UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GERALD NELSON, on behalf of himself and all others similarly situated, Plaintiff, v. TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., MAJOR PHARMACEUTICALS, ZHEJIANG HUAHAI PHARMACEUTICALS, LTD., HUAHAI U.S., INC., and RITE AID CORPORATION, Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Gerald Nelson ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendants Teva Pharmaceutical Industries, Ltd. ("Teva"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Major Pharmaceuticals ("Major"), Zhejiang Huahai Pharmaceuticals, Ltd. ("ZHP"), Huahai U.S., Inc. ("Huahai"), and Rite Aid Corporation ("Rite Aid") (collectively, "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendants Teva, Teva USA, Major, ZHP, and Huahai's manufacturing and distribution of valsartan-containing generic prescription medications contaminated with N-nitrosodimethylamine ("NDMA") and N-Nitrosodiethylamine

("NDEA"), both carcinogenic and liver-damaging impurities. In turn, Defendant Rite Aid sold this contaminated generic medication to Plaintiff and other similarly-situated consumers.

2. Originally marketed under the brand name Diovan, valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure. However, due to manufacturing defects originating from overseas laboratories in China, certain generic formulations have become contaminated with NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens." While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA, such as through the contaminated valsartan medications, can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. NDEA, like NDMA is a probable human carcinogen, and is acutely toxic when consumed orally.

A. The July 13, 2018 recall

5. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications. The recall traced back to a Chinese company, Defendant ZHP, which supplied the active pharmaceutical ingredient, valsartan, to American subsidiaries, as well as other United States companies involved in the manufacturing and distribution of valsartan-containing medication. The recall

was due to the presence of NDMA in the recalled valsartan products. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured." The FDA is "investigating the levels of NDMA in the recalled products, assessing the possible effect on patients who have been taking them and [determining] what measures can be taken to reduce or eliminate the impurity from future batches produced by the company."

6. As part of the July 13, 2018 recall, Defendants Teva and Major announced a recall of "all lots of non-expired products that contain the ingredient valsartan supplied to them by Zhejiang Huahai Pharmaceuticals, Linhai, China."

7. Major Pharmaceuticals, a distribution firm, also announced a nationwide voluntary recall of "all lots within expiry of Valsartan which were supplied by Teva Pharmaceuticals and labeled as Major Pharmaceuticals."

8. Included in the July 13, 2018 notice of recall is a statement from the director of the FDA's Center for Drug Evaluation and Research, Janet Woodcock, M.D.: "We have carefully assessed the valsartan-containing medications sold in the United States, and **we've found that the valsartan sold by these specific companies does not meet our safety standards**. This is why we've asked these companies to take immediate action to protect patients[.]" (Emphasis added).

9. Four days later, on July 17, 2018, the FDA announced a voluntary recall, to the consumer level, of twenty-nine (29) lots of single and fifty-one (51) lots "of combination valsartan medicines [manufactured by Teva USA and] distributed under the Actavis label in the U.S." The recall was due to the presence of NDMA. The contaminated medication was sourced

from Defendant ZHP. The notice instructed patients to return their medications.

10. Teva and Teva USA's issues did not end with the July 2018 recalls.

B. Teva USA expands its valsartan recall on November 27, 2018 due to the presence of a second impurity, NDEA, resulting from manufacturing defects from an overseas supplier in India

11. Originally, the valsartan recall was thought to have been limited to manufacturing practices in China; however, over the next several months, recalls continued to expand to other overseas laboratories in India.

12. Previous recalls, such as a recall by Camber Pharmaceuticals announced on August 8, 2018, implicated specific manufacturing facilities in India as a source of contaminated valsartan medication. Despite these warnings, Teva and Teva USA failed to take immediate action.

13. Teva, acting in concert with Defendant Teva USA, its United States based affiliate, failed to promptly recall its valsartan-containing medications for over four months after the initial recall was announced, and over three months after labs in India were implicated.

14. On November 27, 2018, Teva USA "initiated a voluntary recall in the United States, to the patient level, of all lots of Amlodipine / Valsartan combination tablets and Amlodipine / Valsartan / Hydrochlorothiazide combination tablets (see table below) due to an impurity detected above specification limits in an active pharmaceutical ingredient (API) manufactured by Mylan India. The impurity found in Mylan's valsartan API is known as N-nitroso-diethylamine (NDEA), which has been classified as a probable human carcinogen."

15. Like NDMA, NDEA is acutely toxic when consumed orally.

C. Teva and Teva USA boast about the quality and safety of their valsartan products, even though they are contaminated and unfit for human use

16. Generic drugs reach the market when the brand-name version of the drug comes

off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. According to the FDA, "[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity, and stability as brand-name drugs."

17. Here, the valsartan-containing drugs manufactured by Teva and Teva USA are supposed to be equivalent to the brand-name drug, Diovan. However, they are not because they suffer from a manufacturing defect which caused their generic valsartan to become contaminated with NDMA and/or NDEA.

18. As such, Teva and Teva USA's valsartan-containing medications are neither safe nor of equal quality to the brand-name version of the medication.

19. Defendants Teva and Teva USA are in the business of marketing and distributing generic pharmaceuticals. Both of them boast the safety and efficacy of their medications on their respective websites, on the packaging of the medications, and on additional materials presented to consumers. Plaintiff and Class members relied on these representations when choosing to purchase their valsartan medications from Defendants.

20. Teva's website is rife with blatant misrepresentations about the quality of its medications and API:

> Uncompromising Quality
>
> We know that every one of our products will have an impact on another individual's health
>
> Our dedication to quality in everything we do is uncompromising, and covers every stage of the development, production and marketing of our medicines: from the supply of materials through manufacturing and approval by the strictest authorities in the world.
>
> Our state-of-the-art manufacturing facilities feature the most

> advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products.
>
> Teva's impeccable adherence to Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) is recognized by FDA approval of 26 of our plants, and EMA approval of 31 of our plants. Moreover, each of our pharmaceutical manufacturing facilities is inspected and approved by at least two regulatory authorities worldwide.
>
> We never rest on our laurels, and our passion for excellence drives us to continually improve practices so that processes and procedures are continuously updated.
>
> With a global presence, timely, reliable and cost-effective distribution is critical to our customers' ability to provide their end consumers with safe and effective products at the right time.
>
> Our manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals.
>
> The core and success of our continuous drive for excellence is expressed in the values of our global team. Their commitment and sense of responsibility are derived from the awareness that every product that we make will affect another person's health. And health is the cornerstone of our dedication to making life better.

21. However, each of these representations and warranties are false. The valsartan-containing medications are not safe, effective, or of the same quality as the brand-name medication. Teva and Teva USA sourced their API from ZHP, which, as described more fully below, has a long track record of poor manufacturing processes and knew their valsartan medication was contaminated, but ignored such complaints to increase their profits, with blatant

disregard for the health and well-being of consumers.

22. Teva USA makes similar false and deceptive claims on its website:

> Quality and safety in Teva medicines is paramount at all phases of the product lifecycle.
>
> Quality supervision begins at the test facilities with careful documentation and general conduct of non-clinical safety studies. This ensures compliance with current Good Laboratory Practice (GLP) and consequently, the integrity of the data produced. It then follows through clinical trials, production and distribution, and concludes with shelf-life surveillance.
>
> During clinical stage development, quality supervision guarantees that the fundamentals of current Good Manufacturing Practices (cGMPs) are consistently applied. Quality is built into the different phases of clinical development to secure the safety and rights of our studies' participants, the reliability of the data submitted to health authorities, and the complete adherence to all current Good Clinical Practices (GCPs).
>
> Teva has state-of-the-art manufacturing facilities and uses advanced testing instrumentation, to guarantee the quality of its products. Teva additionally supervises suppliers' procedures in order to ensure that quality materials are used in its products. Once a product gains regulatory approval and enters routine manufacturing, quality is guaranteed throughout the process, for both active and inactive ingredients and finished dosage pharmaceutical products.
>
> Quality doesn't end when the product is released. Teva continues to monitor its products throughout their shelf life. Representative batches of all products are checked for stability to ensure that products remain safe and effective throughout their shelf life. Teva addresses and responds to quality and medical complaints. Information about potential quality or medical issues is shared throughout the Teva network, and appropriate actions are taken.
>
> Once a medicine has been released on the market, physicians, patients, healthcare teams and other caregivers can report side effects and safety concerns. These can either be reported to Teva directly or to the local authorities. All Teva employees attend a pharmacovigilance training course, to ensure effective collection of safety data within our organization.

23. These representations and warranties are false, as Teva USA manufactured and distributed contaminated valsartan-containing medication unfit for human use.

D. The FDA issued ZHP a warning letter on November 29, 2018, documenting prior knowledge of the valsartan contamination, and failure by ZHP to take appropriate action

24. On November 29, 2018, the FDA issued a warning letter to Defendant ZHP following an inspection of its manufacturing facility from July 23 to August 3, 2018.[1] The letter summarized "significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)."

25. The FDA noted that ZHP's "API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

26. The FDA mentioned two major findings in its letter. First, the "[f]ailure of [ZHP's] quality unit to ensure that quality-related complaints are investigated and resolved." The letter then proceeded to explain how ZHP had knowledge of the NDMA contamination from customer complaints in 2016 and 2018, but ignored these issues so that it could continue its sales, uninterrupted:

> *Valsartan API*
>
> **Your firm received a complaint from a customer on June 6, 2018, after an unknown peak was detected during residual solvents testing for valsartan API manufactured at your facility**. The unknown peak was identified as the probable human carcinogen N-nitrosodimethylamine (NDMA). Your investigation (DCE-18001) determined that the presence of NDMA was caused by the convergence of three process-related factors, one factor being the use of the solvent **(b)(4)**). Your investigation concluded that only one valsartan manufacturing process (referred to as

[1] https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628009.htm (last visited 1/9/19).

the **(b)(4)** process in your investigation) was impacted by the presence of NDMA.

However, FDA analyses of samples of your API, and finished drug product manufactured with your API, identified NDMA in multiple batches manufactured with a different process, namely the **(b)(4)** process, which did not use the solvent **(b)(4)**. **These data demonstrate that your investigation was inadequate and failed to resolve the control and presence of NDMA in valsartan API distributed to customers**. Your investigation also failed:

• To include other factors that may have contributed to the presence of NDMA. For example, your investigation lacked a comprehensive evaluation of all raw materials used during manufacturing, including **(b)(4)**.

• To assess factors that could put your API at risk for NDMA cross-contamination, including batch blending, solvent recovery and re-use, shared production lines, and cleaning procedures.

• To evaluate the potential for other mutagenic impurities to form in your products.

Our investigators also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms. For example, valsartan intermediates **(b)(4)** and **(b)(4)** failed testing for an unknown impurity (specification ≤ **(b)(4)**%) with results of **(b)(4)**% for both batches. Your action plan indicated that the impurity would be identified as part of the investigation; however, you failed to do this. In addition, no root cause was determined for the presence of the unknown impurity. You stated that you reprocessed the batches and released them for further production.

Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the **(b)(4)** peak in valsartan API residual solvent chromatograms where the presence of NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your **(b)(4)** process, with **(b)(4)** in 2012 (**(b)(4)**, and **(b)(4)**)

show at least one unidentified peak eluting after the **(b)(4)** peak in the area where the presence of NDMA was suspected to elute.

Your response also states that you were not the only firm to identify NDMA in valsartan API. In your case, FDA analyses of samples identified amounts of NDMA in valsartan API manufactured at your firm that were **significantly higher than the NDMA levels in valsartan API manufactured by other firms**. FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation.

The letter continues:

(b)(4) *API*

Your firm received a customer complaint on September 13, 2016, concerning (b)(4) API batches ((b)(4) and (b)(4)) that exceeded the specification for (b)(4) (≤ (b)(4)ppm). (b)(4) has been classified as a probable human carcinogen. Your customer's test results conflicted with your **(b)(4)** test results, which showed the two batches meeting the specification upon release. Your complaint investigation (CC-16008) identified no clear laboratory error, and no anomalies were detected during the production of the batches. Your investigation failed to evaluate other **(b)(4)** API batches to determine if the presence of excess **(b)(4)** was an adverse trend. For example, **(b)(4)**batches **(b)(4)**, and **(b)(4)** were OOS for **(b)(4)** because of production errors; however, they were not discussed in your complaint investigation.

Your response states that **(b)(4)** API batches **(b)(4)** and **(b)(4)** were returned, reprocessed, and released to customers in non-U.S. markets.

Your response also states that in August 2017 you implemented a new **(b)(4)** test method that uses a **(b)(4)** LC-MS/MS method, to replace the **(b)(4)** LC-MS method that was prone to erroneous OOS results. You failed to verify the reliability of the **(b)(4)** results for all **(b)(4)** API batches (including **(b)(4)** batch **(b)(4)**) originally released using your **(b)(4)** LC-MS method, which you indicated was inferior to your updated method.

27. The second major finding noted by the FDA was ZHP's "[f]ailure to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." This aspect of the letter revealed that the valsartan contamination likely dates back to November of 2011, and that ZHP switched to the new process to increase profit even though the new, unproven process rendered much greater risk of impurities such as NDMA:

> **In November 2011 you approved a valsartan API process change (PCRC - 11025) that included the use of the solvent (b)(4). Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process**. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from **(b)(4)** degradants, including the primary **(b)(4)** degradant, **(b)(4)**. According to your ongoing investigation, **(b)(4)** is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.
>
> You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients.
>
> Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce.
>
> Your response does not describe sufficient corrective actions to ensure that your firm has adequate change management procedures in place: (1) to thoroughly evaluate your API manufacturing

processes, including changes to those processes; and (2) to detect any unsafe impurities, including potentially mutagenic impurities.

28. Based on the egregious deficiencies listed above, the FDA recommended that ZHP engage a consultant "to evaluate your operations and assist your firm in meeting CGMP requirements."

29. The FDA also placed ZHP on import alert following its inspection, which stops all API and finished drug products using API produced by the company from entering the United States.

30. Indeed, FDA Commissioner Scott Gottlieb commented: "The issues cited in the warning letter are associated with the nitrosamine impurities found in these drugs, and these violations reveal a disturbing lack of oversight at this API manufacturer that puts patients at risk."[2]

E. Plaintiff Nelson and Class Members were harmed by purchasing and consuming contaminated valsartan-containing medications manufactured, distributed, and sold by Defendants

31. Plaintiff and the Class were injured by the full purchase price of their valsartan-containing medications. These medications are worthless, as they are contaminated with carcinogenic and harmful NDMA and/or NDEA, and therefore and are not fit for human consumption. Indeed, Plaintiff has been instructed to immediately stop using the medication, and has been instructed to return the remaining medication for another, non-contaminated brand. Plaintiff and the Class are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA and/or NDEA, and for damages related to Defendants' conduct.

[2] https://www.in-pharmatechnologist.com/Article/2018/12/12/US-FDA-notes-disturbing-lack-of-oversight-over-valsartan-contamination (last visited 1/9/19).

32. Plaintiff brings this action on behalf of himself and Class Members for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of the implied warranty of merchantability; (iii) violation of New York's General Business Law § 349; (iv) violation of New York's General Business Law § 350; (v) unjust enrichment; (vi) fraudulent concealment; (vii) fraud; (viii) conversion; (ix) strict products liability; (x) gross negligence; (xi) negligence; and (xii) battery.

PARTIES

33. Plaintiff Gerald Nelson is a citizen of New York who resides in Albertson, New York. During all relevant time periods, Plaintiff Nelson was prescribed valsartan-containing medication manufactured and distributed by Defendants Teva, Teva USA, ZHP, and Huahai, and sold by Defendant Rite Aid. Plaintiff Nelson originally learned about the recall by receiving notices from Express Scripts and Rite Aid. Plaintiff Nelson reviewed the recall letter, cross referenced the affected NDC numbers with the NDC number of the medication he purchased, and determined that he was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Teva, Teva USA, ZHP, and Huahai, and sold by Rite Aid. Further investigation revealed that Plaintiff Nelson has been using the contaminated valsartan for some time. When purchasing his valsartan-containing medications from Defendants Teva, Teva USA, ZHP, Huahai, and Rite Aid, Plaintiff Nelson reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff Nelson relied on these representations and warranties in deciding to purchase his valsartan-containing medications from Defendants Teva, Teva USA, ZHP, Huahai, and Rite Aid, and these representations and warranties were part of the

basis of the bargain, in that he would not have purchased his valsartan-containing medications from Defendants Teva, Teva USA, ZHP, Huahai, and Rite Aid if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Nelson also understood that in making the sale, Rite Aid was acting with the knowledge and approval of Teva, Teva USA, ZHP, and Huahai and/or as the agent of Teva, Teva USA, ZHP, and Huahai. Plaintiff Nelson also understood that each purchase involved a direct transaction between himself and Teva, Teva USA, ZHP, and Huahai, because his medication came with packaging and other materials prepared by Teva, Teva USA, ZHP, and Huahai, including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

34. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli multinational pharmaceutical company headquartered at 5 Basel Street, Petach Tikvah 49131, Israel. Teva on its own and/or through its subsidiaries, including Actavis, and distributors, including Major Pharmaceuticals, regularly conducts business throughout the United States, including in the State of New York. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of contaminated valsartan medication in the United States, specifically in the State of New York.

35. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva. Teva USA on its own and/or through its subsidiaries regularly conducts business throughout the United States, including in the State of New York. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of contaminated valsartan in the United States, specifically

in the State of New York.

36. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. is a corporation organized under the laws of the People's Republic of China, with headquarters in Xunqiao, Linhai, Zhejiang 317024, China. ZHP manufactures and sells API and finished drug products in the United States through American subsidiaries, such as Huahai, and through third-party purchasers of API, such as Teva and Teva USA. At all times material to this case, ZHP manufactured and sold contaminated valsartan API to Defendants Teva and Teva USA. This contaminated valsartan was then sold throughout the United States, specifically the State of New York. Plaintiff Nelson was prescribed, purchased, and consumed contaminated valsartan that originated from Defendant ZHP.

37. Defendant Huahai U.S., Inc. is a corporation organized under the laws of New Jersey, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Huahai US is a subsidiary of ZHP. At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of contaminated valsartan in the United States, specifically in the State of New York. Acting in concert, and with each entity acting as the alter ego of the other, ZHP and Huahai U.S. supplied contaminated valsartan medication to Teva and Teva USA, which led to the July 2018 recall.

38. Defendant Major Pharmaceuticals is a corporation organized under the laws of Michigan, with a corporate headquarters located at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. Defendants Teva and Teva USA supplied contaminated valsartan medication to Major, which then sold the contaminated medication under its label.

39. Defendant Rite Aid Corporation is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 30 Hunter Lane, Camp Hill,

Pennsylvania 17011. Defendant Rite Aid Corporation sells Teva and Teva USA's valsartan containing medication throughout the United States, and specifically in the State of New York. Plaintiff Nelson purchased his contaminated valsartan medication from a Rite Aid store in Albertson, New York.

JURISDICTION AND VENUE

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

41. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, Plaintiff resides in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of contaminated valsartan-containing medications in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

42. Plaintiff seeks to represent a class defined as all persons in the United States who purchased valsartan-containing medications that are contaminated with NDMA and/or NDEA (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or

entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

43. Plaintiff also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in New York (the "New York Subclass").

44. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

45. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

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

(a) whether the valsartan-containing medications manufactured, distributed, and sold

by Defendants were in fact contaminated with NDMA and/or NDEA, thereby breaching the express and implied warranties made by Defendants and making the medication unfit for human consumption and therefore unfit for its intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence, as well as battery as to those who consumed the contaminated medication;

(b) whether Defendants knew or should have known that the valsartan-containing medications were in fact contaminated with NDMA and/or NDEA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

(c) whether Defendants have unlawfully converted money from Plaintiff and the Class;

(d) whether Defendants are liable to Plaintiff and the Class for unjust enrichment;

(e) whether Defendants are liable to Plaintiff and the Class for fraudulent concealment;

(f) whether Defendants are liable to Plaintiff and the Class for violation of the New York General Business Law §§ 349 & 350, *et seq.*;

(g) whether Defendants are liable to Plaintiff for breaches of express and implied warranties;

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

(i) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

(j) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and

(k) Whether the marketing, advertising, packaging, labeling, and other promotional materials for Defendants' valsartan medications are deceptive.

47. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class in that Defendants mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the recalled medications manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiff and Class members by manufacturing, distributing, and selling the contaminated valsartan medication. Plaintiff's claims are typical in that they were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to Plaintiff.

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

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

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

50. In the alternative, the Class may also be certified because:

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

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

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

COUNT I
Breach Of Express Warranty
(On Behalf Of The Nationwide Class)

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

52. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

53. Plaintiff, and each member of the nationwide Class, formed a contract with

Defendants at the time Plaintiff and the other Class members purchased the contaminated valsartan medications. The terms of the contract include the promises and affirmations of fact made by Defendants on the contaminated medication's packaging and through marketing and advertising, including that the product would be of "quality" and "safe." 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.

54. Defendants further expressly warranted that the valsartan-containing medications would contain only what was stated on the label, and would not contain harmful and carcinogenic defects and impurities such as NDMA or NDEA. Plaintiff relied on the express warranty that his medication would contain only what was stated on the label, and that it would not be contaminated with impurities. These express warranties further formed the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

55. Defendants purport, through their advertising, labeling, marketing and packaging to create an express warranty that the medication would be of the same "quality" as the name-brand medication, and that it would be "safe."

56. Plaintiff and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the contaminated medication.

57. Defendants breached express warranties about the contaminated medication and their qualities because Defendants' statements about the contaminated medications were false and the contaminated medications do not conform to Defendants' affirmations and promises described above.

58. Plaintiff and each of the members of the Class would not have purchased the contaminated medications had they known the true nature of the contaminated medications' ingredients and what the contaminated medications contained (*i.e.*, NDMA and/or NDEA).

59. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class have been damaged in the amount of the purchase price of the Product and any consequential damages resulting from the purchases.

60. On January 11, 2019, prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendants a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as Exhibit A.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Nationwide Class)

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

62. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

63. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the valsartan-containing medications (i) contained no NDMA or NDEA and (ii) are generally recognized as safe for human consumption.

64. Defendants breached the warranty implied in the contract for the sale of the contaminated valsartan-containing medications because they could not pass without objection in

the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the valsartan-containing medications manufactured, distributed, and sold by Defendants were contaminated with carcinogenic and liver toxic NDMA and/or NDEA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

65. Plaintiff and Class members purchased the valsartan-containing medications in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

66. The valsartan-containing medications were not altered by Plaintiff or Class members.

67. The valsartan-containing medications were defective when they left the exclusive control of Defendants.

68. Defendants knew that the valsartan-containing medications would be purchased and used without additional testing by Plaintiff and Class members.

69. The contaminated valsartan medication was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class members did not receive the goods as warranted.

70. As a direct and proximate cause of Defendants' breach of the implied warranty of merchantability, Plaintiff and Class members have been injured and harmed because: (a) they would not have purchased the valsartan-containing medication on the same terms if they knew that the products contained NDMA and/or NDEA, and are not generally recognized as safe for human consumption; and (b) the valsartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
Violation Of New York's General Business Law § 349
(On Behalf Of The New York Subclass)

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

72. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

73. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

74. In their sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

75. Plaintiff and members of the Subclass are consumers who purchased products from Defendants for their personal use.

76. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the valsartan-containing medications (i) contained no NDMA and/or NDEA or other harmful impurities; and (ii) are generally recognized as safe for human consumption.

77. The foregoing deceptive acts and practices were directed at consumers.

78. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the valsartan-containing medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

79. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

80. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the Subclass have sustained from having paid for and consumed Defendants' products.

81. As a result of Defendants' violations, Plaintiff and members of the Subclass have suffered damages because: (a) they would not have purchased Defendants' valsartan-containing medications on the same terms if they knew that the products contained NDMA and/or NDEA, and are not generally recognized as safe for human consumption; and (b) Defendants' valsartan products do not have the characteristics, ingredients, uses, or benefits promised.

82. On behalf of himself and other members of the Subclass, Plaintiff seeks to recover his actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York's General Business Law § 350
(On Behalf Of The New York Subclass)

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

84. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

85. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York GBL.

86. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to, that the medication was safe and was not tainted with harmful impurities such as NDMA and/or NDEA ("the Misrepresentations"), were and are directed to

consumers.

87. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

88. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

89. Plaintiff and members of the New York Subclass have been injured because: (a) they would not have purchased the contaminated valsartan-containing medication if they had known that the medications contained liver-toxic and carcinogenic NDMA and/or NDEA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDMA and/or NDEA. As a result, Plaintiff and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

90. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiff has suffered and will continue to suffer economic injury.

91. Plaintiff and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations because they paid more for the medications than they would have had they known the truth about the Products (i.e. the full purchase price).

92. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to enjoin the unlawful acts and practices described herein, to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys'

fees.

COUNT V
Unjust Enrichment
(On Behalf Of The Nationwide Class)

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

94. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

95. Plaintiff and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' contaminated valsartan medication.

96. Defendants voluntarily accepted and retained this benefit.

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

COUNT VI
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

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

99. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

100. Defendants had a duty to disclose material facts to Plaintiff and the Class given their relationship as contracting parties and intended users of the medication. Defendants also had a duty to disclose material facts to Plaintiff and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medications unfit for human

consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

101. Defendants possessed knowledge of these material facts. In fact, reports from government agencies reveal that this contamination may date back to 2011 or 2012. The FDA's Warning Letter to ZHP conclusively establishes knowledge by ZHP in 2016. Defendants therefore withheld the knowledge of the contamination for, at worst, nearly six years before finally disclosing the issue in July 2018, or at minimum, for two years. During that time, Plaintiff and Class members were using the medication without knowing it contained the harmful impurity NDMA. Despite knowledge of the NDMA contamination, Major, Teva, and Teva USA continued to use valsartan API from ZHP in their valsartan products, including those sold to Plaintiff and Class members.

102. Further, despite the initial wave of recalls, Teva and Teva USA continued to sell valsartan-containing medication from India contaminated with NDEA, despite the fact that Indian manufacturers were implicated in the recall as early as August 8, 2018.

103. Defendants Teva and Teva USA continued to manufacture and sell contaminated valsartan medication for over three months after the implication of Indian manufacturers.

104. Defendants failed to discharge their duty to disclose these materials facts.

105. In so failing to disclose these material facts to Plaintiff and the Class, Defendants intended to hide from Plaintiff and the Class that they were purchasing and consuming medications with harmful impurities that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

106. Plaintiff and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the contaminated valsartan medication manufactured,

distributed, and sold by Defendants had they known it was contaminated with NDMA and/or NDEA.

107. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class suffered damages in the amount of monies paid for the defective medication.

108. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
Fraud
(On Behalf Of The Nationwide Class)

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

110. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

111. As discussed above, Defendants provided Plaintiff and Class members with false or misleading material information about the valsartan medications manufactured, distributed, and sold by Defendants on the medication's packaging, labels, and accompanying documentation, as well as on Teva and Teva USA's respective websites. This false and misleading information includes, but is not limited to, the following statements:

> Uncompromising Quality
>
> We know that every one of our products will have an impact on another individual's health.
>
> Our dedication to quality in everything we do is uncompromising, and covers every stage of the development, production and marketing of our medicines: from the supply of materials through manufacturing and approval by the strictest authorities in the world.
>
> Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our

> products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products.
>
> Teva's impeccable adherence to Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) is recognized by FDA approval of 26 of our plants, and EMA approval of 31 of our plants. Moreover, each of our pharmaceutical manufacturing facilities is inspected and approved by at least two regulatory authorities worldwide.
>
> We never rest on our laurels, and our passion for excellence drives us to continually improve practices so that processes and procedures are continuously updated.
>
> With a global presence, timely, reliable and cost-effective distribution is critical to our customers' ability to provide their end consumers with safe and effective products at the right time.
>
> Our manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals.
>
> The core and success of our continuous drive for excellence is expressed in the values of our global team. Their commitment and sense of responsibility are derived from the awareness that every product that we make will affect another person's health. And health is the cornerstone of our dedication to making life better.

Teva USA similarly states that:

> Quality and safety in Teva medicines is paramount at all phases of the product lifecycle.
>
> Quality supervision begins at the test facilities with careful documentation and general conduct of non-clinical safety studies. This ensures compliance with current Good Laboratory Practice (GLP) and consequently, the integrity of the data produced. It then follows through clinical trials, production and distribution, and concludes with shelf-life surveillance.

> During clinical stage development, quality supervision guarantees that the fundamentals of current Good Manufacturing Practices (cGMPs) are consistently applied. Quality is built into the different phases of clinical development to secure the safety and rights of our studies' participants, the reliability of the data submitted to health authorities, and the complete adherence to all current Good Clinical Practices (GCPs).
>
> Teva has state-of-the-art manufacturing facilities and uses advanced testing instrumentation, to guarantee the quality of its products. Teva additionally supervises suppliers' procedures in order to ensure that quality materials are used in its products. Once a product gains regulatory approval and enters routine manufacturing, quality is guaranteed throughout the process, for both active and inactive ingredients and finished dosage pharmaceutical products.
>
> Quality doesn't end when the product is released. Teva continues to monitor its products throughout their shelf life. Representative batches of all products are checked for stability to ensure that products remain safe and effective throughout their shelf life. Teva addresses and responds to quality and medical complaints. Information about potential quality or medical issues is shared throughout the Teva network, and appropriate actions are taken.
>
> Once a medicine has been released on the market, physicians, patients, healthcare teams and other caregivers can report side effects and safety concerns. These can either be reported to Teva directly or to the local authorities. All Teva employees attend a pharmacovigilance training course, to ensure effective collection of safety data within our organization.

112. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase these contaminated valsartan-containing medications.

113. Defendants knew that the medications contained these harmful impurities, but continued to manufacture them for nearly six years until finally reporting the issue. In fact, reports from government agencies reveal that this contamination may date back to 2012.

Defendants therefore withheld the knowledge of the contamination for nearly six years before finally disclosing the issue. At minimum, Defendants knew about the contamination in 2016, when it was reported to ZHP. During that time that Defendants failed to disclose the contamination, Plaintiff and Class Members were using the medication without knowing it contained the harmful impurity NDMA.

114. Further, despite the initial wave of recalls, Teva and Teva USA continued to sell valsartan-containing medication from India contaminated with NDEA, despite the fact that Indian manufacturers were implicated in the recall as early as August 8, 2018.

115. Defendants Teva and Teva USA continued to manufacture and sell contaminated valsartan medication for over three months after the implication of Indian manufacturers.

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

117. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Conversion
(On Behalf Of The Nationwide Class)

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

119. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

120. Plaintiff and the Class have an ownership right to the monies paid for the contaminated medication manufactured, distributed, and sold by Defendants.

121. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the contaminated medication. Defendants have done so every time that Plaintiff

and the Class have paid to have their prescriptions filled.

122. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class suffered damages in the amount of the payments made for each time they filled their prescriptions.

COUNT IX
Strict Liability – Manufacturing Defect
(On Behalf Of The Nationwide Class)

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

124. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

125. The NDMA and NDEA impurities contained in the Defendants' medications were a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurities NDMA and NDEA. NDMA and NDEA were not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.

126. Due to the NDMA and NDEA impurities, the medications were not reasonably safe as marketed because NDMA and NDEA are known carcinogens and are acutely damaging to the liver, and, according to the FDA, the level of NDMA and NDEA in the effected medication far exceeded acceptable levels, warranting an immediate recall of the effected medication.

127. The effected medication was recalled in 22 other countries around the world, in addition to the United States.

128. Plaintiff and all Class members used the product for its intended purpose,

meaning they used the product as prescribed by their respective doctors.

129. There is no way that Plaintiff or Class members could have discovered the defect by exercising reasonable care. There was no way for Plaintiff or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact contaminated with NDMA and NDEA. Nothing short of laboratory tests (which should have been done by Defendants for quality control purposes) would have revealed the defect to the unsuspecting consumer.

130. Because Plaintiff and Class members had no way of knowing that their medication was in fact contaminated, Plaintiff and Class members could not have avoided the injury by exercising ordinary care.

131. Defendants were supposed to manufacture, distribute, and sell valsartan-containing medications without any harmful impurities such as NDMA and NDEA. The valsartan medications were not designed or intended to contain NDMA or NDEA. The impurity resulted from a manufacturing defect which allowed the medication to become contaminated.

132. Plaintiff and class members suffered harm as a result of consuming this contaminated medication. The ingestion of NDMA and NDEA is acutely harmful. NDMA and NDEA, when ingested orally, are immediately harmful to the liver, kidneys, and pulmonary function. Animal studies confirm that acute exposure of NDMA "demonstrated that [NDMA] has high to extreme acute toxicity from inhalation or **oral exposure**." "Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours." As such, both NDMA and NDEA cause harm as soon as they are consumed.

133. Importantly, Plaintiff and the Class members do not seek resolution of downstream effects of NDMA and NDEA exposure such as cancer, jaundice, and other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDMA and NDEA, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

134. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a manufacturing defect which caused Plaintiff and Class members an immediate and concrete harm, Defendants are strictly liable to Plaintiff and Class members.

COUNT X
Gross Negligence
(On Behalf Of The Nationwide Class)

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

136. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

137. Defendants owed a duty of care to Plaintiff and the Class to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

138. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDMA and NDEA.

139. Plaintiff and Class members were injured by ingesting an acutely toxic substance, to wit NDMA and NDEA, which were negligently present in the valsartan medications manufactured, distributed, and sold by Defendants. Plaintiff and Class members also suffered economic damages from the purchase of the valsartan-containing medications.

140. Importantly, Plaintiff and Class members do not seek resolution of downstream effects of ingestion of high levels of NDMA and NDEA such as cancer, jaundice, and other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDMA and NDEA, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

141. Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing. In fact, reports from government agencies reveal that this contamination may date back to 2011 or 2012. The FDA's Warning Letter to ZHP conclusively establishes knowledge by ZHP in 2016. Defendants therefore withheld the knowledge of the contamination for, at worst, nearly six years before finally disclosing the issue in July 2018, or at minimum, for two years. During that time, Plaintiff and Class members were using the medication without knowing it contained the harmful impurity NDMA. Despite knowledge of the NDMA contamination, Teva and Teva USA continued to use valsartan API from ZHP in their valsartan products, including those sold to Plaintiff and Class members.

142. Defendants Teva and Teva USA also continued to sell valsartan medication contaminated with NDEA, despite knowledge of prior recalls from Indian manufacturers dating back to August 8, 2018. Teva and Teva USA did not announce a recall of their valsartan medication produced in India until November 27, 2018, over three months after the initial wave of recalls.

143. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to

Plaintiff and Class members, and because Defendants failed to act to remediate the harmful impurity for nearly six years, Defendants are grossly negligent and are liable to Plaintiff for all injuries proximately caused by Defendants' gross negligence.

COUNT XI
Negligence
(On Behalf Of The Nationwide Class)

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

145. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

146. Defendants owed a duty of care to Plaintiff and Class members to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

147. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDMA and NDEA.

148. Plaintiff and Class members were injured by ingesting acutely toxic substances, to wit NDMA and/or NDEA, which were negligently present in the valsartan medications manufactured, distributed, and sold by Defendants.

149. Importantly, Plaintiff and Class members do not seek resolution of downstream effects of NDMA and NDEA exposure such as cancer, jaundice, and other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDMA and NDEA, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

150. Because the valsartan medications manufactured, distributed, and sold by

Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiff and class members, Defendants are negligent and are liable to Plaintiff and Class members for all injuries proximately caused by Defendants' negligence.

COUNT XII
Battery
(On Behalf Of The Nationwide Class)

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

152. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

153. Defendants manufactured, distributed, and sold the contaminated valsartan medication to Plaintiff and Class members with the knowledge and intent that Plaintiff and Class members would ingest the medication. Defendants thus had knowledge that the harmful medication would come into contact with the bodies of Plaintiff and Class members.

154. The intended contact, i.e. the medication being ingested by Plaintiff and Class members, was harmful in nature because the medication contained the harmful impurities NDMA and/or NDEA.

155. As such, Defendants committed an unlawful battery on Plaintiff and Class members, who ingested the medication.

PRAYER FOR RELIEF

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

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

B. For an order declaring that the Defendants' conduct violates the statutes referenced herein;

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

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

E. For prejudgment interest on all amounts awarded;

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

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiff and the Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

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

Dated: January 16, 2019

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Scott A. Bursor*
Scott A. Bursor

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EXHIBIT A

BURSOR & FISHER P.A.

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Tel: 646.837.7165
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January 11, 2019

Via Certified Mail – Return Receipt Requested

Teva Pharmaceutical Industries Ltd.
5 Basel Street
Petach Tikva 49131
Israel

Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, PA 19454

Zhejiang Huahai Pharmaceutical Co., Ltd.
Xunqiao, Linhai City
Taizhou ZHJ 317024

Huahai U.S., Inc.
2002 Eastpark Blvd.
Cranbury, NJ 08512

Major Pharmaceuticals
17177 North Laurel Park, Suite 233
Livonia, MI 48152

Rite Aid Corporation
30 Hunter Lane
Camp Hill, PA 17011

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Teva Pharmaceutical Industries Ltd. ("Teva"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc. ("Huahai"), Major Pharmaceuticals ("Major"), and Rite Aid Corporation ("Rite Aid") pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties related to our client, Gerald Nelson, and a class of all similarly situated purchasers (the "Class") of contaminated valsartan-containing medication manufactured, distributed, and sold by Teva, Teva USA, ZHP, Huahai,

Major, and Rite Aid. This letter also serves as a notice of violation of New York's General Business Law § 349 and § 350.

Our client was prescribed and purchased valsartan-containing medication manufactured and distributed by ZHP, Huahai, Teva, Major and Teva USA, and sold by Rite Aid. Our client's valsartan-containing medications were contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. On July 13, 2018, the U.S. Food & Drug Administration announced a voluntary recall of several brands of valsartan-containing generic medications, including those manufactured and distributed by ZHP, Teva, Major and Teva USA. The recall was due to the presence of NDMA in the recalled products. This defect rendered the products unusable and unfit for human consumption. In short, the valsartan-containing medications that our client and the Class were purchasing are worthless as they contained a toxic impurity rendering them unfit for human use. ZHP, Teva, Major, Teva USA and Rite Aid each violated express and implied warranties made to our client and the Class regarding the quality and safety of the valsartan-containing medications they purchased. *See* U.C.C. §§ 2-313, 2-314.

Further, on November 27, 2018, Teva USA "initiated a voluntary recall in the United States, to the patient level, of all lots of Amlodipine / Valsartan combination tablets and Amlodipine / Valsartan / Hydrochlorothiazide combination tablets (see table below) due to an impurity detected above specification limits in an active pharmaceutical ingredient (API) manufactured by Mylan India. The impurity found in Mylan's valsartan API is known as N-nitroso-diethylamine (NDEA), which has been classified as a probable human carcinogen." As such, Defendants violated express and implied warranties made to class members. *See* U.C.C. §§ 2-313, 2-314. Defendants also violated New York's General Business Law § 349 and § 350.

On behalf of our client and the Class, we hereby demand that ZHP, Teva, Major, Teva USA, Huahai, and Rite Aid immediately (1) cease and desist from continuing to sell contaminated valsartan-containing medications and (2) make full restitution to all purchasers of the contaminated valsartan-containing medications of all purchase money obtained from sales thereof.

We also demand that ZHP, Teva, Major, Teva USA, Huahai, and Rite Aid preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for ZHP, Huahai, Teva, Teva USA, or Major's valsartan-containing medications;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of valsartan-containing medications manufactured and distributed by ZHP, Teva, Major, Teva USA, and Huahai;

3. All tests of the valsartan-containing medications manufactured and distributed by ZHP, Teva, Major, Teva USA, and Huahai;

4. All documents concerning the pricing, advertising, marketing, and/or sale of valsartan-containing medications manufactured and distributed by ZHP, Teva, Major, Teva USA, and Huahai;

5. All communications with customers involving complaints or comments concerning the valsartan-containing medications manufactured and distributed by ZHP, Teva, Major, Teva USA, and Huahai;

6. All documents concerning communications with any retailer involved in the marketing or sale of valsartan-containing medications manufactured and distributed by ZHP, Teva, Major, Teva USA, and Huahai;

7. All documents concerning communications with federal or state regulators; and

8. All documents concerning the total revenue derived from sales of valsartan-containing medication.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Joseph I. Marchese