UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROSLYN HARRIS, on behalf of herself and all others similarly situated, Plaintiff, v. PFIZER INC., Defendant.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

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

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

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 certain lots of 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]

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."[2] The United States Food & Drug Administration ("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."[3]

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 nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."[4] "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."[5] 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

[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] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75961a-eng.php (last visited 8/5/21).
[3] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/5/21).
[4] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last visited 8/5/21).
[5] *Id.*

approved by FDA."[6]

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."[7] Stated another way, medications containing more than 37 ng of N-nitroso-varenicline are 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."[8]

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

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

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
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
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

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
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) Tablets, 0.5/1 mg	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 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."[9] 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 New Jersey Subclass (as defined below), should consult with their health care provider and return the product subject to the recall.[10] In other words, consumers were to stop using the recalled product and return it because it was unsafe for use.

11. Defendant did not disclose the presence of N-nitroso-varenicline at all on the Product's label 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.

12. 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 New Jersey Subclass. Specifically, the presence of nitrosamines in prescription medications has been the subject of FDA scrutiny for over three years, as well as international regulators such as the European Medicines Agency ("EMA").

13. "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'."[11] The FDA similarly began announcing

[9] 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).
[10] *Id.*
[11] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-

nitrosamine-related recalls in mid-2018.[12]

14. 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."[13] 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."[14]

15. For its part, the FDA, in September 2020, published guidance for the industry entitled "Control of N-Nitrosamine Impurities in Human Drugs."[15] "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."[16]

16. 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.

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impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'.

[12] *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).

[13] 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'.

[14] *Id.*

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

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

17. Had Defendant engaged in proper testing of the Product, 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 New Jersey Subclass.

18. 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 New Jersey 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. At minimum, Plaintiff and members of the Class and New Jersey 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.

19. Plaintiff brings this action on behalf of herself, the Class, and the New Jersey 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 the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 *et seq.*, (iv) unjust enrichment, and (v) fraud.

PARTIES

20. Plaintiff Roslyn Harris is a citizen of New Jersey who resides in Jersey City, New Jersey. Plaintiff Harris purchased a Chantix "Starting Month" pack containing one "Starting Week" pack of eleven 0.5 mg tablets and three "Continuing Weeks" packs of forty-two 1 mg tablets. The package she purchased bore the NDC Code 0069-0471-03, which is one of the NDC Codes subject to the recall. More specifically, the package bore the Lot Number ET1600 with an

expiration date of January 2023. As such, Ms. Harris purchased a now recalled lot of the Product. In choosing to purchase her Chantix medication from Defendant, Ms. Harris reviewed the accompanying labels and disclosures, 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. Ms. Harris 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 she would not have purchased Chantix from Defendant on the same terms if she had known that it was not, in fact, properly manufactured and free from defects. Ms. Harris also understood that each purchase involved a direct transaction between herself and Pfizer because her medication came with packaging and other materials prepared by Pfizer, including representations and warranties that her medications were properly manufactured and free from defects. Plaintiff reviewed the Product label, which contained no disclosure of the actual or potential presence of N-nitroso-varenicline. Plaintiff would not (indeed, could not) have purchased Defendant's Product but for Defendant's concealment of the presence of N-nitroso-varenicline in the Product.

21. 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 States of New York and New Jersey. 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 States of New York and New Jersey.

JURISDICTION AND VENUE

22. 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.

23. This Court has personal jurisdiction over Defendant because Defendant is incorporated and maintains its principal place of business in New York, and is therefore subject to general jurisdiction in New York.

24. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant has its principal place of business in this District.

CLASS ALLEGATIONS

25. Plaintiff seeks to represent a class defined as all persons in the United States who purchased Chantix containing N-nitroso-varenicline (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.

26. Plaintiff also seeks to represent a subclass of all Class members who purchased Chantix containing N-nitroso-varenicline in New Jersey (the "New Jersey Subclass").

27. Subject to additional information obtained through further investigation and

discovery, the foregoing definition of the Class and New Jersey Subclass may be expanded or narrowed by amendment or amended complaint.

28. **Numerosity.** The members of the Class and New Jersey Subclass are geographically dispersed throughout the United States and the State of New Jersey and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are tens of thousands of members in the Class and tens of thousands of members in the New Jersey Subclass. Although the precise number of Class members is unknown to Plaintiff, the true number of Class and New Jersey Subclass members is known by Defendant and may be determined through discovery. Class and New Jersey 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.

29. **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 New Jersey Subclass and predominate over any questions affecting only individual Class and New Jersey 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 New Jersey Subclass for unjust enrichment;

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

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

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

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

(i) whether Plaintiff and the Class and New Jersey 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.

30. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New Jersey 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 Class and New Jersey Subclass members by manufacturing, distributing, and selling the defective Chantix. Plaintiff's claims are typical in that she 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 New Jersey Subclass. Further, there are no defenses

available to Defendant that are unique to Plaintiff.

31. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and New Jersey 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 New Jersey Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and New Jersey Subclass.

32. **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 New Jersey 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 New Jersey Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and New Jersey 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.

33. In the alternative, the Class and New Jersey Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and New Jersey Subclass members would create a risk of inconsistent or varying adjudications with respect to individual

Class and New Jersey Subclass members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class and New Jersey 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 New Jersey 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 New Jersey Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New Jersey Subclass as a whole.

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

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

35. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New Jersey Subclass against Defendant.

36. Plaintiff, and each member of the Class and New Jersey Subclass, formed a contract with Defendant at the time Plaintiff and the other Class and New Jersey Subclass members purchased the defective Chantix. The terms of the contract include the promises and affirmations of fact made by Defendant on Chantix's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as N-nitroso-varenicline. 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 New Jersey Subclass and Defendant.

37. Plaintiff relied on the express warranty that her Chantix was safe and would not contain unsafe levels of N-nitroso-varenicline. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and New Jersey Subclass and Defendant.

38. Defendant purports, through its advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities such as N-nitroso-varenicline.

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

40. 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 New Jersey Subclass purchased do not conform to Defendant's affirmations and promises described above.

41. Plaintiff and each of the members of the Class and New Jersey 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.

42. As a result of Defendant's breach of express warranty, Plaintiff and each of the members of the Class and New Jersey 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.

43. On August 11, 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 New Jersey Subclass)

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

45. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New Jersey Subclass against Defendant.

46. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that Chantix (i) would not contain elevated levels of N-nitroso-varenicline and (ii) is generally recognized as safe for human consumption.

47. 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 New Jersey Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

48. Plaintiff and Class and New Jersey Subclass members purchased Chantix in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

49. The Chantix medication purchased by Plaintiff and members of the Class and New Jersey Subclass was not altered by Plaintiff or Class and New Jersey Subclass members.

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

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

52. The Chantix medications that Plaintiff, the Class, and New Jersey 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 New Jersey Subclass members did not receive the goods as warranted.

53. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff and Class and New Jersey 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.

54. On August 11, 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**.

COUNT III
Violation Of New Jersey's Consumer Fraud Act
(On Behalf Of Plaintiff And The New Jersey Subclass)

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

56. Plaintiff brings this claim individually and on behalf of the members of the proposed New Jersey Subclass against Defendant.

57. The New Jersey Consumer Fraud Act ("NJCFA") prohibits "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice… ." N.J.S.A. § 56:8-2.

58. Plaintiff and members of the New Jersey Subclass are consumers who purchased Chantix for personal, family, or household use.

59. Plaintiff and New Jersey Subclass members suffered an injury in fact and lost money or property as a result of Defendant's violations of the NJCFA.

60. In violation of the NJCFA, Defendant employed unconscionable commercial practices, deception, fraud, and/or false pretense by manufacturing and selling Chantix that is

contaminated with N-nitroso-varenicline and presents a safety risk to consumers and users of Chantix. Defendant misrepresented and/or engaged in deceptive conduct by stating to Plaintiff and members of the New Jersey Sublcass that the Chantix they purchased would contain only the active ingredients stated on the label, and not harmful, carcinogenic impurities such as N-nitroso-varenicline.

61. Defendant's deception was material in that it induced Plaintiff and members of the New Jersey Subclass to purchase the Product under false pretenses, namely that the Product was fit for human use and not contaminated. Plaintiff and New Jersey Subclass members reviewed the labels, advertising, and/or marketing of Defendant's Product, reasonably acted in positive response to those representations and were thereby deceived. Plaintiffs would not have purchased Defendant's Product on the same terms but for Defendant's material misrepresentations. Plaintiffs and members of the Class who purchased Defendant's Product were overcharged for these products, which by law were worthless. At minimum, Plaintiff and members of the New Jersey Subclass paid a considerable price premium for the Product.

62. Additionally, Defendant knowingly failed to disclose and concealed the contamination of the defective Chantix with the intent that Plaintiff and members of the New Jersey Subclass rely on said concealment, in violation of the NJCFA. Defendant's fraudulent omissions were material to Plaintiff and members of the New Jersey Subclass. When Plaintiff and members of the New Jersey Subclass purchased Chantix, they reasonably relied on the expectation that Chantix (i) would not contain dangerously high levels of N-nitroso-varenicline, and (ii) was generally recognized as safe for human consumption. Had Defendant disclosed that Chantix contained dangerously high levels of N-nitroso-varenicline and was unsafe for human consumption, Plaintiff and members of the New Jersey Subclass would not have purchased

Chantix or would they have paid less for it.

63. Defendant knowingly concealed, suppressed and/or omitted the presence of the N-nitroso-varenicline contamination and safety risk in Chantix at the time of sale and at all relevant times thereafter.

64. Defendant owed a duty to disclose the N-nitroso-varenicline contamination and its corresponding safety risk to Plaintiff and members of the New Jersey Subclass because Defendant possessed superior and exclusive knowledge regarding the N-nitroso-varenicline contamination and the risks associated with the consumption of N-nitroso-varenicline.

65. Defendant knew, or should have known, that the N-nitroso-varenicline contamination in Chantix made Chantix unsafe for human consumption. 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.

66. As a direct and proximate result of Defendant's wrongful conduct in violation of the NJCFA, Plaintiff and members of the New Jersey Subclass have suffered and continue to suffer ascertainable loss in the form of monies paid for defective, worthless Chantix medications.

67. On behalf of herself and other members of the New Jersey Subclass, Plaintiff seeks to recover actual damages, treble damages, costs, attorneys' fees, and other damages to be determined at trial. *See* N.J.S.A. § 56:8-19.

68. On August 11, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter advising Defendant of its violation of the NJCFA and demanding full restitution. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit A**.

69. In accordance with N.J.S.A. § 56:8-20, a copy of this complaint will be sent to the

Attorney General within ten (10) days of filing the same.

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

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

71. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New Jersey Subclass against Defendant.

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

73. Defendant voluntarily accepted and retained this benefit.

74. 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 New Jersey Subclass)

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

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

77. As discussed above, Defendant provided Plaintiff and Class and New Jersey Subclass members with materially false or misleading information about the Chantix manufactured by Defendant. Specifically, Defendant marketed Chantix as safe for human consumption, and further represented that the Chantix medications purchased and used by

Plaintiff and the Class and New Jersey 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.

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

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

80. 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.

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

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

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 New Jersey Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and New Jersey 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 New Jersey 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 New Jersey 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), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: August 12, 2021

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Andrew J. Obergfell*
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