UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

DOUG HOUGHTON, on behalf of himself and all others similarly situated, Plaintiffs, v. PFIZER INC., Defendant.	Civil Action No. 1:21-cv-23987 **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Doug Houghton ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendant Pfizer Inc. ("Pfizer" or "Defendant"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendant's manufacturing, distribution, and sale of varenicline-containing medications under the brand name Chantix® ("Chantix" or the "Product") that contain dangerously high levels of N-nitroso-varenicline, a carcinogenic impurity.

2. Chantix is a prescription medication that contains the active ingredient varenicline, which is an ingredient designed to help individuals stop smoking by attaching to nicotine receptors in the brain so that nicotine cannot attach to the receptors. The varenicline still releases dopamine (much like nicotine), but to a lesser degree. This is designed to assist a person using Chantix to quit smoking by resisting the urge to smoke. However, Defendant's manufacturing process has caused Chantix to contain dangerously high levels of N-nitroso-

varenicline, a carcinogenic impurity which was not designed to be in the medication.

3. N-nitroso-varenicline is a nitrosamine. "Nitrosamines are chemical compounds classified as probable human carcinogens on the basis of animal studies."[1] The United States Food & Drug Administration ("FDA") states that nitrosamines, including N-nitroso-varenicline, "are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer (IARC)."[2] "A genotoxin is a chemical or agent that can cause DNA or chromosomal damage. . . . DNA damage in a somatic cell may result in a somatic mutation, which may lead to malignant transformation (cancer)."[3]

4. According to Health Canada, N-nitroso-varenicline "has been shown to cause gene mutations in an in vitro study, indicating that its presence in [Chantix] may be associated with a potential increased cancer risk in humans."[4] The FDA has further stated that "N-Nitroso-varenicline belongs to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens (substances that could cause cancer), based on laboratory tests such as rodent carcinogenicity studies."[5]

5. On July 2, 2021, the FDA issued an alert to patients and healthcare professionals as to Pfizer's recall of nine lots of Chantix to the warehouse level due to the presence of "a

[1] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'. (last visited 8/11/21).
[2] *See* Control of Nitrosamine Impurities in Human Drugs, at 5, available at https://www.fda.gov/media/141720/download#:~:text=Nitrosamine%20compounds%20are%20potent%20genotoxic,Research%20on%20Cancer%20(IARC). (last visited 11/1/21).
[3] David H. Phillips, Genotoxicity: damage to DNA and its consequences, available at https://pubmed.ncbi.nlm.nih.gov/19157059/ (last visited 11/1/21).
[4] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75961a-eng.php (last visited 8/5/21).
[5] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/5/21).

nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."[6] "FDA has determined the recalled varenicline poses an unnecessary risk to patients. Therefore, FDA recommends health care professionals consider other available treatment options for the patient's medical condition."[7] The FDA further noted that "[w]e know impurities in medicines are of great concern to patients and consumers who rely on safe and effective medicines approved by FDA."[8]

6. Later, on July 16, 2021, the FDA announced that to "ensure patient access to varenicline, FDA will not object to certain manufacturers temporarily distributing varenicline tablets containing N-nitroso-varenicline above FDA's acceptable intake limit of 37 ng per day but below the interim acceptable intake limit of 185 ng per day until the impurity can be eliminated or reduced to acceptable levels."[9] Stated another way, medications containing more than 37 ng of N-nitroso-varenicline are not acceptable in the medication under ordinary circumstances, but because of fear of shortage, the FDA has created interim limits for presence of N-nitroso-varenicline. However, the recalled batches of Defendant's Chantix that are the subject of this action contained levels of N-nitroso-varenicline even above the FDA's interim limits, rendering them unsafe for use and unmerchantable as sold.

7. On July 19, 2021, Pfizer expanded its recall to twelve lots of Chantix "due to the presence of N-nitroso-varenicline above the company's acceptable limit for this impurity."[10]

8. Each of the twelve recalled lots were identified by NDC number, as well as other

[6] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/5/21).
[7] *Id.*
[8] *Id.*
[9] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/10/21).
[10] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/10/21).

product identifiers:

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5 mg	0069-0468-56	00019213	2022 JAN	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5 mg	0069-0468-56	EC6994	2023 MAY	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069-0469-56	EA6080	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069-0469-56	EC9843	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020231	2021 SEP	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020232	2021 NOV	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020357	2021 DEC	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020358	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020716	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	ET1600	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	ET1607	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline)	0069-0471-03	ET1609	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Tablets, 0.5/1 mg					containing 42 1 mg tablets

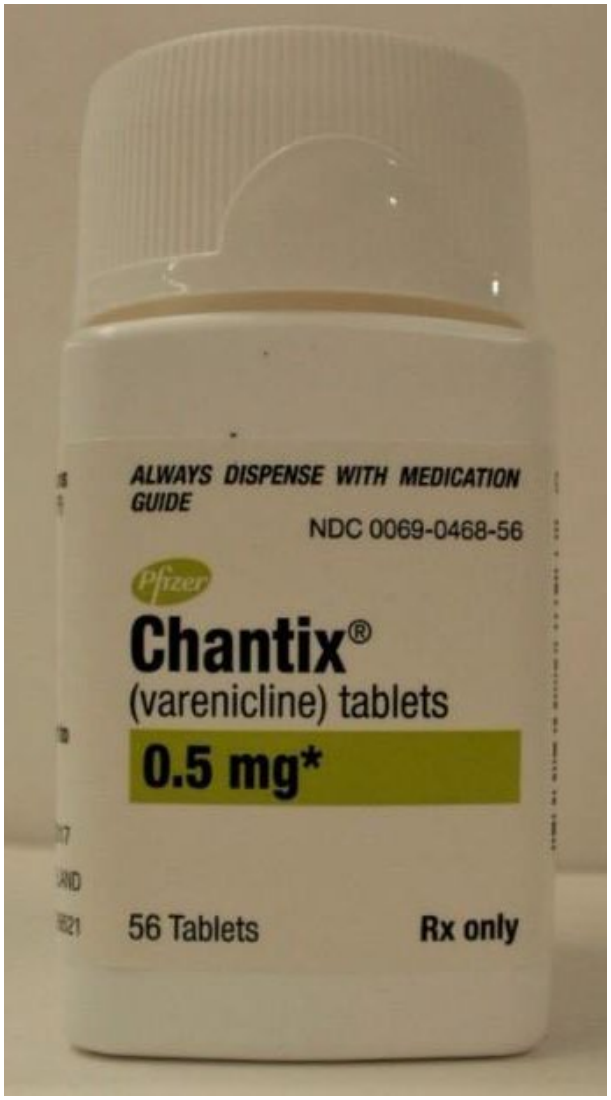
9. In connection with the recall, Pfizer instructed its wholesalers and distributors "with an existing inventory of the lots, listed in the table above, [to] stop use and distribution and quarantine the product immediately."[11] Pfizer made this instruction to its wholesalers and distributors because it knew the Product was carcinogenic, unsafe, unfit for its intended use, and unmerchantable as sold.

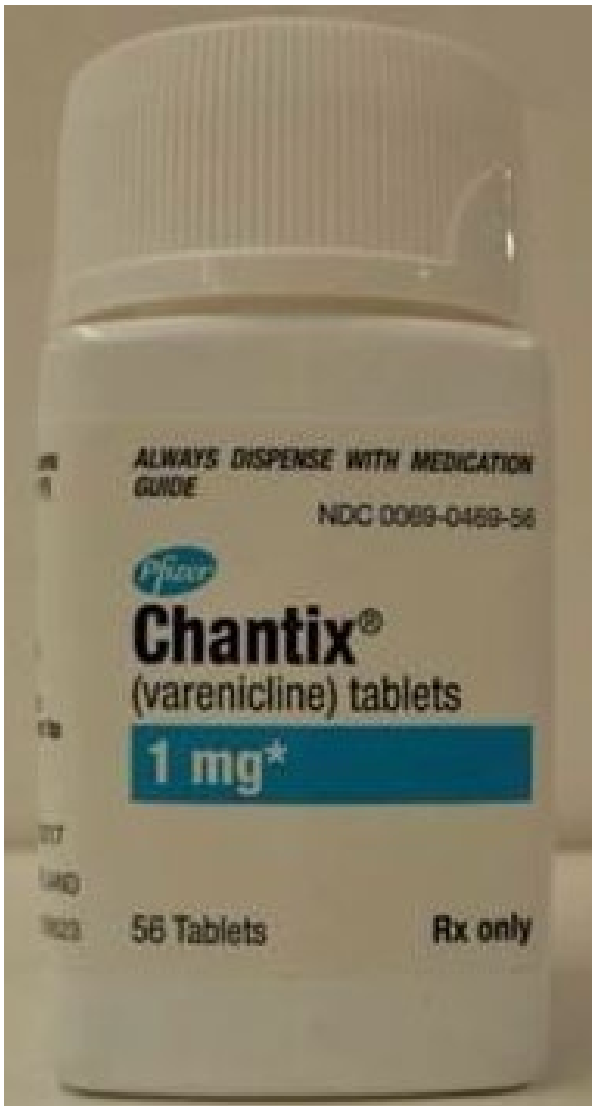
10. The recall notice advised that consumers, like Plaintiff and members of the Class and Florida Subclass (as defined below), should consult with their health care provider and return the product subject to the recall.[12] In other words, consumers were to stop using the recalled product and return it because it was unsafe for use.

11. Later, on September 16, 2021, Pfizer expanded the recall once again to "all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level **due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit**."[13] (Emphasis added). The FDA instructed that "[w]holesalers and Distributors with an existing inventory of Chantix tablets, should stop use and distribution and quarantine the product immediately."[14] Pfizer provided additional product identification information for the recalled

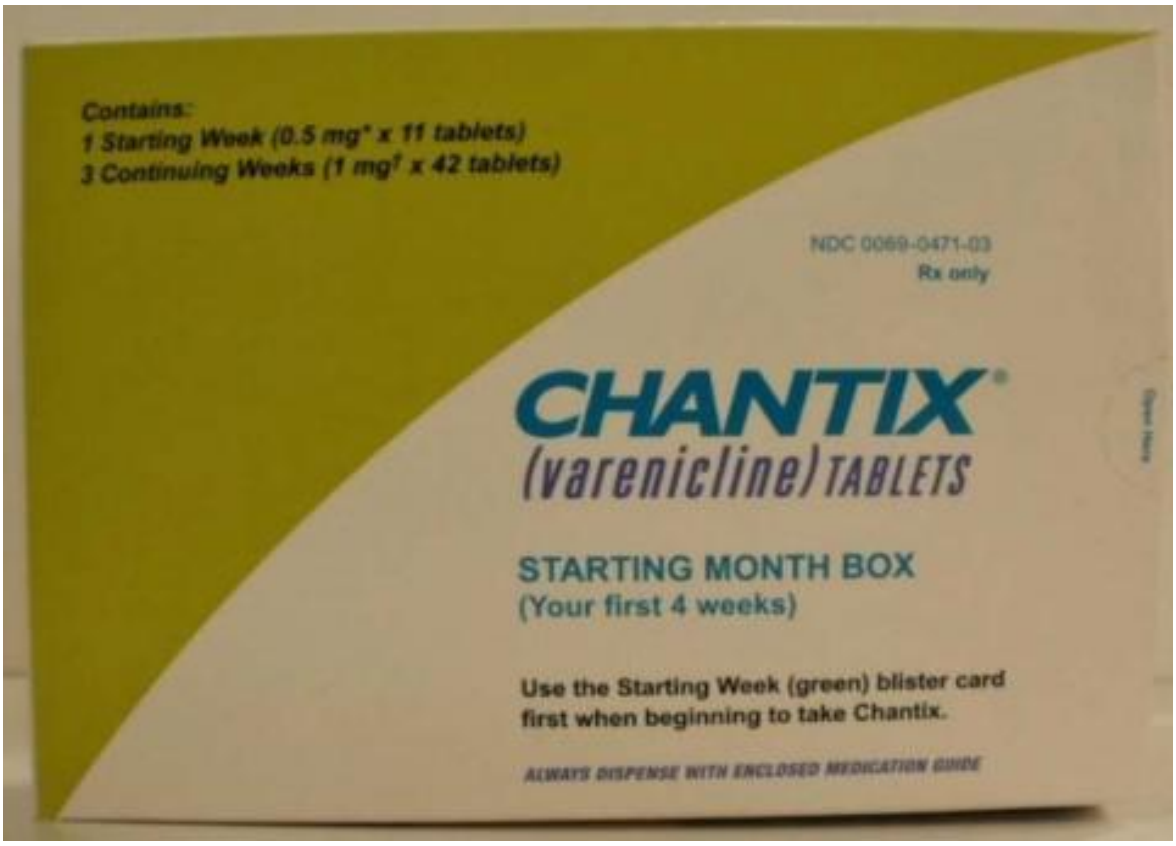
[11] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-issues-voluntary-nationwide-recall-twelve-lots-chantixr-varenicline-tablets-due-n-nitroso (last visited 8/10/21).
[12] *Id.*
[13] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n (last visited 11/1/21).
[14] *Id.*

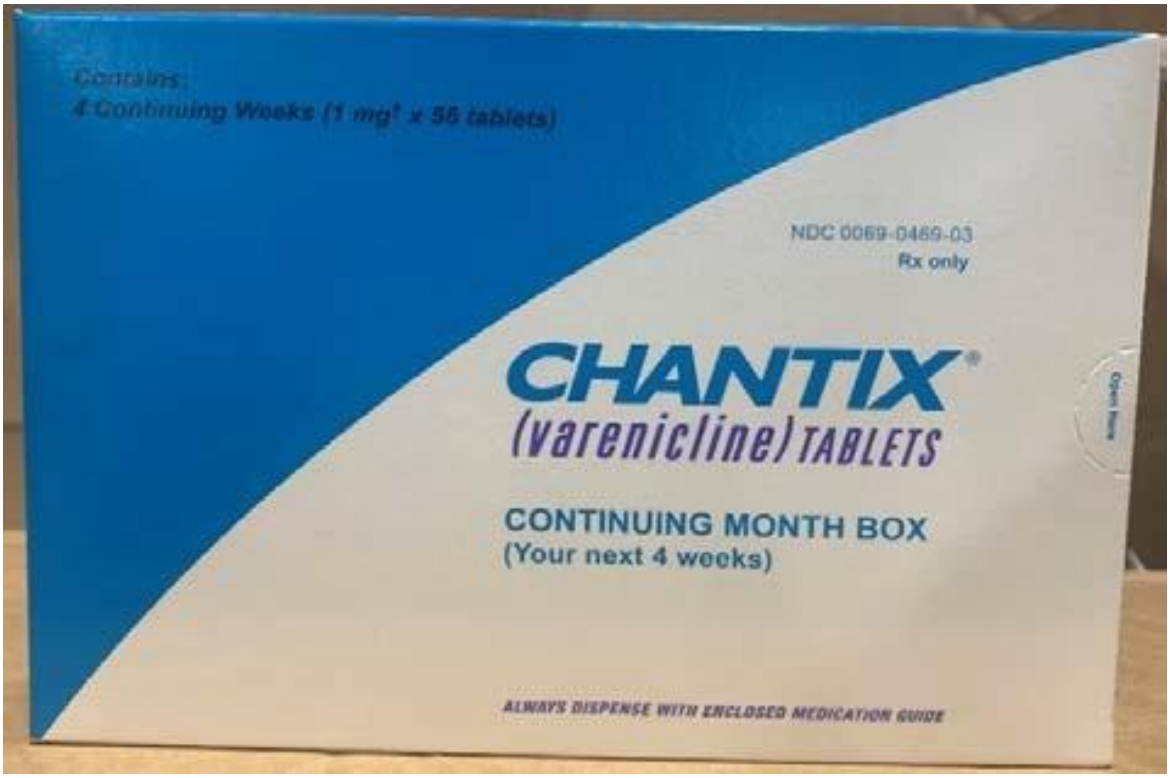
products, including NDC Codes and lot numbers of affected Products.[15] Pfizer also included label images of the affected Products:





[15] *Id.*


Contains:
1 Starting Week (0.5 mg* x 11 tablets)
3 Continuing Weeks (1 mg† x 42 tablets)
NDC 0069-0471-03
Rx only
CHANTIX®
(varenicline) TABLETS
STARTING MONTH BOX
(Your first 4 weeks)
Use the Starting Week (green) blister card first when beginning to take Chantix.
ALWAYS DISPENSE WITH ENCLOSED MEDICATION GUIDE


Contains:
4 Continuing Weeks (1 mg† x 56 tablets)
NDC 0069-0469-03
Rx only
CHANTIX®
(varenicline) TABLETS
CONTINUING MONTH BOX
(Your next 4 weeks)
ALWAYS DISPENSE WITH ENCLOSED MEDICATION GUIDE

12. Regardless of the packaging, each iteration of the Product contains the same representation and warranty that the Product was "Chantix" and "(varenicline) TABLETS." But the Product's labels are false because the Product also contained the genotoxic contaminate N-nitroso-varenicline. The Product was distributed to Plaintiff, Class members, and members of the Florida Subclass in the manufacturer's packaging such that Plaintiff and members of the Class and Florida Subclass reviewed the labels at the point of purchase.

13. The Product's labeling, in each iteration, states "ALWAYS DISPENSE WITH MEDICATION GUIDE" or "ALWAYS DISPENSE WITH ENCLOSED MEDICATION GUIDE." When Plaintiffs and class members filled their Chantix prescriptions, they received and reviewed the medication guide contained therewith. The medication guide contained similar representations and warranties regarding the Product.[16] Notably, the medication guide expressly represents and warrants that the only active ingredient in the medication was "varenicline tartrate."[17] But that is false because the Product also included the genotoxic contaminate N-nitroso-varenicline.

14. Defendant did not disclose the presence of N-nitroso-varenicline at all on the Product's label, in the medication guide, or otherwise. That is because N-nitroso-varenicline is not designed to be contained in the Product, and is in fact a harmful impurity contained therein. No reasonable consumer would have chosen to purchase Defendant's Product had they known that it contained harmful levels of a carcinogenic impurity, to wit N-nitroso-varenicline.

15. Defendant had reason to know of the presence of N-nitroso-varenicline in Chantix, but nevertheless failed to disclose the presence of the same to Plaintiff or members of the Class and Florida Subclass. Specifically, the presence of nitrosamines in prescription

[16] https://www.pfizermedicalinformation.com/en-us/chantix/medguide (last visited 11/1/21).
[17] *Id.*

medications has been the subject of FDA scrutiny for over three years, as well as international regulators such as the European Medicines Agency ("EMA").

16. "EU regulators first became aware of nitrosamines in medicines in mid-2018 when nitrosamine impurities, including N-nitrosodimethylamine (NDMA), were detected in blood pressure medicines known as 'sartans'."[18] The FDA similarly began announcing nitrosamine-related recalls in mid-2018.[19]

17. Since that time, both the FDA and the EMA have implemented control strategies to ensure that medications entering the market and being sold to consumers are not contaminated with nitrosamines. For example, the EMA states that "[c]ompanies are required to have appropriate control strategies to prevent or limit the presence of these impurities and, where necessary, to improve their manufacturing processes."[20] The EMA further admonished that "[m]arketing authorisation holders should review their manufacturing processes for all products containing chemically synthesised or biological active substances to identify and, if necessary, mitigate the risk of presence of nitrosamine impurities."[21]

18. For its part, the FDA, in September 2020, published guidance for the industry entitled "Control of N-Nitrosamine Impurities in Human Drugs."[22] "This guidance recommends steps manufacturers of active pharmaceutical ingredients (APIs) and drug products should take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products."[23]

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[18] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'.

[19] *See, e.g.,* https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/major-pharmaceuticals-issues-voluntary-nationwide-recall-valsartan-due-potential-presence-probable (last visited 8/11/21).

[20] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'.

[21] *Id.*

[22] https://www.fda.gov/media/141720/download (last visited 8/11/21).

[23] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-

19. However, despite this guidance and the known risk of nitrosamine impurities in medications, Defendant's Chantix medication still contained unacceptable levels of nitrosamine impurities, specifically N-nitroso-varenicline.

20. Further, in October of 2020, Health Canada sent a letter to Apotex, Inc. (the distributor of Chantix in Canada) concerning the presence of nitrosamines in drug products. Specifically, Health Canada informed Apotex that it had been informed by other global regulators "of the presence of new nitrosamine impurities in varenicline API [active pharmaceutical ingredient]: 7,8-dinitro-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[d]azepin-N-nitrosamine, 1-(7,8-diamino-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[o'1azepin-3-yl)-N-nitrosamine and N-nitroso varenicline." Health Canada continued: "After a preliminary internal review conducted by Health Canada, it was concluded that there is risk for formation of these new nitrosamine impurities for all MAHs of varenicline drug products in Canada." Thus, Defendant knew or should have known of the issue of nitrosamine contamination months before it ultimately announced the recalls of the Product.

21. Had Defendant engaged in proper testing of the Product and followed prevailing current Good Manufacturing Processes ("cGMP") and industry guidance, it would have known that the Product contained unacceptable amounts of N-nitroso-varenicline. As such, Defendant's conduct amounts to an actionable omission due to its failure to disclose the true nature of the Product to Plaintiff and members of the Class and Florida Subclass.

22. Because Defendant's Product contained unsafe levels of N-nitroso-varenicline, it is economically worthless as it cannot be legally sold in the United States and is generally unfit for human consumption. Stated another way, Plaintiff and members of the Class and Florida

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varenicline-chantix

Subclass paid a price premium in the amount of the full purchase price for the medication. No reasonable consumer would knowingly purchase the Product had they known that the Product contained a carcinogenic impurity, here N-nitroso-varenicline above acceptable intake limits set by the FDA. At minimum, Plaintiff and members of the Class and Florida Subclass paid a premium of the difference between the value of the Product as promised and warranted versus the value of the Product actually received.

23. Plaintiff brings this action on behalf of himself, the Class, and the Florida Subclass (defined below) for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. §§ 501.201 *et seq.*, (iv) unjust enrichment, (v) fraud, and (vi) negligent misrepresentation/omission.

PARTIES

24. Plaintiff Doug Houghton is a citizen of Florida who resides in Fort Lauderdale, Florida. Plaintiff Houghton purchased defective and now recalled Chantix medication from a Walgreens location in Florida. Plaintiff Houghton paid a co-pay for the Product. When Mr. Houghton purchased the Product, he reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was "Chantix" and had the active ingredient varenicline because the Product's label represented that the Product was "(varenicline) TABLETS." He reasonably understood this to mean that the Product would be "Chantix" as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Houghton chose to purchase the Product, relying on Defendant's representations and warranties. But Defendant's representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-

nitroso-varenicline, above acceptable limits set by the FDA. The Product's labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from him by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Houghton suffered harm because he would not have purchased the Product on the same terms had he known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Houghton paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Houghton paid a premium measured as the difference between the Product as warranted and the Product actually received.

25. In choosing to purchase his Chantix medication from Defendant, Mr. Houghton reviewed the accompanying labels and disclosures described herein, and understood them as representations and warranties by the manufacturer that the Product was properly manufactured, free from defects, and safe for its intended use. Mr. Houghton relied on these representations and warranties in deciding to purchase Chantix from Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased Chantix from Defendant on the same terms if he had known that it was not, in fact, properly manufactured and free from defects. Mr. Houghton also understood that each purchase involved a direct transaction between himself and Pfizer because his medication came with packaging and other materials prepared by Pfizer, including representations and warranties described herein.

26. In July 2021, Plaintiff Houghton received an "Urgent Product Recall Information"

letter from Walgreens, which stated that "[t]he manufacturer, Pfizer has initiated a voluntary recall for these drug products. The recall is due to the presence of N-nitroso-varenicline above the Pfizer established Acceptable Daily Intake (ADI) level." Thus, it is clear from the Walgreens letter that the Products Plaintiff Houghton purchased were affected by the recall and were in fact contaminated with N-nitroso-varenicline.

27. To date, Plaintiff Houghton has not received a refund for the defective Chantix medications he purchased, nor would a simple refund be adequate as he and class members are entitled to, among other things, statutory and punitive damages, and recovery of attorneys' fees and costs. Further, Plaintiff Houghton seeks relief not only on his own behalf, but on behalf of a class of similarly-situated consumers.

28. Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Pfizer manufactured and distributed Chantix throughout the United States, and specifically in the State of Florida. At all relevant times, Pfizer was in control of, and responsible for, the manufacturing, testing, marketing, labeling and general oversight of the Product and sales of the same in the United States. Pfizer conducts substantial business in the United States, and specifically in the State of Florida.

JURISDICTION AND VENUE

29. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

30. This Court has personal jurisdiction over Defendant because Plaintiff purchased the defective Chantix medication in this District.

31. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District.

FACTS COMMON TO ALL CLAIMS

32. Plaintiff hereby expressly incorporates by reference all of the facts set forth in the Nature of the Action section.

33. In 2005, Defendant submitted a New Drug Application for Chantix, NDA 21-928.[24] Chantix was approved by the FDA on May 10, 2006. However, the Product, as approved by the FDA, was not designed to contain nitrosamines, and specifically was not designed to contain N-nitroso-varenicline.

34. "For decades, the regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S."[25]

35. Further, "[t]he documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, **what the ingredients of the drug are**, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."[26] In short, every aspect of the drug, including its ingredients and labeling, must conform to the NDA.

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[24] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021928_s000_Chantix_Approv.pdf (last visited 11/2/21).
[25] https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last visited 11/2/21).
[26] *Id.*

36. In turn, consumers like Plaintiff and Class members expect that when they receive a medication, including Chantix, that they will receive the drug as approved by the FDA. But that is not what Plaintiff and Class members received in this case. Instead, they received a drug containing N-nitroso-varenicline, which is not an approved ingredient in Chantix as approved by the FDA. Therefore, Plaintiff and class members received something other than "Chantix" as approved by the FDA, and by representing the Product as "Chantix" and the only active ingredient as varenicline, Defendant breached an express warranty and made an affirmative false representation to Plaintiff and class members.

37. Each of the Chantix medications sold to Plaintiff and Class members contained N-nitroso-varenicline above acceptable daily intake limits prescribed by the FDA. Defendant admitted as much in its recall notice, recalling "all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level **due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit**."[27] (Emphasis added). As such, the Products were unmerchantable as sold because it is unlawful to sell medication containing nitrosamines above the acceptable daily intake limit set by the FDA.

38. The Products were additionally unmerchantable because, as sold, they were both adulterated and misbranded under federal law, and therefore illegal to sell. Notably, Plaintiffs are not seeking to enforce the federal Food, Drug and Cosmetic Act ("FDCA"); rather, that the Products fall below the quality standard and are illegal to sell under federal law demonstrates that they are unmerchantable and unfit for their intended purpose.

39. The Product is adulterated because "it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its

[27] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n (last visited 11/1/21).

quality or purity falls below, the standard set forth in such compendium." 21 U.S.C. § 351(b); *see also* 21 U.S.C. § 351(c) ("If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."); 21 U.S.C. § 351(a) (a drug is adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess"). The Product is adulterated because Defendant failed to comply with cGMPs in manufacturing the Product, leading to its contamination, and because it contains N-nitroso-varenicline above acceptable daily limits. Therefore, the Product's "purity or quality falls below[] that which it purports or is represented to possess." It is also dangerous to health because of the presence of the nitrosamine impurity.

40. A drug product is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). The Products are misbranded because they are advertised as "Chantix" when in fact they contain N-nitroso-varenicline. The Products are also misbranded because they purport to contain only the active ingredient varenicline but in fact contain N-nitroso-varenicline.

41. Both adulterated and misbranded drugs are illegal to sell. 21 U.S.C. § 331.

42. Defendant engaged in extensive marketing to advertise Chantix to consumers, including television commercials.[28]

[28] https://www.youtube.com/watch?v=1oVH1dRgHYY (last visited 11/2/21); https://www.youtube.com/watch?v=s3F21_ncTg4 (last visited 11/2/21).

CLASS ALLEGATIONS

43. Plaintiffs seek to represent a class defined as all persons in the United States who purchased Chantix (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

44. Plaintiff also seeks to represent a subclass of all Class members who purchased Chantix in Florida (the "Florida Subclass").

45. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and Florida Subclass may be expanded or narrowed by amended complaint or at class certification.

46. **Numerosity.** The members of the Class and Florida Subclass are geographically dispersed throughout the United States and the State of Florida and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class and tens of thousands of members in the Florida Subclass. Although the precise number of Class and Florida Subclass members is unknown to Plaintiff, the true number of Class and Florida Subclass members is known by Defendant and/or third-party retailers and may be determined through discovery. Class and Florida Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

47. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and Florida Subclass and predominate over any questions affecting only individual Class and Florida Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Chantix medication manufactured by Defendant contains dangerously high levels of N-nitroso-varenicline, thereby breaching the express and implied warranties made by Defendant and making Chantix unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendant knew or should have known that Chantix contained elevated levels of N-nitroso-varenicline prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant is liable to Plaintiff and the Class and Florida Subclass for unjust enrichment;

(e) whether Defendant is liable to Plaintiff and the Class and Florida Subclass for fraud;

(f) whether Defendant is liable to Plaintiff and the Florida Subclass for violations of Florida's consumer-protection laws;

(g) whether Plaintiff and the Class and Florida Subclass have sustained monetary loss and the proper measure of that loss;

(h) whether Plaintiff and the Class and the Florida Subclass are entitled to declaratory and injunctive relief;

(i) whether Plaintiff and the Class and the Florida Subclass are entitled to restitution and disgorgement from Defendant; and

(j) whether the marketing, advertising, packaging, labeling, and other promotional materials for Chantix are deceptive.

48. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and Florida Subclass in that Defendant mass marketed and sold defective Chantix to consumers throughout the United States. By definition, this defect was present in all of the Chantix manufactured by Defendant. Therefore, Defendant breached its express and implied warranties to Plaintiff and the Class and the Florida Subclass members by manufacturing, distributing, and selling the defective Chantix. Plaintiff's claims are typical in that he and the Class were uniformly harmed in purchasing and consuming the defective Chantix. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as it deceived each member of the Class and the Florida Subclass. Further, there are no defenses available to Defendant that are unique to Plaintiff.

49. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and the Florida Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and the Florida Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and the Florida Subclass.

50. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and Florida Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class and the Florida Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and Florida

Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

51. In the alternative, the Class and the Florida Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and Florida Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and Florida Subclass members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class and Florida Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and Florida Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class and the Florida Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and Florida Subclass as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of Plaintiff, The Class, And The Florida Subclass)

52. Plaintiff hereby incorporates by reference the allegations contained in the Nature of the Action, Facts Common To All Claims, and Parties sections of this complaint.

53. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Florida Subclass against Defendant.

54. Plaintiff, and each member of the Class and the Florida Subclass, formed a contract with Defendant at the time Plaintiff and the other Class and Florida Subclass members purchased the defective Chantix. The terms of the contract include the promises and affirmations of fact made by Defendant on the Product's packaging and through marketing and advertising, including that the Product would be "Chantix" as approved by the FDA, and would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline.

55. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Florida Subclass and Defendant.

56. Plaintiff relied on the express warranty that the Product would be "Chantix" as approved by the FDA, and would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline. These express warranties further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and the Florida Subclass and Defendant.

57. Defendant purports, through its advertising, labeling, marketing and packaging, to create an express warranty that the Product would be "Chantix" as approved by the FDA, and

would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline.

58. Plaintiff and the Class and the Florida Subclass performed all conditions precedent to Defendant's liability under this contract when they purchased the defective medication.

59. Defendant breached express warranties about the defective Chantix and its qualities because Defendant's statements about the defective Chantix were false because the defective Chantix Plaintiff and members of the Class and Florida Subclass purchased do not conform to Defendant's affirmations and promises described above.

60. Plaintiff and each of the members of the Class and the Florida Subclass would not have purchased the defective Chantix on the same terms had they known the true nature of the defective Chantix's composition, specifically that Chantix contained elevated levels of N-nitroso-varenicline and was not, in fact, "Chantix" as approved by the FDA.

61. As a result of Defendant's breach of express warranty, Plaintiff and each of the members of the Class and the Florida Subclass have been damaged in the amount of the purchase price of Chantix, or at minimum the difference between the value of the Product as promised and warranted versus the value of the Product actually received, and any consequential damages resulting from the purchases.

62. On November 12, 2021, prior to filing this action, Plaintiff served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an express warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached

hereto as **Exhibit A**.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of Plaintiff, The Class, And The Florida Subclass)

63. Plaintiff hereby incorporates by reference the allegations contained in the Nature of the Action, Facts Common To All Claims, and Parties sections of this complaint.

64. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Florida Subclass against Defendant.

65. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that Chantix (i) would not contain elevated levels of N-nitroso-varenicline above acceptable daily intake limits, (ii) is generally recognized as safe for human consumption, and (iii) was not adulterated or misbranded such that the Product was lawful to sell in the United States and in the State of Florida. By selling the defective Product to Plaintiff and Class members and members of the Florida Subclass, Defendant breached each of these implied warranties.

66. Defendant breached the warranty implied in the contract for the sale of the defective Chantix because it could not pass without objection in the trade under the contract description, the Chantix was not of fair or average quality within the description, and the Chantix was unfit for its intended and ordinary purpose because the Chantix manufactured by Defendant was defective in that it contained elevated levels of carcinogenic N-nitroso-varenicline above the legal limit, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and Florida Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

67. Plaintiff, Class, and Florida Subclass members purchased Chantix in reliance

upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

68. The Chantix medication purchased by Plaintiff and members of the Class and the Florida Subclass was not altered by Plaintiff or Class or Florida Subclass members.

69. The Chantix was defective when it left the exclusive control of Defendant.

70. Defendant knew that the Chantix medication would be purchased and used without additional testing by Plaintiff and the Class and the Florida Subclass members.

71. The Chantix medications that Plaintiff, the Class, and the Florida Subclass purchased were defectively manufactured and unfit for their intended purpose because they contained elevated levels of N-nitroso-varenicline above the legal limit, and Plaintiff and Class and Florida Subclass members did not receive the goods as warranted. The Product was also adulterated and misbranded, and as such was unfit for use as a prescription medication because adulterated and misbranded medications are illegal to sell.

72. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff and Class and Florida Subclass members have been injured and harmed because: (a) they would not have purchased Chantix on the same terms if they knew that Chantix contained harmful levels of N-nitroso-varenicline, and is not generally recognized as safe for human consumption; and (b) Chantix does not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

73. On November 12, 2021, prior to filing this action, Plaintiff served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-314, 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached

hereto as **Exhibit A**.

74. On November 1, 2021, prior to filing the First Amended Complaint, Plaintiff Allen served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as **Exhibit B.**

COUNT III

Violation Of The Florida Deceptive And Unfair Trade Practices Act, Fla. Sta. §§ 501.201, *et seq.*

(On Behalf Of Plaintiff And The Florida Subclass)

75. Plaintiff hereby incorporates by reference the allegations contained in the Nature of the Action, Facts Common To All Claims, and Parties sections of this complaint.

76. Plaintiff brings this claim individually and on behalf of the members of the proposed Florida Subclass against Defendant.

77. FDUTPA renders unlawful unfair methods of competition, unconscionable acts or practice, and unfair or deceptive acts or practices in the conduct of any trade or commerce. Fla. Stat. § 501.204.

78. Among other purposes, FDUTPA is intended "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202.

79. FDUPTA can be violated in two ways, both of which are relevant to this case. First, Defendant has committed a "traditional" violation of FDUPTA by engaging in unfair and/or deceptive acts and practices which caused injury to Plaintiff and members of the Subclass.

80. Second, Defendant has committed a *per se* violation of FDUPTA predicated on a violation of the FDCA. Specifically, by selling adulterated and misbranded Products which is *per se* illegal in violation of 21 U.S.C. § 351 and 21 U.S.C. § 352 of the FDCA, and because the FDCA is designed to protect consumers from harmful and dangerous drugs, Defendant has committed *per se* violations of FDUPTA. Fla. Stat. Ann. § 501.203(3)(c) (explaining that a FDUPTA violation may be based on "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices.").

81. While FDUPTA does not define "deceptive" or "unfair," Florida courts have looked to the Federal Trade Commission's interpretations for guidance. "[D]eception occurs if there is a representation, omission, or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment." *Lombardo v. Johnson & Johnson Consumer Companies, Inc.*, 124 F. Supp. 3d 1283, 1287 (S.D. Fla. 2015) (internal quotation marks and citation omitted). Courts define a "deceptive trade practice" as any act or practice that has the tendency or capacity to deceive consumers. *Fed. Trade Comm'n v. Partners In Health Care Ass'n, Inc.*, 189 F. Supp. 3d 1356, 1367 (S.D. Fla. 2016). Courts define an "unfair trade practice" as any act or practice that "offends established public policy and one that is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." *Kenneth F. Hackett & Assocs., Inc. v. GE Capital Info. Tech. Sols., Inc.*, 744 F. Supp. 2d 1305, 1312 (S.D. Fla. 2010). Defendant engaged in conduct that is likely to deceive members of the public. This conduct includes representing that the Products were "Chantix" as approved by the FDA when in fact they were not, and that the Products would contain only the active ingredients stated on the label, when in fact they contained harmful, carcinogenic impurities such as N-nitroso-

varenicline.

82. As alleged herein, Plaintiff has suffered injury in fact and lost money as a result of Defendant's conduct because he purchased the Products from Defendant in reliance on Defendant's representation that the Products were "Chantix" as approved by the FDA when in fact they were not, and that the Products would contain only the active ingredients stated on the label, when in fact they contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

83. As alleged herein, Defendant's actions are deceptive and in clear violation of FDUTPA, entitling Plaintiff and the Florida Subclass to damages and relief under Fla. Stat. §§ 501.201-213.

84. By committing the acts alleged above, Defendant engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA.

85. Defendant's conduct is substantially injurious to consumers. Consumers are purchasing and using Defendant's Products without knowledge that the Products are adulterated with a human carcinogen. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for the Products, which are contaminated with N-nitroso-varenicline, but for Defendant's false labeling, advertising, promotion, and material omissions. Thus, Plaintiff and the Florida Subclass have been "aggrieved" (*i.e.*, lost money) as required for FDUTPA standing, and such an injury is not outweighed by any countervailing benefits to consumers or competition.

86. Indeed, no benefit to consumers or competition results from Defendant's conduct. Because consumers reasonably rely on Defendant's representation of the ingredients contained

on Products' label and injury resulted from ordinary use of the Products, consumers could not have reasonably avoided such injury.

87. Accordingly, Defendant is liable to Plaintiff and the Florida Subclass for damages in amounts to be proven at trial, including attorneys' fees and costs.

COUNT IV
Unjust Enrichment
(On Behalf Of Plaintiff, The Class, And The Florida Subclass)

88. Plaintiff hereby incorporates by reference the allegations contained in the Nature of the Action, Facts Common To All Claims, and Parties sections of this complaint.

89. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Florida Subclass against Defendant.

90. Plaintiff and the Class and the Florida Subclass conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Chantix medications.

91. Defendant voluntarily accepted and retained this benefit.

92. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT V
Fraud
(On Behalf Of Plaintiff, The Class, and The Florida Subclass)

93. Plaintiff hereby incorporates by reference the allegations contained in the Nature of the Action, Facts Common To All Claims, and Parties sections of this complaint.

94. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Florida Subclass against Defendant.

95. As discussed above, Defendant provided Plaintiff, the Class and the Florida

Subclass members with materially false or misleading information about the Chantix manufactured by Defendant. Specifically, Defendant affirmatively represented on the Product's packaging and labeling that the Product was "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

96. Defendant marketed Chantix as safe for human consumption, and further represented that the Chantix medications purchased and used by Plaintiff and the Class and the Florida Subclass would contain only the ingredients stated on the label, and not harmful carcinogens such as N-nitroso-varenicline. As indicated above, however, these representations are false and misleading as Defendant's Chantix medications contained elevated levels of N-nitroso-varenicline which rendered them unfit for use.

97. Defendant also engaged in material omissions by concealing from Plaintiff and Class members and members of the Florida Subclass the presence of the harmful carcinogen N-nitroso-varenicline in the Product.

98. Defendant's material misrepresentations and omissions occurred at the point of sale.

99. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class and Florida Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and Florida Subclass members to purchase defective Chantix.

100. Defendant knew or reasonably should have known that Chantix was contaminated with this harmful impurity, but continued to manufacture it nonetheless. As discussed herein, both the FDA and international regulators have imposed more stringent testing requirements for

nitrosamine contamination, which if followed would have revealed the presence of N-nitroso-varenicline. If Defendant followed cGMPs and industry standards as described herein, and adequately tested the Product, it would have known of the nitrosamine contamination.

101. The fraudulent actions of Defendant caused damage to Plaintiff and Class and Florida Subclass members, who are entitled to damages and other legal and equitable relief as a result.

102. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VI
Negligent Misrepresentation/Omission
(On Behalf Of Plaintiff, The Class, and The Florida Subclass)

103. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

104. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Florida Subclass against Defendant.

105. In representing that the Product was "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline, Defendant negligently provided false information to Plaintiff and Class members and members of the Florida Subclass.

106. Plaintiff and Class members were reasonably foreseeable recipients of the false information promulgated by Defendant because Plaintiff and Class members and members of the Florida Subclass were the intended purchasers of the Products. Defendant's labels were designed to advertise the Product to consumers like Plaintiff and Class members.

107. Plaintiff and Class and Florida Subclass members justifiably relied on the false information promulgated by Defendant because they reasonably believed that the Product was, in fact, "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline. Plaintiff and Class members and members of the Florida Subclass purchased the Product based on Defendant's false representations regarding the Product. Had Plaintiff and Class members known the truth about the Products, they would not have purchased the Products on the same terms.

108. The damages asserted by Plaintiff and Class members and members of the Florida Subclass were proximately caused by the false statements because Plaintiff and Class members and members of the Florida Subclass reviewed the Products' labeling and representations, specifically the claims that the Product was "Chantix" as approved by the FDA and that the Product would contain only the active ingredients stated on the label, and chose to purchase the Products based on those false representations.

109. Plaintiff and Class members and members of the Florida Subclass are entitled to damages and other legal and equitable relief as a result of Defendant's conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

A. For an order certifying the nationwide Class and the Florida Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and the Florida Subclass and Plaintiff's attorneys as Class Counsel;

B. For an order declaring the Defendant's conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the Class, and the Florida Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief; and

G. For an order awarding Plaintiff and the Class and the Florida Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: November 12, 2021

Respectfully submitted,

BURSOR & FISHER, P.A.

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