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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA
FRESNO DIVISION

JOHN JUDSON AND JO ANN HAMEL, on behalf of themselves and others similarly situated,

Plaintiffs,

v.

PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC;

-and-

SOLCO HEALTHCARE U.S., LLC;

-and-

HUAHAI US INC.;

-and-

TEVA PHARMACEUTICAL INDUSTRIES, LTD.;

-and-

TEVA PHARMACEUTICALS USA, INC., a Delaware corporation,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

1. VIOLATIONS OF CAL. CIV. CODE §§ 1750, ET SEQ.
2. COMMON LAW FRAUD, INCLUDING FRAUDULENT INDUCMENT, AND FRAUDULENT CONCEALMENT
3. VIOLATIONS OF CAL. CIV. CODE §§ 1709, 1710
4. VIOLATIONS OF CAL. CIV. CODE §§ 1792 & 1791.1(a), ET SEQ. (implied warranty of merchantability)
5. VIOLATIONS OF CAL. CIV. CODE §§ 1792.1 & 1791.1(b), ET SEQ. (implied warranty of fitness)
6. COMMON LAW IMPLIED WARRANTY OF MERCHANTABILITY
7. COMMON LAW IMPLIED WARRANTY OF FITNESS
8. VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.(unfair and fraudulent prongs)
9. VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.(unlawful prong)

JURY TRIAL DEMANDED

This is a putative class action on behalf of Plaintiffs John Judson and Jo Ann Hamel ("Plaintiffs") and a nationwide Class and California Subclass of all similarly situated individuals against Defendants Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC and Solco Healthcare U.S., LLC (together "Solco"), Huahai US Inc. ("Huahai US"), and Teva Pharmaceutical Industries, Ltd. ("Teva Pharmaceutical") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (together "Teva"). Upon the investigation of counsel and, where so alleged, upon information and belief, Plaintiffs allege as follows:

I. NATURE OF THE CASE

1. Plaintiffs bring this nationwide and California class action individually and on behalf of the Class and Subclass defined below of hundreds of thousands of consumers who paid

for Defendants' generic Valsartan ("Valsartan") that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA").

2. At all times during the period alleged herein, Defendants represented and warranted to consumers that their Valsartan products were therapeutically equivalent to and otherwise the same as brand Diovan®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at the Zhejiang Huahai Pharmaceuticals ("ZHP") manufacturing plant in China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA and/or other impurities.

4. These adulterated Valsartan drugs were introduced into the American market at least as far back as 2015 by Defendants who profited from their sale to American consumers, such as Plaintiffs and Class Members. However, evidence now suggests that the contamination dates back at least as far as 2012. Plaintiffs and Class Members paid for all or part of their Valsartan prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of and profit from these adulterated drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. JURISDICTION AND VENUE

5. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action. In addition, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

6. This Court has personal jurisdiction over Defendants because Defendants have

sufficient minimum contacts in California, and otherwise intentionally avails itself of the markets within California through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District, a substantial part of the property that is the subject of this action is situated in this District, and the Defendants are subject to personal jurisdiction in this District.

III. PARTIES

8. Plaintiff John Judson is a California resident. During the class period, Judson paid money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Judson that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Judson would not have paid for Defendants' Valsartan products.

9. Plaintiff Jo Ann Hamel is a California resident. During the class period, Hamel paid money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Hamel that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Hamel would not have paid for Defendants' Valsartan products.

10. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Prinston is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of California.

11. Defendant Solco Healthcare U.S., LLC ("Solco U.S.") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Solco is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Solco U.S. has been engaged in the manufacturing, sale, and distribution of adulterated generic

Valsartan in the United States, including in the State of California.

12. Defendant Huahai US Inc. ("Huahai US") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Huahai US is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of California.

13. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Pharmaceutical") is a foreign company incorporated and headquartered in Peta Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States including in California.

14. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical. Teva USA on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States including in California. Collectively, Teva Pharmaceutical and Teva USA are referred to as "Teva" herein.

IV. FACTUAL ALLEGATIONS

A. Valsartan Background

15. Valsartan is a potent, orally active nonpeptide tetrazole derivative which, when injested, causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

16. Valsartan is the generic version of the registered listed drug ("RLD") DIOVAN® ("Diovan"), which was marked in tablet form by Novartis AG ("Novartis") beginning in July 2001 upon approval by the U.S. Food and Drug Administration ("FDA").

17. Diovan® was an immensely popular drug. Globally, Diovan® generated $5.6 billion

in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States.

18. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product.

19. Although Novartis's Diovan® patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. The Generic Drug Approval Framework

20. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

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

22. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

23. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

24. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

25. And finally, a generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

26. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of their generic products.

27. According to the FDA, there are fifteen Abbreviated New Drug Applications ("ANDAs") approved for generic Diovan, *i.e.*, Valsartan.

C. Background on Current Good Manufacturing Practices ("cGMPs")

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

29. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: 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.

30. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacting laws adopting or mirroring these federal standards.

31. Per 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 continuing quality of the subcontractors' operations.

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

> (a) 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).

D. <u>The Zhejiang Huahai Pharmaceuticals ("ZHP") Manufacturing Facilities</u>

33. Zhejiang Huahai Pharmaceuticals ("ZHP") is a subsidiary of Huahai Pharmaceutical, which is also the corporate parent of Defendants Prinston, Huahai US, and Solco. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities is located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese

companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and European Union.

34. ZHP serves as a contract manufacturer of Defendants' Valsartan products (including Defendant Teva's Valsartan products), and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

35. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

36. On or about March 27-30, 2007, the FDA inspected ZHP's Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

37. On May 15-19, 2017, FDA again inspected ZHP's Linhai City facilities. That inspection resulted the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

38. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. These are disturbing signs of systematic data manipulation designed to intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

39. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and black metallic particles found in API batches.

E. Defendants Were Aware of Potential NDMA Contamination As Early As 2012

40. Upon information and belief, ZHP changed its Valsartan manufacturing processes in or about 2012, if not earlier.

41. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after Zhejiang Huahai introduced changes to its manufacturing process in 2012."[1]

42. NDMA is yellow, oily liquid with a faint, characteristic odor and a sweet taste, and is often produced as a by-product of industrial manufacturing processes.

43. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

44. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a "B2" rating, meaning that it is "probably carcinogenic to humans" with little or no human data.

45. Anecdotally, NDMA has also been used in intentional poisonings.[2]

46. Most assuredly, NDMA is not an FDA-approved ingredient for branded Diovan® or generic Valsartan. None of Defendants' Valsartan products (or any Valsartan product, for that matter) identifies NDMA as an ingredient on the products' labels or elsewhere.

47. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

48. 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:

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[1] *See* European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, *at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1 (last accessed Aug. 31, 2018).

[2] *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 Aug. 31, 2018).

> 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).

49. And as reproduced above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

50. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants and ZHP, the NDMA contamination in Defendants' Valsartan products would have been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their Valsartan products were adulterated as early as 2012.

51. However, there are indications that Defendants and ZHP had actual knowledge of Valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

52. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing" and routinely disregarded sampling anomalies suggestive of impurities.

53. These discoveries by the FDA's investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

54. Defendants were also specifically aware of the manufacturing issues at ZHP based on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's inspections of ZHP's facilities in March 2007 and May 2017.

55. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical, and Solco was specifically aware, or should be imputed with actual knowledge, of ZHP's willful deviations from cGMPs. Solco and Huahai US have

offices in the same office building in Cranbury, New Jersey.

56. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their Valsartan products only after the FDA had threatened an involuntary recall.

F. FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan

57. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their Valsartan products manufactured by ZHP.[3] The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' Valsartan manufactured 2012 and beyond was also contaminated with NDMA.

58. On or about July 27, 2018, the FDA announced expanded recalls of additional Valsartan products manufactured by Defendants and non-parties, and re-packaged by third parties.[4]

59. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. 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.

G. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

60. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

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[3] FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, *at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm (last accessed Aug. 31, 2018).

[4] FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, *at* https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Aug. 31, 2018).

61. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[5] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

62. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

63. By introducing their respective Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan® and with the FDA-approved label that is the same as that of Diovan, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with Diovan.

64. Furthermore, Defendant Solco states on its "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[6]

65. On the "Drug Safety" page of Solco's website, Solco states that "Solco Healthcare is committed in providing … its patients with high quality, FDA-approved generic medications."[7]

66. Defendant Solco lists its Valsartan products on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's Valsartan Prescribing Information.[8] Clicking the "Prescribing Information" link loads a .pdf of the Prescribing Information with a Solco URL address

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[5] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Aug. 31, 2018).

[6] Solco, OVERVIEW, *at* http://solcohealthcare.com/about-solco.html (last accessed Aug. 31, 2018).

[7] Solco, TRADE PARTNER INFORMATION, *at* http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Aug. 31, 2018).

[8] Solco, VALSARTAN TABLETS, *at* http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last accessed Aug. 31, 2018).

(http://www.solcohealthcare.com/uploads/product/info/valsartan-pi-artwork_170524_141555.pdf).

67. Defendant Teva has a "Generics FAQs" on its website.[9] In response to the question "Are generic drugs safe?" Defendant Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

68. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Defendant Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

69. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" through Teva's "impeccable adherence to … [cGMPs][.]"

70. Each Defendant's Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic manufacturers of Valsartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

71. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing or informational materials that their Valsartan product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

72. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan® and thus non-therapeutically

[9] Teva, PRODUCTS, *at* http://www.tevapharm.com/our_products/generic_qa/ (last accessed Aug. 31, 2018).

interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan®, and breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not contained in Diovan®, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

73. At all relevant times, Defendants have also impliedly warranted that their Valsartan products were merchantable and/or fit for their ordinary purposes.

74. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence of NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

75. For these and other reasons, Defendants' Valsartan is therefore adulterated and it was illegal for Defendants' to have introduced such Valsartan for sale and distribution in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

76. Adulterated Valsartan is essentially worthless. No consumer would knowingly purchase an adulterated Valsartan product. Indeed, the purchase of adulterated Valsartan product is not allowed because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

H. <u>New Revelations Continue to Unfold About Other Manufacturing Plants</u>

77. The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement

expanding the recall to other Valsartan products manufactured at another plant in India, and by other non-parties. *See supra* n.4. On August 20, 2018 the FDA announced that it was going to test all Valsartan products for NDMA.[10] Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

I. Fraudulent Concealment and Tolling

78. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products.

79. Alternatively, any statute of limitation or prescriptive period is equitably tolled Defendants' fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

80. For instance, no Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan® until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

81. To the contrary, each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

82. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[11]

83. Because of this, Plaintiffs and other Class Members did not discover, nor would they discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations,

[10] FDA Statement, STATEMENT FROM FDA COMMISSIONER, *at* http://freepdfhosting.com/1c7e5ed26e.pdf (last accessed Aug. 31, 2018).

[11] Huahai US, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, *at* https://www.huahaius.com/media.html (last accessed Aug. 31, 2018).

lulled Plaintiffs and Class Members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

84. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs 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, Plaintiffs were 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.

J. Plaintiffs' Factual Allegations

85. Plaintiff John Judson is a resident of Mountain House, California.

86. On or about May 14, 2018, Plaintiff Judson filled a 90-day prescription for Valsartan manufactured by the Solco Defendants and paid a co-pay. Upon information and belief, Plaintiff Judson filled addititional Valsaratn prescriptions during the Class Period manufactured by one or both of the Solco and Teva Defendants.

87. The generic Valsartan purchased by Plaintiff Judson manufactured by the Solco and/or Teva Defendants on May 14, 2018 and at other times during the Class Period was not therapeutically equivalent to brand Diovan®, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

88. The Solco Defendants and/or Teva Defendants' generic Valsartan was sold illegally to Plaintiff Judson.

89. Plaintiff Jo Ann Hamel is a resident of Merced, California.

90. On or about the following dates, Plaintiff Hamel purchased the Teva Defendants' generic Valsartan products and paid the listed co-pay amounts:

- March 17, 2014 ($10.60)
- June 17, 2014 ($12.33)
- February 7, 2015 ($10.59)
- March 13, 2015 ($28.78)
- May 15, 2015 ($28.78)
- September 2, 2015 ($28.78)
- November 30, 2015 ($25.20)
- February 5, 2016 ($22.26)
- April 15, 2016 ($22.26)
- July 27, 2016 ($22.32)
- October 26, 2016 ($21.65)
- February 13, 2017 ($22.04)

- May 25, 2017 ($26.61)
- August 22, 2017 ($26.61)
- November 16, 2017 ($21.40)
- February 12, 2018 ($21.40)
- April 16, 2018 ($7.88)
- May 21, 2018 ($7.88)
- July 10, 2018 ($21.40)

91. The generic Valsartan purchased by Plaintiff Hamel manufactured by the Solco and/or Teva Defendants during the Class Period was not therapeutically equivalent to brand Diovan®, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

92. The Solco Defendants and/or Teva Defendants' generic Valsartan was sold illegally to Plaintiff Hamel.

V. CLASS ACTION ALLEGATIONS

93. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of a Nationwide Class defined below:

> All individuals in the United States of America and its territories and possessions who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants.

94. In the alternative, Plaintiffs allege Sub-Classes for all individuals in each State, territory, or possession including specifically the State of California who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative California Sub-Class and other state sub-classes are referred to as the "Class."

95. Excluded from the Class and Sub-Class[es] are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

96. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create further sub-classes as the Court deems necessary.

97. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class and Sub-Class[es].

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

99. **Commonality**: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding Defendants' Valsartan products;

b. Whether each Defendant's Valsartan product was in fact the same as brand Diovan® consistent with such express or implied warranties;

c. Whether each Defendant's Valsartan product was contaminated with NDMA;

d. Whether each Defendant's Valsartan product containing NMDA was adulterated;

e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan products;

f. Whether each Defendant affirmatively misrepresented or omitted facts that its Valsartan product was the same as brand Diovan® and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs and/or was not adulterated;

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

i. Whether a common damages model can calculate damages on a classwide basis;

j. When Plaintiffs' and Class Members' causes of action have accrued;

k. Whether Defendants fraudulently concealed Plaintiffs' and Class Members' causes of action.

100. **Typicality**: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and

Class Members all suffered the same type of economic harm. Plaintiffs have 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 all other Class Members.

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

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

103. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, 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 is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' 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.

COUNT I
VIOLATION OF CALIFORNIA CONSUMER LEGAL REMEDIES ACT
CAL. CIV. CODE §§ 1750, *et seq.*
(On Behalf of Plaintiffs and the Class(es))

104. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

105. Plaintiffs have standing to pursue this claim as Plaintiffs have suffered injury in fact and lost money or property as a result of Defendants' actions.

106. At all times relevant hereto, Defendants were and are "persons" as defined in Cal. Civ. Code § 1761(d).

107. At all times relevant hereto, Plaintiffs and each Class Member were and are "consumers" as defined in Cal. Civ. Code § 1761(d).

108. At all times relevant hereto, Defendants' Valsartan products constitute "goods" as defined in Cal. Civ. Code § 1761(a).

109. At all times relevant hereto, Defendants' sales of their Valsartan products to Plaintiffs and members of the Class, constitute "transactions" as defined in Civil Code § 1761(e).

110. The following subsections of Cal. Civ. Code § 1770(a) prohibit the following unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction which is intended to result or which results in the sale or lease of goods or services to any consumer:

> (2) Misrepresenting the source, sponsorship, approval, or certification of goods or services;
>
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have;
>
> (7) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

(9) Advertising goods or services with intent not to sell them as advertised;

(16) Representing that the subject of a transaction has been supplied in accordance with a previous representation when it has not.

111. Defendants have violated and continue to violate the above-enumerated provisions of Cal. Civ. Code. § 1770(a) by representing that their generic Valsartan products are the same as brand Diovan®; and that their generic Valsartan products were distributed "as approved" by the FDA. Defendants distributed their generic Valsartan products with the intent not to sell as advertised (i.e., the same as brand Diovan).

112. Defendants have violated and continues to violate the above-enumerated provisions of Cal. Civ. Code. § 1770(a) by making fraudulent omissions that were contrary to representations actually made by Defendant; and, fraudulently omitting material facts Defendant was obliged to disclose.

113. To the extent necessary, Plaintiffs and Class Members relied on such omissions.

114. Plaintiffs will file the declaration of venue required by Cal. Civ. C. § 1780(d).

115. Pursuant to Cal. Civ. Code § 1780(a), Plaintiffs currently seek restitution and an order enjoining Defendants from engaging in the methods, acts, and practices alleged herein, and any other relief deemed proper by the Court.

116. Either before or concurrent with filing the Complaint, Plaintiffs have sent or are sending Defendants notice advising Defendants of their violations of Section 1770 of the CLRA (the "Notice"). The Notice complied in all respects with Section 1782 of the CLRA. Plaintiffs sent the Notice by Certified U.S. Mail, return-receipt requested to Defendants at Defendants' principal places of business. Plaintiffs' Notice advised Defendants they must correct, repair, replace or otherwise rectify its conduct alleged to be in violation of Section 1770. If Defendants fail to correct, repair, replace or otherwise rectify the conduct alleged herein, Plaintiffs will amend this Complaint to seek damages.

117. Pursuant to Cal. Civ. Code § 1780(e), Plaintiffs seek an award of restitution, costs and attorney's fees.

COUNT II
COMMON LAW FRAUD, INCLUDING FRAUDULENT INDUCEMENT, AND FRAUDULENT CONCEALMENT
(*On Behalf of Plaintiffs and the Class(es)*)

118. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

119. Defendants made or caused to be made false and fraudulent representations of material facts, and failed to disclose material facts, to Plaintiffs and all Class Members regarding Defendants' Valsartan products.

120. Defendants affirmatively misrepresented material facts including, *inter alia*, that their Valsartan products were therapeutically equivalent to brand Diovan® and/or complied with cGMPs and/or were not adulterated.

121. Defendants failed to disclose material facts to render non-misleading its statements about, *inter alia*, that their Valsartan products were not therapeutically equivalent to brand Diovan® and/or did not comply with cGMPs and/or were adulterated.

122. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' Valsartan product – product which Defendants knew or should have known was not therapeutically equivalent to brand Diovan® and/or did not comply with GMPs and/or were adulterated. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' Valsartan product had they known the truth.

123. Defendants 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.

124. Defendants 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 Defendants' Valsartan products.

125. Defendants' misrepresentations and omissions were material.

126. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' Valsartan product.

127. But for these misrepresentations and omissions, Plaintiffs and other Class Members would not have paid for Defendants' Valsartan product.

128. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' 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 Defendants' Valsartan product but-for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

129. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

COUNT III
VIOLATION OF CAL. CIV. CODE §§ 1709, 1710
(Deceit by Concealment)
(*On Behalf of Plaintiffs and the Class(es)*)

130. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

131. Defendants engaged in deceit by suppressing facts that each was bound to disclose. Namely, Defendants sold their generic Valsartan products to Plaintiffs and the Class and did not disclose the fact that their generic Valsartan products were not the same as brand Diovan®, and were in fact adulterated with NDMA and manufactured not in compliance with cGMPs.

132. Defendants' deceitful conduct was perpetrated with the intent to induce Plaintiffs and Class Members to act in reliance thereon.

133. Plaintiffs and Class Members reasonably believed Defendants' representations that their Valsartan products were therapeutically equivalent and interchangeable with brand Diovan®.

134. Plaintiffs and Class Members would not have purchased Defendants' Valsartan products if the deceit had been disclosed.

135. As a direct and proximate result of the foregoing acts, omissions, Plaintiffs and Class Members have suffered injury in fact and are entitled to restitution in an amount to be

determined at trial.

COUNT IV
VIOLATION OF SONG-BEVERLY CONSUMER WARRANTY ACT FOR BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY, CAL. CIV. CODE §§ 1792 & 1791.1(a)
(On Behalf of Plaintiffs and the Class(es))

136. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

137. Plaintiffs and Class Members are "retail buyers" within the meaning of §1791(b) of the California Civil Code.

138. Defendants' Valsartan products are "consumer goods" within the meaning of §1791(a) of the California Civil Code.

139. Each Defendant is a "distributor", "manufacturer", and/or "retailer" of generic Valsartan products within the meaning of §1791(e), (j), and (l) of the California Civil Code.

140. Defendants impliedly warranted to Plaintiffs and Class Members that their Valsartan products were "merchantable" within the meaning of §§ 1791.1(a) and 1792 of the California Civil Code.

141. Defendants breached the implied warranty of merchantability to Plaintiffs and Class Members because Defendants' Valsartan products were not manufactured in accordance with Defendants' approved ANDA, and were not the same as brand Diovan®, and because Defendants' Valsartan products were adulterated with NDMA and manufactured not in compliance with cGMPs. All of these failures resulted in Defendants' Valsartan products being illegally distributed in the United States, rendering them non-merchantable.

142. Defendants' failure to warn Plaintiffs and Class Members of these risks was willful.

143. As a proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and Class Members sustained damages including but not limited to the receipt of goods they would not have otherwise purchased and which are not fit for the ordinary purpose for which they are used.

144. Pursuant to §§ 1791.1(d) and 1794 of the California Civil Code, Plaintiff Judson and

Hamel and Subclass Members seek and are entitled to restitution, civil penalties and other legal and equitable relief including, a right of reimbursement, as well as costs, expenses and attorneys' fees. Plaintiffs will amend this complaint to seek damages.

COUNT V
VIOLATION OF SONG-BEVERLY CONSUMER WARRANTY ACT FOR BREACH OF IMPLIED WARRANTY OF FITNESS, CAL. CIV. CODE §§ 1792.1 & 1791.1(b)
(On Behalf of Plaintiffs and the Class(es))

145. Plaintiffs re-alleges and incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

146. Plaintiffs and Class Members are "retail buyers" within the meaning of §1791(b) of the California Civil Code.

147. Defendants' Valsartan products are "consumer goods" within the meaning of §1791(a) of the California Civil Code.

148. Each Defendant is a "distributor", "manufacturer", and/or "retailer" of Valsartan products within the meaning of §1791(e), (j), and (l) of the California Civil Code.

149. Defendants breached the implied warranty of merchantability to Plaintiffs and Class Members because Defendants' Valsartan products were not manufactured in accordance with Defendants' approved ANDA, and were not the same as brand Diovan®, and because Defendants' Valsartan products were adulterated with NDMA and manufactured not in compliance with cGMPs. All of these failures resulted in Defendants' Valsartan products being illegally distributed in the United States, rendering them non-merchantable.

150. Plaintiffs and Class Members did in fact purchase Defendants' Valsartan products for the particular purpose of consuming a generic version of the brand drug Diovan® as approved by the FDA's ANDA process.

151. Plaintiffs and Class Members did in fact reasonably rely on Defendants' skill or judgment to supply suitable pharmaceutical products for that purpose.

152. Defendants breached their implied warranty of fitness for a particular purpose and are liable to Plaintiffs and Class Members.

153. Defendants' failure to warn Plaintiffs and Class Members was willful.

154. As a proximate result of Defendants' breach of the implied warranty of fitness, Plaintiffs and Class Members sustained damages including but not limited to the receipt of goods they would not have otherwise purchased and which are not fit for the ordinary purpose for which they are used.

155. Pursuant to §§ 1791.1(d) and 1794 of the California Civil Code, Plaintiffs and Class Members are entitled to and hereby seek restitution, civil penalties and other legal and equitable relief including, a right of reimbursement, as well as costs, expenses and attorneys' fees. Plaintiffs will amend this complaint to seek damages.

COUNT VI
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf of Plaintiffs and the Class(es))

156. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

157. Defendants are merchants within the meaning of Cal. Comm. Code § 2314.

158. Each Defendant's Valsartan product constituted "goods" or the equivalent within the meaning of the above statute and related provisions.

159. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

160. Each Defendant knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan®, and impliedly warranted that same was of merchantable quality and fit for that purpose.

161. Each Defendant breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

162. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'

Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

163. Plaintiffs are concurrently giving notice of Defendants' breach. Plaintiffs will amend this complaint to seek damages in an amount to be determined at trial.

COUNT VII
BREACH OF EXPRESS WARRANTIES
(On Behalf of Plaintiffs and the Class(es))

164. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

165. Each Defendant expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Diovan®. In other words, Defendants expressly warranted that their products were the same as Diovan®.

166. Each Defendant sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

167. Each Defendant's Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

168. Each Defendant made express warranties regarding its Valsartan products as set forth in Cal. Comm. Code § 2313.

169. At the time that each Defendant marketed and sold its Valsartan product, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members.

170. Each Defendant breached its express warranties with respect to its Valsartan product as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated.

171. As a direct and proximate result of each Defendant's breach of implied warranty,

Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

172. Plaintiffs are concurrently giving notice of Defendant's breach. If the violations are not remedied or cured, Plaintiffs will amend this complaint to seek damages in an amount to be determined at trial.

COUNT VIII
VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW
CAL. BUS. & PROF. CODE § 17200, *et seq.*
("unfair" and "fraudulent" prongs)
(On Behalf of Plaintiffs and the Class(es))

173. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

174. California Business & Professions Code section 17200 prohibits "unfair competition" which includes "unfair" and "fraudulent" business practices.

175. Defendants engaged in unfair and fraudulent business practices by advertising, marketing, and selling Valsartan products as therapeutically equivalent to and interchangeable with brand Diovan® when that was not true.

176. Defendants engaged in unfair and fraudulent business practices by advertising, marketing, and selling Valsartan products representing that their Valsartan was manufactured in accordance with their respective ANDA approvals and in compliance with FDA's cGMPs. However, this was factually untrue because Defendants' Valsartan products were contaminated with NDMA and were not manufactured in accordance with cGMPs.

177. Defendants' business practices, as alleged herein, are unfair because: (1) the injury to the consumer is substantial—they were charged significant sums for products that are contaminated with a probable human carcinogen that was illegally distributed to them and which they cannot use for their intended purpose; (2) the injury is not outweighed by any countervailing benefits to consumers or competition, as there can be no benefit to consumers where they pay for a product that is illegally manufactured and distributed to them and which is contaminated with a probable human carcinogen; and (3) consumers could not reasonably have avoided the injury.

178. Defendants' business practices are also unfair because their materially false and misleading advertising, marketing, promotion, and sale of their Valsartan products (namely, representing they were the same as brand Diovan® and therapeutically interchangeable with brand Diovan®) offends an established public policy and is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers. Such public policy is tethered to a specific constitutional, statutory provision, including California's consumer protection statutes, as alleged herein.

179. Defendants' business practices as alleged herein are fraudulent because Defendants make and have made material misrepresentations and omissions in the marketing, promotion, and sale of their Valsartan products. These misrepresentations and omissions by Defendants were material, in that a reasonable consumer would attach importance to whether Defendants' generic Valsartan products were therapeutically interchangeable with brand Diovan® and/or were free of adulteration with carcinogenic substances.

180. Defendants' conduct is likely to deceive reasonable consumers. Indeed, reasonable consumers would believe that the marketing, promotion, and sale of prescription drugs called "Valsartan" carries an express assurance that Defendants' products are in fact manufactured as approved by the FDA and are free of contamination and/or are therapeutically interchangeable with brand Diovan®.

181. Plaintiffs and Class Members relied on Defendants' misrepresentations and omissions of material facts. Had Defendants disclosed that their products were not manufactured in accordance with the FDA approved label and/or were contaminated with NDMA and/or were not therapeutically equivalent to brand Diovan, Plaintiffs and Class Members would not and could not have paid for the products.

182. Defendants' acts and practices were false, misleading, deceptive, and unfair to consumers, in violation of the California Unfair Competition Law.

183. As a direct and proximate result of Defendants' deceptive, fraudulent, and unfair practices, Plaintiffs and members of the Class have lost money and suffered injury in fact in an amount to be determined at trial.

184. Plaintiffs, on behalf of themselves and all others similarly situated, demand

judgment against the Defendant for restitution and injunctive relief.

COUNT IX
VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW
CAL. BUS. & PROF. CODE § 17200, *et seq.*
("unlawful" prong)
(On Behalf of Plaintiffs and the Class(es))

185. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as though set forth fully herein.

186. The actions of Defendant, as alleged herein, constitute illegal and unlawful practices committed in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*

187. Defendants have engaged in a scheme of introducing adulterated non-FDA approved Valsartan products into the U.S. market manufactured out of compliance with cGMPs and which are not therapeutically equialent to brand Diovan. In undertaking these actions, Defendants are violating the law, including the common law and violations of: (1) Cal. Civ. Code §§ 1770(a)(2), 1770(a)(5), and 1770(a)(9); (2) Cal. Civ. Code §§ 1709 & 1710; (3) Cal. Civ. Code §§ 1791 & 17922; and Cal. Bus. & Prof. Code § 17200 et seq.

188. Pursuant to Cal. Bus. & Prof. Code § 17203, Plaintiffs and Class Members seek an order of this Court enjoining Defendants from engaging in the unfair competition alleged herein in connection with advertising, marketing, promoting, and selling products based upon misrepresentations and omissions of material facts, as alleged in greater detail above.

189. Additionally, Plaintiffs request an order awarding Plaintiffs and the Class restitution of the money wrongfully acquired by Defendants by means of the unfair competition alleged herein.

190. As a direct and proximate result of Defendants' deceptive, fraudulent, and unfair practices, Plaintiffs and members of the Class have lost money and suffered injury in fact in an amount to be determined at trial.

191. Plaintiffs, on behalf of themselves and all others similarly situated, demand judgment against the Defendant for restitution and injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and on behalf of the members of the Class defined herein, pray for relief and judgment on all Counts of the Complaint and request the following:

A. An order certifying the action may be maintained as a class action and appointing Plaintiffs as the Class Representatives and their counsel as Class Counsel;

B. For restitution on behalf of Plaintiffs and all Class Members;

C. Imposition of a constructive trust upon all monies and assets Defendants have acquired as a result of unfair practices;

D. For all appropriate declarative and injunctive relief, enjoining Defendant from pursuing and/or continuing the unlawful conduct complained in herein;

E. For an order declaring and/or a judicial determination of the respective rights and duties of Plaintiffs, the Class and Defendants with respect to whether Defendants violated Cal Civ. C. §§ 1750, *et seq.*, Cal. Civ. Code §§ 1709, 1710, Cal. Civ. Code §§ 1791, 1792, Cal. Bus. & Prof. C. §§ 17200, *et seq*., and the common law;

F. For attorneys' fees and reimbursement of all costs for the prosecution of this action;

G. For pre-judgment and post-judgment interest; and,

H. For such other and further relief this Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand a trial by jury on all issues within the instant action so triable.

Dated: October 11, 2018

/s/ Allan Kanner
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JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

John Judson & Jo Ann Hamel

(b) County of Residence of First Listed Plaintiff San Joaquin
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Allan Kanner; Conlee S. Whiteley; Layne Hilton; Michael L. Slack; John R. Davis; Ruben Honik; David Stanoch (see complaint for contact information)

DEFENDANTS

Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC; Solco Healthcare U.S., LLC; Huahai US Inc.; Teva Pharmaceutical Industries

County of Residence of First Listed Defendant Middlesex Cnty, New Jersey
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
n/a

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332(d)

Brief description of cause:
Proposed Class Action for breach of warranties and violation of consumer protection statutes

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/11/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Allan Kanner

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.