UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROSLYN HARRIS and MARY ALLEN, Plaintiffs,	:	21cv6789 (DLC)
-v-	:	OPINION AND ORDER
PFIZER INC., Defendant.	:	

APPEARANCES:

For plaintiffs:
Andrew Obergfell
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For defendant:
Colleen Gulliver
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DENISE COTE, District Judge:

Roslyn Harris and Mary Allen bring this putative class action against Pfizer Inc. ("Pfizer") after its voluntary recall of the drug Chantix, which was found to be contaminated with excess levels of a N-nitroso-varenicline. Pfizer has moved to dismiss the complaint. For the following reasons, the motion is granted.

Background

The following facts are derived from the first amended complaint ("FAC"), unless otherwise noted, and are assumed to be true for the purposes of this motion. Pfizer is a New York corporation, with its principal place of business in New York. Pfizer manufactures and distributes Chantix, a prescription drug used to help consumers quit smoking. Chantix's medication guide recommends that most people take the medication for up to 12 weeks, with the possibility of another 12-week course afterward if necessary.[1] The active ingredient in Chantix is varenicline.

Plaintiffs' claims arise out of Pfizer's recall of Chantix due to the presence of N-nitroso-varenicline. N-nitroso-varenicline is a nitrosamine, a chemical compound classified as possibly carcinogenic. On July 2, 2021, the Food and Drug Administration ("FDA") announced Pfizer's recall of nine lots of Chantix to the warehouse level due to contamination from N-nitroso-varenicline above the FDA's acceptable intake level of 37 nanograms per day. To abate a shortage of the medication, the FDA increased its acceptable intake level to an interim level of 185 nanograms per day. Nevertheless, Pfizer expanded

[1] See CHANTIX® Medication Guide, Pfizer (Feb. 2019), https://www.pfizermedicalinformation.com/en-us/chantix/medguide.

its recall to twelve lots of Chantix on July 19, 2021, and then to all lots of Chantix to the consumer level on September 16, 2021, due to the presence of N-nitroso-varenicline exceeding the interim acceptable intake level.

Plaintiff Roslyn Harris is a citizen of New Jersey. She purchased four one-month boxes of Chantix in New Jersey between 2019 and 2021, each of which was subject to recall. Plaintiff Mary Allen is a citizen of New York. She purchased three one-month boxes of Chantix in New York between 2020 and 2021, each of which was subject to recall.

Both plaintiffs paid a co-pay for Chantix, and consumed at least some of the medication they purchased. Neither plaintiff, however, alleges that they have suffered any detriment to their health as a result. Instead, the plaintiffs allege that they did not know that Chantix contained N-nitroso-varenicline, that they did not see it listed as an ingredient on the medication's box or labeling, and that they would not have purchased the medication if they had known it was contaminated. The plaintiffs complain that the presence of N-nitroso-varenicline

rendered the product they paid for worthless. They seek damages solely for their economic injury.[2]

Plaintiff Rosalyn Harris brought this action against Pfizer on August 12, 2021. Pfizer moved to dismiss the complaint on October 21. The complaint was then amended on November 10, adding Mary Allen as a plaintiff. Pfizer moved to dismiss the amended complaint on December 1, and the plaintiffs opposed the motion on December 22. The motion became fully submitted on January 12, 2022.

This Court has jurisdiction pursuant to the Class Action Fairness Act of 2005 ("CAFA"). CAFA confers federal jurisdiction over "certain class actions where: (1) the proposed class contains at least 100 members; (2) minimal diversity exists between the parties; and (3) the aggregate amount in controversy exceeds $5,000,000." Purdue Pharma L.P. v. Kentucky, 704 F.3d 208, 213 (2d Cir. 2013) (citation omitted). The FAC alleges that there are over 100 class members, and that the aggregate amount of the class members' claims exceeds $5,000,000. Additionally, Harris is a resident of New Jersey,

[2] Pfizer has offered a full rebate for any unused Chantix purchased by consumers. Therefore, this lawsuit seeks damages for economic injury attributable to Chantix tablets that the plaintiffs consumed.

while Pfizer is a New York corporation headquartered in New York. CAFA's diversity, numerosity, and amount-in-controversy requirements have therefore been satisfied.

Discussion

The FAC brings causes of action against Pfizer for breach of express warranty, breach of the implied warranty of merchantability, violation of New Jersey's Consumer Fraud Act, unjust enrichment, fraud, negligent misrepresentation, and violation of New York General Business Law §§ 349, 350. Pfizer has moved to dismiss the case for lack of standing pursuant to Fed. R. Civ. P. 12(b)(1), and for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6).

It is worth noting at the outset what claims the plaintiffs do not bring. The plaintiffs' claims arise out of Pfizer's recall of Chantix due to contamination from N-nitroso-varenicline exceeding the legal limit. But the Food, Drug, and Cosmetic Act does not create a private cause of action. PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997). The plaintiffs therefore disclaim any attempt to privately enforce the FDA's limits on nitrosamine contamination. Instead, when a consumer is injured by a defective pharmaceutical, the consumer typically brings a state-based tort action for products

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