UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUZANNA BOWLING and EDWARD BUCHANNAN, individually and on behalf of all others similarly situated,

Plaintiffs,

- against -

JOHNSON & JOHNSON, McNEIL-PPC, INC., and JOHNSON & JOHNSON HEALTHCARE PRODUCTS,

Defendants.

OPINION AND ORDER

14-cv-3727 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

On May 23, 2014, Suzanna Bowling filed this action on behalf of herself and others similarly situated, alleging that Johnson & Johnson ("J&J") violated (1) numerous state statutes,[1] as well as (2) the Magnuson-Moss Warranty Act ("MMWA"),[2] when it misbranded Listerine Total Care ("LTC"), a line of mouthwashes. J&J moved to dismiss on the grounds that the state law claims are

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[1] *See* Plaintiffs' Class Action Complaint with Demand for Jury Trial ("Complaint"), ¶¶ 46-96.

[2] *See id.* ¶¶ 36-45.

preempted by the Food Drug and Cosmetics Act ("FDCA"), and the MMWA claim is legally deficient.[3] For the reasons set forth below, J&J's motion is GRANTED.

II. BACKGROUND

Because plaintiffs' substantive allegations are largely irrelevant to the legal analysis, they will be summarized only briefly. J&J owns the Listerine brand of dental hygiene products. LTC is one line of mouthwashes under the umbrella Listerine brand.[4] The LTC label represents various health benefits, including — as relevant here — that LTC products "Restore[] Enamel."[5]

According to plaintiffs, "an overwhelming consensus of medical and dental experts concludes that the loss of tooth enamel is permanent," making it "false and misleading" to represent that LTC restores enamel.[6] Put simply, the claim "cannot *possibly* be true," because restoring enamel "is physically impossible."[7]

The Food and Drug Administration ("FDA") has issued two

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[3] *See* Memorandum of Law in Support of Defendants' Motion to Dismiss ("Def. Mem."), at 1-3.

[4] *See* Complaint ¶ 1.

[5] *See id.*

[6] *Id.*

[7] Plaintiffs' Opposition to Defendants' Motion to Dismiss ("Opp. Mem."), at 4 (original emphasis omitted).

"monographs" that set out labeling regulations for over-the-counter ("OTC") dental hygiene products.[8] *First*, in 1980, the FDA published a proposed monograph ("1980 Monograph"), which found, inter alia, that "[t]he deposition of fluoride in dental enamel has been shown to increase resistance to enamel solubility and therefore dental decay"[9] — or in plain English, flouride is good for preserving enamel. *Second*, in 1995, the FDA published a final monograph ("1995 Monograph"), which permits manufacturers of OTC drugs containing sodium fluoride (such as LTC) to market the product as "aid[ing] the prevention of dental . . . decay,"[10] along with "other truthful and nonmisleading statements [further] describing [this] use."[11] In other words, pursuant to the 1995 Monograph, manufacturers of OTC drugs containing sodium fluoride are allowed (1) to represent that such drugs prevent tooth decay and (2) to provide further labeling to

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[8] "Monograph" is the term of art for the regulations that the FDA issues in connection with OTC drugs. *See NRDC v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013) (explaining in greater detail what monographs are, and how they fit into the broader landscape of FDA regulation).

[9] FDA Notice of Proposed Rulemaking, Anticaries Drug Products for Over-the-Counter Human Use Establishment of a Monograph ("1980 Monograph"), 45 Fed. Reg. 20666, 20671 (Mar. 28, 1980).

[10] FDA Final Monograph, Anticaries Drug Products for Over-the-Counter Human Use ("1995 Monograph"), 60 Fed. Reg. 52474, 52508 (Oct. 6, 1995).

[11] *Id.* at 52508-09.

explain how decay is prevented.

One way the FDA exercises its regulatory authority is by sending "warning letters" to industry actors. On multiple occasions, the FDA has sent such letters to manufacturers of OTC drugs containing sodium fluoride — including, but not exclusively, J&J — to clarify the parameters of the 1995 Monograph (the "Warning Letters").[12] In each of these letters, the FDA has objected to certain labeling practices — for example, the representation that sodium fluoride "fights plaque"[13] — but it has expressed no concern about the label "Restores Enamel."[14]

III. APPLICABLE LAW

A. Federal Preemption Under The FDCA

The FDCA sets out a comprehensive statutory framework for

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[12] *See* 9/27/10 Letter from FDA to Gregory Watson, CEO of Walgreen Company ("Watson Letter"), Exhibit ("Ex.") F to Declaration of Steven Z. Zalesin in Support of Defendants' Motion to Dismiss ("Zalesin Decl."); 9/27/10 Letter from FDA to Tom Ryan, CEO of CVS Corporation ("Ryan Letter"), Ex. G to Zalesin Decl.; 9/27/10 Letter from FDA to Mark Bowden ("Bowden Letter"), Ex. H to Zalesin Decl.

[13] *See* Watson Letter at 1 (stating that the label, "Fights Unsightly Plaque Above the Gum Line," departs from the parameters of the 1995 Monograph); Ryan Letter at 1 (same); Bowden Letter at 1 (same).

[14] *See, e.g.*, Ryan Letter at 1 (identifying the label "Rebuilds Enamel and Strengthens Teeth" as among the labels considered in the FDA's analysis); Bowden Letter at 1 (same, but with respect to the label "Restores Minerals to Enamel").

regulating the development and marketing of food, drugs, and cosmetics. The Act defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[15] "Drugs," by contrast, are defined as

> (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.[16]

Under this definition, LTC is a drug.[17] The FDCA prohibits the misbranding of drugs; "[a drug] shall be deemed to be misbranded [if] its labeling is false or misleading in any particular."[18] The FDA has exclusive regulatory

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[15] 21 U.S.C. § 321(f).

[16] *Id.* § 321(g)(1).

[17] Plaintiffs are confused on this point. Their brief in opposition is littered with references to "food and beverage labeling," which — plaintiffs suggest — is an area governed by a presumption *against* preemption. *See* Opp. Mem. at 5-6. But "food and beverage labeling" is not the relevant category. Much of plaintiffs' argument is founded on the mistaken premise that LTC is a "food," which leads them to invoke — and rely on — a preemption standard that is wholly inapplicable to the case at hand.

[18] Opp. Mem. at 10 (citing 21 U.S.C. § 343(a)(1)). In fact, the actual citation in plaintiffs' papers reads "[a] *food* shall be deemed to be misbranded [if] its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). Because Listerine Total is not "a food," plaintiffs have cited the incorrect section

authority over the enforcement of this provision. Under section 379r of the FDCA, state law claims that depart in any way from FDA regulation — claims that would impose labeling requirements "different from," "in addition to," or "otherwise not identical with" federal labeling requirements — are expressly preempted.[19]

B. The MMWA

"The MMWA grants relief to [] consumer[s] 'who [are] damaged by the failure of a . . . warrantor . . . to comply with any obligation . . . under a written warranty.'"[20] By the statute's express terms, "[n]o claim shall be cognizable" under the MMWA "if the amount in controversy of any individual claim is less than the sum or value of $25."[21]

II. STANDARD OF REVIEW

Motions to dismiss are governed by Rule 12(b)(6) of the Federal Rules of Civil Procedure. The question is whether the moving party's allegations

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of the FDCA. I address their argument on the assumption that they *intended* to cite section 352(a), which deals with the "false or misleading" branding of drugs (including OTC drugs). *See id.* § 352(a).

[19] 21 U.S.C. § 379r(a)(2).

[20] *Wilbur v. Toyota Motor Sales, U.S.A.*, 86 F.3d 23, 26 (2d Cir. 1996) (citing 15 U.S.C. § 2310(d)(1)).

[21] 15 U.S.C. § 2310(d)(3)(A).

"'plausibly give rise to an entitlement for relief.'"[22] In assessing this question, the court must "accept[] all factual allegations in the complaint as true, and draw[] all reasonable inferences in the plaintiff's favor."[23]

V. DISCUSSION

A. Plaintiffs' State Law Claims Are Preempted by the FDCA

In the context of OTC drugs, the FDCA expressly preempts state law labeling requirements that are "different from," "addition[al] to," or "otherwise not identical with" federal labeling requirements.[24] Under this standard, preemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is *also* appropriate when a state law prohibits labeling that is *not prohibited* under federal law. The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*. In settings "[w]here federal requirements address the subject

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[22] *Taveras v. UBS*, 513 Fed. App'x 19, 22 (2d Cir. 2013) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

[23] *Freidus v. Barclays Bank PLC*, 734 F.3d 132, 137 (2d Cir. 2013) (citing *Gorman v. Consolidated Edison Corp.*, 488 F.3d 586, 591-92 (2d Cir. 2007)).

[24] 21 U.S.C. § 379r(a)(2).

matter that is being challenged through state law claims"[25] — as is true of the 1995 Monograph — the "state requirements are not permitted unless they are *identical* to federal standards."[26]

J&J argues that the text of the 1995 Monograph, in tandem with the FDA's silence as to the "Restores Enamel" label in its Warning Letters, leads to the conclusion that "the FDA . . . has reviewed and permitted labels featur[ing] enamel restoration claims."[27] Plaintiffs view this interpretation as "disingenuous," because no inference of permission should be drawn from the FDA's decision "not to prosecute claims regarding the representation 'Restores Enamel.'"[28] After all, "[t]here are all kinds of reasons why the FDA [might choose] not to prosecute [certain] claims."[29]

But even if they are correct that no inference of permission can be drawn from the FDA's silence, plaintiffs have misunderstood their legal burden. For plaintiffs to establish that their state law claims are not preempted, it is

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[25] *In re Pepsi Co., Inc., Bottled Water and Sales Practice Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008) (emphasis added).

[26] *Id.* at 539.

[27] Def. Mem. at 7.

[28] Opp. Mem. at 9.

[29] *Id.*

insufficient to show that the FDA has not permitted the label "Restores Enamel." Rather, plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the label. Otherwise, plaintiffs' state law causes of action would be, in effect, imposing a labeling requirement that is "not identical with" labeling requirements under federal law.

Plaintiffs cannot meet this burden. If the FDA had prohibited the "Restores Enamel" label, there would be a regulation saying so. But there is no such regulation. This case might be different if the FDA had issued *no* guidance as to dental hygiene products, making it possible to conclude that LTC falls beyond the scope of federal regulation entirely.[30] As it stands, however, the FDA has issued a monograph directly on point but declined, in spite of that, to indicate — either in the monograph itself or in advisory interpretations of the monograph — that "Restores Enamel" is misleading. If successful, this litigation would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using state law causes of action to bootstrap labeling requirements that are "not identical with" federal regulation.

In the alternative, plaintiffs argue that even if the state law causes of

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[30] *See, e.g.*, *Red v. Craft Foods*, 754 F. Supp. 2d 1137, 1141 (C.D. Cal. 2010) (holding that the logic of *In re Pepsi Co.* does not apply to "state law claims [that are] premised on misrepresentations concerning subject matter that the FDA has not endeavored to regulate") (internal citation omitted).

action are preempted, their misbranding claim can proceed because it arises independently under federal law. For support, plaintiffs point to the "misbranding" provision of the FDCA, which provides that "'[a drug] shall be deemed to be misbranded [if] its labeling is false or misleading in any particular.'"[31] According to plaintiffs, if their central allegation is correct — that "the loss of [] enamel is permanent"[32] — it follows that the label "Restores Enamel" is "false or misleading."[33] Therefore, plaintiffs conclude that they have a private cause of action under the FDCA.[34]

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[31] Opp. Mem. at 10 (citing 21 U.S.C. § 343(a)(1)).

[32] *Id.* at 1.

[33] *Id.* at 8 (emphasis omitted). Plaintiffs clearly regard this argument as open-and-shut — they repeatedly emphasize the permanence of enamel loss, as though the fact speaks for itself. In reality, however, the argument relies on a specific understanding of the word "restore." In common usage, "restore" has (at least) two meanings. In some settings, "to restore" means (as the plaintiffs emphasize) "to rebuild" — for example, in the phrase "we restored our old house," or "restoring a friendship." In other settings, however, "to restore" means something more like "to improve" — for example, in the phrase, "restoring a painting," or "conditioner can restore damaged hair." Under this construction, it would be perfectly reasonable to speak of "restoring enamel," in the sense of fortifying tooth enamel that currently exists. If anything, the lexical ambiguity underscores the importance of leaving the FDA free to draw on its regulatory expertise.

[34] *See* Opp. Mem. at 10 ("[B]ecause Listerine Total Care does not work as labeled, [J&J's] conduct violates state and federal law, *including the FDCA*.") (emphasis in original).

This argument rests on a mistaken premise. The FDCA does not authorize private causes of action.[35] With respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to private litigants — or judges — to decide what is "false or misleading." It is up to the FDA. Plaintiffs' claim under the FDCA is foreclosed for substantively the same reason that their state law claims are foreclosed: both seek to supercede the FDA's regulatory authority.[36]

B. This Court Lacks Subject Matter Jurisdiction Over Plaintiffs' MMWA Claim

Finally, plaintiffs advance a claim under the MMWA. They allege that J&J "issued a written warranty . . . that [LTC] would 'Restore[] Enamel,"[37] and because "the product does not, in fact, restore enamel," J&J violated that warranty.[38]

J&J offers three arguments why the MMWA claim should be dismissed. *First*, it argues that MMWA claims are preempted — in a manner analogous to the preemption of state law claims — when they clash with the

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[35] *See, e.g.*, *Schering-Plough Healthcare Prods. v. Schwartz Pharma, Inc.*, 586 F.3d 500, 509 (7th Cir. 2009) ("[T]he Food, Drug, and Cosmetics Act [] does not authorize a private cause of action.").

[36] *See* 21 U.S.C. § 371 (giving the FDA regulatory authority over the enforcement of the FDCA).

[37] Complaint ¶ 41.

[38] *Id.* ¶ 42.

FDCA.[39] *Second*, J&J argues that the "Restores Enamel" label is not a "warranty" within the meaning of the statute because it does not "guarantee performance over a 'specific period of time.'"[40] *Third*, J&J argues that plaintiffs have failed to meet the MMWA's amount-in-controversy requirement.[41]

Because I agree with the second argument, there is no need to address the other two.[42] The MMWA defines a "warranty" as a "written affirmation" that a

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[39] *See* Opp. Mem. at 10 (arguing that by its own terms, "the MMWA [] is 'inapplicable to any written warranty the making or content of which is otherwise governed by federal law,'" which renders plaintiffs' MMWA claim preempted by the FDCA) (citing 15 U.S.C. § 2311(d)).

[40] *Id.* at 10-11 (quoting 15 U.S.C. § 2301(6)).

[41] *See id.* at 11.

[42] It is worth noting, however, that plaintiffs' MMWA claim does appear to contain a major jurisdictional defect. The MMWA is quite clear that "[n]o claim shall be cognizable [in federal court] . . . if the amount in controversy of any individual claim is less than the sum or value of $25." 15 U.S.C. § 2310(d)(3)(A). The parties disagree about the significance of this requirement. J&J construes it as a mandatory predicate of any cause of action under the MMWA. Plaintiffs, by contrast, understand it as necessary for relying on the MMWA as a basis for federal subject matter jurisdiction, but not mandatory if there is another basis for exercising such jurisdiction.

Even assuming, *arguendo*, that plaintiffs' general theory is correct, it provides them no help in *this* case, because federal jurisdiction does not otherwise lie. If plaintiffs' state law claims were viable, the Class Action Fairness Act would give rise to federal jurisdiction, just as plaintiffs contend. *See* Opp. Mem. at 16-17. *See also* 28 U.S.C. § 1332(d)(2)(A) (granting federal jurisdiction over cases that meet a threshold diversity requirement and involve "more than 100 class members and [an] aggregate amount in controversy [] exceed[ing] $5,000,000"). But their state law claims are *not* viable, which means the MMWA is the only basis for suit.

consumer product will be "defect free or will meet a specified level of performance *over a specified period of time*."[43] Defendants maintain that the label "Restores Enamel" explains how LTC works; it "does not guarantee enamel restoration over any period of time."[44] In response, plaintiffs argue that the temporal requirement is satisfied by the "Best Buy" date on LTC bottles — "purchasers of LTC were promised that," as long as they respected the "Best Buy" date, "the product would 'Restore[] Enamel.'"[45]

Plaintiffs' argument proves too much. If the existence of a "Best Buy" date were enough to transform all labels into warranties, virtually any grievance about a consumer product — food or drug — would be actionable under the MMWA. That is not how the statute was meant to work.[46] A recent case from

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If the lead plaintiff's claim is any indication, many class members will not be able to clear the $25 hurdle. *See* Def. Mem. at 11 ("Plaintiffs have not alleged that the value of each individual class member's claim exceeds the $25 threshold. In fact, Bowling alleges that she purchases [LTC] for approximately $9.49, which means even her own claim falls below the statute's threshold.") (internal citations omitted). And it is very likely, therefore, that the MMWA does not provide the Court with subject matter jurisdiction in this case.

[43] 28 U.S.C. § 2301(6) (emphasis added).

[44] Def. Mem. at 11.

[45] Opp. Mem. at 15.

[46] *See Skelton v. General Motors Corp.*, 660 F.2d 311, 316 n.7 (7th Cir. 1980) (explaining that making MMWA claims contingent on the articulation of a specified period of time in connection with a given promise is "consistent with the

the Eastern District of New York — *In re Frito-Lay* — is instructive.[47] There, Judge Rosalyn Mauskopf held that Frito-Lay's "All Natural" label was not a warranty within the meaning of the MMWA because it did not "promise that the product 'will meet a specified level of performance over a specified period of time.'"[48] Rather, the label was, "at most," a "product description."[49] The same logic applies here. "Restores Enamel" is a product description, not a promise of performance over time. The MMWA claim fails as a matter of law.

VI. CONCLUSION

For the foregoing reasons, J&J's motion to dismiss is GRANTED. The Clerk of the Court is directed to close this motion and this case.

FTC's interpretation of [the statute], which [provides that] 'Certain representations, such as energy efficiency ratings for electrical appliances [and] care labeling of wearing apparel . . . may be express warranties under the Uniform Commercial Code. However, these disclosures alone are not written warranties under [the MMWA] . . . [because] product information disclosure without a specified time period . . . is [] not a written warranty.'") (citing 16 C.F.R. § 700.3(a) (1980)).

[47] *See In re Frito-Lay N. Am. Inc. All Nat'l Litig.*, No. 12 Civ. 2413, 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013).

[48] *Id.* at *17 (citing *Wilson v. Frito-Lay N. Am. Inc.*, No. 12 Civ. 1586, 2013 WL 1320468 (N.D. Cal. Apr. 1, 2013)).

[49] *Id.*

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
November 4, 2014

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