UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

MICHAEL PATRICK SLAVICH, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US, INC., PRINSTON PHARMACEUTICAL, INC., and SOLCO HEALTHCARE U.S., LLC, Defendants.	)	Civil Action No. _____ Section: _____

COMPLAINT AND JURY DEMAND

Complainant, MICHAEL PATRICK SLAVICH, a resident of and domiciled in the State of Louisiana, Parish of St. Tammany, complaining of ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., a corporation organized and existing under the laws of the People's Republic of China, HUAHAI US, INC., a New Jersey corporation, authorized to do and doing business in the State of Louisiana and specifically within the Eastern District of Louisiana, PRINSTON PHARMACEUTICAL, INC., a Delaware corporation, authorized to and doing business in the State of Louisiana and specifically within the Eastern District of Louisiana, and SOLCO HEALTHCARE U.S., L.L.C., a Delaware limited liability company, authorized to and doing business in the State of Louisiana and specifically within the Eastern District of Louisiana, respectfully represents that:

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.§1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of Louisiana. As set forth more fully below, all defendants are entities organized in states other than the State of Louisiana, all Defendants have their principal place of business in a state other than the State of Louisiana, and none of the Defendants is a citizen or resident of the State of Louisiana.

2. This court has personal jurisdiction over Defendants because they conduct business in the State and/or are systematically and continuously conducting business in the State of Louisiana, including, but not limited to, the marketing, advertising, selling and distributing of drugs, including Valsartan, to the residents in this State and/or purposefully direct or directed their actions toward the State, they submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

3. Venue is proper in this District pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.

4. The Defendants marketed, advertised, promoted, sold and distributed the dangerous product in this District; Plaintiff was prescribed and administered adulterated Valsartan in this District; Plaintiff's injuries, harms, losses and damages occurred in this District; Defendants do substantial business in the State of Louisiana and within this

District; and all time relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, warranted and/or sold Valsartan in interstate commerce.

II. TAG ALONG ACTION

5. This is a potential tag-along action and, in accordance with 28 U.S.C. 1407, may be transferred by the Joint Panel in Multi-District Litigation ("JPML"), MDL No. 2875 – IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION, pending before the JPML.

III. PARTIES

6. Plaintiff, MICHAEL PATRICK SLAVICH, is a resident of and domiciled in the State of Louisiana, Parish of St. Tammany. During all relevant times, Plaintiff was prescribed and administered the drug Valsartan which is the subject of this litigation. The Valsartan (NDC #43547-369-09) prescribed and taken by Plaintiff was developed, manufactured, promoted, marketed, distributed and/or sold by defendants, Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US, Inc., Prinston Pharmaceutical, Inc., Solco Healthcare U.S., LLC.

7. Upon information and belief, the defendant, ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., ("Zhejiang") is a corporation organized and existing under the laws of the People's Republic of China, and it maintains its principal place of business as Xunqiao, Linhai, Zhejiang 317024, China. On information and belief, Zhejiang is the manufacturer of the prescription drug Valsartan, which is the subject of this litigation. The company touts on its website that: (a) Its "workshops of formulation are designed in strict compliance with the international cGMP standard..." and (b) It is it the "first pharmaceutical company in China that has passed USA FDA approval."

8. Defendant, HUAHAI US, INC., ("Huahai") is a corporation organized and existing under the laws of the State of New Jersey, and it maintains its principal place of

business at 2001 Eastpark Boulevard, Cranbury, New Jersey. On information and belief, Huahai conducts substantial business in the State of Louisiana and manufactures, markets and/or distributes Valsartan for use in generic drugs. On information and belief, and according to its website, Huahai is a wholly-owned subsidiary of Zhejiang focusing on the sales and marketing of active pharmaceutical ingredients ("APIs") and Intermediates and lists Valsartan as one of its products.

9. Defendant, PRINSTON PHARMACEUTICAL, INC., ("Prinston") is a corporation organized and existing under the laws of the State of Delaware, and it maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey. On information and belief, Prinston conducts substantial business in the state of Louisiana and manufactures, markets and/or distributes generic drugs, including the prescription drug Valsartan, by incorporating Valsartan manufactured in China by Zhejiang.

10. Defendant, SOLCO HEALTHCARE U.S., LLC, ("Solco") is a limited liability company organized under the laws of the State of Delaware, and it maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey. On information and belief, Solco is a fully owned subsidiary of Prinston Pharmaceuticals, Inc. and Zhejiang Huahai Pharmaceutical, L.L.C. On information and belief, Prinston is the sole member of Solco. According to Prinston's website, Solco is the U.S. sales and marketing division of Prinston. On information and belief, Solco conducts substantial business in the State of Louisiana by marketing and distributing generic drugs, including the prescription drug Valsartan, which is the subject matter of this litigation.

IV. FACTUAL ALLEGATIONS

11. Valsartan is a generic prescription drug mainly used to treat hypertension, high blood pressure and congestive heart failure. It was originally marketed and sold under the brand name Diovan.

12. Due to manufacturing defects, certain generic formulations of Valsartan have become adulterated with an organic chemical known as N- nitrosodimethylamine (more commonly known as and hereinafter referred to as "NDMA") a carcinogenic and liver-damaging impurity.

13. Plaintiff seeks to recover damages from the Defendants for developing, manufacturing, promoting, marketing, supplying, distributing and ultimately selling Valsartan to Plaintiff which was adulterated and defective because it contained NDMA, which rendered the Valsartan adulterated, unsafe, and dangerous for consumption by humans ("the Adulterated Valsartan").

14. 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.

15. The EPA classifies NDMA as a B2 (probable human) carcinogen, based on the induction of tumors in both rodents and non- rodent mammals exposed to NDMA by various routes. According to the EPA, in animal studies of various species including rats and mice, exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels. These potential symptoms of overexposure to NDMA include but are not limited to "enlarged liver, reduced function of liver, kidneys and lungs."

16. NDMA is listed as a "priority toxic pollutant" in federal regulations including the Clean Water Act. See 40 CFR § 131.36.

17. The U.S. Department of Health and Human Services states that NDMA is reasonably anticipated to be a human carcinogen (DHHS 2011). The American Conference of Governmental Industrial Hygienists has classified NDMA as a Group A3 confirmed animal carcinogen with unknown relevance to humans (ACG1H 2012).

18. The U.S. Food & Drug Administration ("FDA") is an agency within the U.S. Department of Health and Human Services. The FDA protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices.

19. On or about July 13, 2018, the FDA announced a voluntary recall of several brands of drugs containing Valsartan, including those manufactured, promoted, marketed, supplied, distributed and/or sold by Defendants ("the Recall").

20. The Adulterated Valsartan is composed of certain specific lots ("the Lots"). The FDA has issued a list of the Lots that are subject to the Recall. According to the Recall, the Lots of the Adulterated Valsartan identified on the Recall List contained NDMA.

21. Defendants manufactured, promoted, marketed, supplied, distributed and/or sold, respectively, the Lots of Adulterated Valsartan that are subject to the Recall.

22. Plaintiff purchased and ingested Adulterated Valsartan from the Lots subject to the Recall that were manufactured, promoted, marketed, supplied, distributed and/or sold by the Defendants.

23. Defendant, Zhejiang, manufactured and supplied the Valsartan used in the manufacture of the Adulterated Valsartan that is subject to the Recall.

24. In addition to the Recall in the United States, prescription drugs containing Valsartan have been recalled in approximately 21 other countries.

25. According to the FDA, numerous Valsartan-containing prescription medications are subject to the Recall.

26. Plaintiff was prescribed Valsartan by his primary care physician, in 2016 to treat hypertension.

27. Plaintiff purchased and filled his prescriptions for what, unbeknownst to him, was Adulterated Valsartan.

28. Pursuant to his prescription, Plaintiff consumed the Adulterated Valsartan on a daily basis.

29. On or about January 5, 2018, after ingesting Valsartan on a daily basis for over one year, Plaintiff was diagnosed with bladder cancer.

30. The Adulterated Valsartan purchased and consumed by Plaintiff was included in the Lots subject to the Recall on or about July 13, 2018. Prior to the recall, Plaintiff was never made aware that the Valsartan he was consuming on a daily basis was adulterated and contained the dangerous carcinogen, NDMA.

31. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications, including those manufactured and distributed by Defendants Solco and Prinston. The recall was due to the presence of NDMA in the recalled 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."

32. On or about July 17, 2018, the FDA determined that health professionals should know that: "The FDA has determined the recalled valsartan products pose an

unnecessary risk to patients. Therefore, FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition. If you have medication samples from these companies, quarantine the products and do not provide them to patients."

33. On or about July 17, 2018 according to Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research:

34. "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]

35. 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. The generic equivalent is supposed to be of equal quality and equal safety. Defendant, Solco, who is in the business of marketing and distributing generic pharmaceuticals, explains on its website:

> Generic pharmaceuticals are **identical (bioequivalent)** to the branded medications with regard to:
>
> - Intended use
> - Effectiveness
> - Dosage form
> - Strength
> - **Safety**
> - Route of administration
> - **Quality**

36. Solco's website further explains:

37. Our products are **manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements.** Solco is a fully owned subsidiary of Prinston Pharmaceuticals, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products. Together we strive to offer greater access to affordable medications that **you can trust.**

38. To the contrary, the Defendants' Adulterated Valsartan at issue in this matter is neither safe nor of "high quality." In fact, the European Medicines Agency explained in July of 2018 that "NDMA is an unexpected impurity that was not detected by routine tests carried out by Zhejiang Huahai," and that the change in the manufacturing process which led to the impurity was introduced in 2012 and is "believed to have produced NDMA as a side product." As such, this contamination likely existed for approximately six years without being detected.

39. On August 21, 2018, Huahai posted information on its website. According to that post, a review of manufacturing and optimization processes in early June 2018 resulted in the discovery of NDMA, an impurity, in its Valsartan. According to Huahai, NDMA is a carcinogen.

40. Huahai has publicly stated that it isolated its storage of Valsartan API on hand, suspended its further release and manufacture, and notified the FDA and other regulatory agencies of its findings.

41. Huahai also purportedly notified its customers and instructed them to suspend the further use of its Valsartan API. Huahai then initiated a voluntary recall and provided periodic updates to both regulatory agencies and customers.

42. At all times relevant herein, Defendants intended to and did convey to Plaintiff that its prescription drug Valsartan was of the quality necessary to be utilized for its intended purpose.

43. At all times relevant herein, Defendants were negligent in manufacturing, promoting, marketing, supplying, distributing and/or selling the Adulterated Valsartan as a prescription drug safe for consumption by Plaintiff because they failed to have adequate quality control procedures in place to determine that Valsartan API was adulterated.

44. As a result of failing to maintain appropriate quality control procedures, Defendants failed to detect NDMA in the Adulterated Valsartan.

45. Defendants made false and misleading representations and, prior to the Recall, failed to disclose to Plaintiff that the Adulterated Valsartan was contaminated with NDMA.

46. As a result of ingesting and consuming Adulterated Valsartan on a daily basis for over one year, Plaintiff was subjected and exposed to an increased risk of developing cancer and disease ultimately resulting in serious injuries, including but not limited to, the development of bladder cancer.

47. These injuries, including but not limited to the bladder cancer, required certain medicines, intense medical care and treatment, and resulted in Plaintiff experiencing excessive pain and suffering, mental anguish and anxiety, loss of enjoyment of lifestyle and psychological injuries.

48. The Adulterated Valsartan purchased by Plaintiff was not only dangerous but also worthless.

49. Plaintiff suffered serious economic damages when he purchased Adulterated Valsartan. Plaintiff would not have purchased the worthless Adulterated Valsartan from Defendants had he known that it was contaminated with NDMA.

50. Had Defendants disclosed to Plaintiff that the Adulterated Valsartan was contaminated with NDMA, would not have purchased the Adulterated Valsartan and would not have ingested the Adulterated Valsartan and been exposed to NDMA.

51. Plaintiff therefore maintains an action for the serious injuries and damages that he suffered as a result of the actions and inactions of the Defendants, including bladder cancer which resulted in pain and suffering, mental anguish and anxiety, loss of enjoyment of life, economic damages, loss of consortium, psychological and emotional injuries and all other elements of damages including punitive damages allowed under Louisiana law.

52. Plaintiff incurred substantial medical expenses related to the medications, medical care and treatment he received as a result of the injuries and damages he sustained from his daily consumption of the Adulterated Valsartan, including but not limited to his development of bladder cancer.

V. LEGAL CAUSES OF ACTION

COUNT I

Defect in Construction or Composition Under La. Rev. Stat. Ann. § 9:2800.55

53. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

54. At all times relevant, the Adulterated Valsartan was unreasonably dangerous in construction and/or composition because, at the time it left its manufacturer's control, the medication deviated in a material way from the

manufacturer's specifications or performance standard for the product or from otherwise identical products manufactured by the same manufacturer.

55. The deviation in the Adulterated Valsartan was that it contained NDMA, a carcinogen.

56. On information and belief, the NDMA impurity contained in the Defendants' medications was a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurity NDMA. NDMA was not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.

57. Due to the NDMA impurity, the product was not reasonably safe as marketed because NDMA is a known carcinogen and is damaging to the liver, and, according to the FDA, the level of NDMA in the effected medication far exceeded acceptable levels, warranting an immediate recall of the effected medication.

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

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

60. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic and non-economic damages, harms and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT II

Design Defect Under La. Rev. Stat. Ann. § 9:2800.56

61. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

62. At all times relevant, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Adulterated Valsartan as hereinabove described that was used by Plaintiff.

63. Adulterated Valsartan was expected to and did reach the usual consumers, handlers and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

64. At the time of Plaintiff's use of the Adulterated Valsartan, the Adulterated Valsartan was being used for the purposes and in a manner normally intended.

65. At those times, the Adulterated Valsartan was in an unsafe, defective and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff because it was adulterated and contaminated by NDMA, a carcinogen.

66. At all times relevant, Defendants knew or had reason to know that the Adulterated Valsartan was defective and unsafe, especially when used in the form and manner as provided by Defendants.

67. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

68. In creating the Adulterated Valsartan, Defendants created a product that was and is unreasonably dangerous for its normal, intended use, and a safer alternative design existed, namely properly manufactured Valsartan medication.

69. The Adulterated Valsartan designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached the intended users in the same defective and unreasonably dangerous conditions in which the Adulterated Valsartan was manufactured.

70. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product that created an unreasonable risk to the health of consumers, its intended users, and to Plaintiff in particular; and Defendants are therefore liable for the injuries and damages sustained by Plaintiff.

71. The Adulterated Valsartan designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Adulterated Valsartan and it was unreasonably dangerous, and it was more dangerous and posed risk greater than an ordinary consumer would expect.

72. Plaintiff could not, by the exercise of reasonable care, have discovered the Adulterated Valsartan's defects mentioned herein and perceived its danger.

73. Defendants' defective design, manufacturing defect and inadequate warnings of the Adulterated Valsartan were acts that amount to willful, wanton and/or reckless conduct by Defendants.

74. As a result of the foregoing acts and omissions, Defendants caused Plaintiff, to suffer severe injuries (including cancer) as well as economic and non-economic damages, harms and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT III

Inadequate Warning Under La. Rev. Stat. Ann. § 9:2800.57

75. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

76. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Adulterated Valsartan into the stream of commerce, and in the course of same, directly advertised or marketed Adulterated Valsartan to consumers or persons responsible for consumers, and therefore, had a duty to Plaintiff, to warn of risks associated with the use of the product, including, but not limited to, the risk of serious injury, development of cancer or other diseases and death.

77. Defendants had/have a duty to warn of adverse drug reactions and risks associated with drugs, including, but not limited to, cancer, disease and other injuries, which they knew or should have known can be caused by the use of Adulterated Valsartan and/or are associated with the use of Adulterated Valsartan.

78. The Adulterated Valsartan designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects and risks, including, but not limited to, the risk of severe injury and death, including cancer, disease and other injuries, associated with the use of Adulterated Valsartan. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and risks and, in particular, the risks of serious injury, cancer and death.

79. The Adulterated Valsartan was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, pharmaceutical and/or

scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks associated with its use, thereby rendering Defendants liable to the Plaintiff.

80. Defendants failed to provide adequate warnings to users, including Plaintiff of the increased risk of cancer associated with Adulterated Valsartan, although Defendants promoted the product.

81. The dangers of consuming Adulterated Valsartan, which Defendants failed to warn Plaintiff of, arose from a reasonably anticipated use of the Adulterated Valsartan.

82. Plaintiff's injuries and damages arose from a reasonably anticipated use of the Adulterated Valsartan as Plaintiff consumed the Adulterated Valsartan on a daily basis in accordance with his prescription.

83. Due to the inadequate warning regarding the serious risk of cancer, disease and other injuries, Adulterated Valsartan was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

84. Defendants' failure to adequately warn Plaintiff of the serious risk of severe injury and death, including but not limited to the risk of cancer and/or the increased risk of developing cancer and disease, prevented Plaintiff from correctly and fully evaluating the risks and benefits of the Adulterated Valsartan.

85. Had Plaintiff been adequately warned of the serious risk of severe injury and death, including but not limited to the risk of cancer and/or the increased risk of developing cancer and disease associated with Adulterated Valsartan, Plaintiff would not have taken Adulterated Valsartan.

86. As a direct and proximate result of Defendants' failure to warn of the severe risks associated with Adulterated Valsartan, Plaintiff suffered serious injuries, including but not limited to the development of cancer.

87. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries as well as economic and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT IV

Breach of Express Warranty Under La. Rev. Stat. Ann. § 9:2800.58

88. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

89. Defendants expressly warranted that the Adulterated Valsartan was safe and effective to members of the consuming public, including Plaintiff. Defendants, through their advertising, labeling, marketing and packaging, created an express warranty that the medication would be of the same "quality" and the "bioequivalent" of the name-brand medication, and that it would be "safe."

90. Plaintiff formed a contract with Defendants at the time Plaintiff purchased the contaminated valsartan medication. 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 Defendants.

91. 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. Plaintiff relied on the express warranty that their 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 Defendants.

92. Adulterated Valsartan does not conform to these express representations, because the Adulterated Valsartan is not safe and has numerous serious side effects and risks associated with consumption of it, including but not limited to the risk of cancer and/or the increased risk of developing cancer, disease and other injuries, many of which were not accurately warned about by Defendants.

93. As a direct and proximate result of the breach of these warranties, Plaintiff suffered severe injuries and damages.

94. Plaintiff relied on Defendants' express warranties. Furthermore, the express warranties represented by Defendants were relied upon and part of the basis for Plaintiff's use of the Adulterated Valsartan. Plaintiff would not have purchased the contaminated medication had he known the true nature of the contaminated medication's ingredients and what the contaminated medication contained (i.e., NDMA).

95. At the time of the making of express warranties, Defendants knew of the purpose for which Adulterated Valsartan was to be used, and warranted the contaminated medication to be in all respects safe, effective and proper for such use.

96. Defendants expressly represented to Plaintiff that the Adulterated Valsartan was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects and risks in excess of those risks associated with other similar medications, that the side effects and risks it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

97. Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that the Adulterated Valsartan was not safe and fit for the use intended, and, in fact, the Adulterated Valsartan produced serious injuries and risks to the users that were not accurately identified and represented by Defendants.

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

99. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

100. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries, as well as economic and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT V

Redhibition

101. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

102. Pursuant to Louisiana Civil code article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The Adulterated Valsartan, which was sold and promoted by Defendants, possesses a redhibitory defect because it is unreasonably dangerous, as described above, which renders the Adulterated Valsartan useless or so inconvenient that it must be presumed that Plaintiff would not have purchased the Valsartan had he known of the defects.

103. Pursuant to Louisiana Civil Code article 2520 et seq., Defendants, through their manufacturing, marketing, sales, and/or distribution of Adulterated Valsartan, warranted to Plaintiff that this Valsartan medication was free of redhibitory effects.

104. The Defendants were aware of the substantial risks of severe injury and death, including but not limited to cancer and/or increased risk of developing cancer and disease, associated with Adulterated Valsartan but failed to fully disclose those risks to Plaintiff.

105. In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of the Adulterated Valsartan, are deemed to be aware of its redhibitory defects.

106. Defendants owed a duty to Plaintiff, as a buyer of prescription Valsartan, that the medication would be free from redhibitory defects.

107. Plaintiff, as a purchaser of Adulterated Valsartan, had no knowledge of the defects and could not have discovered the defects. The redhibitory defects in the Adulterated Valsartan were neither known nor apparent to Plaintiff.

108. The risk of cancer and death from ingesting carcinogens contained within the Adulterated Valsartan to treat hypertension are redhibitory defects that rendered the Defendants' Adulterated Valsartan totally useless for its intended purposes.

109. Plaintiff would not have paid for the Adulterated Valsartan if he had known of its redhibitory defects. The characteristics of the Adulterated Valsartan rendered it unfit for its intended purposes.

110. Defendants had actual and/or constructive knowledge that the Adulterated Valsartan they manufactured, sold and/or distributed had redhibitory defects but omitted to inform Plaintiff of these defects.

111. Instead, Defendants falsely represented that Adulterated Valsartan was a safe and effective medication when Defendants knew or should have known that it was not.

112. The redhibitory defects existed at the time Plaintiff purchased and paid for the Adulterated Valsartan.

113. But for the Defendants' false representations and omissions about the ingredients of the Adulterated Valsartan, Plaintiff would not have purchased and paid for these prescriptions.

114. Defendants breached their warranty of rehibition which directly and proximately caused Plaintiff to suffer the damages alleged herein.

115. Defendants are liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff of a product unfit for its intended use.

116. Due to the redhibitory defects in the Adulterated Valsartan, Plaintiff is entitled to the return of purchase price paid for of the Adulterated Valsartan, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorney fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiff may be entitled.

117. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries as well as economic and non-economic damages, harm and losses,

including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT VI

Negligence and Negligent Misrepresentation

118. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

119. The Defendants supplied, manufactured, promoted, marketed, distributed and/or sold valsartan as a drug for consumption by Plaintiff.

120. The Defendants had a duty to exercise ordinary care to supply, manufacture, distribute and/or sell valsartan to Plaintiff that was not adulterated.

121. The Defendants breached their duty of care owed to Plaintiff by:

a. Supplying, manufacturing, promoting, marketing, distributing and/or selling Valsartan that was adulterated because it was contaminated by NDMA, a carcinogen;

b. Failing to maintain appropriate quality control procedures thereby allowing NDMA to contaminate Valsartan purchased and consumed by Plaintiff.

122. Defendants' breach of the duty of care proximately caused damage to Plaintiff by causing him to suffer serious injuries, including cancer.

123. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, promoting, selling, and distributing highly dangerous Adulterated Valsartan to Plaintiff.

124. Each Defendant had an obligation to exercise due care in manufacturing, marketing, promoting, selling and distributing highly dangerous Adulterated Valsartan to Plaintiff.

125. Each Defendant owed a duty to Plaintiff because his use and therefore the potential for injury was foreseeable.

126. As described above in allegations expressly incorporated herein, the Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous Adulterated Valsartan by failing to monitor for and report NDMA levels in their medications. Because the very purpose of these duties was to prevent the resulting harm — ingestion of dangerous impurities and carcinogens — the causal connection between the Defendants' breach of duties and misrepresentations and the ensuing harm to Plaintiff was entirely foreseeable.

127. On information and belief, the Defendants' breaches were a result of conduct that was willful, wanton, reckless, oppressive and/or fraudulent.

128. The Defendants' breaches of their duties and misrepresentations were the cause-in fact of Plaintiff's injuries.

129. The Defendants failed to disclose the material facts that, inter alia, they were not in compliance with the laws and regulations required of them to maintain a system to prevent and protect against lethal carcinogens and severe harm, and specifically monitor its operations. But for these material factual omission, the Defendants would not have been able to sell Adulterated Valsartan.

130. The Defendants' actions, inactions and/or omissions create a rebuttable presumption of negligence and negligent misrepresentations under Louisiana law.

131. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic (direct, incidental or consequential pecuniary losses) and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT VII

Gross Negligence

132. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

133. Defendants owed a duty of care to manufacture, distribute, and sell medications free from harmful defects and impurities.

134. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDMA, Adulterated Valsartan.

135. Defendants' conduct resulted in an extreme risk to Plaintiff.

136. Plaintiff was injured by ingesting the acutely toxic substance, NDMA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants.

137. Upon information and belief, the Defendants should have known of the extreme risk to Plaintiff but continued with their conduct anyway. As this defective presence of NDMA in Adulterated Valsartan traces back to 2012, with nearly six years between when the defect arose and any action was taken, Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

138. The Defendants' reckless and wanton conduct was more than just negligence, it amounts to gross negligence resulting from an extreme departure from the ordinary standard of care owed to Plaintiff.

139. The Defendants' conduct was so unreasonable and dangerous that it was highly probable that harm would result.

140. The Defendants' conduct amounted to a reckless disregard for the safety of its consumers as it created circumstances constituting an imminent or clear and present danger.

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

142. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic and non-economic damages, harms and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT VIII

Fraud and Fraudulent Concealment

143. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

144. Under Louisiana law, "Fraud is a misrepresentation or a suppression of the truth made with the intention either to obtain an unjust advantage for one party or to cause a loss or inconvenience to the other. Fraud may also result from silence or inaction." La. Civ. Code art. 1953.

145. Defendants had a duty to disclose material facts to Plaintiff given their relationship as contracting parties and Plaintiff as intended user of the medication. Defendants also had a duty to disclose material facts to Plaintiff, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medication unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

146. Defendants possessed knowledge of these material facts. 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 in July 2018. During that time, Plaintiff was using the medication without knowing it contained the harmful impurity NDMA.

147. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information which made statements by the Defendants knowingly false. The Defendants acted intentionally and/or unlawfully.

148. These false representations and concealments were reasonably calculated to deceive Plaintiff and did in fact deceive Plaintiff.

149. In so failing to disclose these material facts to Plaintiff, Defendants intended to hide from Plaintiff and the consuming public 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.

150. Plaintiff 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. Plaintiff justifiably relied on the Defendants' representations and/or concealments, both directly and indirectly. His injuries were directly and proximately caused by this reliance.

151. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff suffered serious injuries and damages including but not limited to development of cancer, medical expenses associated with treatment for the injuries and cancer, money paid for the worthless Adulterated Valsartan, pain and suffering, emotional distress, mental anguish and anxiety and loss of enjoyment of life. Plaintiff seeks all legal and

equitable relief as allowed by law, including but not limited to all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT IX

Unjust Enrichment

152. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

153. Plaintiff conferred a benefit on Defendants by purchasing the Valsartan, which was worthless, adulterated, dangerous, and contained NDMA, a carcinogen.

154. Defendants voluntarily accepted and retained this benefit.

155. 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.

156. It is inequitable and unjust for Defendants to retain the revenues obtained from purchases of the Adulterated Valsartan by Plaintiff because Defendants misrepresented the qualities of the Adulterated Valsartan and the Adulterated Valsartan could not be used in the manner represented by Defendants.

157. Accordingly, because Defendants will be unjustly enriched if they are allowed to retain such funds, Defendants must pay restitution to Plaintiff in the amount which Defendants were unjustly enriched by each purchase of the Adulterated Valsartan.

COUNT X

Battery

158. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

159. Defendants manufactured, distributed, and sold the Adulterated Valsartan to Plaintiff with the knowledge and intent that Plaintiff and the consuming public would ingest the medication. Defendants thus had knowledge that the harmful medication would come into contact the bodies of Plaintiff.

160. The intended contact, i.e. the medication being ingested by Plaintiff, was harmful in nature because the medication contained the harmful impurity NDMA.

161. As such, Defendants committed an unlawful battery on Plaintiff who ingested the medication.

162. Plaintiff was unaware of the substantial health and safety risk inherent in the use of Adulterated Valsartan and did not consent to the exposure of NDMA into his body.

163. As a direct and proximate result of Defendants' wrongful acts set forth herein, Plaintiff was exposed to NDMA, intentionally causing harmful contact with Plaintiff. As a direct and proximate result of this unwanted harmful contact, Plaintiff suffered grievous bodily injury, requiring extensive medical treatment, have incurred and in the future will incur substantial medical bills and have suffered and will in the future suffer inconvenience and severe mental anguish.

164. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological

injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT XI

Breach of Contract

165. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

166. Plaintiff formed a contract with the Defendants at the time he purchased the Adulterated Valsartan medication.

167. The terms of the contract include the promises and affirmations of fact in the advertising, and on the packaging and labeling for the medicine, including that the valsartan would not contain harmful and carcinogenic impurities such as NDMA. Defendants represented that the valsartan was safe. The promises and affirmations of fact became part of the basis of the bargain and are a part of the contract between Plaintiff and the Defendants.

168. Defendants also represented that the Adulterated Valsartan was safe, efficacious and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects without warning, and that it was adequately tested.

169. Plaintiff relied on Defendants' representations that their valsartan was safe and therefore would not contain harmful and carcinogenic impurities such as NDMA.

170. Plaintiff performed all conditions precedent pursuant to his contract with Defendants.

171. Defendants breached the contract because the Valsartan was adulterated and contaminated with the carcinogen NDMA.

172. Plaintiff would not have purchased the Valsartan if he had known that it was adulterated and contaminated with the carcinogen NDMA.

173. Plaintiff has been damaged in the amount of the purchase price of the Adulterated Valsartan and consequential economic damages, including incidental medical expenses, resulting therefrom.

174. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer) as well as economic and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT XII

Breach of Implied Warranty of Merchantability

175. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

176. Defendants as the designers, marketers, promoters, manufacturers, distributors and/or sellers of the Valsartan impliedly warranted that the Valsartan purchased by Plaintiff was safe for human consumption, that the Valsartan was not adulterated, and that the Valsartan did not contain NDMA, a carcinogen.

177. Defendants breached the warranty implied in the contract for the sale of the valsartan because the Adulterated Valsartan could not pass without objection in the trade under the contract description, it was not of the quality described, and it was unfit for its intended and ordinary purpose because it was adulterated and contaminated with the toxic and carcinogenic NDMA, and therefore unfit for human consumption. As a result, Plaintiff did not receive the valsartan as impliedly warranted by the Defendants to be merchantable.

178. Plaintiff purchased the Adulterated Valsartan in reliance on the Defendants' implied warranties of fitness for a particular purpose.

179. Plaintiff did not alter the Adulterated Valsartan.

180. The Adulterated Valsartan was defective when it left the exclusive control of the Defendants.

181. Defendants knew that the Adulterated Valsartan would be purchased and used without additional testing by Plaintiff.

182. The Adulterated Valsartan was defectively manufactured and unfit for its intended purpose, and Plaintiff did not receive the Adulterated Valsartan as warranted.

183. As a direct and proximate result of the Defendants' breach of the implied warranty, Plaintiff has been harmed and injured because (a) he would not have purchased the Adulterated Valsartan containing the carcinogen NDMA if he had known that such valsartan was adulterated and contained a carcinogen; (b) the Adulterated Valsartan does not have the characteristics, ingredients, uses, or benefits as promised by the Defendants; (c) the Adulterated Valsartan has never been tested for human consumption; (d) the Adulterated Valsartan has never been tested for efficacy; and (e) the Adulterated Valsartan is worthless.

184. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic and non-economic damages, harms and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT XIII

Failure to Warn

185. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

186. Defendants violated a duty of care by failing to report known risks associated with the consumption of the Adulterated Valsartan.

187. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his physicians, of the true risks of the Adulterated Valsartan, including the risks associated with the consumption of NDMA, a carcinogen.

188. Defendants provided high risk and unreasonably dangerous contaminated drug, Adulterated Valsartan, to patients, including Plaintiff, in the place of safe, medically acceptable medication.

189. Defendants' conduct was reckless. Defendants risked the lives and health of consumers, including Plaintiff, based on the suppression of knowledge relating to the safety and efficacy problems associated with the Adulterated Valsartan.

190. Upon information and belief, Defendants made a conscious decision not to notify the FDA, healthcare professionals, and the public, thereby putting increased profits over the public safety, including the safety of Plaintiff. Further, as this defective condition dates back to approximately 2012, with approximately six years between when the defect arose and any action taken, Defendants' conduct evinces a complete indifference and/or reckless disregard for the rights and safety of others, including Plaintiff, and as such, Defendants' reckless actions and omissions as alleged herein demonstrate an utter disregard for human safety, warranting the imposition of punitive damages to deter this conduct by others.

191. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer severe injuries (including cancer), as well as economic and non-economic damages, harm and losses, including, but not limited to: medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

COUNT XIV

Conversion

192. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

193. Defendants have wrongly asserted dominion over the payments illegally and wrongfully diverted to them from Plaintiff for the contaminated medication (Adulterated Valsartan). Defendants have done so every time that Plaintiff paid to have his prescription filled.

194. As a direct and proximate cause of Defendants' conversion, Plaintiff has suffered damages in the amount of the payment made for each time that Plaintiff filled his prescription for Valsartan.

COUNT XV

Violation of Louisiana Unfair Trade Practices Act

195. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

196. The actions and inactions of the Defendants named herein constitute unfair and deceptive trade practices under La. R.S. 51:1405, et seq.

197. Under the Louisiana Unfair Trade Practices Act, "unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." La. Rev. Stat. Ann. § 51:1405.

198. The Defendants committed repeated and willful unfair or deceptive acts or practices in the conduct of commerce.

199. Specifically, the Defendants were aware of and/or should have been aware of the dangerous risks (including the risk of developing cancer, disease and other serious injuries) associated with the Adulterated Valsartan that they promoted, marketed, distributed and sold to Plaintiff yet Defendants failed to remedy or warn of the defect in the Adulterated Valsartan.

200. 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, were and are directed to consumers.

201. Because of the dangerous carcinogens contained within the Adulterated Valsartan, the Defendants' marketing, sales, and/or distribution practices unlawfully caused countless citizens, including Plaintiff, to ingest carcinogens, significantly increasing their likelihood of developing life-threatening cancer.

202. Plaintiff has been injured because: (a) He would not have purchased the contaminated valsartan-containing medication if he had known that the medications contained liver-toxic and carcinogenic NDMA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDMA.

203. Plaintiff seeks and is entitled to all available damages under the Louisiana Unfair Trade Practices Act and simultaneously with the filing of this Complaint is

sending a copy of same to the Louisiana Attorney General's Office pursuant to La. R.S. 51:1409.

204. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur; serious physical injury and disability, including the development of cancer, pain, suffering, emotional distress, loss of enjoyment of life, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, and other economic damages for which Defendants are liable.

V. PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

WHEREFORE, Plaintiff prays for relief against all defendants, as follows:

a. Compensatory damages, in in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;

b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, and

pain and suffering.

c. Exemplary damages

d. Punitive damages as allowed by law;

e. Attorneys' fees, expenses, and costs of this action;

f. Pre and post-judgment interest in the maximum amount allowed by law; and

g. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: January 4, 2019

Respectfully submitted,

/s/ Paige Boldt
Paige Boldt
TX State Bar No. 24082626
David McLendon
LA State Bar No 298626
Shelly A. Sanford
TX State Bar No. 00784904
Mikal C. Watts
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ATTORNEYS FOR PLAINTIFF

JS 44 (Rev. 06/17)

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

MICHAEL PATRICK SLAVICH

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Paige N. Boldt, Watts Guerra LLP
5726 W. Hausman Rd., Suite 119, San Antonio, Texas 78249
(210) 448-0500

DEFENDANTS

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US, INC., PRINSTON PHARMACEUTICAL, INC., and SOLCO HEALTHCARE U.S., LLC

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

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

Attorneys *(If Known)*

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
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 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 U.S.C. Sec. 1332

Brief description of cause:
Personal Injuries due to defective product

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
January 4, 2019

SIGNATURE OF ATTORNEY OF RECORD
/s/ Paige Boldt

FOR OFFICE USE ONLY

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

JS 44 Reverse (Rev. 06/17)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

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.