UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHANNON WEBB, individually, and on behalf of all others similarly situated, Plaintiff, v. PFIZER, INC., Defendant	Case No. _____ **CLASS ACTION COMPLAINT** **JURY DEMAND**

Plaintiff Shannon Webb ("Plaintiff"), by and through their undersigned counsel, brings this action individually and on behalf of all others similarly situated, to seek economic damages for those who paid for or made reimbursements for generic varenicline-containing drugs ("VCDs") that were illegally and willfully manufactured, distributed, and/or introduced into the market by Defendant Pfizer, Inc. ("Pfizer").

INTRODUCTION

1. This case arises from adulterated, misbranded, and unapproved varenicline-containing drugs ("VCDs") that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Defendant Pfizer, Inc., in the United States under the brand name Chantix®. These VCDs are non-merchantable, and are not of the quality represented by Defendant.

2. The brand name drug Chantix is known generically as varenicline (as the tartrate salt), and is a partial nicotine agonist. It is a first-line therapy in the treatment to aid in smoking cessation. Unlike many other smoking cessation aids, Chantix does not contain nicotine.

3. Pfizer obtained approval from the United States Food and Drug Administration

("FDA") to sell Chantix as a first of its kind treatment in May 2006.

4. Chantix quickly became one of Pfizer's fastest growing products. Major media spending on Chantix totaled $55 million in 2007 (the year after its approval). In the year Chantix was launched, Pfizer spent $4.3 million in medical journal advertisements alone.

5. The market rapidly embraced Chantix, and continues to do so to this day. For example, from launch through 2015, the number of Chantix prescriptions amongst Medicaid beneficiaries increased 13,277% (thirteen-thousand, two-hundred seventy-seven percent).[1]

6. The price for Chantix has steadily climbed since its launch. Price estimates at launch were approximately $113.98, which climbed to $254.50 as of 2015. In 2018, the price nearly doubled to $485 for a 30-day supply, bringing in $997 million in sales that year.[2]

7. The market for smoking cessation treatments remains robust and continues to grow. Pfizer's Chantix sales remain strong, with sales of at least $919 million last year. Indeed, Chantix was Pfizer's eight-best-selling product in 2020. To this day, Chantix remains one of the few, and most prevalent, smoking cessation drug treatments, and one of Pfizer's top drug products. Pfizer extended patent protection on Chantix to ensure exclusivity through at least August 2022, thus ensuring Pfizer's Chantix is the exclusive varenicline product without generic competition currently.

8. At all pertinent times for this action, Defendant represented and warranted to consumers that its VCDs were therapeutically equivalent to and otherwise the same as the FDA-approved brand name drug Chantix. Specifically, Defendant represented and warranted that the

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[1] Xiaomeng Yue, et al., TRENDS IN UTILIZATION, SPENDING, AND PRICES OF SMOKING-CESSATION MEDICATIONS IN MEDICAID PROGRAMS: 25 YEARS EMPIRICAL DATA ANALYSIS, 1991-2015, Am. Health Drug Benefits 2018 Sep; 11(6):275-285, *at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207314/* (last accessed Sept. 27, 2021).

[2] *Price of Pfizer's smoking-cessation drug Chantix doubles in just 5 years: report*, Fierce Pharma (June 26, 2018) at https://www.fiercepharma.com/pfizer-hikes-price-smoking-cessation-drug-chantix-106-5-years-report (last accessed Sept. 27, 2021).

VCDs were fit for their ordinary uses, met the specifications of Defendant's FDA-approved labeling materials, and were manufactured and distributed in accordance with all applicable laws and regulations.

9. However, Defendant willfully ignored warnings about the operating standards, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded VCDs for purchase in the United States by consumers.

10. Defendant VCDs were adulterated and/or misbranded (and thereby rendered worthless) through contamination with a probable human carcinogen known as n-nitroso-varenicline. Additionally, Defendant was on notice of other potential nitrosamines as well, such as n-nitrosdimethylamine ("NDMA") and n-nitrosodiethlamine ("NDEA").

11. According to the FDA and other global health authorities, nitrosamines are dangerous probable human carcinogens.

12. According to FDA testing, VCDs subject to this action contained NDMA contamination levels many times higher than the FDA's updated interim limits for NDMA and other nitrosamine impurities.

13. On July 2, 2021, and July 19, 2021, Pfizer initiated recalls of VCDs "because [the product] may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."[3] The FDA has yet to release full testing results for other nitrosamine impurities. On September 16, 2021, Pfizer extended its recall to all Chantix.[4]

14. -Upon information and belief, N-nitroso-varenicline contamination of Defendant's

[3] FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix) *at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last accessed Sept. 27, 2021).
[4] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n (last accessed Sept. 27, 2021).

VCDs dates back many years, at which point Defendant had actual and/or constructive notice of the contamination.

15. Ironically, the Defendant's wrongful acts resulted in persons who sought to use smoking products *less* end up with a Chantix pill that contained a carcinogen.

16. The Class Plaintiffs paid for VCDs that were illegally and willfully introduced into the market by Defendants, which caused them and the millions of other VCD consumers, to sustain economic damages. Defendant's VCDs were not fit for their ordinary use and Defendant has been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs. Defendant's conduct, as detailed in this Complaint, also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law.

PARTIES

A. Plaintiff

17. Plaintiff Shannon Webb is a citizen and resident of Schenectady, New York. During the class period, Plaintiff Webb paid money for one or more of Defendant's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Defendant. Defendant in this paragraph expressly and impliedly warranted to Plaintiff Webb (either directly or indirectly by adopting warranties that were passed along to and incorporated by another Defendant further downstream and as mentioned in this paragraph) that their respective VCDs were the same as the branded Chantix. But in fact, Plaintiff Webb bought a product that was not the same as Chantix. Had Plaintiff Webb known the product was not the same, Plaintiff Webb would not have paid for these Defendant's VCDs. Likewise, had Defendant's deception about the impurities within their products been made known earlier, Plaintiff Webb would not have paid for Defendant's VCDs.

B. Defendant

18. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017. Pfizer on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Pfizer has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs in the United States.

FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

19. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

20. Pharmaceutical manufacturers produce drugs that they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

21. Third-party payors ("TPPs") contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing generic drugs, such as VCDs, on the TPPs' formularies.

22. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are bioequivalent or otherwise the

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