UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

MICHAEL LESTER, individually and on behalf of all others similarly situated,

Plaintiff,

22-cv-7334 (PKC)

-against-

OPINION AND ORDER

CVS PHARMACY, INC.,

Defendant.

----------x

CASTEL, Senior Judge:

Plaintiff Michael Lester brings a putative class action against defendant CVS Pharmacy, Inc. ("CVS"), alleging that the phrase "For treatment of minor cuts & abrasions" contained on the front label of defendant's CVS Health brand 3% hydrogen peroxide solution is false and misleading because it inaccurately conveys that the product assists in healing wounds or shortens healing time. Lester asserts that the product cannot perform either function and therefore cannot "treat" minor cuts and abrasions.

Lester asserts claims for violation of sections 349 and 350 of the New York General Business Law ("GBL") and for the violation of similar consumer protection statutes in other states. Lester also brings claims for breach of express warranty, breach of the implied warranties of merchantability and fitness for a particular purpose, violation of the Magnuson Moss Warranty Act, negligent misrepresentation, fraud, and unjust enrichment. CVS has moved to dismiss under Rule 12(b)(6), Fed. R. Civ. P. (ECF 22.)

For the reasons discussed below, the Court concludes that Lester's claims are preempted by federal law. CVS's motion to dismiss is therefore granted.

I. BACKGROUND

A. Factual Background

CVS manufactures and sells a 3% hydrogen peroxide solution (the "Product") under the CVS Health brand. (ECF 1, Complaint ¶ 1). Lester alleges that he purchased the Product on at least one occasion at a Manhattan CVS between May and June 2022 for $1.79. (Id. ¶¶ 25, 55). The front label of the Product's packaging identifies it as a "First Aid Antiseptic" and an "Oral Debriding Agent." (Id. ¶ 1.) The front label also states that the Product is used "[f]or treatment of minor cuts & abrasions[.]" (Id.)

Lester's claims turn on his interpretation of this phrase—specifically, the word "treatment." According to Lester, consumers who see this packaging are misled because "[d]ictionaries define 'treat' as attempting to heal, improve or cure a condition," (id. ¶ 6), and although "hydrogen peroxide may reduce the number of bacteria at a wound, no credible evidence supports a connection between the number of bacteria and reduction in healing time of a clean wound," (id. ¶ 7). Based upon his interpretation of "treatment," he asserts that the label "tells purchasers it [the Product] will assist in the healing process and shorten healing time," and that this is a "false, misleading" statement that is "not authorized by any applicable body." (Id. ¶ 19). Lester alleges that hydrogen peroxide's "caustic properties negatively effect [sic] healthy cells involved in wound healing," (id. ¶ 13), and had he "known the truth, he would not have bought the Product or would have paid less for it," (id. ¶ 24).

Lester seeks to represent a class of consumers who purchased the Product in New York (the "New York Class"), and in addition, a multi-state class of consumers of the Product in Montana, Alabama, Arkansas, Utah, Kansas, Alaska, Wyoming, and Nebraska (the "Multi-State Class"). (Id. ¶ 62).

The Complaint asserts the following federal and state law claims: (1) violation of sections 349 and 350 of the GBL (and the consumer fraud statutes of the other states relevant to the proposed Multi-State Class), (2) breach of express warranty, breach of the implied warranties of merchantability and fitness for a particular purpose, and violation of the Magnuson Moss Warranty Act, (3) negligent misrepresentation, (4) fraud, and (5) unjust enrichment. (Id. ¶¶ 69-104.) The Complaint seeks compensatory and punitive damages. (Id. at 14 ¶ 2).

B. Procedural History

This Court has subject matter jurisdiction over Lester's claims pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d)(2). (Id. ¶ 26.) Additionally, venue is proper in this district because Lester alleges that he purchased the Product in Manhattan. (Id. ¶¶ 33, 55.)

Lester filed his Complaint on August 27, 2022. (Id. at 14.) CVS moved to dismiss the Complaint pursuant to Rule 12(b)(6), Fed. R. Civ. P. (ECF 22.) In his opposition brief, Lester urges the Court to either deny defendant's motion or grant him leave to file an amended complaint. (ECF 24 at 15.)

CVS filed a reply (ECF 25), and later filed three Notices of Supplemental Authority directing the Court's attention to several recent cases[1] in which plaintiffs bring similar or identical claims regarding the labeling of 3% hydrogen peroxide solutions against different manufacturers and retailers, in which the labeling claim was held to be preempted by federal law. (ECF 26, 27, 28.) In addition, the Court also takes judicial notice of a more recent case from the

[1] Abron v. Vi-Jon, LLC, No. 3:22-cv-50238 (N.D. Ill. June 20, 2023) (ECF 26); Novotney v. Walgreen Company, 2023 WL 4698149 (N.D. Ill. July 20, 2023) (ECF 27); Wright v. Walmart, Inc., 2023 WL 5348861 (S.D. Ill. Aug. 21, 2023) (ECF 28).

Northern District of New York, also dismissing on preemption grounds. See Solak v. Target Corporation, 2023 WL 5806326, at *7 (N.D.N.Y. Sept. 7, 2023).[2]

The Court's own analysis of the claims at issue here reaches the same conclusion as these other district courts: Lester's claims regarding the Product are preempted by federal law. Lester's complaint will therefore be dismissed.

II. LEGAL STANDARD

A. Motion to Dismiss for Failure to State a Claim

To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), Fed. R. Civ. P., a plaintiff must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 570 (2007)). In assessing a complaint, courts draw all reasonable inferences in favor of the non-movant. See In re Elevator Antitrust Litigation, 502 F.3d 47, 50 (2d Cir. 2007). Legal conclusions are not entitled to any presumption of truth, and a court assessing the sufficiency of a complaint disregards them. Iqbal, 556 U.S. at 678. Instead, the court must examine only the well-pleaded factual allegations, if any, "and then determine whether they plausibly give rise to an entitlement to relief." Id. at 679.

"[O]n a motion to dismiss [under Rule 12(b)(6)], a court may consider 'documents attached to the complaint as an exhibit or incorporated in it by reference, . . . matters of which judicial notice may be taken, or . . . documents either in plaintiffs' possession or of

[2] And even more recently, the Western District of Michigan came to the same conclusion in a case regarding Meijer's brand of 3% hydrogen peroxide solution. See Bridges v. Meijer, Inc., 2024 WL 1007883, at *6 (W.D. Mich. Feb. 20, 2024), report and recommendation adopted, 2024 WL 1141865 (W.D. Mich. Mar. 15, 2024).

which plaintiffs had knowledge and relied on in bringing suit.'" Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002) (quoting Brass v. American Film Technologies, Inc., 987 F.2d 142, 150 (2d Cir. 1993)). Federal regulations published in the Federal Register "shall be judicially noticed." 44 U.S.C. § 1507; see also Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 60 (2d Cir. 2016) (citations omitted) ("[W]e may properly take judicial notice of this document (without converting Acorda's motion to dismiss into a motion for summary judgment) because the [FDA "Guidance for Industry" document] is publicly available and its accuracy cannot reasonably be questioned.").

B. Federal Preemption

Federal preemption is a doctrine that derives from the Supremacy Clause of the Constitution. "The Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" Gibbons v. Bristol-Myers Squibb Company, 919 F.3d 699, 707–08 (2d Cir. 2019) (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011) (quoting U.S. CONST. art. VI, cl. 2)). If federal law and state law conflict such that a party cannot follow both, "state law must give way" to federal law. Id. (citation omitted).

Although preemption is an affirmative defense, "preemption 'can still support a motion to dismiss if the statute's barrier to suit is evident from the face of the complaint.'" Glover v. Bausch & Lomb Inc., 6 F.4th 229, 236 n.3 (2d Cir. 2021) (quoting Ricci v. Teamsters Union Local 456, 781 F.3d 25, 28 (2d Cir. 2015) (citations and internal quotation marks omitted)), certified question answered, 275 A.3d 168 (Conn. 2022).

III. DISCUSSION

A. The FDCA and Hydrogen Peroxide Monographs

CVS argues that Lester's state law claims are expressly preempted by the Food, Drug, and Cosmetic Act ("FDCA"). The FDCA regulates the labeling of both prescription and nonprescription drugs.[3] See 21 U.S.C. § 301 et. seq. To further the goal of establishing national uniformity for nonprescription over-the-counter ("OTC") drug labeling, the Act prohibits states from imposing "any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter[.]" Id. § 379r(a)(2). CVS characterizes Lester's argument as imposing state law requirements on the labeling of the Product beyond those imposed by the FDCA, in direct violation of the Act's prohibition.

The Court concludes that Lester's Complaint seeks to hold CVS liable under state law for its failure to label the Product in a manner that is "different from," "in addition to," or "otherwise not identical with" FDCA labeling requirements. Lester's state law claims are therefore preempted by federal law.

1. The FDCA and Preemption

"The FDCA statutory regime is designed primarily to protect the health and safety of the public at large." POM Wonderful LLC v. Coca-Cola Company, 573 U.S. 102, 108 (2014) (citations omitted). The FDCA empowers the Food and Drug Administration ("FDA") to regulate the marketing of drugs to ensure their safety and effectiveness. 21 U.S.C. § 393(a),

[3] The Act defines a "drug," in relevant part, as "articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them . . . articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals; and . . . articles intended for use as a component of" the preceding articles. 21 U.S.C. § 321(g)(1).

(b)(1), (b)(2)(B). To accomplish this mission, the FDA sets out detailed conditions under which OTC drugs are "generally recognized as safe and effective." 21 C.F.R. § 330.1. These conditions include the format and content of product labeling. Id. § 201.66.

In interpreting identical language of the provision of the FDCA covering another regulated class of products—cosmetics—the Second Circuit explained: "[T]he FDCA preempts not only those state laws that are in conflict with it (i.e., any law that is 'different from' the FDCA), but also any state law that provides for labeling requirements that are not exactly the same as those set forth in the FDCA and its regulations (i.e., any law that is 'in addition to' the FDCA)." Critcher v. L'Oreal USA, Inc., 959 F.3d 31, 35–36 (2d Cir. 2020) (quoting 21 U.S.C. § 379s(a)). In other words, the FDCA statute expressly preempts any state law that would impose different or additional labeling requirements on the products it regulates, including OTC drugs. Id. (citing 21 U.S.C. § 379s(a)) (interpreting same language in section of FDCA regulating cosmetics); see also Glover, 6 F.4th at 236 (citing 21 U.S.C. § 360k) (discussing same language in section of FDCA regulating medical devices).

2. The FDA's Hydrogen Peroxide Monographs

The FDA must generally approve drugs to be "generally recognized as safe and effective" ("GRAS/E") individually, but it also utilizes a "monograph" system that allows manufacturers to "bypass" this individual review; instead, the "FDA issues a detailed regulation—a 'monograph'—for each therapeutic class of OTC drug products." Natural Resource Defense Council, Inc. v. United States Food and Drug Administration, 710 F.3d 71, 75 (2d Cir. 2013). Hydrogen peroxide 3% solution was first regulated under a tentative final monograph issued by the FDA in 1991. See Topical Antimicrobial Drug Products for Over-the-

Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products, 56 Fed. Reg. 33644 (July 22, 1991), 1991 WL 303853.

This monograph included a specific section on 3% hydrogen peroxide solution that outlined the manufacturers' submissions of safety and effectiveness data, as well as a manufacturer's product sample provided to the review panel. Id. at 33659 (Section H, "Comments on Hydrogen Peroxide"). The manufacturer's submission "included labeling for a currently marketed product containing hydrogen peroxide U.S.P. 3 percent," and that labeling read: "'First aid antiseptic' 'For treatment of minor cuts and abrasions.'" Id. (emphasis added). After reviewing the submissions, the FDA concluded that "[h]ydrogen peroxide achieves its intended benefit" and that it "has been demonstrated to be both safe and effective for use in minor wounds"; the FDA therefore proposed that a 3% hydrogen peroxide solution should be categorized "for use as a first aid antiseptic drug product." Id.

The 1991 Tentative Final Monograph regulating 3% hydrogen peroxide solution became a final administrative order with the passage of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") in March 2020. 21 U.S.C. § 355h(b)(8)(A); see also Pub. L. 116-136, 134 Stat 281 (Mar. 27, 2020). Consequently, the final monograph conditions regulating hydrogen peroxide were released in May 2023 by the FDA. See Over-the-Counter (OTC) Monograph M003: First Aid Antiseptic Drug Products for Over-the Counter Human Use ("Monograph M003").[4] Although not attached to the Complaint, the Court takes judicial notice

[4] U.S. Food & Drug Admin., Final Administrative Order (OTC000030): Over-the-Counter (OTC) Monograph M003: First Aid Antiseptic Drug Products for Over-the Counter Human Use (2023), https://dps-admin.fda.gov/omuf/omuf/sites/omuf/files/primary-documents/2023-05/Final%20Administrative%20Order%20OTC000030_M003-First%20Aid%20Antiseptic%20products%20for%20OTC%20Human%20Use_0.pdf (last visited Mar. 27, 2024).

of this publicly available monograph issued by the FDA, as well as the 1991 monograph published at 56 Fed. Reg. 33644. See Apotex, 823 F.3d at 60.

The final monograph expressly provides that an "(OTC) first aid antiseptic drug product . . . is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1." See Monograph M003 § M003.1. The FDCA states that a "drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). The monograph states that "[t]he representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide"; specifically, it defines a first aid antiseptic as an "antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns." Monograph M003 § M003.3(a), (b). The monograph includes "hydrogen peroxide topical solution" in its list of the "Active Ingredients" contained in first aid antiseptics. Id. § M003.10(i). Furthermore, the monograph sets out labeling requirements for this category of drugs, including identification as a "first aid antiseptic," indications for use, warnings, and directions (e.g., "Apply a small amount of this product on the area 1 to 3 times daily."). Id. § M003.50(a)-(e).

The monograph provides that the product label include a phrase under the heading "Uses" that incorporates one of "the following: 'First aid to help' (select one of the following: 'prevent,' ('decrease' ('the risk of' or 'the chance of')), ('reduce' ('the risk of' or 'the chance of')), 'guard against,' or 'protect against') (select one of the following: 'infection,' 'bacterial contamination,' or 'skin infection') 'in minor cuts, scrapes, and burns.' Other truthful and nonmisleading statements, describing only the indications for use that have been established and

listed in § M003.50(b), may also be used, as provided in 21 CFR 330.1(c)(2). . . ." Id. § M003.50(b).

Finally, the FDCA provides that an OTC drug "is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph." 21 C.F.R. § 330.1.

B. CVS Health Brand's 3% Hydrogen Peroxide Label

The Court concludes that CVS Health brand's 3% hydrogen peroxide solution labeling meets the above conditions set out by the FDA in 21 C.F.R. § 330.1 and Monograph M003 for OTC first aid antiseptic drug products.

In accordance with the FDA's conditions, the front label identifies the CVS Product as a "First Aid Antiseptic," as well as an "Oral Debriding Agent." (ECF 1 ¶ 1.) Below that, the label contains two bullet points: "For treatment of minor cuts & abrasions," and "For use as a gargle or rinse."[5] (Id.) The "Drug Facts" back label also meets the criteria set out by the FDA and includes all content requirements. 21 C.F.R. § 201.66(c). This label lists hydrogen peroxide as the active ingredient, identifies its purpose as a first aid antiseptic, and under "Uses," provides that the product is used as "first aid to help prevent the risk of infection in minor cuts, scrapes, and burns." See id.; see generally Monograph M003; (ECF 1 ¶ 9).

Lester argues that the phrase "treatment of minor cuts & abrasions" on the Product's front label describes a "function . . . distinct" from the FDA-authorized phrase on the Product's back label: "first aid to help prevent the risk of infection in minor cuts, scrapes and burns." (ECF 1 ¶ 9.) His argument hinges on his definition of "treatment," which Lester claims

[5] Lester does not object to any of the statements or language about the Product's use as an "oral debriding agent" or its use as a "gargle or rinse." (Id.)

misleads consumers into believing the Product "will assist in the healing process and shorten healing time," which he alleges it cannot do. (Id. ¶ 19.) Lester thus claims that he is attacking manufacturer representations that are untrue and that contravene FDA authorization.

These arguments are unpersuasive. The Second Circuit has explained, "[T]he FDA has promulgated rules regulating what must be included on labels. The regulations have therefore stated, with specificity, what information is necessary to avoid misleading consumers . . . . In light of the technical nature of such requirements—combined with Congress's broad, categorical statement of preemption in the FDCA—we are reluctant to conclude that states may impose other labeling requirements that have not been imposed by Congress or the FDA. If we were to impose such additional labeling requirements, we would be construing state law to impose many 'requirements' that are not contained in the federal statute, or in the regulations issued thereunder, and to disrupt what Congress intended to be a uniform—and federally-led—regulatory scheme." Critcher, 959 F.3d at 38.

C. Lester's Claims are Preempted

Even taking Lester's preferred definition of "treat"—to "attempt to heal, improve, or cure a condition"—as true, as Lester urges the Court to do (ECF 24 at 4-5), Lester's claims fail. The FDA has issued guidance on this area in its monograph and has not prohibited the use of the word "treat." Lester's preferred terminology is "substantially similar" to the language that the FDA has expressly approved, and any difference in nuance is de minimis. Finally, any attempts by Lester to challenge the FDA's findings on the medical effectiveness of hydrogen peroxide in the context of this action is exactly the type of conduct that is precluded by the

FDCA. See Critcher, 959 F.3d at 38. For these reasons, Lester's state law claims are foreclosed by federal law.

To determine whether a plaintiff is attempting to impose "additional" or "different" requirements, the Court first must determine whether the FDA has issued guidance in this area. When deciding other OTC drug labeling claims, courts in this district have held that "[f]or plaintiffs to establish that their state law claims are not preempted, it is insufficient to show that the FDA has not permitted the label [in question]. Rather, plaintiffs would need to plead facts suggesting that the FDA has affirmatively prohibited the label." Bowling v. Johnson & Johnson, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014). In that case, plaintiff argued that the label "Restores Enamel" on a bottle of OTC mouthwash was a misleading description that "cannot possibly be true" because to restore tooth enamel "is physically impossible." Id. at 373 (internal citations omitted). But the court disagreed, concluding that, "If the FDA had prohibited the 'Restores Enamel' label, there would be a regulation saying so. But there is no such regulation. . . . [T]he 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." Id. at 376. The court noted that if the "FDA had issued no guidance" as to this type of product, it might have been possible to conclude that the product "falls beyond the scope of federal regulation entirely," but that this was not the case. Id. (footnote omitted).

Here, the FDA has issued a monograph "directly on point" in relation to Lester's claims about the medical efficacy of hydrogen peroxide. See Monograph M003; Bowling, 65 F. Supp. 3d at 376. The FDA has not prohibited the use of the term "treat"; and, indeed, as CVS notes, the FDA considered the exact phrase at issue here, "For treatment of minor cuts and

abrasions," in the monograph (56 Fed. Reg. 33644, 33659), and did not prohibit it. (ECF 22 at 8-9.) See also Goldstein v. Walmart, Inc., 637 F. Supp. 3d 95, 110 (S.D.N.Y. 2022) (Liman, J.), appeal withdrawn, 2023 WL 2260322 (2d Cir. Jan. 13, 2023) (dismissing claims that OTC drug should have included a label warning of drowsiness where, in the relevant monograph, "the FDA considered Plaintiff's claim that [the ingredient] caused drowsiness and determined that insufficient data existed to support such a finding").

Lester's definition of "treat" is also significantly similar to the phrases explicitly approved by the FDA. Any differences in nuance are de minimis. See Solak, 2023 WL 5806326 at *5 (quoting Wright, 2023 WL 5348861, at *5) (citing Novotney, 2023 WL 4698149 at *5) ("[Plaintiff's] leap from the treatment of minor cuts and scrapes to a shortened healing time was wholly unsupported. Indeed, the back panel even specifies that the solution should be used in 'first aid to help prevent the risk of infection in minor cuts, scrapes, and burns.' The FDA has approved the solution as an antiseptic and has the authority to regulate the package labelling and marketing. Any discrepancies are de minimis. . . ."). See also Sapienza v. Albertson's Companies, Inc., 2022 WL 17404919, at *3-4 (D. Mass. Dec. 2, 2022) (claims were preempted under the FDCA where the challenged phrase, "rapid release," was "significantly similar" to the phrases approved by the FDA—"immediate release" and "rapidly dissolving").

Finally, the battle over the various definitions here—between "first aid to help prevent the risk of infection in minor cuts, scrapes and burns," which Lester concedes is authorized and not misleading (ECF 1 ¶ 9), and "attempting to heal, improve, or cure" minor cuts and abrasions or "assist in the healing process and shorten healing time" of minor cuts and abrasions (id. ¶¶ 6, 19)—is immaterial. Litigating the scientific properties of hydrogen peroxide in an area where the FDA has already considered the evidence and authorized language is

exactly the type of claim that is preempted by the FDCA. See Critcher, 959 F.3d at 38; see also Solak, 2023 WL 5806326 at *5 (quoting Wright, 2023 WL 5348861 at *5) ("Plaintiff's attempt 'to circumvent preemption by arguing that the very claims made on the packaging, i.e. "For Treatment of Minor Cuts & Abrasions," induced [him] to purchase the product in violation of [state law], but that is the very conduct that the FDCA regulates. Hydrogen peroxide is regulated as a topical antiseptic and it has achieved GRAS/E status when used in that [manner]; [state law] cannot impose additional requirements.'"); see also Novotney, 2023 WL 4698149 at *5 (citation and footnote omitted) ("[T]he Court agrees with defendant that whether the FDA specifically approved the use of the word 'treatment' is beside the point. The content of the product's label as it relates to its safety or effectiveness is a matter of federal law, and by claiming that some other terminology is necessary to ensure that the label is not misleading, plaintiff impermissibly claims that state law imposes requirements that are different from, additional to, or otherwise not identical with, the requirements of the FDCA.").

The Court therefore does not address the news articles and websites, links to which Lester included in footnotes in his Complaint, that he claims demonstrate that hydrogen peroxide cannot "heal" wounds (ECF 1 ¶¶ 5 n.1, 12 n.2). Again, the FDA has reviewed the scientific evidence contained in the monograph, and to force the FDA to specify that the Product does not "heal" wounds would impose an additional or different labeling requirement than what the agency has already authorized.[6]

[6] Lester also argues that the alleged misrepresentation about the Product was made to Lester himself, rather than the FDA. But as other courts deciding on these very claims have found, this argument misses the mark. See Solak, 2023 WL 5806326 at *6 (quoting Novotney, 2023 WL 4698149, at *3) ("This [argument] seems to mischaracterize the federal-law requirement at issue, which is not about what the defendant or another drug manufacturer can say to the FDA about hydrogen peroxide; it is about how the product is to be labeled in relation to its intended use."); see also Abron, 22-c-50238 ("Representations made on product labels to consumers like plaintiff are precisely what the FDA is regulating in OTC Monograph M003. Plaintiff's argument is baseless.") (ECF 26 at 3).

The Court therefore concludes that Lester's state law claims are preempted by the FDCA and dismisses them.

D. Lester's Claims under the MMWA Also Fail

Finally, while Lester's state law claims are preempted, the Court still must address his remaining claim under federal law: violation of the Magnuson Moss Warranty Act ("MMWA"), 15 U.S.C. § 2301, et seq.

The MMWA protects consumers who are "damaged by the failure of a . . . warrantor . . . to comply with any obligation . . . under a written warranty." Wilbur v. Toyota Motor Sales, U.S.A., Inc., 86 F.3d 23, 26 (2d Cir. 1996) (quoting 15 U.S.C. § 2310(d)(1)). Section 2311(d) of the MMWA, however, provides that, "This chapter . . . shall be inapplicable to any written warranty the making or content of which is otherwise governed by Federal law. If only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter." 15 U.S.C. § 2311(d). Because the MMWA provides federal jurisdiction only for underlying state law claims, "claims under the [MMWA] 'stand or fall with the express and implied warranty claims under state law.'" Valcarcel v. Ahold U.S.A., Inc., 577 F. Supp. 3d 268, 283 (S.D.N.Y. 2021) (Rakoff, J.) (quoting Cali v. Chrysler Group LLC, 2011 WL 383952, at *4 (S.D.N.Y. Jan. 18, 2011) (Rakoff, J.), aff'd, 426 F. App'x 38 (2d Cir. 2011) (summary order)).

"The majority of courts that have considered whether § 2311(d) bars an MMWA claim founded on the labels of products governed by the FDCA have concluded that the MMWA claim is barred." Reid v. GMC Skin Care USA Inc., 2016 WL 403497, at *13 (N.D.N.Y. Jan. 15, 2016) (collecting cases); see, e.g., Goldstein, 637 F. Supp. 3d at 102 ("[T]he Court concludes

that Plaintiff's claims are preempted under the FDCA. For that reason, the Court concludes that Plaintiff's MMWA claim fails as well and need not reach the sufficiency of Plaintiff's pleadings on her state claims . . . ."); Dayan v. Swiss-American Products, Inc., 2017 WL 9485702, at *12 (E.D.N.Y. Jan. 3, 2017), report and recommendation adopted, 2017 WL 1214485 (E.D.N.Y. Mar. 31, 2017) ("Plaintiff brings his MMWA claim solely because of the product's SPF-45 label. Both parties agree this label is governed by the FDCA, and so § 2311(d) bars Plaintiff's MMWA claim."). This Court joins in this reasoning and concludes that Lester's claims under the MMWA are barred by section 2311(d).

CVS also argues that Lester's MMWA claim fails because it does not meet the statutory requirements of section 2310(d)(3) of the MMWA. Lester argues that the requirements in section 2310(d)(3) do not apply here because he has an independent basis for subject matter jurisdiction under CAFA (ECF 24 at 13-14), while CVS argues that Lester is conflating subject matter jurisdiction with the statutory elements of a claim under the MMWA, (ECF 22 at 18; ECF 25 at 12). Neither party addresses the fact that this is currently an issue of contention among various Circuits, but recent opinions in this district disagree with Lester's interpretation. See, e.g., Ghaznavi v. De Longhi America, Inc., 2023 WL 4931610, at *10 (S.D.N.Y. Aug. 2, 2023) (Failla, J.) ("After considering statutory text, structure, and history, the Court joins the Third and Ninth Circuits in finding that CAFA does not displace the MMWA's stringent federal jurisdictional requirements.").

This Court joins with those others who find that a failure to meet these "stringent" requirements of section 2310(d)(3) bars a claim under the MMWA. Section 2310(d)(3) provides: "No claim shall be cognizable in a suit brought under paragraph (1)(B) of this subsection—(A) if the amount in controversy of any individual claim is less than the sum or

value of $25; (B) if the amount in controversy is less than the sum or value of $50,000 (exclusive of interests and costs) computed on the basis of all claims to be determined in this suit; or (C) if the action is brought as a class action, and the number of named plaintiffs is less than one hundred." 15 U.S.C. § 2310(d)(3); see Gavilanes v. Gerber Products Company, 2021 WL 5052896, at *7 (E.D.N.Y. Nov. 1, 2021) (citing Abraham v. Volkswagen of America, Inc., 795 F.2d 238, 246 (2d Cir. 1986)) (plaintiff's MMWA "claim must fail because a [MMWA] claim is not 'cognizable . . . if the amount in controversy of any individual claim is less than the sum or value of $25' or 'if the action is brought as a class action, and the number of named plaintiffs is less than one hundred.'").

Lester's claims fail prong (A)—he alleges only that the Product cost $1.79, and that he bought it "at or exceeding the above-referenced price," but he does not allege that he purchased the Product a sufficient number of times to meet the $25 threshold. (ECF 1 ¶¶ 25, 55, 58.)

The Court concludes that Lester's MMWA claims are barred, both because his state law claims are preempted under the FDCA and because his claims fail to meet the requirements of section 2310(d)(3).

IV. CONCLUSION

The Court concludes Lester's state law claims for violations of New York GBL sections 349 and 350, violations of similar consumer protection statutes in other states, breach of express warranty, breach of implied warranties of merchantability and fitness for particular

purpose, negligent misrepresentation, fraud, and unjust enrichment are preempted by federal law. Lester also fails to establish his MMWA claim.

Finally, although Lester seeks, in the alternative, to amend his complaint (ECF 24 at 15), the Court invited Lester to do so, and in his letter of January 3, 2023, Lester stated that he did not believe such amendment was necessary. (ECF 19 at 1.)

Accordingly, in a Scheduling Order dated January 17, 2023, the Court Ordered that the time for Lester to amend or move to amend be limited to the later of the following: "(a) the date to amend as of right under Rule 15, Fed. R. Civ. P.; or (b) 21 days from the filing of the motion to dismiss." (ECF 20 at 1.) Lester did not amend or move to amend his Complaint within this timeframe. The Court thus denies Lester's request to do so now. See Parker v. Columbia Pictures Industries, 204 F.3d 326, 339-40 (2d Cir. 2000) (holding that "the district court did not abuse its discretion in denying [plaintiff's] motion on the ground that the motion was brought after the court-ordered deadline for amending the pleadings . . . despite the lenient standard of Rule 15(a), a district court does not abuse its discretion in denying leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause").

Additionally, even if it had been timely, such amendment would be futile. Lester has not "articulate[d] . . . any additional allegations that he could assert in a[n] amended complaint that could save his . . . claims from preemption." See Melendez v. Sirius XM Radio, Inc., 50 F.4th 294, 309 (2d Cir. 2022).

The Court GRANTS CVS's Motion to Dismiss with respect to all claims. The Clerk of Court is respectfully directed to terminate the motion (ECF 22), grant judgment for the defendant, and close the case.

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
March 27, 2024