UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 24-10552-RGS

GUNTER CROMMELIN,
individually and on behalf of all
others similarly situated

v.

TAKEDA PHARMACEUTICALS U.S.A., INC.;
TAKEDA PHARMACEUTICALS AMERICA, INC.; and
TAKEDA MANUFACTURING U.S.A., INC.

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS

September 4, 2024

STEARNS, D.J.

Plaintiff Gunter Crommelin filed this putative class action against defendants Takeda Pharmaceuticals U.S.A., Inc.; Takeda Pharmaceuticals America, Inc.; and Takeda Manufacturing USA, Inc. (collectively, Takeda) on behalf of herself and all others similarly situated. She alleges that Takeda breached an express warranty (Count I) and violated the consumer protection laws of Massachusetts (Count II) and Alabama (Count III) by selling her "empty capsules [of medication] or capsules containing less of the active ingredient than indicated." Am. Compl. [Dkt # 14] ¶ 5. Takeda moves to dismiss Counts II and III pursuant to Federal Rule of Civil Procedure

12(b)(6), and to strike the class allegations pursuant to Federal Rule of Civil Procedure 12(f). For the following reasons, the court will allow both motions.

BACKGROUND

Takeda manufactures and sells the prescription medicine Vyvanse, "an FDA-approved central nervous system stimulant prescription medication containing lisdexamfetamine dimesylate." *Id.* ¶ 100. Relevant here,[1] Vyvanse "is used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adults, age six or older." *Id.* ¶ 1.

Crommelin suffers from ADHD and was prescribed 40 mg of Vyvanse (with an as-needed supplement of Dextroamphetamine) by her doctor. Crommelin "did not take Vyvanse every day but instead, primarily took it during the week while she was at school or work." *Id.* ¶ 14. She routinely supplemented the Vyvanse dose with Dextroamphetamine two to three times each week.

On September 12, 2023, Crommelin paid $60 to fill her prescription at a local pharmacy in her home state of Alabama (September Refill). She received a bottle labeled "Vyvanse 40 MG Capsule," *id.* ¶ 16, which contained twenty-eight capsules matching the physical appearance of Takeda-manufactured Vyvanse, *see id.* ¶¶ 16, 64, 71, 75, 76. While using the pills from

[1] Vyvanse also is approved to treat Binge Eating Disorder in adults.

her September Refill, Crommelin "felt her medicine was not performing properly to treat her ADHD." *Id.* ¶ 18. She found herself needing to supplement her dosage with Dextroamphetamine every day rather than her typical two to three times a week.

When only five pills remained in the September Refill, Crommelin learned that a friend of hers had received empty Vyvanse capsules from a different local pharmacy. At her friend's urging, Crommelin opened all five capsules and discovered that they were empty. Her mother called the pharmacy to report the issue, but Crommelin received neither a refund for the cost of the refill nor a replacement for the empty capsules.

On November 17, 2023, Crommelin again paid $60 to fill her prescription at a local pharmacy (November Refill). She opened five of the pills from this refill and "observed that there was some medication inside, but only about half of each capsule was filled." *Id.* ¶ 25. Crommelin does not appear to have commissioned any laboratory testing to determine how much, if any, lisdexamfetamine dimesylate was present in these partially-filled capsules.

DISCUSSION

I. Motion to Dismiss

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Two basic principles guide the court's analysis. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. A claim is facially plausible if its factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678.

a. Massachusetts Consumer Protection Act (Count II)

Count II asserts a claim under the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A (Chapter 93A), which prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." *Id.* § 2(a). Conduct is unfair within the scope of this provision "if it is (1) within the penumbra of a common law, statutory, or other established concept of unfairness; (2) immoral, unethical, oppressive, or unscrupulous; or (3) causes substantial injury to [consumers,]

competitors or other business people." *Tomasella v. Nestle USA, Inc.*, 962 F.3d 60, 79 (1st Cir. 2020) (alteration in original), quoting *Heller Fin. v. Ins. Co. of N. Am.*, 410 Mass. 400, 408 (1991). Conduct is deceptive, on the other hand, "when it has the capacity to mislead consumers, acting reasonably under the circumstances, to act differently from the way they otherwise would have acted (*i.e.*, to entice a reasonable consumer to purchase the product)." *Dumont v. Reily Foods Co.*, 934 F.3d 35, 40 (1st Cir. 2019), quoting *Aspinall v. Philip Morris Cos.*, 442 Mass. 381, 396 (2004).

Here, however artfully framed, *see* Am. Compl. ¶ 117 (separately alleging that Takeda: (1) represented the pills as containing a quality or ingredient they did not have; (2) failed to reveal to consumers that the product did not contain the represented 40 mg of lisdexamfetamine dimesylate;[2] and (3) misrepresented that the pills contained a specified

[2] To the extent Crommelin also alleges that Takeda "failed to reveal to consumers that its capsules did not comply with cGMPs and/or were adulterated and/or misbranded," *id.*, the Amended Complaint is devoid of any factual support for her conclusory assertion that Takeda failed to comply with good manufacturing practices. At best, Crommelin pleads that Takeda *must have* violated good manufacturing practices because empty capsules found their way into the market. *See, e.g.*, *id.* ¶¶ 52-53, 58. But precedent is clear that this type of "merely consistent with" allegation is insufficient to plausibly establish liability at the pleading stage. *Iqbal*, 556 U.S. at 678, quoting *Twombly*, 550 U.S. at 545. The court needs something more substantial than the mere fact that Crommelin (or even Crommelin, her friend, and her brother, assuming they received brand-name Vyvanse and not a generic version) received empty pills in one refill to reasonably infer

dosage of lisdexamfetamine dimesylate and could treat ADHD), Crommelin's Chapter 93A claim at its core hinges on a single act: the receipt of empty Vyvanse capsules in her September Refill.[3] Although it is troubling to contemplate a consumer receiving empty capsules in the place of prescribed medication, the court agrees with Takeda that nothing in the Amended Complaint plausibly establishes that any error on Takeda's part "rose above the level of mere negligence." *Brown v. Bank of Am. Corp.*, 2011 WL 1311278, at *3 (D. Mass. Mar. 31, 2011). Crommelin does not, for example, allege that Takeda knew that it was supplying empty capsules at the time Crommelin's prescription was filled (much less that it intended to sell its customers short). Nor does she plead any factual basis from which the court could reasonably infer that Takeda *should have* known, *e.g.*, because it

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that Takeda failed to meet its quality control and sampling obligations – especially where, as here, the capsules passed through other hands on the way to the point of sale.

[3] The court can reasonably infer from the mere fact that the five capsules from the September Refill were empty that they did not contain the advertised 40 mg of lisdexamfetamine dimesylate. There is no basis, however, for the court to infer that the partially-filled capsules from the November Refill lacked the represented 40 mg of lisdexamfetamine dimesylate. Crommelin does not, for example, allege that the capsules had been tested and found to contain less than 40 mg of lisdexamfetamine dimesylate or that she had usually found her 40 mg capsules to have been completely filled. She does not even allege that she felt the pills in her November Refill were lacking in potency, as was the case with the pills from the September Refill.

knowingly or recklessly continued to operate in the face of glaring and known manufacturing defects. *See supra* note 2. There is nothing, in short, to suggest that Takeda's representation, hollow as it may have been, was "unfair" or "deceptive" within the scope of Chapter 93A. *See Darviris v. Petros*, 442 Mass. 274, 278 (2004) (noting that, while Chapter 93A "is a statute of broad impact, the limits of which are not precisely defined, a violation . . . requires, at the very least, more than a finding of mere negligence") (internal quotation marks and citations omitted).

b. Alabama Deceptive Practices Act (Count III)

Count III asserts a claim under the Alabama Deceptive Practices Act (ADTPA), Ala. Code §§ 8-19-1, *et seq.*, which, as relevant here, prohibits:

> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have . . . .
>
> (6) Representing that goods are original or new if they are deteriorated, reconditioned, reclaimed, used, secondhand, or altered to the point of decreasing their value or rendering the goods unfit for the ordinary purpose for which they were purchased . . . .
>
> (7) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.
>
> (9) Advertising goods or services with intent not to sell them as advertised.

> (27) Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

Id. § 8-19-5. The parties agree that knowledge is a necessary component of a successful ADTPA claim, although knowledge may be constructive rather than real. *See id.* § 8-19-3(9) (defining knowledge as "[e]ither actual awareness or such awareness as a reasonable person should have considering all the surrounding circumstances").

Crommelin argues that Takeda should have known[4] she would receive empty pills because, for empty pills to make it into the market, Takeda must have been violating good manufacturing practices. This is a classic *res ipsa loquitur* argument that, standing alone, does not suffice to satisfy Crommelin's pleading burden in the context of a claim of unfair business practices. The court needs something more than the mere fact that Crommelin received empty pills in one refill to reasonably infer that Takeda knew or should have known that it was violating sound manufacturing practices. *See supra* note 2; *cf. Bolling v. Mercedes-Benz USA, LLC,* 2024 WL 371876, at *15-16, *18 (N.D. Ga. Jan. 30, 2024) (finding knowledge sufficiently pled where plaintiffs alleged, *inter alia*, that defendants had conducted pre-sale durability testing that would have revealed the defect;

[4] Crommelin does not assert (either in the Amended Complaint or her Opposition) that Takeda had actual knowledge.

monitored the NHTSA's website, which was replete with consumer complaints about the defect; and reimbursed dealerships for repairs related to the defect). The Alabama claim accordingly must be dismissed.

c. Choice of Law

Although the court doubts whether Massachusetts substantive law should govern here under proper application of choice of law principles, it need not decide the issue considering its finding that a Massachusetts Chapter 93A claim, even if viable, is insufficiently pled.

II. Motion to Strike

Takeda moves to strike the class allegations under Federal Rule of Civil Procedure 12(f). The court approaches the request with caution, as striking class allegations is generally disfavored in the early stages of litigation. *See Manning v. Bos. Med. Ctr. Corp.*, 725 F.3d 34, 59 (1st Cir. 2013). This caution should not, however, deter the court from "delet[ing] the complaint's class allegations" if "it is obvious from the pleadings that the proceeding cannot possibly move forward on a classwide basis." *Id.*; *see also Camey v. Force Factor, LLC*, 2016 WL 10998440, at *2 (D. Mass. May 16, 2016).

Takeda argues that it is obvious from the pleading that no class action can exist here because, given how extensively state warranty law varies from

state to state, individualized issues of fact are certain to predominate.[5] Crommelin does not appear to substantively dispute the premise that "[t]here are tremendous differences among state warranty laws."[6] *Camey*, 2016 WL 10998440, at *7. She nonetheless seeks to postpone any ruling on the validity of her class allegations because that issue is "neither necessary nor appropriate for the Court or the parties to attempt to analyze, at the pleading stage." Opp'n at 17. The problem is this: Crommelin offers no explanation for how further development of the factual record would have any impact on whether – and how – warranty laws vary from state to state. The court accordingly sees no reason to delay resolution of the issue. And because the court agrees with Takeda on the merits that significant variations among state warranty law will preclude the establishment of any viable class as to Count I, it allows the motion to strike the class allegations.

[5] Because the court has allowed the motion to dismiss Counts II and III, it addresses only the portion of the motion to strike addressed to Count I.

[6] Crommelin's substantive argument largely relies on Chapter 93A to "provide[] a sufficient basis for a nationwide claim." Pl.'s Opp'n to Mot. for Summ. J. (Opp'n) [Dkt # 21] at 16. Because the court found this claim insufficiently pled, it is unavailing to her here.

ORDER

For the forgoing reasons, Takeda's motions are ALLOWED. Counts II and III are dismissed without prejudice, and Count I will proceed to discovery only on an individual basis.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE