify the plaintiff's physician or to assert when s/he treated the plaintiff or what information, if any, the physician possessed regarding [the product]").

Beyond these state law inadequacies, the Complaint also fails adequately to plead violation of a parallel federal "requirement" to avoid preemption, instead alleging, in conclusory fashion, violations of cGMPs or PMA requirements. RA29, RA30, RA32. Critically lacking are alleged facts plausibly showing that Genzyme deviated from its FDA-approved labeling. *See, e.g.*, *King*, 983 F.2d at 1136 (defendant "cannot be forced to change [the product's] packaging and

labeling by virtue of these state law damage claims."); *Bryant*, 623 F.3d at 1205 ("Even if federal law *allowed* [defendant] to provide additional warnings, as Plaintiffs alleged, any state law imposing an additional requirement is preempted by § 360k."). Without such allegations, plaintiff's failure-to-warn claim fails.

Conclusion

For all the foregoing reasons, amicus Washington Legal Foundation respectfully requests that this Court reverse the decision of the Superior Court and dismiss plaintiff's First Amended Complaint.

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Dated: August 25, 2020

Certification Under Mass. R. App. P. 17(c)(9)

I, Stephen Stich, certify that the foregoing brief complies with the rules of court that pertain to the filing of briefs, including but not limited to Rules 17 and 20. This brief contains 4,280 non-excluded words, which I ascertained using Microsoft Word 2016's word count function. The brief uses Times New Roman 14-point font and was composed in Microsoft Word 2016.

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Certificate Of Service Under Mass. R. App. P. 13(e)

I, Stephen Stich, certify that on August 25, 2020, on behalf of amicus Washington Legal Foundation, I electronically filed the foregoing *Brief of Washington Legal Foundation As Amicus Curiae In Support Of Appellant* in Dunn v. Genzyme, SJC-12904, via e-fileMA, with which counsel for Appellees, Matthew J. Dunn and Meghan E. Hall, are registered and will receive automatic service. I also served counsel for Appellant, John C. Doherty and Keelan F. Diana, who have consented to electronic service, via email at the email addresses noted below. The contact information of the aforementioned counsel is:

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