UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

TAMMY LAMOTTE, individually and on behalf of all others similarly situated, Plaintiff, v. PFIZER, INC., Defendant.	Case No.: **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Tammy LaMotte ("Plaintiff"), individually and on behalf of all other similarly situated, files this Class Action Complaint against Defendant Pfizer, Inc. and alleges as follows:

INTRODUCTION

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

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

3. Pfizer obtained approval from the United States Food and Drug Administration ("FDA") to sell Chantix as a first of its kind treatment in May 2006.

4. Chantix quickly became one of Pfizer's fastest growing products. Major media spending on Chantix totaled approximately $55 million in 2007 (the year after its approval). In the

year Chantix launched, Pfizer spent approximately $4.3 million in medical journal advertisements alone.

5. The market rapidly embraced Chantix and continues to do so to this day. For example, from its launch through 2015, the number of Chantix prescriptions for Medicaid beneficiaries increased 13,277%.[1]

6. The price for Chantix has also steadily climbed since its launch. Price estimates at launch were approximately $113.98 climbing to $254.50 in 2015. By 2018, the price had more than doubled to $485 for a 30-day supply, bringing in $997 million in sales that year.[2]

7. The market for smoking-cessation treatments remains strong with sales of Chantix at approximately $919 million for last year alone. Chantix remains one of the few, and most prevalent, smoking-cessation drug treatments, and one of Pfizer's top drug products. Pfizer's extended patent protection on Chantix ensures exclusivity through at least August 2022.

8. At all pertinent times for purposes of this action, Defendant Pfizer represented and warranted to consumers that its VCDs (that is, what it purports to be Chantix) were therapeutically equivalent to, and otherwise the same as, the actual FDA-approved brand name drug Chantix. Specifically, Defendant Pfizer represented and warranted that the VCDs were fit for their ordinary uses, met the specifications of Defendant's FDA-approved labeling materials, and that it manufactured and distributed the VCDs in accordance with all applicable laws and regulations.

---

[1] Xiaomeng Yue, et al., *Trends in Utilization, Spending, and Prices of Smoking-Cessation Medications in Medicaid Programs: 25 Years Empirical Data Analysis, 1991–2015*, AM. HEALTH DRUG BENEFITS, at 275-85 (Sept. 2018), www.ncbi.nlm.nih.gov/pmc/articles/PMC6207314/.

[2] Arlene Weintraub, *Price of Pfizer's smoking-cessation drug Chantix doubles in just 5 years: report*, FIERCE PHARMA (June 26, 2018), https://www.fiercepharma.com/pfizer-hikes-price-smoking-cessation-drug-chantix-106-5-years-report.

9. Defendant willfully disregarded these standards, and knowingly and fraudulently manufactured, sold, labeled, marketed, or distributed adulterated or misbranded VCDs for purchase in the United States by consumers.

10. Defendant's VCDs were adulterated, misbranded, or both (and thereby rendered worthless), through contamination with a probable human carcinogen known as N-nitroso-varenicline. Additionally, Defendant was on notice of other potential contamination from nitrosamines such as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA").

11. Defendant's VCDs also were adulterated, misbranded, or both by virtue of Defendant's failure to adhere to current Good Manufacturing Practices ("cGMPs") and related practices and regulations in the manufacture and distribution of Chantix. When a drug is manufactured in a non-cGMP compliant manner, that means the manufacturer cannot assure that the drugs meet the appropriate quality, purity, identity or strength. Accordingly, such drugs are adulterated or misbranded or both.

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

13. According to FDA testing, Defendant's VCDs contained nitrosamine levels many times higher than the FDA's updated interim limits for nitrosamine impurities.

14. On July 2, 2021, and July 19, 2021, Pfizer began recalling its VCDs "because [the product] may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's

acceptable intake limit."[3] The FDA has yet to release full testing results for other nitrosamine impurities. On September 16, 2021, Pfizer extended its recall to all Chantix.[4]

15. On information and belief, N-nitroso-varenicline contamination of Defendant's VCDs dates back many years, at which point Defendant had actual or, at a minimum, constructive notice of the contamination.

16. Ironically, the Defendant's wrongful acts caused those people trying to use smoking products *less* to take a pill containing carcinogens similar to those contained in cigarettes.

17. Plaintiff paid for VCDs that were illegally and willfully introduced into the market by Defendant, which caused them and hundreds of other purchasers paying for or reimbursing prescriptions for these VCDs to sustain substantial economic damages. Defendant's VCDs were not fit for their ordinary use and Defendant has been unjustly enriched through the sale of these knowingly adulterated and misbranded drugs. Defendant's conduct, as detailed in this Complaint, also constitutes actionable common law fraud, consumer fraud, and violates state and federal law.

PARTIES

18. Plaintiff Tammy LaMotte is a citizen and resident of Minnesota. During the class period, Plaintiff paid money for one or more of Defendant's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Defendant. Defendant expressly and impliedly warranted and represented to Plaintiff (either directly or indirectly by adopting

[3] *FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix.

[4] *Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n.

warranties or representations that were passed along further downstream) that the VCDs were 'the same' as the branded Chantix. But in fact, Plaintiff bought a product that was not the same as Chantix. Had Plaintiff known the product was not the same, and rather that it was contaminated, adulterated, and/or misbranded, Plaintiff would not have paid for these Defendant's VCDs. Likewise, had Defendant's deception about the impurities within their products been made known earlier, Plaintiff would not have paid for Defendant's VCDs.

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

20. Defendant has manufactured and distributed Chantix throughout the United States, for which consumers made co-payments, and purchasers either paid or reimbursed. On information and belief, the Plaintiff's payments include those payments for Defendant's VCDs, which were also manufactured, distributed, and sold during that same period.

JURISDICTION AND VENUE

21. This Court has original jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendant, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

22. This Court has personal jurisdiction over Defendant under 28 U.S.C. § 1407, and because Defendant has sufficient minimum contacts in the State of Minnesota, and because Defendant has otherwise intentionally availed itself of the markets within the State of Minnesota

through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

23. Venue is proper in this District because the claims alleged in this action accrued in this District and Defendant regularly transacts its affairs in this District.

24. Defendant is subject to the personal jurisdiction of this Court because the Defendant conducts business within the State of Minnesota, maintains and carries out continuous and systematic contacts within the State of Minnesota and this judicial District, regularly transacts business within the State of Minnesota and this judicial District, and regularly avails themselves of the benefits of their presence in the State of Minnesota and this judicial District.

FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

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

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

27. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug

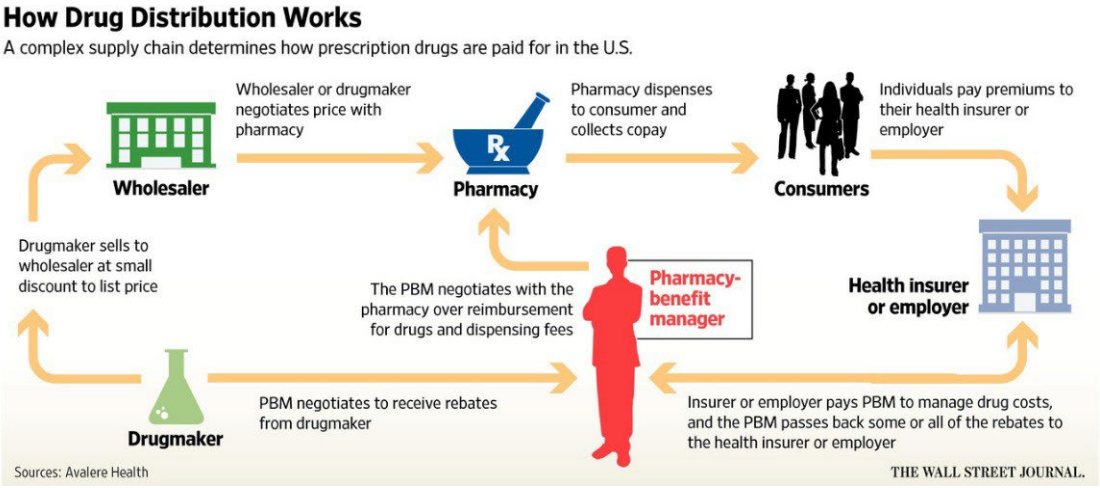
costs. In some instances, PBMs are responsible for placing drugs, such as Chantix, on the TPPs' formularies.

28. In managing formularies, TPPs and their PBMs reasonably expect that branded prescription drugs reimbursable on their formularies are the same as the respective FDA-approved branded drugs. The TPPs permitted Chantix, and VCDs, to be included on their formularies based on the Defendant's misrepresentations that their VCDs were bioequivalent and the same as FDA-approved branded Chantix, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

29. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that plan beneficiaries will purchase the drug instead of a more expensive alternative. As a result, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

30. The following chart, published by the Wall Street Journal,[5] broadly illustrates the pharmaceutical supply chain:

[5] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.



31. When patients present their prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBM for reimbursement. PBMs then accumulate those individual reimbursements and present them to TPPs for payment.

B. Prescription Drug Product Identification and Tracing

32. For each approved product (whether brand or generic) the FDA issues a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler), the strength, dosage form, and formulation of the drug, and the package size and type.[6]

33. The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and, therefore, every transaction is accompanied by and labeled with the NDC.

[6] *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (last updated Dec. 18, 2020); *National Drug Codes Explained*, DRUGS.COM, https://www.drugs.com/ndc.html (last updated Oct. 1, 2020).

This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase.

34. Retail prescription labels display the NDC of the dispensed product, which is part of the electronic dispensing record. In many cases, the "lot" number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate whether the recall applies to the particular pills in the bottle.[7]

35. The lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events ("AE") (that is, patient-specific side effects or complications associated with the use of a prescription drug). This is an important part of drug safety monitoring in the United States and has led to recalls or relabeling of numerous drugs. Pharmacists make such reports using the FDA's MedWatch system using Form 3500.[8]

C. The Drug Supply Chain Security Act Requires Tracing of Product

36. The Drug Supply Chain Security Act ("DSCSA")[9] was enacted in 2013, and requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to "[e]xchange information about a drug and who handled it each time it is sold in the U.S. market."

---

[7] A lot number is an identification number tied to a particular lot of pills from a single manufacturer.

[8] *Instructions for Completing Form FDA 3500*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem (last updated Mar. 27, 2018).

[9] 21 U.S.C. § 360eee.

37. The DSCSA was implemented as one part of the Drug Quality and Security Act ("DQSA"), aimed at addressing vulnerabilities in the drug supply chain, and facilitating tracing of certain prescription drugs in finished dosage form through the supply chain.[10]

38. While the DSCSA was enacted in 2013, participants in the pharmaceutical supply chain maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

39. The DSCSA generally requires participants in the drug supply manufacturing chain (starting from the manufacturer, through the wholesaler, to the retail pharmacy) to retain, for every pharmaceutical drug transaction, the following information about that transaction: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.

40. The DSCSA requires that this data be kept in a manner to allow these authorized participants to respond within 48 hours to requests from appropriate federal or state officials—in the event of a recall or for the purpose of investigating suspect product or an illegitimate product—for the transaction history of the pharmaceutical product.[11]

41. The supply chain for distribution of prescription drugs in the U.S. is highly concentrated. This means that data obtained from a relatively small number of market participants

[10] Daniel R. Levinson, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, U.S. DEPT. HEALTH & HUM. SERVS., at 2 (Mar. 2018), https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf.

[11] *Title II of the Drug Quality and Security Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act (last updated Dec. 16, 2014).

can provide detailed information about the large majority of Chantix and VCD sales, transfers, and prescription fills.

42. The entire process of reimbursing pharmacies and consumers for end-purchases depends on the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of that drug. This system has necessarily resulted in very high levels of data standardization in this industry. Although pharmacies maintain their own "pharmacy log" data reflecting dispensing, sales and return activity, the key elements are fundamentally similar.

43. Because pharmacies require similar information for their own tracking and inventory systems, and wholesalers sell to multiple pharmacy chains, the key elements are fundamentally the same.

44. Further, all pharmacies must use the basic data fields, definitions and formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs, the use of which was made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).[12] Because of these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

45. As a general matter, for Medicare and Medicaid compliance, pharmacies typically keep prescription records for ten years.[13]

[12] 45 C.F.R. § 162.1802.
[13] 42 C.F.R. § 423.505(d).

46. A key part of the DSCSA is the requirement that "product tracing information should be exchanged" for each transaction and retained for at least six years,[14] including the following transaction information ("TI"):[15]

a. Proprietary or established name or names of the product

b. Strength and dosage form of the product

c. National Drug Code (NDC) number of the product

d. Container size

e. Number of containers

f. Lot number of the product

g. Date of the transaction

h. Date of the shipment, if more than 24 hours after the date of the transaction

i. Business name and address of the person from whom and to whom ownership is being transferred

47. For example, the DSCSA also mandates use of a composite "product identifier" that Defendant was required to begin applying to prescription drug packages and cases.[16]

[14] *Protect Your Patients*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/113114/download (last visited Sept. 13, 2022); 21 U.S.C. §§ 360eee-1(b)(1)(A)(ii), (c)(bb)(BB)(II)(v)(I), and (d)(1)(A)(iii).

[15] *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, U.S. FOOD & DRUG ADMIN., at 8-9 (Sept. 2015), https://www.fda.gov/media/93779/download.

[16] *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifier-requirements-under-drug-supply-chain-security-act-compliance-policy-guidance.

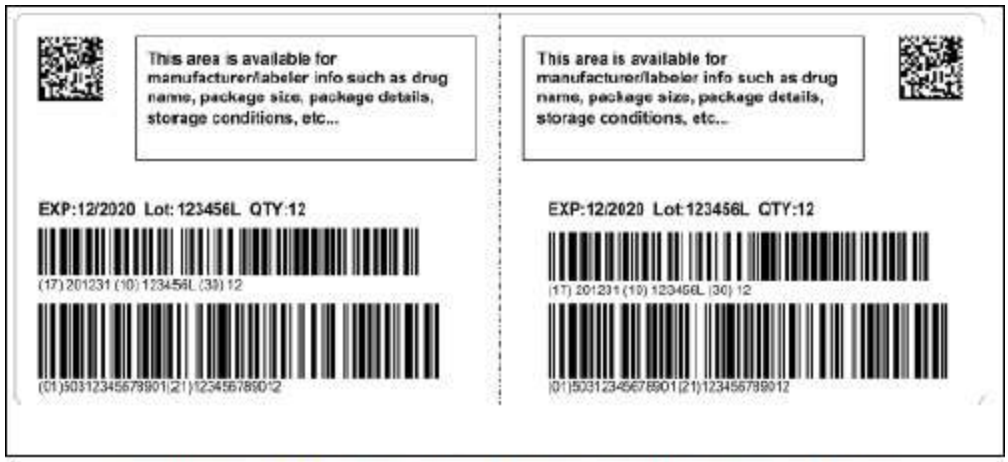
48. The term "product identifier" "means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . the standardized numerical identifier, lot number, and expiration date of the product."[17]

49. Publicly available Guidelines published by AmerisourceBergen require that "each Prescription Drug lowest saleable unit" it receives from a manufacturer must have the clearly indicated product identifier on the unit label.[18] In addition, case labels, and partial case labels must list the lot number and expiration date.[19] The Guidelines illustrate these requirements as reproduced below.

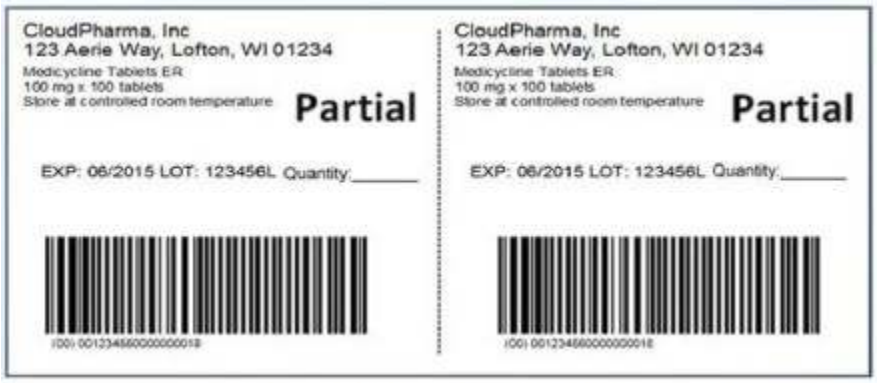
AmerisourceBergen Manufacturer Labeling Requirements[20]

DSCSA RX Serialized Unit Label

[17] 21 U.S.C. § 360eee(14).
[18] *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, AMERISOURCEBERGEN, at 14 (Jan. 2019), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf.
[19] *Id.* at 15-16.
[20] *Id.* at 14-16.



Example of Rx Serialized Homogenous Case Label



Example Partial Case Labeled with SSCC

D. The Drug Approval Framework

50. Brand drug companies submitting a New Drug Application ("NDA") must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

51. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing in the United States.

52. An NDA is supposed to provide enough information to permit the FDA to decide (i) whether the drug is safe and effective for its proposed uses and whether the benefits of the drug outweigh the risks; (ii) whether the drug's proposed labeling is appropriate and what it should contain; and (iii) whether the methods used in manufacturing the drug and the controls used to

maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[21]

53. As the FDA puts it, the submitted NDA documentation "is supposed to tell the drug's whole story," including "what the ingredients of the drug are."[22]

54. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

55. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or, in other words, when the drug is not the same as its corresponding brand-name drug, the manufacturer may no longer rely on the drug's labeling.

E. Approval of the NDA for Chantix

56. Chantix is known generically as varenicline (as the tartrate salt) and is a partial nicotine agonist. It is a first-line therapy in the treatment to aid in smoking cessation. At a very high level, the drug works by interfering with the nicotine receptors in the human brain. This has the effect of lessening the pleasure a person gets from smoking or lessening the craving to smoke.

57. The FDA approved Chantix in May 2006. Pfizer later succeeded in extending its patent exclusivity for Chantix through August 2022, meaning Chantix has not faced generic drug competition since its launch.

58. Chantix's FDA-approved labeling specifies the active and inactive ingredients. Neither N-nitroso-varenicline nor NDMA nor any other nitrosamine is listed among the FDA-approved ingredients nor are any of these contaminants FDA-approved ingredients of Chantix.

---

[21] *See, e.g.*, *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last updated Jan. 21, 2022).

[22] *Id.*

F. Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices

59. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

60. Moreover, 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

61. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

62. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

63. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

64. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

65. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

66. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

G. Adulterated or Misbranded Drugs Are Illegal to Sell

67. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See*

21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

68. Among the ways a drug may be adulterated or misbranded are:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health";[23]

b. "if . . . 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 . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess";[24]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium";[25] or

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[26]

69. A drug is misbranded:

a. "If its labeling is false or misleading in any particular";[27]

[23] 21 U.S.C. § 351(a)(2)(A).
[24] 21 U.S.C. § 351(a)(2)(B).
[25] 21 U.S.C. § 351(b).
[26] 21 U.S.C. § 351(d).
[27] 21 U.S.C. § 352(a)(1).

b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use";[28]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient";[29]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users";[30]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein";[31]

f. "if it is an imitation of another drug";[32]

g. "if it is offered for sale under the name of another drug;"[33]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof";[34]

i. If the drug is advertised incorrectly in any manner;[35] or

[28] 21 U.S.C. § 352(c).
[29] 21 U.S.C. § 352(e)(1)(A)(ii).
[30] 21 U.S.C. § 352(f).
[31] 21 U.S.C. § 352(g).
[32] 21 U.S.C. § 352(i)(2).
[33] 21 U.S.C. § 352(i)(3).
[34] 21 U.S.C. § 352(j).
[35] 21 U.S.C. § 352(n).

j. If the drug's "packaging or labeling is in violation of an applicable regulation."[36]

70. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[37]

71. The introduction into commerce of any adulterated or misbranded drug is also prohibited.[38]

72. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[39]

73. Defendant's contaminated, unapproved VCDs were adulterated or misbranded, or both, for the reasons demonstrated above.

74. Plaintiff references federal law in this Complaint, not in any attempt to enforce it, but to demonstrate that its state-law tort claims do not impose any additional obligations on Defendant, beyond what is already required of it under federal law.

II. The Drugs Purchased by Plaintiff Were Not Chantix, But Adulterated and Misbranded Varenicline-Containing Drugs, Not of the Same Quality

75. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated

[36] 21 U.S.C. § 352(p).
[37] 21 U.S.C. § 331(g).
[38] 21 U.S.C. § 331(a).
[39] 21 U.S.C. § 331(c).

> by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[40]

76. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[41]

77. Accordingly, the FDA requires the submission of an NDA by manufacturers whenever a new active ingredient is added to a drug, as the drug has become a new and differing drug from those previously approved by the FDA. Absent such an application, followed by a review and approval by the FDA, the new drug remains a distinct, unapproved product.[42]

78. This new and unapproved drug with additional active ingredients (such as nitrosamines) cannot have the same label as the brand-name drug, as the two products are no longer the same.

79. At the very least and alternatively, drugs with differing and dangerous ingredients than brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[43]

---

[40] *Human Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/regulated-products/human-drugs#drug (last updated Mar. 5, 2021).
[41] 21 C.F.R. § 210.3(b)(7).
[42] *See* 21 C.F.R. § 310.3(h).
[43] *See generally Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA*, U.S. DEP'T JUST. (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

80. Here, N-nitroso-varenicline and other nitrosamines resulted from the deficient manufacturing process of the VCDs, rendering the VCDs different than the FDA-approved version of Chantix. Importantly, N-nitroso-varenicline and other nitrosamines can cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, N-nitroso-varenicline and other nitrosamines are, by definition, an active ingredient in a drug.

81. Because the VCDs purchased by Plaintiff, and ultimately ingested by their beneficiaries, were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

82. The presence of additional active ingredients (N-nitroso-varenicline and other nitrosamines) and potentially other deviations from Defendant's NDA rendered Defendant's VCDs of a lesser quality than FDA-approved Chantix.

83. A contaminated and adulterated VCD is not a substitute for FDA-approved Chantix and has no value to a purchaser of Chantix.

84. Plaintiff and Class Members reimbursed purchases of FDA-approved Chantix, but that is not what their members received.

85. Plainly, Defendant did not deliver the product that Plaintiff and Class Members paid for.

III. Defendant Made False Statements in the Labeling

86. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[44] and conform to requirements governing the appearance of the label.[45]

[44] 21 C.F.R. § 201.5.
[45] 21 C.F.R. § 801.15.

87. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[46] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

88. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[47]

89. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[48]

90. Because Defendant did not disclose that its product contained N-nitroso-varenicline or other nitrosamines as an ingredient, the subject drugs were misbranded.

91. In addition, by referring to its drugs as "Chantix," Defendant was making false statements.

92. It is unlawful to introduce a misbranded drug into interstate commerce.[49] Thus, the Chantix products ingested by consumers (and paid for or reimbursed by TPPs) were unlawfully distributed and sold.

IV. Defendant Represented VCDs Were Manufactured in Compliance with Current Good Manufacturing Practices

93. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract

[46] *See id.*
[47] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[48] 21 C.F.R. §§ 201.6; 201.10.
[49] 21 U.S.C. § 331(a).

out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

94. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

95. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

96. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

97. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

98. Defendant's VCDs did not conform with the NDA specifications, which demonstrates inadequate production, process, and quality oversight by Defendant.

99. Defendant's failure to conform to cGMPs resulted in the production, and ultimate sale and reimbursement, of a product that was so contaminated and adulterated with high—not merely trace—levels of N-nitroso-varenicline that it could not be considered Chantix, yet Defendant still falsely labeled its products as FDA-approved Chantix.

V. Defendant's Actions Resulted in Contaminated, Adulterated and Misbranded VCDs

100. On October 26, 2020, Health Canada, the FDA analogue for Canada, sent a letter to Apotex, Inc., concerning risk of the presence of nitrosamine impurities in drugs.

101. Apotex distributed a varenicline product in Canada.

102. Defendant also received notice from Health Canada about its own Chantix product sold in Canada.

103. 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."

104. Health Canada continued: "After a preliminary internal review conducted by Health Canada, it was concluded that there is risk for formation of these new nitrosamines impurities for all MAHs of varenicline drug products in Canada. Additional risks for other nitrosamines (e.g. NOMA, N-nitrosodiethylamine (NOEA)) might exist if nitrocellulose is being used as a component of the blister packaging for varenicline products."

105. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.[50]

[50] *Toxicological Profile for N-Nitrosodimethylamine*, U.S. ENVIRONMENTAL PROT. AGENCY (Jan. 2022), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

106. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[51]

107. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

108. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[52]

109. The U.S. Department of Health and Human Services ("DHHS") similarly states that NDMA is reasonably anticipated to be a human carcinogen.[53] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[54]

110. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[55]

111. WHO and IARC classify NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

---

[51] *Technical Fact Sheet (NDMA)*, U.S. ENVIRONMENTAL PROT. AGENCY (Nov. 2017), https://www.epa.gov/sites/default/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*

112. Anecdotally, NDMA has also been used in intentional poisonings.[56]

113. Other nitrosamines with similar or even more severe carcinogenic risk profiles include N- nitrosodiethylamine ("NDEA"), as well as N-nitroso-varenicline.

114. Nitrosamines are considered genotoxic compounds, as it contains nitroso groups, which are gene-mutating groups.[57]

115. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005, or earlier.[58]

116. Defendant took no action in the United States for many months with respect to nitrosamine issues and Chantix.

117. In late June 2021, Defendant recalled certain lots of VCDs because of the presence of N-nitroso-varenicline and/or other nitrosamines.

118. A couple of weeks later, on July 19, 2021, Defendant announced a wider recall of additional VCDs due to N-nitroso-varenicline or other nitrosamine contamination.

119. The recalls were due to the presence of N-nitroso-varenicline above established acceptable daily intake levels. The precise levels were not disclosed.

---

[56] *See* Chase Purde, *A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

[57] Ketan Agravat, *Nitroso Impurities In Valsartan: How Did We Miss Them?*, PHARM. ONLINE (Oct. 30, 2018), https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

[58] Lutz Muller et al., *A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity*, REGUL. TOXICOLOGY & PHARMACOLOGY (Dec. 26, 2005), https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%3Dihub.

120. The presence of N-nitroso-varenicline above established acceptable daily intake levels caused the VCDs sold by Defendant to no longer be FDA-approved Chantix, but rather a different product that Plaintiff and Class Members did not bargain for.

121. On September 16, 2021, Defendant expanded its recall to include all lots of VCDs "due to the presence of a nitrosamine[.]"[59]

VI. Defendant Had Actual or Constructive Notice of Nitrosamine Contamination of Its Adulterated, Misbranded, or Unapproved VCDs

122. Neither N-nitroso-varenicline nor other nitrosamines are FDA-approved ingredients of Chantix. Moreover, none of Defendant's VCDs identify N-nitroso-varenicline or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogens and are not approved to be included in the active pharmaceutical ingredient ("API") or finished-dose product. Their inclusion in Defendant's VCDs renders the VCDs adulterated and misbranded compared to Defendant's warranties and representations.

123. If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled its quality assurance obligations, Defendant would have identified the presence of these nitrosamine contaminants almost immediately.

124. This is certainly true since at least 2018, when many manufacturers of valsartan, losartan, and irbesartan instituted massive waves of recalls due to nitrosamine contamination. That knowledge alone should have informed Defendant to check its VCDs for nitrosamines then, if not sooner. Indeed, industry and regulatory standards prior to and after the recalls of these other

[59] *See Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n (last updated Sept. 17, 2021).

products were in place to detect, characterize, analyze, and quantify nitrosamines well before Defendant either initiated its recalls of VCDs in the United States, or Health Canada's informing Apotex and Defendant about the nitrosamines detected in Defendant's VCDs.

125. Prior to initiating recalls in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

126. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods. 21 C.F.R. § 211.110(c).

127. And, as shown above, Defendant's quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

128. Also, as shown above, the quality control units for all of Defendant's manufacturing were grossly deficient in fulfilling their responsibilities.

129. If these sampling-related and quality-control-related cGMPs were properly observed by Defendant, the nitrosamine contamination in Defendant's VCDs would have been discovered almost immediately, and Defendant was thus (at minimum) on constructive notice from the moment its VCDs became contaminated.

130. However, there are indications that Defendant had actual knowledge of its VCDs' contamination, and certainly not later than Health Canada's communication to Apotex in 2020.

131. And yet, Defendant knowingly, recklessly, or negligently introduced adulterated or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendant failed to recall its VCDs because they feared permanently ceding market share to competitors.

VII. Defendant's Warranties and Fraudulent and Deceptive Statements to Purchasers Regarding Its VCDs

132. Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to purchasers about its adulterated or misbranded VCDs.

133. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" known as the Orange Book.[60] The Orange Book is a public document; Defendant sought and received the inclusion of its VCD products in the Orange Book upon approval of its NDAs.

134. Defendant's VCDs are accompanied by an FDA-approved label. By presenting purchasers with an FDA-approved VCD label, Defendant made representations and express or implied warranties of the "sameness" of its product to the Orange Book listed Chantix, and that its products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels or were not adulterated or misbranded or misbranded.

135. The VCDs produced and sold by Defendant were not FDA-approved Chantix.

136. By introducing its VCDs into the United States marketed as "Chantix," Defendant represented and warranted to purchasers that its VCDs are in fact the same as Chantix. Much of the drug supply chain, including the most critical components of that supply chain (for example, patients and purchasers) rely on these representations and warranties.

---

[60] *Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last updated Mar. 11, 2022).

137. In addition, Defendant affirmatively misrepresented and warranted to purchasers through its websites, brochures, and other marketing or informational materials that its VCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

138. The presence of nitrosamines in Defendant's VCDs: (1) renders Defendant's VCDs equivalent (that is, not the same) to listed Chantix, thus breaching Defendant's express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendant's VCDs worthless, thus breaching Defendant's express warranties of sameness; and (3) results in Defendant's VCDs containing an ingredient that is not also contained in the FDA-approved label, also breaching Defendant's express warranty of sameness (and express warranty that the products contained the ingredients listed on Defendant's FDA-approved label). Defendant willfully, recklessly, or negligently failed to ensure its VCDs' labels and other advertising or marketing statements accurately conveyed information about its products.

139. The presence of nitrosamines in Defendant's VCDs and serial and willful failures to comply with cGMPs and other shortcomings in Defendant's drug manufacturing processes have resulted in Defendant's VCDs being adulterated or misbranded.

140. At all relevant times, Defendant also impliedly warranted that its VCDs were merchantable and fit for their ordinary purposes.

141. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, nitrosamines including NDMA are not FDA-approved ingredients in VCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendant's VCDs means that Defendant has violated implied warranties to Plaintiff and Class Members. The presence of NDMA and other nitrosamines in Defendant's VCDs makes Defendant's VCDs non-

merchantable and not fit for its ordinary purposes, breaching Defendant's implied warranty of merchantability and/or fitness for ordinary purposes.

142. For these and other reasons, Defendant's VCDs are, therefore, adulterated, misbranded, or unapproved, and it was illegal for Defendant to have introduced or sold such VCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

143. Adulterated, misbranded, or unapproved VCDs contaminated with cancer- causing compounds, or manufactured in a non-cGMP compliant manner, are essentially worthless. No reasonable purchaser (including Plaintiff) would purchase (or reimburse) these nitrosamine-laden VCDs. Nor could they. As an adulterated, misbranded, or unapproved VCDs cannot be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, or unapproved VCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved VCDs do not possess the same safety and efficacy profiles as their branded equivalents. As such, the VCDs were not what they were supposed to be.

144. Because of the seriousness of the impurity—unsafe levels of a carcinogen—all or virtually all purchasers immediately stopped paying for the tainted drug products after receiving notice of the recall. Purchasers paid for reimbursed payments for a safe alternative. VCDs had no use or value and were thus discarded.

VIII. Fraudulent Concealment and Tolling

145. Plaintiff's and Class Members' causes of action accrued on the date the FDA announced the recall of Defendant's VCDs.

146. Alternatively, any statute of limitation or prescriptive period is equitably tolled on because of fraudulent concealment. Defendant affirmatively concealed from Plaintiff and other Class Members its unlawful conduct. Defendant affirmatively strove to avoid disclosing their knowledge of its cGMP violations with related to their VCDs, and of the fact that their VCDs were

adulterated and/or misbranded and contaminated with nitrosamines and were not the same as the FDA-approved Chantix.

147. For instance, Defendant did not reveal to the public that its VCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to FDA-approved Chantix.

148. To the contrary, Defendant continued to represent and warrant that its VCDs were actually "Chantix" when they were not the same as Chantix.

149. Because of this, Plaintiff and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendant's false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for Defendant's VCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

150. As a result of Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

CLASS ACTION ALLEGATIONS

151. Plaintiff seeks to represent a Nationwide Class under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

> **National Class:** All entities in the United States and its territories and possessions who paid any amount of money for a varenicline-

containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

Minnesota Subclass: All entities in Minnesota and its territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

152. Plaintiff alleges additional sub-classes for all purchasers in each State, territory, or possession—or combinations of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment—that paid any amount of money out of pocket for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant (collectively, the "Subclasses").

153. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the "Class."

154. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendant and affiliated entities, and their employees, officers, directors, and agents; (c) Defendant's legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

155. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

156. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

157. **Numerosity:** While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially hundreds of entities nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

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

a. Whether Defendant made express or implied warranties of "sameness" to Plaintiff and Class Members regarding its VCDs;

b. Whether Defendant's VCDs were, in fact, the same as Chantix consistent with such express or implied warranties;

c. Whether Defendant's VCDs were contaminated with nitrosamines or similar contaminants;

d. Whether Defendant's VCDs containing nitrosamines or similar contaminants were adulterated or misbranded;

e. Whether Defendant violated cGMPs regarding the manufacture of its VCDs;

f. Whether Defendant falsely claimed that its VCDs were the same as Chantix and thus therapeutically interchangeable;

g. Whether Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

h. Whether Plaintiff and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiff's and Class Members' causes of action accrued; and

k. Whether Defendant fraudulently concealed Plaintiff's and Class Members' causes of action.

159. **Typicality:** Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

160. **Adequacy of Representation:** Plaintiff is committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

161. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

162. **Superiority:** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized

rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiff's counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

CAUSES OF ACTION

COUNT I
BREACH OF EXPRESS WARRANTIES

163. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

164. Plaintiff, and each member of the Class, formed a contract with Defendant at the time Plaintiff and the other Class Members purchased the VCDs. The terms of the contract include the promises and affirmations of fact made by Defendant on the VCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to and the same as the name-brand medication Chantix, and would be of same "quality" and have the same safety and efficacy profile as branded Chantix. 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 Defendant.

165. Defendant expressly warranted that its VCDs were fit for its ordinary use as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as branded Chantix. In other words, Defendant expressly warranted that its products were the same as branded Chantix.

166. Defendant sold VCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

167. Defendant's VCDs did not conform to Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

168. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2- 313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

169. At the time that Defendant marketed and sold its VCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as

branded Chantix, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other Class Members including but not limited to express representations made in referring to its VCDs.

170. Defendant breached its express warranties with respect to its VCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

171. Plaintiff and each member of the Class would not have purchased the VCDs had they known these drugs were not the same as branded Chantix, did not contain the same ingredients, did not have the same safety and efficacy profile of branded Chantix, and contained NDMA.

172. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the VCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

COUNT II
BREACH OF IMPLIED WARRANTIES

173. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

174. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code.

§ 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

175. Defendant was a merchant within the meaning of the above statutes.

176. Defendant's VCDs constituted "goods" or the equivalent within the meaning of the above statutes.

177. Defendant was obligated to provide Plaintiff and other Class Members reasonably fit VCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendant are involved such that the product was of fit and merchantable quality.

178. Defendant knew or should have known that its VCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to branded Chantix (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that its VCDs were of merchantable quality and fit for that purpose.

179. Defendant breached its implied warranty because Defendant's VCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

180. Plaintiff and other Class Members purchased the VCDs in reliance on Defendant's skill and judgment and the implied warranties of fitness for the purpose.

181. The VCDs were not altered by Plaintiff or Class members.

182. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendant's VCDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

COUNT III
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301 *et seq.*

183. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

184. Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

185. Plaintiff and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

186. Defendant expressly or impliedly warranted its VCDs as alleged in the First and Second Causes of Action.

187. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to

this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

188. Defendant has not acted on the opportunity to cure its failure with respected to its warranted VCDs.

189. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiff is entitled to receive an award of attorneys' fees and expenses and pray for the same.

COUNT IV
FRAUD

190. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

191. Defendant affirmatively misrepresented material facts including, among other things, that its VCDs were therapeutically equivalent and the same as its branded Chantix or complied with cGMPs or were not adulterated or misbranded.

192. Defendant omitted material facts including, among other things, that its VCDs were not therapeutically equivalent or the same as branded Chantix and did not comply with cGMPs or were adulterated, misbranded, or unapproved.

193. Defendant's actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendant's VCDs—products which Defendant knew or should have known were not therapeutically equivalent to or the same as branded Chantix or did not comply with cGMPs or were adulterated or misbranded. Plaintiff and other Class Members would not have purchased Defendant's VCDs had they known the truth. Indeed, Plaintiff and other Class Members could not have paid for Defendant's VCDs had they known the truth because Defendant's VCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiff and Class Members based on Defendant's fraudulent misrepresentations and omissions.

194. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

195. Defendant knowingly, or at least recklessly, represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

196. Defendant knew, or reasonably should have known, that its misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

197. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendant's VCDs.

198. Defendant's misrepresentations and omissions were material.

199. Defendant actively concealed its misrepresentations and omissions from the Class, government regulators, and the public.

200. To the extent applicable, Defendant intended its misrepresentations and omissions to induce Plaintiff and other Class Members to pay for Defendant's VCDs.

201. But for these misrepresentations and omissions, Plaintiff and other Class Members would not have paid for Defendant's VCDs.

202. To the extent applicable, Plaintiff and other Class Members were justified in relying on Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendant. No reasonable consumer would have paid what they did for Defendant's VCDs but for Defendant's unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

203. Plaintiff and other Class Members were damaged by reason of Defendant's misrepresentations and omissions as alleged here.

COUNT V
NEGLIGENT MISREPRESENTATION AND OMISSION

204. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

205. Defendant had or undertook a duty to represent to the quality, nature, and characteristics of its VCDs accurately and truthfully.

206. Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its VCDs.

207. Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its VCDs.

208. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

209. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its

misrepresentations and omissions would induce Class members to make purchases of Defendant's VCDs.

210. Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of VCDs. Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the risks of nitrosamine contamination and related cGMP deviations or failures that meant Defendant could not assure that its VCDs were of appropriate quality, identity, purity, or strength, was a breach of Defendant's duty.

211. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiff and other Class Members have suffered harm, and will continue to do so.

212. Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiff's and other Class Members' paying for VCDs.

213. Defendant intended its misrepresentations or omissions to induce Plaintiff and Class Members to make purchases or reimbursements of VCDs or had reckless disregard for same.

214. But for these misrepresentations (or omissions), Plaintiff and other Class Members would not have made purchases of Defendant's VCDS.

215. Plaintiff and other Class Members were justified in relying on Defendant's misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, or the same or substantively identical omissions were not communicated, to each Class Member.

216. Plaintiff and other Class Members were damaged by reason of Defendant's misrepresentations or omissions alleged here.

COUNT VI
VIOLATION OF STATE CONSUMER PROTECTION LAWS

217. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

218. Defendant has violated the consumer protection statutes as follows:

a. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendant has violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendant has violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendant has violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*;

h. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.;

k. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq*.;

l. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.;

m. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.;

o. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.;

p. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ff. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, *et seq.*;

kk. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

nn. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

rr. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

219. Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

220. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendant's misconduct within the meaning of the above statutes.

221. To the extent applicable, Defendant knew, intended, or should have known that its fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages—an ascertainable loss—in an amount to be proved at trial.

COUNT VII
UNJUST ENRICHMENT

222. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

223. As alleged herein, Defendant was unjustly enriched at the expense of Plaintiff and other Class Members by virtue of the latter's paying for Defendant's VCDs.

224. Defendant profited immensely from introducing a carcinogen into the United States for human consumption. What's more, because Defendant's VCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

225. Plaintiff and other Class Members were unjustly deprived of money obtained by Defendant as a result of the improper amounts paid for Defendant's VCDs. It would be inequitable and unconscionable for Defendant to retain the profit, benefit, and other compensation obtained from Plaintiff and other Class Members as a result of its wrongful conduct alleged in this Master Complaint. There is no adequate remedy at law for Plaintiff and other Class Members.

226. Plaintiff and other Class Members are entitled to seek and do seek restitution from Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendant by virtue of its wrongful conduct.

COUNT VIII
NEGLIGENCE

227. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

228. Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing of its VCDs.

229. Defendant owed a duty to Plaintiff and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to branded Chantix and complied with cGMPs and were not adulterated or misbranded.

230. Defendant owed a duty to care to Plaintiff and the Class because they were the foreseeable, reasonable, and probable user of VCDs and victim of Defendant's fraudulent and deceptive activities. Defendant knew, or should have known, that its VCDs were not therapeutically equivalent to branded Chantix and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

231. Defendant failed to do this. Defendant inadequately oversaw the manufacture and sale of its own VCDs. Defendant knew that ignoring the manufacturing issues surrounding its VCDs would damage Plaintiff and the Class and increase its own profits.

232. Defendant maintained or should have maintained a special relationship with Plaintiff and the Class, as they were obligated to ensure that its VCDs complied with cGMPs and was not adulterated or misbranded.

233. Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of VCDs. Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the risks of nitrosamine contamination and related cGMP deviations or failures that meant Defendant could not assure that its VCDs were of appropriate quality, identity, purity, or strength, was a breach of Defendant's duty.

234. Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class. Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its VCDs.

235. Defendant breached duties owed to Plaintiff and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the Class.

236. As a direct and proximate result of Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT IX
NEGLIGENCE PER SE

237. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

238. Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing of its VCDs.

239. Defendant owed a duty to Plaintiff and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to branded Chantix and complied with cGMPs and were not adulterated or misbranded.

240. Defendant owed a duty to Plaintiff and the Class because each state, territory, and possession has adopted or adheres to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

a. Alabama Code §§ 20-1-24 and -27(1);

b. Alaska Statutes § 17.20.290(a)(1);

c. Arizona Statutes §§ 32-1965(1), (2) and -1966(3);

d. Arkansas Code § 20-56-215(1);

e. California Health and Safety Code §§ 111295 and 111400;

f. Colorado Statutes §§ 25-5-403(1)(a), (b) and -414(1)(c);

g. Title 16, Delaware Code §§ 3302 and 3303(2);

h. District of Columbia Code § 48-702(2);

i. Florida Statutes §§ 499.005(1) and .006(3);

j. Georgia Code § 26-3-3(1);

k. Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);

l. Idaho Code § 37-115(a);

m. Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);

n. Iowa Code §§ 126.3(1) and .9(1)(c);

o. Kentucky Statutes § 217.175(1);

p. Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);

q. Massachusetts General Laws chapter 94 §§ 186 and 190;

r. Minnesota Statutes §§ 151.34(1) and .35(1);

s. Missouri Statutes § 196.015(1);

t. Montana Code §§ § 50-31-305(3) and -501(1);

u. Nebraska Revised Statutes §§ 71-2461(2) and -2481;

v. Nevada Statutes § 585.520(1);

w. New Hampshire Revised Statutes §§ 146:1(I) and :4(V);

x. New Mexico Statutes §§ 26-1-3(A) and -10(A);

y. New York Education Law § 6811;

z. North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);

aa. Ohio Code § 3715.52(A)(1);

bb. Oklahoma Statutes title 63 § 1-1402(a);

cc. Title 35, Pennsylvania Statutes § 780-113(a)(1);

dd. Title 21, Rhode Island General Laws § 21-3-3(1);

ee. South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);

ff. South Dakota Code §§ 39-15-3 and -10;

gg. Title 18, Vermont Statutes § 4052(1);

hh. Virginia Code § 54.1-3457(1);

ii. West Virginia Code §§ 16-7-1 and -2(a)(3); and

jj. Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

241. Defendant failed to comply with federal cGMPs and federal adulteration standards.

242. As a result of Defendant's failures to do so, Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

243. As a direct and proximate result of Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

For these reasons, Plaintiff prays for the following judgment:

a. An order certifying this action as a class action;

b. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

c. A declaration that Defendant is liable under each and every one of the above-enumerated causes of action;

d. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendant described above;

e. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the VCDs; the costs to replace or return VCDs because of recalls; and the increases in the amounts paid for non-adulterated, non-misbranded, VCDs in the wake of the recalls;

f. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

g. An award of statutory penalties to the extent available;

h. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

i. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiff respectfully requests a trial by jury on all causes of action so triable.

Dated: September 23, 2022

Respectfully submitted,

/s/ Marlene J. Goldenberg

Marlene J. Goldenberg
GoldenbergLaw, PLLC
800 LaSalle Ave., Suite 2150
Minneapolis, MN 55402
Phone: (612) 333-4662
Fax: (612) 568-9946
Email: mjgoldenberg@goldenberglaw.com