UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ROBERT GUSTAVSEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE, on behalf of themselves and all others similarly situated, Plaintiffs, v. ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.; FALCON PHARMACEUTICALS, LTD.; SANDOZ, INC.; ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; PFIZER INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; BAUSCH AND LOMB INCORPORATED; ATON PHARMA, INC.; MERCK & CO., INC.; MERCK, SHARP & DOHME CORP., PRASCO, LLC; and AKORN, INC., Defendants.	)	Civil Action No. 1:14-cv-11961-MLW

MEMORANDUM IN SUPPORT OF DEFENDANTS' OMNIBUS MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER FED. R. CIV. P. 12(b)(1) AND 12(b)(6)

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I. INTRODUCTION

In this putative class action lawsuit, Plaintiffs challenge Defendants' manufacture and/or sale of FDA-approved prescription eye drop medications, not because the medications harmed them, or were ineffective, or because Defendants deceived Plaintiffs into purchasing the medications, but solely because Plaintiffs believe the eye drops are too big. According to Plaintiffs, because the drops dispensed from Defendants' FDA-approved containers are all larger than the size Plaintiffs perceive to be "ideal" (15 microliters) ("15 μL"), and because some of the eye drop solution runs down Plaintiffs' cheeks instead of being absorbed by their eyes, Defendants have committed unfair practices in violation of consumer protection statutes of twenty-six states and the District of Columbia, and are liable for unjust enrichment under the laws of seventeen additional states. Based on this theory, Plaintiffs ask this Court to issue an unprecedented order refunding money Plaintiffs and putative class members willingly paid for these effective eye drop medications—which Plaintiffs claim amounts to hundreds of millions of dollars (*see, e.g.*, First Amended Complaint ("FAC") ¶ 117)—and enjoining Defendants from selling their FDA-approved medications exactly as FDA has approved them.

Two similar eye drop cases filed by the same plaintiffs' counsel have already been dismissed with prejudice at the pleading stage. *See Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007 (E.D. Mo. 2014); *Carter v. Alcon Labs., Inc.*, No. 4:13CV00977 AGF, 2014 WL 989002 (E.D. Mo. Mar. 13, 2014).[1] For a host of reasons, this case should meet the same fate. First, as a threshold matter, Plaintiffs lack Article III standing because they have suffered no injury in fact. Plaintiffs purchased and used Defendants' medications as prescribed by their

[1] This same plaintiffs' counsel dismissed yet another eye drop case nearly identical to *Gustavsen* on the eve of oral argument on Defendants' motions to dismiss. *See Freburger v. Alcon Labs.*, No. 1:13-cv-24446-PAS (S.D. Fla. June 3, 2014). Though one court concluded that two other cases filed by the same plaintiffs' counsel, *Eike, et al. v. Allergan, Inc., et al.*, No. 3:12-cv-01141-SMY-DGW (S.D. Ill.), and *Fields v. Alcon*, No. 3:13-cv-00197-SMY-DGW (S.D. Ill.) survived Defendants' motions to dismiss, Defendants have moved for reconsideration (in light of an intervening Seventh Circuit opinion) and, alternatively, for certification of issues for interlocutory appeal. (*See Eike*, Dkt. No. 149; *Fields*, Dkt. Nos. 57-58.) Those motions are pending.

doctors, and the medications were effective in treating their eye conditions. Plaintiffs contend they were nonetheless economically injured based on the theory that eye drop medications must be designed to maximize cost-effectiveness, and that if Defendants' eye drops were smaller, no solution would run down Plaintiffs' cheeks and they would somehow save money. But Plaintiffs have not been "injured," and they are not entitled to any refund, just because the design of Defendants' dropper tips is not what Plaintiffs consider optimal. Nor have Plaintiffs alleged any facts leading to a plausible inference that if Defendants redesigned their products to Plaintiffs' desired specifications, it would necessarily result in cost savings for consumers. In addition, while Plaintiffs theorize about hypothetical physical harm that could result from use of Defendants' eye drops, Plaintiffs do not allege that Defendants' eye drops have ever caused them any physical injury, thus foreclosing any claim of Article III injury on that basis.

Second, Plaintiffs' claims are preempted under federal law. Plaintiffs seek to impose on Defendants a state-law duty to unilaterally reduce the volume of their eye drops and, consequently, reduce each dose of medication dispensed—something Defendants cannot do without FDA's prior approval. Because FDA pre-approval is required for the changes Plaintiffs contend are required under state law, proper application of U.S. Supreme Court precedent requires that the state-law claims be dismissed in their entirety.

Third, Plaintiffs fail to state a claim under the Massachusetts Consumer Protection Act, Mass. Gen. Laws, Ch. 93A ("Chapter 93A"), because conduct "permitted" by federal law is exempted from the scope of the Act. Thus, the fact that FDA reviewed and approved each of Defendants' medications, including the packaging, forecloses Plaintiffs' "unfair" practices claim. Plaintiffs also do not allege any conduct that Massachusetts would consider "unfair," because while Defendants' FDA-approved eye drops might not be Plaintiffs' ideal size, they do not violate any government standard. In addition, for the same reasons they lack Article III standing, Plaintiffs have suffered no cognizable injury under Massachusetts law.

Fourth, Plaintiffs fail to state a claim for unjust enrichment and money had and received under New York law. Plaintiffs have not asserted an "unfair" practices claim under New York

consumer protection laws because the New York legislature has precluded any private right of action, and Plaintiffs cannot circumvent that bar by recasting their claim as one for "unjust enrichment." And in any event, there can be no unjust enrichment or money had and received claim when Plaintiffs got the benefit of their bargain.

Finally, Plaintiffs' effort to invoke the laws of forty-one states and the District of Columbia, in addition to Massachusetts and New York law, when neither Plaintiffs nor their transactions have any discernible connection to those states, violates the Commerce Clause.

For all of these reasons, the Court should dismiss the FAC with prejudice.

II. PLAINTIFFS HAVE NOT PLAUSIBLY ALLEGED INJURY IN FACT AND THUS LACK ARTICLE III STANDING.

"To establish Article III standing, a plaintiff must first demonstrate that he has suffered an 'injury in fact.'" *In re Fruit Juice Prods. Mktg. & Sales Pracs. Litig.*, 831 F. Supp. 2d 507, 510 (D. Mass. 2011) ("*Fruit Juice*") (citing *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)). The injury must be concrete and the alleged harm "actual or imminent, not 'conjectural' or 'hypothetical.'" *Id.* (citing *City of L.A. v. Lyons*, 461 U.S. 95, 101–02 (1983)). "If a plaintiff fails to allege sufficient facts to satisfy this requirement, the case must be dismissed." *Id.*

Here, Plaintiffs assert economic injury amounting to some portion of the money they paid for Defendants' FDA-approved prescription eye drop medications. But Plaintiffs do not allege that Defendants induced Plaintiffs to purchase the medications by misrepresenting or concealing any information about them. Nor do Plaintiffs allege that the medications they purchased and used were ineffective for their prescribed use. Instead, Plaintiffs' "injury" theory is that, by buying and using Defendants' admittedly effective prescription eye drop medications, as directed by their physicians, they suffered economic harm because not every microliter of every drop they dispensed was absorbed by their eyes, and some of the eye drop solution may have run down their cheeks. (FAC ¶¶ 3-5.) Plaintiffs believe that Defendants' eye drops are too big, and ask this Court to award Plaintiffs a partial refund for the portion of each drop exceeding Plaintiffs' hypothetical "ideal" size. (*Id.* ¶¶ 17, 83, 84, 103, 115-17, 140.)

Plaintiffs' contention that they have suffered an Article III injury in fact is meritless. Courts have repeatedly rejected claims that consumers have been "injured" in the amount of all or part of the purchase price of a product where the product, as it does here, works exactly as it is supposed to. In *Fruit Juice*, for example, the plaintiffs alleged that Defendants' orange juice drinks contained lead, and that had plaintiffs known about the lead content, they would never have purchased the product. 831 F. Supp. 2d at 510. Plaintiffs contended that because the presence of lead rendered the juice "valueless" to them, they had suffered economic injury in the amount of the purchase price. *Id.* at 512. The court dismissed for lack of Article III standing:

> In this case, Plaintiffs have . . . failed to allege that the fruit juice products had any diminished value because of the presence of lead or that they would have purchased different or cheaper fruit juice products had they known about the lead. Plaintiffs' allegations only support the contention that the levels of lead in Defendants' products were unsatisfactory to them. This allegation is simply insufficient to support a claim for injury in fact.

Id. at 513. Courts around the country have dismissed similar "diminished value" claims under Rule 12(b)(1). *See Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010) (affirming dismissal because plaintiff who purchased lipstick containing lead had not suffered concrete injury in fact "[a]bsent any allegation that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect"); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319-21 (5th Cir. 2002) (holding that plaintiff lacked Article III standing where she "paid for an effective pain killer, and she received just that—the benefit of her bargain," and noting that "[m]erely asking for money does not establish an injury in fact"); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176-78 (D.D.C. 2003) (dismissing plaintiffs' consumer protection claims regarding inflated prices for OxyContin because they did "not allege that OxyContin failed to provide them effective pain relief or that they suffered any adverse consequences[.]"). The same analysis requires that Plaintiffs' claims be dismissed here. Plaintiffs purchased eye drop medications that did exactly what they were prescribed to do—effectively treat Plaintiffs' eye conditions—and thus they received the benefit

of their bargain. *See Thompson*, 993 F. Supp. 2d at 1012 (rejecting similar claim directed at sale of eye drop medications because plaintiffs failed to "allege[] that the [eye drop products] [are] anything other than what [they have] always purported to be" and received the "benefit of the bargain").

Indeed, Plaintiffs are asking this Court to take this already-rejected "diminished value" theory to new extremes. Unlike in *Fruit Juice*, *Koronthaly*, *Rivera*, and *Williams*, Plaintiffs do not even allege that Defendants concealed the size of their eye drops, and thus Plaintiffs' theory is not based on a claim that they would have refrained from purchasing Defendants' products or would have purchased a cheaper alternative. Rather, having purchased and used Defendants' effective medication with full knowledge of the facts, Plaintiffs ask this Court to intervene to provide them with a partial refund on the sole basis that Defendants' eye drops are bigger than the size Plaintiffs perceive to be "ideal." That remarkable proposition, if accepted, would completely upend the way everyday consumer transactions work. A consumer is not injured when a product is not designed or packaged in a way the consumer believes would maximize cost-effectiveness.[2] *See generally Batson v. Live Nation Entm't, Inc.*, 746 F.3d 827, 834 (7th Cir. 2014) (rejecting claim that plaintiff was injured under Illinois consumer protection laws in paying for concert ticket just because the bundled price included a mandatory charge for parking he could not use); *see also In re Motions to Certify Classes Against Court Reporting Firms for Charges Relating to Word Indices*, 715 F. Supp. 2d 1265, 1267-68 (S.D. Fla. 2010) (noting that if the court accepted plaintiffs' invitation to use consumer protection laws to regulate amounts court-reporting firms charge for index pages versus transcript pages, then "the American public would find itself surrounded by countless examples of 'unfair' or 'deceptive' conduct or practices, many of which are and have been long accepted as a normal part of life"). If Plaintiffs have an idea for a commercially viable dropper tip design that they believe might be cheaper and

[2] Otherwise, consumers would suffer an Article III injury whenever they are unable to squeeze the last of the toothpaste out of the tube or ketchup out of the bottle, or because a spray bottle or aerosol might dispense more product than consumers believe is absolutely necessary.

more efficient for end-users, then they can pitch that idea to the market.[3] But Plaintiffs cannot file a lawsuit in an Article III court, claim that they have been "injured," and ask this Court to refund them money they already paid for medication that worked exactly as it was supposed to.

In addition, to the extent Plaintiffs intend to rely on allegations of a hypothetical risk of physical injury from allegedly being exposed to too much medicine or from running out of medicine too quickly and being unable to afford more (*see, e.g.*, FAC ¶¶ 5, 13-14, 52, 70-79, 184-87), such allegations are insufficient as a matter of law to confer Article III standing under this same line of cases. None of the Plaintiffs alleges that he or she has actually experienced any physical injury as a result of using Defendants' eye drops, and courts "have made clear that the type of speculative future injury" based on potential harm that has yet to occur "cannot form the basis of a lawsuit." *Fruit Juice*, 831 F. Supp. 2d at 511; *see also Koronthaly*, 374 F. App'x at 259 (holding that because plaintiff had suffered "no adverse health effects from using the lipsticks," she had "asserted only a subjective allegation that the trace amounts of lead in the lipsticks are unacceptable to her, not an injury-in-fact sufficient to confer Article III standing"); *Rivera*, 283 F.3d at 320 (holding that Plaintiffs failed to allege Article III injury in fact from use of drug that allegedly caused liver failure where Plaintiffs "were not among the injured").

Beyond the fact that they received the benefit of their bargain and suffered no physical injury, Plaintiffs have not stated any Article III injury for another reason: Plaintiffs' injury theory depends entirely on the premise that, if Defendants manufactured and distributed their eye drop medications in bottles that dispensed drops of Plaintiffs' "ideal" size, Defendants would then sell these hypothetical products at a price that would ensure an overall cost savings for consumers. (*See* FAC ¶ 103) (asserting that consumers have been injured because if the maximum drop size was 15 µL, "the medication in the bottles would last longer and Class

[3] The FTC presumes that, absent coercion or misrepresentation, the competitive market adequately self-regulates product design and price. *See* FTC Unfairness Policy Statement, reprinted in *In the Matter of Int'l Harvester Co.*, 104 F.T.C. 949 (1984). Plaintiffs here have not alleged, and nor could they, that the drop sizes of Defendants' medications are the result of any kind of anti-competitive conduct.

Members would spend substantially less on their therapy than they do with larger, substantially wasted, eye drops"). But a theory of injury that depends on how defendants would price a hypothetical product is, by definition, "hypothetical" or "conjectural," and cannot give rise to Article III standing. *Lyons*, 461 U.S. at 101–02. In *Dominguez v. UAL Corp.*, 666 F.3d 1359 (D.C. Cir. 2012), for example, the plaintiffs claimed that they were injured by United Airlines' no-transfer policy related to certain discounted tickets because if the tickets could be freely transferred, plaintiffs would pay lower prices on the secondary market. *Id.* at 1364. The court recognized, however, that, without a no-transfer policy, United may "need to alter its pricing strategy, which may very well result in higher average ticket prices if it stopped offering discounts." *Id.* Accordingly, plaintiffs lacked Article III standing because their theory of injury required "pil[ing] speculation atop speculation" as to how United would price its tickets in the future. *Id.*

The same analysis requires dismissal of Plaintiffs' claims here for lack of standing. To survive a motion to dismiss, Plaintiffs must allege facts, not just conclusions. *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). While Plaintiffs point to sentences from a couple of articles commenting that smaller eye drops would lead to cost savings for consumers (FAC ¶¶ 104-06), no facts are cited anywhere in those articles or in the FAC that would allow this Court to plausibly infer that a hypothetical product with a redesigned dropper tip would have to be priced in a way that would result in an economic benefit to consumers. Plaintiffs do not allege, for example, that pharmaceutical manufacturers are required to price their eye drop medications in proportion to the amount of solution in each eye drop, without accounting for other cost variables and competitive market factors. Indeed, as courts have recognized in dismissing nearly identical claims at the pleading stage, no such requirement exists. In *Thompson*, the plaintiffs, represented by the same lawyers representing Plaintiffs here, sued Allergan, asserting that it had engaged in an unfair practice under the Missouri Merchandising Practices Act by "overfilling" its eye drop dispensers without valid reason so that consumers would be forced to purchase more medicine than necessary. *Thompson*, 993 F. Supp. 2d at 1009. Just as Plaintiffs allege here with respect to

the size of Defendants' eye drops, Thompson alleged that "if . . . Defendants included smaller quantities of medication in the Restasis vials, the prescriptions would be less expensive and consumers would not have to spend so much on the medication." *Id.* at 1012. The court rejected the argument that these allegations stated a plausible claim of injury, holding that "[e]ven assuming that less medication would produce a less expensive product for the consumer, the courts are not regulators of the fair market price of products." *Id.* Accordingly, the court concluded that the contention that "including smaller quantities of medication in the Restasis vials would make it less expensive to consumers" was "without sufficient logical or factual foundation." *Id.* at 1013; *see also Carter*, 2014 WL 989002, at *4 ("[E]ven if Defendants sold bottles with less medication, Plaintiff has not suggested there is anything to preclude them from charging what they now charge for the bottles currently available for purchase."); *see generally Capital Ford Truck Sales, Inc. v. Ford Motor Co.*, 819 F. Supp. 1555, 1566 (N.D. Ga. 1992) (applying economic principle that "a manufacturer is free to set prices at any level it chooses"). If anything, it is more plausible that Defendants may be compelled to ***increase*** their prices, given the additional costs that would be associated with redesigning, repackaging, and then trying to obtain regulatory approval for newly packaged and dosed eye drop products.

Plaintiffs' theory of "injury" requires this Court to determine that Plaintiffs' ideal product design—which has never been developed, manufactured, approved by FDA, or marketed—would necessarily result in cost savings for consumers based on nothing more than a guess about what Defendants would ultimately charge for each hypothetical product. Because this kind of "conjectural" or "hypothetical" injury does not confer Article III standing, the FAC should be dismissed in its entirety with prejudice.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW

Plaintiffs' state-law claims, which attempt to force Defendants to redesign their federally approved droppers to dispense drops of 15 μL or less, should be dismissed for the additional, independent reason that such claims are preempted because they directly conflict with federal law regulating manufacturers of prescription drugs. Conflict preemption occurs either when

"compliance with both federal and state law is in effect physically impossible," or when "the state law stands as an obstacle to the accomplishment and execution of the full objectives of Congress." *Palmer v. Liggett Grp., Inc.*, 825 F.2d 620, 624-25 (1st Cir. 1987) (citing Supreme Court cases). Both types of conflict preemption apply here. It is impossible for Defendants to comply with their federal law obligations, which prohibit Defendants from selling their prescription eye drop medications at a reduced drop volume without first obtaining FDA approval, and at the same time comply with a purported state-law duty to redesign their medication containers to deliver smaller drops. In addition, Plaintiffs' asserted state-law duty to reduce the drop volume would frustrate the purposes and objectives of Congress in granting FDA authority to determine the appropriate dosage and packaging of prescription eye medications.[4]

A. Under Federal Law, It Is Impossible For Defendants To Reduce Drop Volume To 15 µL Without Prior FDA Approval.

U.S. Supreme Court precedent holds that if Defendants cannot make the changes to their products Plaintiffs contend are required by state law without seeking prior approval from FDA, then the state-law claims are barred by conflict preemption. In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court held that the relevant question when determining "impossibility" under a conflict preemption analysis is "whether the private party could independently do under federal law what state law requires of it." *Id*. at 2579 (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)). The Court recognized it was impossible for generic drug manufacturers to comply with their federal duty of "sameness"—requiring the label of a generic drug to match the reference listed drug's label at all times—while also simultaneously complying with their alleged state-law duty to change their labels to include additional safety information: "[W]hen a party cannot satisfy its state duties without the Federal Government's special

[4] The imposition of damages under state tort law is a form of state action subject to preemption. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000). Indeed, "a tort judgment . . . establishes that the defendant has violated a state-law obligation" and "disrupts the federal scheme no less than state regulatory law to the same effect." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008).

permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2581.

In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Court extended these same conflict preemption principles to any major change to either generic or brand-name drugs. The *Bartlett* Court observed that, "once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Id*. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). Thus, "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id*. at 2479. While brand name manufacturers are free to make certain *labeling* changes unilaterally, neither a brand name nor generic manufacturer can make "major changes" to the design, manufacturing process, and containers for prescription drugs without FDA's prior approval. *See generally* 21 C.F.R. § 314.70(b); *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 246 n.8 (3d Cir. 2009), *aff'd*, 131 S. Ct. 1068 (2011) (contrasting a brand-name drug manufacturer's ability to unilaterally strengthen labeling with "FDA's far-more extensive control and oversight of the approval of a drug's design and alteration").

Plaintiffs here insist that various state laws require Defendants to redesign their container closure systems so that they dispense drops no larger than 15 µL. But as the Court in *Bartlett* recognized, once Defendants' drug applications were approved by FDA for the medications at issue,[5] federal regulations required Defendants to obtain prior FDA approval for any "major

[5] No new drug may be sold in interstate commerce unless approved under a new drug application ("NDA") or, for a generic drug, an abbreviated new drug application ("ANDA"). 21 U.S.C. §§ 355(a), (b), (j). An NDA must include, among many other things, "a full list of the articles used as components of such drug," "a full statement of the composition of such drug," "a full description of the methods used in . . . the manufacture, processing, and packing of such drug," and "specimens of the labeling proposed to be used for such drug." *Id.* § 355(b)(1). An ANDA must include information showing that the active ingredient, route of administration, dosage

changes" to the products, including "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." 21 C.F.R. § 314.70(b)(1); *see also* 21 U.S.C. § 356a(c). Pursuant to 21 C.F.R. § 314.70(b)(2), "major changes" include, among other things: (i) "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application"; (ii) "[c]hanges requiring completion of studies in accordance with [21 C.F.R. part 320] to demonstrate the equivalence of the drug product to the drug product as manufactured without the change"; (iii) "[c]hanges that may affect drug substance or drug product sterility assurance"; (iv) "[c]hanges in labeling" (with certain limited exceptions); and (v) "[c]hanges in a drug product container closure system that controls the drug product delivered to a patient." 21 C.F.R. §§ 314.70(b)(2)(i)-(iii), (v)-(vi).[6]

If Plaintiffs' proposed reduction in drop volume fits ***any*** of these categories, then such a change would require FDA's prior approval before it could be implemented, and Plaintiffs' claims are preempted. *See Thompson*, 993 F. Supp. 2d at 1013-14 (dismissing similar complaint as preempted because eye drop manufacturer could not reduce fill volume in dropper vials without prior FDA approval); *see also Dopson-Troutt v. Novartis Pharms. Corp.*, 975 F. Supp. 2d 1209, 1218-19 (M.D. Fla. 2013) (claims that brand-name manufacturer should have added black-box warning to drug labeling were preempted because FDA regulations required prior approval); *Ray v. Allergan, Inc.*, No. 3:10cv136, 2012 WL 2120018, at *7 (E.D. Va. June 1, 2012) (same). Here, a change in drop volume falls within each of these categories.

First, Plaintiffs' claims seek to impose a requirement on Defendants to unilaterally

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form, strength, and labeling proposed for the new drug are the same as that of the reference listed drug, and that the new drug is bioequivalent to the reference listed drug. *Id.* § 355(j)(2)(A)(ii)-(v).

[6] 21 C.F.R. § 314.70(b)(2) is the same regulation at issue in *Bartlett*.

reduce each dose of medication dispensed by their droppers by an average of more than 60%. (*See* FAC ¶¶ 91, 102-03) (alleging that current droppers dispense an average volume of 39 µL and Defendants should limit them to 15 µL). Reducing the size of patients' doses as proposed here would be a major change requiring prior approval. *See* 21 C.F.R. §§ 314.70(b)(2)(i) and (ii). Such a change necessarily would reduce the quantity of the active and inactive ingredients in each dose (i.e., each drop), and a reduction in the active ingredient in each dose amounts to a change in "dosage strength." *See* Drugs@FDA Glossary of Terms, *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm ("strength" refers to "how much of the active ingredient is present in each dosage"). 21 C.F.R. § 320.21 (c)(1) requires that any change to "dosage strength" be supported by study data to demonstrate equivalence to the product as previously approved by FDA, and 21 C.F.R. § 314.70(b)(2)(ii) provides that any change requiring completion of studies in accordance with 21 C.F.R. Part 320 is a major change as a matter of law. Binding FDA Guidance further makes clear that "[c]hanges that may affect the controlled (or modified) release, metering or ***other characteristics (e.g., particle size) of the dose delivered to the patient***" are categorically major changes that must be pre-approved by FDA. FDA, CDER, Guidance for Industry, Changes to an Approved NDA or ANDA, 2004 WL 3199016, at *10 (April 2004) (emphasis added).

Second, the medications at issue here are sterile solutions. 21 C.F.R. § 200.50(a)(1) ("[A]ll preparations offered or intended for ophthalmic use . . . should be sterile."); *id.* §§ 200.50(a)(2)-(3), (c) (non-sterile ophthalmic medicines and droppers may be regarded as adulterated and misbranded under federal law). The regulations provide that any change that may affect "drug substance or drug product sterility assurance" of a sterile product is a major change. *Id.* at § 314.70(b)(2)(iii). FDA has stated unequivocally that the change Plaintiffs propose—"changing the design and dimension" of the container closure system to reduce drop volume (FAC ¶ 130)—fits squarely within that provision and would require pre-approval:

> All container closure systems changes must be supported with data to demonstrate that various characteristics of the drug product and/or

> container closure system are unchanged or equivalent (e.g., physical, chemical). For a sterile drug product, however, data must also be provided to support that the sterility assurance level and the maintenance of sterility for the product has not been affected. Sterility of drug products is a fundamental and essential quality attribute of these drugs and is a critical aspect of the safety assessment. . . . ***FDA considers changes in the container closure system for sterile drug products to be changes that may affect the sterility assurance and/or maintenance of sterility of a drug and, therefore, may have significant potential to affect the safety of the drug. Therefore, FDA has identified this change as one that requires prior approval*** . . . .[7]

Indeed, FDA has issued binding guidance to manufacturers advising that "[c]hanges in the size and/or shape of a container for a sterile drug product" are major changes requiring pre-approval. FDA, 2004 WL 3199016, at *16. This is true even if the change to the container's size or shape might be considered "very minor," such as "minute adjustments in [its] packaging components." 69 Fed. Reg. 18,728-01, 18,745 (Apr. 8, 2004) ("Changes in the container closure system, even if minimal, may affect the sterility assurance of the drug product and are a major change.").

Third, unless expressly excepted, any changes to drug labeling are major changes requiring prior approval. 21 C.F.R. §§ 314.70(b)(2)(v). For example, the FDA-approved label for Pfizer's Xalatan states how much of the active ingredient, latanoprost, is contained in each drop, noting that "[o]ne drop contains approximately 1.5 µg of latanoprost" and that "[t]he recommended dosage is one drop (1.5 µg) in the affected eye(s) once daily in the evening."[8] Unless Plaintiffs are proposing that the formulation of the drug be altered—which would itself be a major change (21 C.F.R. § 314.70(b)(2)(i))—Plaintiffs' proposal to reduce the volume of the drops by half or more would necessarily reduce the amount of latanoprost in each drop by that amount. Accordingly, Plaintiffs' claims would require Pfizer to change its labeling related to dosage and administration, which would require FDA pre-approval.

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[7] Supplements and Other Changes to an Approved Application, Final Rule, 69 Fed. Reg. 18,728, 18,751 (Apr. 8, 2004) (amending 21 C.F.R. § 314.70) (emphasis added).

[8] Xalatan Label, *available at* http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cc16fa68-4b68-4cdb-8e52-30c803292c22 (referenced at FAC ¶ 152 n.81). Documents expressly referenced in a complaint may be considered in deciding a Rule 12(b)(6) motion. *Clorox Co. Puerto Rico v. Proctor & Gamble Comm. Co.*, 228 F.3d 24, 32 (1st Cir. 2000).

Finally, FDA must pre-approve any change to a drug product container closure system that, as here, controls the drug product delivered to the patient. 21 C.F.R. § 314.70(b)(2)(vi) (major changes include "***[c]hanges in a drug product container closure system that controls the drug product delivered to a patient*** or changes in the type . . . or composition . . . of a packaging component that may affect the impurity profile of the drug product") (emphasis added). As FDA has explained:

> For some drug products, the container closure system itself, rather than a person, regulates the amount of drug product that is administered to a patient. These container closure systems are considered to "control drug delivery." For example, a patient that uses a metered dose inhalation product as instructed cannot control the amount of drug product the container closure system delivers or verify that the appropriate amount has been administered. ***Where a drug product container closure system controls drug delivery, FDA requires information to be submitted to support that the container closure system can accurately and repeatedly deliver the required amount of drug product***. The design and operation of these container closure systems is critical to ensure that the patient receives the correct dose. A drug product may not be safe or effective if a patient receives too much or too little of the drug product. ***Changes in these systems are considered to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product***.

69 Fed. Reg. at 18,739 (emphasis added); *see also* FDA, 2004 WL 3199016, at *16 n.20. Eye droppers are included among the primary packaging components that control the dose delivered to patients. *See* FDA, CDER/CBER, Guidance for Industry, Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing, and Controls Documentation, 1999 WL 33935258, at 8 (May 1999) (examples of packaging components relevant to drug delivery include droppers, spray bottles, transdermal patches, metered-dose inhalers, and dry powder inhalers). Indeed, Plaintiffs have premised their lawsuit on the allegation that "the size of the drop is determined by . . . the dimensions of the plastic dropper tip." (FAC ¶ 10); (*see also id.* ¶ 107) ("the design of eyedropper tips . . . determines the [drop] size and flow rate of the bottle"); (*id.* ¶¶ 128-33.)

For each of these independent reasons, Defendants cannot unilaterally reduce the drop

volume/dosage for their eye medications without first obtaining FDA approval. Plaintiffs' claims thus directly conflict with federal law and are preempted.[9]

B. Requiring Defendants To Comply With A Purported State-Law Duty To Reduce Drop Volume Would Interfere With The Purposes And Objectives Of The FDCA.

Plaintiffs' claims also stand as an obstacle to congressional intent that FDA determine the appropriate dosage and packaging for prescription eye medications sold in the United States. *See generally* 21 U.S.C. § 301, *et seq*. The federal Food, Drug, and Cosmetic Act ("FDCA") created a regulatory framework that grants FDA exclusive authority to address the complex scientific and public health issues related to the safety and effectiveness of prescription drugs. *See Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) ("The entire statutory scheme envisages that the FDA will perform the difficult task of investigation and scientific evaluation usually required to determine whether a drug product is safe and effective.").[10]

When considering a manufacturer's new drug application, FDA carefully reviews every

[9] In an unsuccessful attempt to plead around preemption, Plaintiffs allege that a few studies showed varying drop sizes for certain Merck, Alcon, and Pfizer products at different points in time, and that because these companies did not submit supplemental applications for modified dropper tips during the relevant time periods, the only explanation for the variation in drop sizes among the studies is that Merck, Alcon, and Pfizer must have secretly changed their dropper tips without prior FDA approval. (*See* FAC ¶¶ 148-50, 152.) Plaintiffs conclude from there that it must be the case that changes to dropper tips can be made unilaterally, and so their claims are not preempted. (*Id.* ¶¶ 146-47.) The more sensible explanation for varying drop size figures is that—as Plaintiffs expressly acknowledge in their own Complaint—drops of the same medication (and from the same bottle) can vary in size based on many factors, including the dispensing angle, and thus the drop sizes varied not because the dropper tips had been modified without FDA's knowledge or approval, but because the drops were being dispensed differently by different people. (*See* FAC ¶ 140) (change in dispensing angle affected drop size by 14.5%); (*id.* ¶ 143) (differences in dispensing angle changed drop size by as much as 19.4%). In any event, Plaintiffs' speculation that Merck, Alcon, and Pfizer flouted FDA requirements and put unapproved dropper tips on the market is not just wildly implausible, but irrelevant. The fact remains that federal regulations unambiguously require prior approval for the changes Plaintiffs contend should be ordered under state law, and Plaintiffs' claims are thus preempted as a matter of law.

[10] *See also Brief for the United States, Mut. Pharm. Co. v. Bartlett*, No. 12-142, 2013 WL 314460, at *1-6 (U.S. Jan. 22, 2013) ("U.S. Brief") (describing FDA's extensive regulatory scheme for prescription drugs).

aspect of the drug, including, among other things, detailed reports of investigations addressing the safety and effectiveness of the drug, all of its components, the drug's composition, the methods, facilities, and controls used in the manufacture, processing, and packing of the drug, and the drug's proposed labeling. *See* 21 U.S.C. § 355(b)(1). FDA's regulation of the manufacture of prescription drugs is so "pervasive[]" that it extends right "down to the requirements for plumbing and ventilation systems at each manufacturing facility." *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1079 (2011) (citations omitted). As such, in enacting the FDCA, Congress has charged FDA with exclusive responsibility to determine the appropriate dosage, strength, and packaging of prescription eye medications sold in the United States.

Plaintiffs' claims, if allowed, would frustrate these congressional purposes and objectives. Plaintiffs' claims in this case would require, for each drug, reducing the amount of the active ingredient (and other components of the drug product) patients receive in each dose by half or more, thereby creating a risk of underdosing, especially for patients who may occasionally miss their eye or partially miss their eye when instilling drops. The wisdom of such a reduction and whether or how this reduction would impact the effectiveness or safety of a particular medication for any particular patient group are issues for FDA scientists – not for lay juries or the courts, which lack the expertise to make such complex scientific determinations. *See Premo*, 629 F.2d at 803 (whether a drug is "safe and effective" . . . "is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue"). If a judge or jury is permitted to independently decide such critical issues for an FDA-approved drug, "Congress's purposes of ensuring that expert, science-based judgments are made by FDA, and the assurance that FDA approval provides for market participants, would be undermined by ad-hoc reconsiderations on a State-by-State and lawsuit-by-lawsuit basis." U.S. Brief, at *13.[11]

[11] Relying on hypotheses and some general statements from a few small studies reported in the published literature, Plaintiffs would universally impose a dose reduction to 15 μL or lower for prescription eye medications sold in multi-dose containers, regardless of their individual potency, chemical composition, or other characteristics. In contrast, FDA examines the safety

FDA's extensive authority likewise extends to the design of these eye droppers. *See* 21 C.F.R. § 314.70(b)(2)(vi); FDA, 2004 WL 3199016, at *16. Whether Defendants should be forced to redesign their droppers to reduce drop volume raises a host of scientific issues that go beyond the scope of Plaintiffs' Complaint and the expertise of a lay jury or this Court. For example, FDA must consider not only the corresponding reduction in dosage, but also whether redesigned droppers with much smaller (and more pointed) tips (*see, e.g.*, photograph at FAC ¶ 131) might pose a risk of injury for any particular patient group, such as glaucoma patients and elderly patients, who may have impaired vision or dexterity and thus be at greater risk for touching their eye with the pointed dropper tip. *See, e.g.*, FDA, 2004 WL 3199016, at *16 (requiring prior FDA approval for a "change to a new container closure system if the new container closure system does not provide the same or better protective properties than the approved container closure system"). FDA has the experience and access to pertinent patient data and other resources necessary to make these decisions; this Court (or a lay jury) does not.

Adequacy of dosage and dropper safety are just two of numerous medical and scientific issues raised by Plaintiffs' claims that properly fall within FDA's purview. To allow a Massachusetts jury to make judgments about the appropriate dose and container design for prescription eye medications for patients throughout the United States would usurp FDA's authority as the federal agency with the expertise to address these issues.

The recent case of *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014), is instructive. There, the Massachusetts Public Health Department banned the sale of the FDA-approved prescription drug Zohydro ER because the drug did not have an abuse-resistant formulation. *Id.* at *1. The manufacturer sought to enjoin the ban. The issue was whether, in light of FDA's approval of the drug, the Commonwealth could "interpose[] its

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and efficacy of each drug individually, considering "full reports of investigations," "a full list of the articles used as components," "a full statement of [the drug's] composition," and "methods used in . . . the manufacture," and requires "substantial evidence" showing that "the drug will have the effect it purports or is represented to have" under the conditions of use in the proposed labeling. 21 U.S.C. §§ 355(b)(1), (d).

own conclusion about Zohydro ER's safety and effectiveness." *Id.* at *2. The court held that it could not and prohibited the ban as obstructing "FDA's Congressionally-given charge." *Id.* "The FDA has the authority to approve for sale to the public a range of safe and effective prescription drugs . . . . ***If the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health***." *Id.* (emphasis added). The ban further obstructed FDA's purposes and objectives "because the drug Massachusetts wants Zogenix to adopt—Zohydro ER with an 'abuse-resistant formulation'—has not been approved by the FDA. To satisfy the Commonwealth, Zogenix would be required to return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe." *Id.* Plaintiffs' claims here effectively seeking to ban the sale of Defendants' FDA-approved eye medications and force Defendants to seek approval for medications with reduced dosage strength and redesigned container closure systems similarly obstructs FDA's mandate. Plaintiffs' claims would frustrate the purposes and objectives of the FDCA, are thus preempted, and should be dismissed.

IV. PLAINTIFFS FAIL TO STATE A CLAIM UNDER MASSACHUSETTS GENERAL LAWS CHAPTER 93A.

In addition to the fact that Plaintiffs have not asserted a cognizable Article III injury in fact and that their claims are preempted, Plaintiffs' claims must be dismissed for the independent reason that they have failed to state a claim under their respective states' laws. With regard to Plaintiffs' attempts in Count I to assert a claim under Massachusetts General Laws Chapter 93A, Defendants' FDA-approved medications are exempt from the statutory scheme, Defendants' alleged acts or practices do not meet the Massachusetts standard for unfairness, and Plaintiffs have not alleged a cognizable injury.

A. Defendants' Alleged Unfair Conduct Is Exempt Under Chapter 93A.

Chapter 93A expressly exempts "transactions or actions otherwise permitted" by a federal or state regulatory scheme. Mass. Gen. Laws ch. 93A, § 3 ("Section 3"). This exemption

protects a defendant from liability for engaging in an act or practice permitted by federal or state law, even where it is alleged to be immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. *Cablevision of Boston v. Pub. Improvement Comm'n*, 38 F. Supp. 2d 46, 61 (D. Mass. 1999) (Wolf, J.) (citing *Bierig v. Everett Square Plaza Assocs.,* 611 N.E.2d 720, 728 n. 14 (Mass. App. Ct. 1993)); *see also Fleming v. Nat'l Union Fire Ins. Co.*, 837 N.E.2d 1113, 1120-21 (Mass. 2005); *DePasquale v. Ogden Suffolk Downs, Inc.*, 564 N.E.2d 584, 587 (Mass. App. Ct. 1990). Where the allegations of the complaint and "other allowable sources of information" establish the Section 3 exemption with certitude, the court should dismiss the exempt Chapter 93A claim. *Riccio v. Ford Motor Credit Co.*, 238 F.R.D. 44, 47 (2006); *see also Fleming*, 837 N.E.2d at 1120-21.

Here, Plaintiffs' FAC and applicable federal law establish with certitude that the design of Defendants' eye droppers and the resulting size of Defendants' eye drops is permitted by the federal regulatory scheme administered by FDA. To obtain FDA approval for each new drug identified in the FAC, Defendants had to submit comprehensive applications, including the container specifications, dosing regimen, labeling, and volume. *See* 21 U.S.C. §§ 355(a), (b), (j); 21 C.F.R. § 200.50; FDA, 1999 WL 33935258, at 9, 13-15, 25, Table 4. Likewise, for each generic drug identified in the FAC, Defendants were required to submit an application showing the drug was identical in all material respects to a previously-approved brand-name or reference listed drug. 21 U.S.C. § 355(j)(2)(A). Defendants' drugs were therefore all reviewed and approved for consumer use by FDA with their existing dropper designs and at their existing drop volumes.[12] *See* "Search by Drug Name" at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name (containing approval history for all products referenced in the FAC).[13]

[12] The complex regulatory scheme governing the FDA's approval of new and generic drugs is addressed in greater detail above in support of Defendants' federal preemption argument. *See* Section III, *supra*.

[13] This Court may take judicial notice of these FDA records. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 878-79 (N.D. Cal.

Because Defendants manufacture or sell FDA-approved dispensers emitting FDA-approved dosages as permitted by the federal regulatory scheme FDA administers, their alleged "unfair acts or practices" are exempt from Chapter 93A pursuant to Section 3. In *Animal Legal Defense Fund Bos., Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Mass. 1986), for example, this Court relied on Section 3 to dismiss a complaint raising Chapter 93A claims against a veal producer for allegedly failing to inform consumers that veal "might be unhealthful" because it came from calves fed with sub-therapeutic levels of antibiotics. The Court found that the alleged conduct fell within Section 3's safe harbor, because the defendant's use of antibiotics was controlled by a regulatory scheme administered by FDA and the U.S. Department of Agriculture, and the plaintiff did not allege any failure to comply with this scheme. *Id*. at 283-84; *see also Riccio*, 238 F.R.D. at 45-46 (dismissing Chapter 93A claim challenging Ford's calculation of sales tax in accordance with Massachusetts regulations); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234-35 (S.D. Fla. 2007) (relying on Section 3 to dismiss in part a putative class action under Chapter 93A for alleged marketing of a cholesterol-lowering drug as being effective to reduce the risk of heart disease, where FDA had approved the drug to reduce the risk of heart attacks and thus impliedly approved the advertisements); *In re Celexa and Lexapro Mktg. & Sales Pracs. Litig.*, MDL No. 09–2067–NMG, 2014 WL 866571, at *5 (D. Mass. Mar. 5, 2004) (dismissing putative class action based on marketing and sale of FDA-approved drug under California safe harbor, which protects defendants from liability for engaging in conduct the legislature permits). The same result holds here.

B. Defendants' Alleged "Failure" To Meet Plaintiffs' Invented 15 µL Drop Size Standard Is Not An Unfair Act Or Practice.

Plaintiffs also have not alleged that Defendants have engaged in any "unfair" conduct. Plaintiffs are demanding that Defendants manufacture and sell bottles that emit eye drops of 15

2013) ("because all of the documents at issue appear on the FDA's public website, they may be judicially noticed"); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246, n.2 (S.D.N.Y. 2013) (same); *Erickson v. Bos. Scientific Corp.*, 846 F. Supp. 2d 1085, 1089 (C.D. Cal. 2011); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 805 (W.D. La. 2008).

μL or less. (FAC ¶¶ 80-101, 176.) But Chapter 93A is not an instrument for Plaintiffs to impose upon Defendants their own invented dosage standards. The alleged "failure" to meet a standard is not "unfair" and thus is not actionable under Chapter 93A unless the standard is "one legally required by and enforced by the government." *Iannacchino v. Ford Motor Co.*, 888 N.E.2d 879, 888 (Mass. 2008); *see also Kerin v. Titeflex Corp.*, No. 13-cv-30141-MAP, 2014 WL 67239, at *1 (D. Mass. Jan. 7, 2014).

In *Iannacchino*, the plaintiffs based their Chapter 93A claims on the defendant's alleged failure to meet either a federal safety standard or its own internal safety standards when manufacturing and selling door handles on automobiles. 888 N.E.2d at 883. The Supreme Judicial Court affirmed the trial court's dismissal of plaintiffs' Chapter 93A claims with respect to the federal safety standard, because the complaint failed to allege non-compliance with the standard. *Id.* at 887. As to the defendant's ***internal*** safety standards, the Court held that the alleged failure to meet a standard "not . . . legally required by and enforced by the government" is not actionable under Chapter 93A. *Id*. at 888-89. Rather, plaintiffs must "include allegations that would connect" the alleged defect "to a legal requirement." *Id*.

Here, like in *Iannacchino*, Plaintiffs have failed to connect their proposed 15 μL limit on drop size to any "legal requirement" enforced by the government that compels eye drop manufacturers or sellers to deliver eye drops of 15 μL or less. To the contrary, Plaintiffs base their proposed drop size standard exclusively upon alleged "scientific principles . . . recognized in peer-reviewed medical and pharmaceutical literature over the past four decades[.]" (FAC ¶ 53.) Yet FDA, which has had the benefit of this same literature all this time, has never adopted a 15 μL drop size standard as a legal requirement. Plaintiffs' failure to allege any legally required and enforced drop size standard is fatal to their unfair practices claim.

C. Plaintiffs Have Not Pleaded A Cognizable Injury Or Causation.

Lastly, a Chapter 93A claim is subject to dismissal where it lacks well-pleaded facts demonstrating that an unfair act or practice actually caused some cognizable harm. *See* Mass. Gen. Laws ch. 93A, § 9(1). In *Tyler v. Michaels Stores, Inc.*, 984 N.E.2d 737, 745-56 (Mass.

2013), the Supreme Judicial Court made clear that an "injury" under Chapter 93A not only requires the existence of an unfair act, but also some other separate and distinct harm, with a causal connection between the act and the harm. These requirements of injury and causation serve a gatekeeping function, preventing impermissible "vicarious suits by self-constituted private attorneys-general" under Chapter 93A. *Hershenow v. Enterprise Rent-A-Car Co.*, 840 N.E.2d 526, 538-39 (Mass. 2006) (Cowin, J., concurring); *Roberts v. Enterprise Rent-A-Car Co.*, 840 N.E.2d 541, 543-44 (Mass. 2006).

Here, Plaintiffs principally allege that they have suffered an economic "injury" because the drops are too large and some of their medicine was "wasted." In addition, while never alleging that they have suffered any physical injury, Plaintiffs also suggest that there is a hypothetical risk of physical injury from allegedly being exposed to too much medicine or from running out of medicine too quickly and being unable to afford more. (*See, e.g.,* FAC ¶¶ 5, 13-17, 52, 102-21, 196.) For the same reasons discussed above as to the requirements for Article III injury in fact, these theories do not add up to a viable claim of "harm" under Massachusetts law. In *Rule v. Fort Dodge Animal Health, Inc.*, 607 F.3d 250, 251 (1st Cir. 2010), for example, the plaintiff alleged economic harm resulting from the purchase of heartworm medication for her dog, because the defendants allegedly had not disclosed safety concerns that ultimately led to an FDA-initiated recall. 607 F.3d. at 251. The First Circuit held that the plaintiff could not allege a cognizable injury caused by defendants' alleged conduct, because the plaintiff's dog had fully consumed the product, no physical harm had been caused, and the plaintiff had suffered no real economic injury. *Id*. at 251-53; *see also Hershenow*, 840 N.E.2d at 534-35 (holding that alleged unfair waiver in rental agreement did not harm plaintiff during rental period and, therefore, plaintiff did not suffer an injury).

Like the plaintiff in *Rule*, Plaintiffs actually used and benefited from Defendants' products and do not allege that they suffered any adverse side effects, that the products failed to treat their ailments, that they could not afford enough medicine, or that their medications are worth less than what they paid. Even if some medicine was allegedly "wasted," as Plaintiffs

contend, post-sale usage and waste does not support the conclusion that the product was worth less than Plaintiffs paid for it. *See Spera v. Samsung Elecs. Am. Inc.*, No. 12-cv-05412, 2014 WL 1334256, at *5 (D.N.J. Apr. 2, 2014) (a plaintiff must present facts to "quantify the difference in value between the promised product and the actual product received"); *Hemy v. Perdue Farms, Inc.*, No. 11–888 (FLW), 2011 WL 6002463, at *5 (D.N.J. Nov. 30, 2011) (pleading must set forth specific facts, rather than unsupported conclusory statements, showing that plaintiff paid a premium because of the defendant's unfair conduct). Plaintiffs have not alleged a single fact showing that they were somehow deceived into paying more for their medications than what they were worth, or that they received anything less than the full and expected benefit of their bargain.

V. PLAINTIFFS FAIL TO STATE A CLAIM UNDER NEW YORK LAW FOR UNJUST ENRICHMENT OR MONEY HAD AND RECEIVED.

In Counts II and III, Plaintiffs assert unjust enrichment and money had and received claims respectively, relying on the same factual allegations pleaded in support of their claims under consumer protection statutes. (*See* FAC ¶¶ 16, 52-162, 204, 241.) Unjust enrichment and money had and received are quasi-contract claims based in equity. They typically apply where a "defendant, though guilty of no wrongdoing, has received money to which he or she is not entitled." *Corsello v. Verizon N.Y., Inc.*, 18 N.Y.3d 777, 791 (N.Y. 2012). To state a claim for unjust enrichment, plaintiffs must allege that (1) defendants were enriched, (2) at plaintiffs' expense, and (3) "equity and good conscience" require defendants to return the benefit to plaintiffs. *Georgia Malone & Co., Inc. v. Rieder*, 19 N.Y.3d 511, 516 (N.Y. 2012). The elements of a money had and received claim are almost identical: (1) the defendant received money belonging to the plaintiff, (2) the defendant benefitted from receipt of the money, and (3) under principles of equity and good conscience, the defendant should not be permitted to keep the money. *Goel v. Ramachandran*, 975 N.Y.S.2d 428, 437 (N.Y. App. Div. 2013).

Courts in New York have questioned whether money had and received and unjust enrichment are distinct causes of action at all. *See, e.g.*, *Maxus Leasing Grp., Inc. v. Kobelco*

Am., Inc., No. 04–CV–518, 2007 WL 655779, at *5 n.15 (N.D.N.Y. Feb. 26, 2007) ("The causes of action for unjust enrichment and money had and received are identical."); *see also In re Estate of Witbeck*, 666 N.Y.S.2d 315, 317 (N.Y. App. Div. 1997) (noting that unjust enrichment is not "well-defined" and is really just an action for restitution or in quasi-contract, which "may take various forms including . . . an action for money had and received"). At the very least, because the elements of the claims are the same, the claims rise and fall together. *See Cadogan Mgmt., LLC v. Wright*, No. 102496/09, 2011 WL 10501656, at * 6 (N.Y. Sup. Ct. Aug. 11, 2011) (noting that because they share the same elements, cause of action for money had and received was "duplicative" of unjust enrichment cause of action).

Here, Counts II and III should both be dismissed because (1) Plaintiffs cannot use unjust enrichment or money had and received to create private causes of action where the New York Legislature determined none should exist, and (2) Plaintiffs do not allege the safe and effective prescription eye drop medications they purchased were not worth the price they paid.

A. Plaintiffs Cannot Relabel Their Consumer Protection Claims As Unjust Enrichment Or Money Had And Received Claims To Circumvent The Legislature's Preclusion Of Private Enforcement Of Unfair Business Acts.

The New York Legislature, like several other state legislatures, restricts enforcement of "unfair" business practices to its state attorney general. *See* N.Y. Gen. Bus. Law § 349(a), (h) (McKinney) (creating a private cause of action only for "[d]eceptive acts or practices in the conduct of any business, trade or commerce"); N.Y. Exec. Law § 63(12) (McKinney) (authorizing the attorney general to prosecute unfair business activities "in the name of the people of the state of New York"). New York's General Business Law ("GBL") grants a private cause of action only for "deceptive act" claims, which Plaintiffs do not allege. (*See* FAC ¶¶ 204-40.) Nor can they. The Complaint does not allege Defendants made misrepresentations "likely to mislead a reasonable consumer acting reasonably" (*Spagnola v. Chubb Corp.*, 574 F.3d 64, 74 (2d Cir. 2009)), nor does the GBL authorize New York courts to regulate as "deceptive practices" the prices businesses charge for their products. *See Super Glue Corp. v. Avis Rent A Car Sys., Inc.*, 557 N.Y.S.2d 959, 961 (N.Y. App. Div. 1990) (finding excessive price claims are

not "deceptive practices" because "courts are not empowered to set policy on prices"). Recognizing this obstacle, Plaintiffs artfully resort to reframing their "unfair practice" theory as an unjust enrichment claim. (FAC ¶ 243) (alleging under the unjust enrichment count that "Defendants engaged in unfair and deceptive acts or practices").

Plaintiffs, however, cannot subvert the legislature's intent to restrict prosecution of unfair business acts to its Attorney General simply by recasting statutory consumer protection claims as unjust enrichment or money had and received claims. "When a plaintiff does not possess a private right of action under a particular statute, and does not allege any actionable wrongs independent of the requirements of the statute, a claim[] for ... unjust enrichment [is] properly dismissed as an effort to circumvent the legislative preclusion of private lawsuits for violation of the statute." *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 203 (2d Cir. 2005) (internal quotations omitted); *see also Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007) (holding that plaintiff could not "substitute unjust enrichment to avoid the statutory limitations" imposed on GBL claim); *Walts v. First Union Mortg. Corp.*, 686 N.Y.S.2d 428, 430 (N.Y. App. Div. 1999) (holding that where applicable insurance law did not allow for private right of action, "Plaintiffs' claims for money had and received are mere attempts at 'artful pleading' to circumvent this bar against private actions, and are therefore dismissed").[14]

The same result is required here. Plaintiffs' unjust enrichment and money had and received claims are premised on factual allegations identical to their statutory unfair practice claims. (FAC ¶¶ 241-47.) Plaintiffs cannot "plead around" GBL's restrictions by reframing unfair practice claims as unjust enrichment or money had and received claims.

[14] Unjust enrichment is not a "catchall" claim that can be used to make up for deficiencies in other claims. *Corsello*, 18 N.Y.3d at 790 (stating unjust enrichment is "not available where it simply duplicates, or replaces, a conventional contract or tort claim"). Courts have held that plaintiffs cannot "save a nonviable claim under the General Business Law by renaming it an 'unjust enrichment' claim." *Canestaro v. Raymour & Flanigan Furniture Co.*, No. 2012-1639, 2013 WL 6985415, at *4 (N.Y. Sup. Ct. 2013) (dismissing putative class action alleging that a furniture manufacturer was unjustly enriched when it charged consumers higher prices if they had selected low-financing incentives when the allegations did not amount to a violation of the GBL).

B. Plaintiffs' Unjust Enrichment And Money Had And Received Claims Must Be Dismissed Because Plaintiffs Received The Safe And Effective Medications They Bargained For.

Plaintiffs' unjust enrichment and money had and received claims also fail because Plaintiffs received exactly what they paid for: safe and effective prescription eye drops that worked as represented. As a matter of law, no claim for money had and received or unjust enrichment lies where purchasers "have consumed what they have received, unless the money exceeds the fair value of that which the defendant gave them." *Schank v. Schuchman*, 212 N.Y. 352, 358 (1914) (Cardozo, J.). "If the defendant's work and wares were paid for at fair prices, the plaintiffs have had a just return for every dollar they have parted with, and the defendant, therefore, can keep the money with good conscience." *Id.* Accordingly, to state a claim, Plaintiffs must allege facts demonstrating "some disparity between the value and the price" of the prescription medications that they purchased and used. *Id.* at 360 (dismissing claim for money had and received because plaintiffs received the value of purchased wagons).

Simply because a portion of the eye drop solution may not have been absorbed into their eyes does not mean that the medications Plaintiffs received were somehow worth less than they paid. Plaintiffs were prescribed Defendants' eye drop medications by their doctors, and purchased and used those medications, which did exactly what they were prescribed to do.[15] Where, as here, plaintiffs received exactly the benefit they bargained for, New York courts routinely dismiss unjust enrichment claims on the pleadings. In *Smith v. Chase Manhattan Bank, USA, N.A.*, the court affirmed dismissal on the pleadings of putative class plaintiffs' claims that Chase unjustly enriched itself with commissions. 741 N.Y.S.2d 100, 103 (N.Y. App. Div. 2002). The court dismissed the claims because customers who purchased products from Chase received the benefit of those products, and the plaintiffs did not plausibly allege that the products conferred a lesser benefit than what the consumers had bargained for. *Id.*; *see also Sokoloff v.*

[15] Indeed, as noted above, another court faced with very similar claims about eye drop volume recognized that plaintiffs received the benefit of their bargain and thus dismissed the complaint with prejudice. *Thompson*, 993 F. Supp. 2d at 1012.

Town Sports Int'l Inc., 778 N.Y.S.2d 9, 11 (N.Y. App. Div. 2004) (affirming dismissal "since plaintiff bargained for and received the use of the health club"); *Castillo v. Tyson*, 701 N.Y.S.2d 423, 425 (N.Y. App. Div. 2000) (affirming dismissal of putative class action alleging that fight promoters were unjustly enriched at expense of plaintiff viewers when boxer was disqualified, because "plaintiffs received what they paid for, namely, 'the right to view whatever event transpired'"); *Granite Partners, L.P. v. Bear, Stearns & Co. Inc.*, 17 F. Supp. 2d 275, 312 (S.D.N.Y. 1998) (dismissing claims because "[t]he enrichment which was allegedly 'unjust' was simply the payment of a bargained-for sales price for the securities which were in fact delivered to the Funds"). Likewise, the court in *Carter* dismissed the plaintiffs' identical "unwanted eye drop" claim for money had and received. 2014 WL 989002, at *4.

There is nothing "unjust" or "inequitable" about a consumer having purchased, for a certain price, a product that performs as represented. Plaintiffs' unjust enrichment and money had and received claims must be dismissed.

VI. PLAINTIFFS' CLAIMS UNDER THE LAWS OF FORTY-ONE STATES AND THE DISTRICT OF COLUMBIA, WITH WHICH THEIR TRANSACTIONS HAVE NO CONNECTION, ARE CONSTITUTIONALLY IMPERMISSIBLE.

The seven named Plaintiffs in this lawsuit are residents of either Massachusetts or New York. (FAC ¶¶ 18-24.) Nevertheless, Plaintiffs purport to assert causes of action not only under their home states' laws, but also under the laws of forty-one other states and the District of Columbia, which have no discernible connection to Plaintiffs or their transactions with Defendants. (*Id.* ¶¶ 204-40) (purporting to assert claims under the consumer protection laws of twenty-five states and the District of Columbia, in addition to Massachusetts law); (*id.* at ¶¶ 241-54) (purporting to assert claims under the common law of sixteen states, in addition to New York common law). While Plaintiffs have styled this case as a putative class action, no class has been certified, and thus the only parties currently asserting claims under the laws of forty-three states and the District of Columbia are the seven named Plaintiffs. *See Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 659 (3d Cir. 1998) ("Until the putative class is certified, the action is one between the [named plaintiffs] and the defendants. Accordingly, the First Amended

Complaint must be evaluated as to these particular plaintiffs."); *Villano v. TD Bank*, No. 11–cv–6714, 2012 WL 3776360, at *1 (D.N.J. Aug. 29, 2012) (same); *Smith v. Berg*, No. CIV. A. 99 2133, 1999 WL 1081065, at *3 (E.D. Pa. Dec. 1, 1999) ("This case has not been certified as a class action; therefore, the Court must consider only those alleged predicate acts that relate to the named plaintiffs"). Thus, the question here is whether these New York- and Massachusetts-resident plaintiffs have stated a valid claim for violations of each of these other states' laws. The answer, for several reasons, is no.[16]

First, Plaintiffs' attempt to invoke laws of forty-one states and the District of Columbia, which have no connection to Plaintiffs or their transactions, is constitutionally impermissible. The "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989); *see also Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 311 (1st Cir. 2005) ("A state statute is per se invalid under the dormant Commerce Clause when it 'regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state.'").

Courts have applied this principle to dismiss claims where, as here, plaintiffs try to use a state consumer protection statute to regulate transactions occurring wholly outside of that state's borders. For example, in *Elyazidi v. SunTrust Bank*, CIV.A. DKC 13-2204, 2014 WL 824129, at *8 (D. Md. Feb. 28, 2014), the court dismissed the plaintiff's claim under the Maryland Consumer Protection Act because "the conduct about which Plaintiff complain[ed] occurred entirely in the Commonwealth of Virginia[.]" *Id.* Applying the rule that "one State cannot

[16] Plaintiffs will likely argue that the question of whether these New York and Massachusetts Plaintiffs can seek to recover under forty-one other states' and the District of Columbia's laws should be deferred until the Court evaluates whether a class should be certified. But Defendants are not asking the Court to conclude at this time that a multistate class cannot be certified. If, notwithstanding the numerous problems identified in this Motion, this Court concludes that the Complaint can survive dismissal, then Plaintiffs would be free to argue at class certification that putative class members' home states' laws, despite their significant variations, are so similar that a multistate class action would be manageable.

regulate activity occurring in another State," the court held the statute had "no extraterritorial effect, [and thus] Plaintiff's state law claims [could not] be maintained." *Id.*; *see also Consumer Prot. Div. v. Outdoor World Corp.*, 603 A.2d 1376, 1383 (Md. Ct. Spec. App. 1992) (noting that the Maryland statute does not grant authority "to preclude sales practices that occur entirely within other States"); *The In Porters, S.A. v. Hanes Printables, Inc.*, 663 F. Supp. 494, 501 (M.D.N.C. 1987) (dismissing extraterritorial claims under the North Carolina Unfair Trade Practices Act); *Rios v. Cabrera*, No. 3:10-CV-636, 2010 WL 5111411, at *3 (M.D. Pa. Dec. 9, 2010) ("Ms. Rios, as a New York consumer, cannot invoke Pennsylvania consumer protection statutes regarding conduct occurring outside Pennsylvania."); *Friedman v. Dollar Thrifty Auto. Grp., Inc.*, No. 12-cv-02432-WYD-KMT, 2013 WL 5448078, at *6-7 (D. Colo. Sept. 27, 2013) (dismissing extraterritorial claims under Colorado, Florida, and Oklahoma consumer protection statutes).

Indeed, reflecting this constitutional principle, many of the consumer protection statutes that Plaintiffs seek to invoke are limited by their terms to in-state conduct (*see, e.g.*, Conn. Gen. Stat. § 42-110a; Idaho Code § 48-602; Kan. Stat. § 50-624; Me. Rev. Stat. tit. 5, § 206; Neb. Rev. Stat. § 59-1601; N.H. Rev. Stat. § 358-A:1; N.M. Stat. § 57-12-2; Ohio Rev. Code § 1345.04; Or. Rev. Stat. § 646.605; R.I. Gen. Laws § 6-13.1-1; Wash. Rev. Code § 19.86.010), or have been so limited by the courts. *See Elyazidi*, 2014 WL 824129, at *8 (Maryland); *Friedman*, 2013 WL 5448078, at *6-7 (Oklahoma); *Rios*, 2010 WL 5111411, at *3 (Pennsylvania). Plaintiffs' non-Massachusetts and non-New York claims must be dismissed.[17]

Second, the claims under these forty-one states' and the District of Columbia's laws fail

[17] Choice-of-law principles also require application of Plaintiffs' home states' laws to Plaintiffs' transactions. *See Faherty v. CVS Pharmacy, Inc.*, 09-CV-12102, 2011 WL 810178, at *5 (D. Mass. Mar. 9, 2011) (citing *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1018 (7th Cir. 2002)) ("State consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules."); *see also S. States Police Benev. Ass'n, Inc. v. First Choice Armor & Equip., Inc.*, 241 F.R.D. 85, 93 (D. Mass. 2007) ("[B]ecause state consumer protection laws are intended to protect consumers, the Court concludes that the laws of the home states will govern here.").

for the same fundamental reasons that the claims under Massachusetts and New York law fail—namely, a lack of any unfair practice, any inequitable conduct, or any damages. But they also fall short for reasons that vary from state-to-state, including, but not limited to, failing to allege any conduct that falls within the specified prohibited acts in the relevant statutes (*see, e.g.,* Ind. Code § 24-5-0.5-3), being barred by broad exemptions that protect defendants from liability for conduct regulated by the government (*see, e.g., Liss v. Lewiston-Richards, Inc.*, 732 N.W.2d 514 (Mich. 2007); *Chavers v. Fleet Bank (RI), N.A.*, 844 A.2d 666 (R.I. 2004)), violating statutory prohibitions against bringing claims on a classwide basis (*see, e.g.,* Mont. Code Ann. § 30-14-133(1); S.C. Code Ann. § 39-5-140(a)), and failing to comply with statutory notice requirements (*see, e.g.,* Ind. Code Ann. § 24-5-0.5-5). In the event this Court concludes that Plaintiffs' FAC can survive dismissal and that they can somehow assert out-of-state causes of action notwithstanding the limitations imposed by the Commerce Clause, Defendants would respectfully request the opportunity to brief each of the claims under the forty-one additional states' laws and the law of the District of Columbia in greater detail and explain why they all must be dismissed as a matter of law.

VII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their omnibus motion and dismiss Plaintiffs' FAC in its entirety with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified in the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on October 10, 2014.

Dated: October 10, 2014

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