UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

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

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

[1] Xiaomeng Yue, et al., TRENDS IN UTILIZATION, SPENDING, AND PRICES OF SMOKING-CESSATION MEDICATIONS IN MEDICAID PROGRAMS: 25 YEARS EMPIRICAL DATA ANALYSIS, 1991-2015, Am. Health Drug Benefits 2018 Sep; 11(6):275-285, *at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207314/* (last accessed Sept. 27, 2021).
[2] *Price of Pfizer's smoking-cessation drug Chantix doubles in just 5 years: report*, Fierce Pharma (June 26, 2018) at https://www.fiercepharma.com/pfizer-hikes-price-smoking-cessation-drug-chantix-106-5-years-report (last accessed Sept. 27, 2021).

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

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

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

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

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

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

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

[3] FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix) *at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix (last accessed Sept. 27, 2021).

[4] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n (last accessed Sept. 27, 2021).

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

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

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

PARTIES

A. Plaintiff

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

B. Defendant

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

FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

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

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

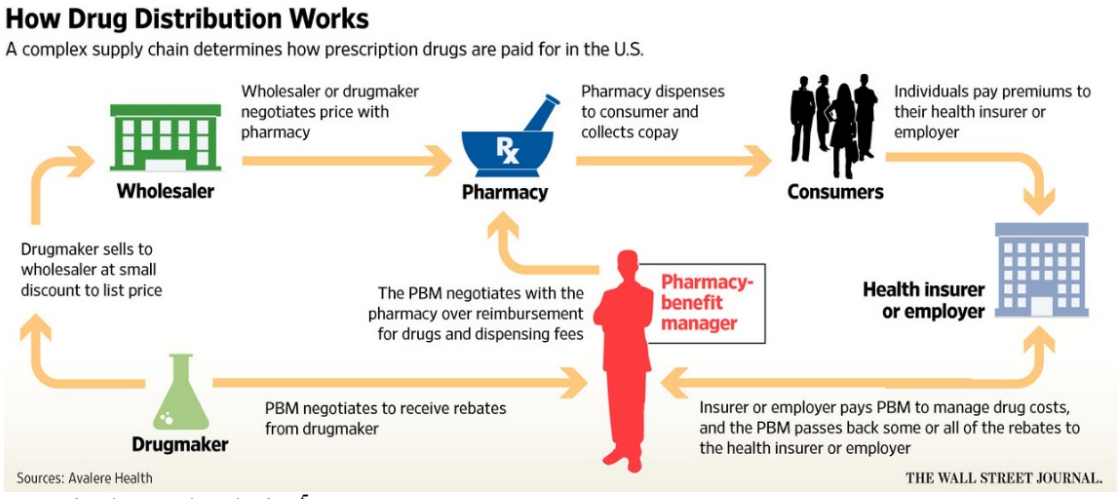
21. Third-party payors ("TPPs") contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies,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

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

same as their RLD counterparts. TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these generic drugs, such as the Defendant's VCDs, comply with their respective ANDAs, which state that the generic drugs are bioequivalent to their respective branded drug. Thus, the TPPs permitted the VCDs to be included on their formularies based on the Defendant's misrepresentations that their VVCDs were bioequivalent to Chantix, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

23. 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.

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



[5] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed June 11, 2019).

25. When a patient presents his/her 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

26. 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]

27. 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. 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.

28. 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]

29. 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") (*i.e.*, patient-

[6] United States Food and Drug Administration, "National Drug Code Directory," accessed June 9, 2021 at https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm; FDA, "National Drug Codes Explained," accessed June 9, 2021 at https://www.drugs.com/ndc.html.

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

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

30. 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."

31. 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]

32. While the DSCSA was enacted in 2013, participants in the pharmaceutical supply chain (including various Defendant here) maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

33. 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

[8] FDA, "Instructions for Completing Form FDA 3500," accessed June 9, 2021 at https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem.
[9] 21 U.S. Code § 360eee.
[10] U.S. Department of Health and Human Services, Drug Supply Chain Security: Dispensers Received Most Tracing Information, March 2018, accessed March 11, 2020 at https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf, at p. 2.

product.

34. 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]

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

36. The entire process of reimbursing pharmacies and consumers for end-purchases depends upon 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.

37. 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.

38. 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

[11] FDA, Title II of the Drug Quality and Security Act, December 16, 2014, accessed March 11, 2020 at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.

[12] Federal Register, August 17, 2000 (Volume 65, Number 160), at pp. 50311-50372; NCPDP, *Pharmacy: A Prescription for Improving the Healthcare System*, October 2009, accessed January 30, 2019 at

these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

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

40. 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]

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

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

42. 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

https://www.ncpdp.org/NCPDP/media/pdf/wp/RxforImprovingHealthcare.pdf, at p. 14.

[13] CFR § 423.505(d)

[14] FDA, *Protect Your Patients*, accessed June 9, 2021 at https://www.fda.gov/media/113114/download; DSCSA, Sections 582 (b)(1)(A)(ii), 582 (c)(bb)(BB)(II)(v)(I), 582 (d)(1)(A)(iii).

[15] FDA, *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, September 2015, accessed June 9, 2021 at https://www.fda.gov/media/93779/download, at pp. 8-9.

[16] Enforcement of this rule was delayed by the FDA until November 2018. DA, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry, September 2018, accessed June 9, 2021 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifier-requirements-under-drug-supply-chain-security-act-compliance-policy-guidance.

identifier, lot number, and expiration date of the product."[17]

43. 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]

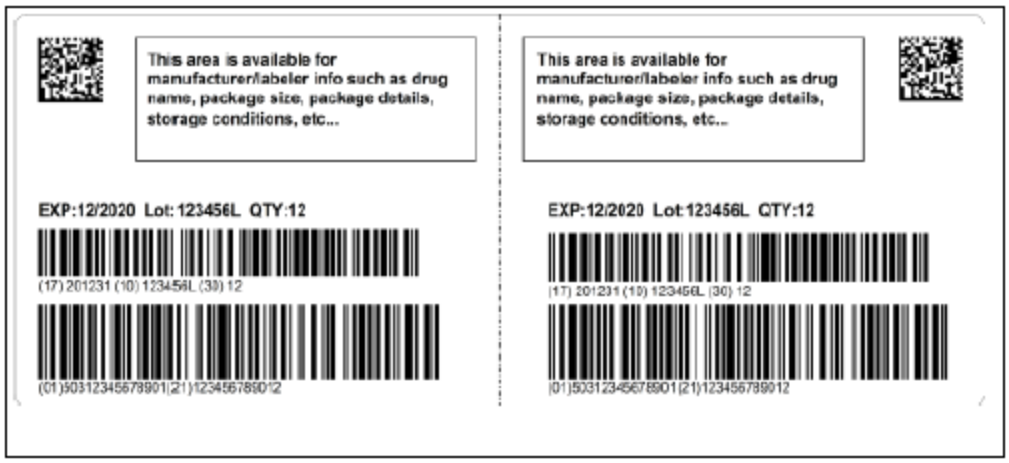
DSCSA RX Serialized Unit Label

[17] 21 U.S. Code § 360eee.(14).

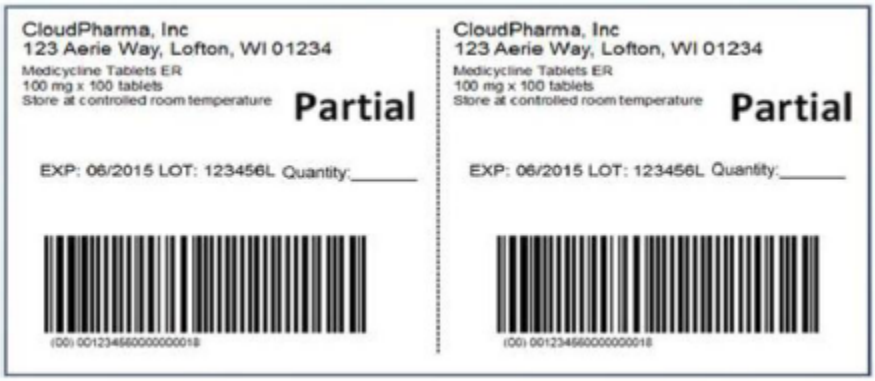
[18] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, accessed June 9, 2021 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at p. 14.

[19] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, accessed February 25, 2020 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at pp. 15-16.

[20] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, accessed June 9, 2021 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at pp. 14, 15, 16.



Example of Rx Serialized Homogenous Case Label



Example Partial Case Labeled with SSCC

D. The Drug Approval Framework

44. 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.*

45. 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.

46. 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 use(s) 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]

47. 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]

48. 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.

49. 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 generic manufacturer may no longer rely on the brand-name drug's labeling.

E. Approval of the NDA for Chantix

50. 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.

51. 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.

52. 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 any varenicline-containing product.

[21] *See, e.g.*, https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last accessed Sept. 27, 2021).
[22] *Id.*

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

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

54. 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.

55. 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.

56. 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.

57. 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).

58. 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.

59. 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.

60. "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

61. 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.

62. Among the ways a drug may be adulterated and/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]; and/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]

63. 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]; and/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]

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

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

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

67. As articulated in this Complaint, Defendant's' unapproved VCD drugs were adulterated and/or misbranded in violation of all of the above-cited reasons.

68. Plaintiff's reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendant, beyond what is already required of them under federal law.

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

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

[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).
[40] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

70. 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]

71. Accordingly, the FDA requires the submission of a New Drug Application 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]

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

73. 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]

74. Here, N-nitroso-varenicline and other nitrosamines resulted from the deficient manufacturing process of the VCDs, rendering the VCDs different than the NDA-approved version of Chantix. Importantly, N-nitroso-varenicline and other nitrosamines can cause cancer by

[41] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.
[42] *See* 21 C.F.R. § 310.3(h).
[43] *See generally* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false (last accessed June 6, 2019).

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.

75. Because the VCDs ingested by Plaintiff were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

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

77. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

III. Defendant Made False Statements in the Labeling

78. 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]

79. "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.

80. "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]

---

[44] 21 C.F.R. § 201.5.
[45] 21 C.F.R. § 801.15.
[46] *Id.* 65 Fed. Reg. 14286 (March 16, 2000).
[47] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

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

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

83. In addition, by referring to their drugs as "Chantix", Defendant was making false statements regarding Chantix.

84. It is unlawful to introduce a misbranded drug into interstate commerce.[49] Thus, the Chantix products ingested by Plaintiff were unlawfully distributed and sold.

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

85. 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.

86. 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

[48] 21 C.F.R. § 201.6; 201.10.
[49] 21 U.S.C. § 331(a).

company. 21 C.F.R. § 211.22(a).

87. 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.

88. 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.

89. "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.

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

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

91. 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.

92. Apotex was the distributor of Chantix in Canada on Defendant's behalf.

93. Health Canada informed Apotex that it had been informed by other global regulators "of the prences 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."

94. 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."

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

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

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

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

99. 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]

[50] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.
[51] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[52] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[53] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[54] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

100. 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]

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

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

103. Other nitrosamines with similar or even more severe carcinogenic risk profiles include n-nitrosodiethlamine ("NDEA"), as well as n-Nitroso varenicline.

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

105. 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]

106. In late June 2021, Defendant recalled certain lots of VCDs because of the presence of n-Nitroso varenicline and/or other nitrosamines.

107. A couple of weeks later, on July 19, 2021, Defendant announced a wider recall of additional VCD products due to n-Nitroso varenicline and/or other nitrosamine contamination.

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

109. On September 16, 2021, Pfizer expanded its recall to include all lots of Chantix

---

[55] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.
[56] *See* Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/ (last accessed June 5, 2019).
[57] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[58] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

"due to the presence of a nitrosamine[.]"[59]

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

110. 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 carcinogen active ingredients and are not approved to be included in the API. Their inclusion in Defendant's VCDs renders the VCDs adulterated and misbranded compared to Defendant's warranties and representations.

111. 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.

112. 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.

113. 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).

[59] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n

114. 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.

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

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

117. 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.

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

VII. Defendant's Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their VCDs

119. Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded VCDs.

120. 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;

[60] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at*

Defendant sought and received the inclusion of their VCD products in the Orange Book upon approval of their NDAs.

121. Defendant's VCD(s) is/are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved VCD label, Defendant made representations and express or implied warranties of the "sameness" of their 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 and/or were not adulterated and/or misbranded or misbranded.

122. By introducing their VCDs into the United States market as "Chantix," Defendant represent and warrant to end-users 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 (e.g., end-user patients) rely on these representations and warranties.

123. In addition, Defendant affirmatively misrepresented and warranted to consumers through their 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.

124. The presence of nitrosamines in Defendant's VCDs: (1) renders Defendant's VCDs non-bioequivalent (i.e., 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, thus breaching Defendant's express warranties of sameness; and (3) results in Defendant' 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

https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed June 5, 2019).

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 their products.

125. 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 and/or misbranded compared to Defendant's representations and warranties.

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

127. 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 have violated implied warranties to Plaintiffs and Class Members. The presence of NDMA in Defendant's VCDs makes Defendant's VCDs non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendant's implied warranty of merchantability and/or fitness for ordinary purposes.

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

129. Adulterated, misbranded, and/or unapproved VCDs contaminated with cancer-causing compounds are essentially worthless. No reasonable consumer (including Plaintiff) would purchase (or reimburse for) these nitrosamine-laden VCDs. Nor could they, as an adulterated, misbranded, and/or unapproved VCDs cannot even be legally sold or purchased within the United

States. At a minimum, adulterated, misbranded, and/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.

130. Moreover, every consumer (and every TPP's insured) who purchased and ingested VCDs, including Plaintiff (or Plaintiff's insureds), has been exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, and may give rise to future potential health consequences.

131. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. VCDs had no use or value and were thus discarded.

VIII. Fraudulent Concealment and Tolling

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

133. 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. Each 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.

134. For instance, no Defendant revealed to the public that their VCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to FDA-approved Chantix.

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

136. 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 their VCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

137. 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/or 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.

IX. CLASS ACTION ALLEGATIONS

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

> **National Class:** All individuals and 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.
>
> **Pennsylvania Subclass:** All individuals and entities in Pennsylvania 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.

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

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

141. 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.

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

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

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

145. **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 and/or misbranded;

e. Whether Defendant violated cGMPs regarding the manufacture of their 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.

146. **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.

147. **Adequacy of Representation**: Plaintiff is committed to pursuing this action and have 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.

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

149. **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 Plaintiff. 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.

FIRST COUNT
BREACH OF EXPRESS WARRANTIES

150. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

151. 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 the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. 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 Defendants.

152. Each Defendant expressly warranted that its VCDs were fit for its ordinary use as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendant expressly warranted that their products were the same as their RLDs.

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

154. Each 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.

155. 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.

156. At the time that each Defendant marketed and sold its VCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, 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 their VCDs.

157. Each 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.

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

159. As a direct and proximate result of each 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.

SECOND COUNT
BREACH OF IMPLIED WARRANTIES

160. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

161. 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.

162. Each Defendant was a merchant within the meaning of the above statutes.

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

164. Each 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.

165. Each 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 their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their VCDs were of merchantable quality and fit for that purpose.

166. Each Defendant breached its implied warranty because each 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.

167. Plaintiff and other Class members purchased the VCDs in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

168. The VCDs were not altered by Plaintiffs or Class members.

169. As a direct and proximate result of each 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.

THIRD COUNT
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*

170. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

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

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

173. Each Defendant expressly or impliedly warranted their VCDs as alleged in the First and Second Causes of Action.

174. 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.

175. No Defendant has acted on the opportunity to cure its failure with respected to its warranted VCDs.

176. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action,

Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

FOURTH COUNT
FRAUD

177. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

178. Defendant affirmatively misrepresented material facts including, inter alia, that their VCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

179. Defendant omitted material facts including, inter alia, that their VCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

180. 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 their RLDs and/or did not comply with cGMPs and/or were adulterated and/or misbranded. Plaintiffs 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 Plaintiffs and Class Members based on Defendant's fraudulent misrepresentations and omissions.

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

182. Defendant also knew, or had reason to know, that their misrepresentations and

omissions would induce Class members to pay for some or all of the cost of Defendant's VCDs.

183. Defendant's misrepresentations and omissions were material.

184. Defendant's actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

185. To the extent applicable, Defendant intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendant's VCDs.

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

187. 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 Defendants. 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.

188. Plaintiff and other Class Members were damaged by reason of Defendant's misrepresentations and omissions alleged herein.

FIFTH COUNT
NEGLIGENT MISREPRESENTATION AND OMISSION

189. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

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

191. Each Defendant failed to exercise ordinary care in making representations (or in

failing to disclose facts) concerning the quality, nature, and characteristics of its VCDs.

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

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

194. Each 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. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's VCDs.

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

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

197. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of VCDs, , or had reckless disregard for same.

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

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

200. Plaintiff and other Class Members were damaged by reason of each Defendant's

misrepresentations or omissions alleged herein.

SIXTH COUNT
VIOLATION OF STATE CONSUMER PROTECTION LAWS

201. Plaintiff re-alleges and incorporate the preceding paragraphs as if fully set forth herein.

202. Each Defendant has violated the consumer protection statutes as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

t. Defendant have engaged in unfair competition or unfair or deceptive acts or

practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

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

v. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

pp. Defendant have engaged in unfair competition or unfair or deceptive acts or

practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

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

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

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

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

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

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

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

xx. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

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

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

aaa. Defendant have 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.

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

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

205. To the extent applicable, each Defendant knew, intended, or should have known that their 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.

SEVENTH COUNT
UNJUST ENRICHMENT

206. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

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

208. Defendant profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendant's VCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

209. 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 their wrongful conduct alleged in this Master Complaint. There is no adequate remedy at law for Plaintiff and other Class members.

210. 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.

EIGHTH COUNT
NEGLIGENCE

211. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

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

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

214. Each 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 each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its VCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

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

216. Each Defendant maintained or should have maintained a special relationship with

Plaintiffs and the Class, as they were obligated to ensure that its VCDs complied with cGMPs and was not adulterated or misbranded.

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

218. Each 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.

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

NINTH COUNT
NEGLIGENCE PER SE

220. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

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

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

223. Each 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:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);

- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;

- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

224. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

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

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

TENTH COUNT
MEDICAL MONITORING

227. Plaintiff repeats and re-alleges the preceding paragraphs as if fully set forth herein.

228. Each Defendant owed a duty to Plaintiff and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its VCDs.

229. Each Defendant owed a duty to Plaintiff and the Classes to ensure that the VCDs it sold in the United States were not contaminated, contained only the ingredients stated in the label, were therapeutically equivalent to brand Diovan, and/or complied with cGMPs, and/or was not contaminated or adulterated.

230. Each Defendant owed a duty of care to Plaintiff and the Classes because they were the foreseeable, reasonable, and probable users of VCDs. Each Defendant knew, or should have known, that its product was contaminated with nitrosamines, did not contain only the ingredients stated, was not therapeutically equivalent to Chantix and/or did not comply with cGMPs, and/or

were contaminated, adulterated, and each was in the best position to uncover and remedy these shortcomings.

231. Defendant negligently manufactured and/or distributed and/or sold the VCDs at issue, causing or failing to detect and prevent contamination with nitrosamines, which are carcinogens.

232. Each Defendant failed to discharge its duties of reasonable care. Each Defendant inadequately conducted or oversaw the manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the VCDs. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiff and other Class Members.

233. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiff and other Class Members, and the medical and regulatory communities, of the potential and actual contamination with nitrosamines as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a carcinogen and thus causing continued exposure to the carcinogenic contamination, and delaying necessary testing, examinations, surveillance, and treatment.

234. Defendant's negligent or grossly negligent conduct created and then exacerbated an unreasonable, dangerous condition for Plaintiff and other Class Members.

235. Defendant acted with recklessness and willful and wanton disregard for the health of Plaintiff and other Class Members.

236. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiff and other Class Members and created a foreseeable risk of harm to Plaintiff and other Class Members.

237. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff

and other Class Members have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

238. Plaintiff and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to nitrosamine contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

For these reasons, Plaintiff pray 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/or 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 and/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. The creation of a medical monitoring fund and/or program that is reasonably necessary to detect the elevated cancer risk;

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

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

JURY DEMAND

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

Dated: September 29, 2021

Respectfully Submitted,

/s/ Ruben Honik

Ruben Honik
David J. Stanoch
Honik LLC
1515 Market Street, Suite 1100

Philadelphia, PA 19102
Tel: 267-435-1300
ruben@honiklaw.com
david@honiklaw.com

ClassAction.org