UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

Maxine Fisher, Plaintiff, VS. TAKEDA PHARMACEUTICALS U.S.A. INC., and TAKEDA PHARMACEUTICALS AMERICA, INC.; Defendants.	Case No.1:20-cv-4124 **COMPLAINT** **JURY TRIAL DEMANDED**

COMES NOW THE PLAINTIFF, Maxine Fisher ("Plaintiff"), and by and for his/her Complaint against Defendants, states and alleges upon information and belief and based upon the investigation of counsel, as follows:

INTRODUCTION

This is a personal injury action for damages arising from Plaintiff's use of Defendants' (Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively "Defendants")) dangerously defective prescription drug, Uloric, prescribed for the treatment of gout. Defendants designed, marketed, and distributed Uloric in the United States, all the while knowing significant risks that were never disclosed to the medical and healthcare community, including Plaintiff's prescribing doctor, Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff, and/or the public in general. Further, Defendants failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

Throughout the time Defendants marketed Uloric, Defendants withheld material adverse events from the public, medical community and FDA. Defendants failed to disclose the serious link between Uloric use and "Major Adverse Cardiovascular Events" ("MACE") which ultimately culminated in a mandatory FDA imposed "Black Box" Warning. Ultimately, tens of thousands of patients, including Plaintiff, were placed at risk and harmed as a result of this misleading conduct.

PARTIES

1. At all times relevant hereto, Plaintiff Maxine Fisher was a citizen and resident of Saline County, in the State of Arkansas.

2. Upon information and belief, Plaintiff consumed and regularly used Defendants' Uloric® (febuxostat) product. As a result of his use of Defendants' Uloric product, Plaintiff suffered from severe physical and emotional injuries, including but not limited to a Stroke. Based on information and belief, Plaintiff's ingestion of Uloric caused his injuries.

3. Defendant, Takeda Pharmaceuticals U.S.A., Inc. (hereinafter "TPUSA."), is a wholly owned U.S. subsidiary of Takeda Pharmaceutical Company, Limited – a Japanese corporation. TPUSA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015. TPUSA is one of the largest pharmaceutical companies in the United States with annual sales in excess of five billion dollars.

4. Defendant, Takeda Pharmaceuticals America, Inc. (hereinafter "TPA."), is a wholly owned U.S. subsidiary of TPUSA and a U.S. commercial organization of Takeda Pharmaceutical Company, Limited. TPA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015.

5. Defendants directly or through their agents or employees designed, manufactured, marketed, and sold Uloric in the United States which is used to lower blood uric acid levels in adults with gout.

JURISDICTION AND VENUE

6. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds $75,000.00 and the Parties are citizens of different states.

7. This Court has supplemental jurisdiction over the remaining common law and state claims

pursuant to 28 U.S.C. §1367.

8. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because at least one Defendant conducts business in this District and is incorporated under the laws of the State of Illinois.

9. Defendants currently transact business in Illinois and within this District. Specifically, TPUSA and TPA's principal place of business is located within this District.

GENERAL ALLEGATIONS

10. Uloric is a xanthine oxidase inhibitor, which contains the active ingredient, febuxostat. Febuxostat is a nonpurine inhibitor of xanthine oxidase, and it is designed for patients with hyperuricemia and gout, and also to patients who have exhibited sensitivities to allopurinol. Allopurinol was a "first line" drug used for the treatment of hyperuricemia and gout.

11. Since 1946, allopurinol has been used as a xanthine oxidase inhibitor for treatment of hyperuricemia and gout. In 2009, the FDA approved febuxostat as an alternative therapy for hyperuricemia and gout.

12. Hyperuricemia is defined as high levels of uric acid in the blood. In most cases, where elevated serum uric acid is noted without inflammatory response, patients are asymptomatic and treatment is not advised. However, in the cases where painful inflammation around the crystallized urate in the joint has already formed, the patient is generally diagnosed with gout leading to treatment.

13. Gout is an inflammatory arthritic disease with growing incidence. Gout was originally associated with individuals consuming a high-fat diet coupled with a relatively inactive lifestyle. Currently, gout is now considered a metabolic disorder and is linked to a variety of other disease states. In recent years, gout was associated with an assortment of

other conditions including, hypertension, obesity, kidney disease, hyperlipidemia, metabolic syndrome and cardiovascular disease. Most patients exhibit elevated serum uric acid levels for years before symptoms arise. Gout is most commonly observed in males over fifty years of age.

A. Defendants' File an NDA with FDA Ultimately Leading to Uloric's Approval; and Defendants' Scheme to Down-Play the Number of Adverse Events Stemming from Uloric use.

14. On information and belief, Defendants submitted their originally New Drug Application ("NDA") for Uloric to Food and Drug Administration (hereinafter "FDA") in 2003-2004. FDA ultimately approved the sale and distribution of Uloric in February 2009.

15. The NDA process, required Defendants to comply with all adverse event reporting requirements, including the reporting requirements set forth in 21 C.F.R. §314.80.

16. On information and belief, Defendants failed to comply with these requirements, construction a scheme designed to intentionally conceal a substantial number of adverse event reports from FDA and the public.

17. By way of example, Defendants suppressed knowledge of, and failed to submit full and complete Periodic Adverse Drug Experience Reports to FDA, which evidenced an risks from Uloric associated with Drug/Drug Interaction while treating gout. Such conduct by Defendants deviated from the duties and conduct of a responsible pharmaceutical manufacturer and demonstrated a failure to ensure its own minimal compliance with requirements of the Federal Food Drug and Cosmetic Act.

18. Upon information and belief, Defendants submitted false Periodic Adverse Drug Experience Reports to FDA. Defendants did so because it failed to include numerous Drug/Drug Interaction adverse events as serious adverse events.

B. Major Cardiac Adverse Effects, Including Thromboembolic Events

19. Prior to Uloric's original approval for marketing in the United States, Defendants interacted with FDA for nearly five years in an effort to obtain approval. In fact, due to concerns about the increased risk of cardiac thromboembolic events compared to placebo or allopurinol, Defendants were asked to provide further data to FDA before it would approve the NDA.

20. In response to FDA's concerns about cardiovascular safety, Defendants submitted a reanalysis that included a re-adjudication of previously reported events, which FDA ultimately concluded was inadequate to address the agency's concerns.

21. In 2008, Defendants approached FDA with a new application for approval of Uloric. Ultimately, FDA convened an Advisory Committee to review the data provided by Defendants. Based upon the paucity of data, most members felt that it was impossible to draw firm conclusions about the cardiovascular safety of the drug. As such, many committee members were only willing to approve the drug with a requirement that additional studies be required to assess the cardiovascular safety of the drug.

22. The approval required Defendants to submit a protocol for the study in 2009, begin the trial in 2010 and complete the trial by January, 2014.

23. Despite the time table laid out by FDA, the post-marketing trial conducted by Defendants did not conclude until several years after required by FDA. The post-marketing trial Defendants' conducted is known as The Cardiovascular Safety of Febuxostat and Allopurinol in Patients with Gout and Cardiovascular Morbidities (CARES) trial. The data from this trial was published in the New England Journal of Medicine in March 2018 and concluded all-cause mortality and cardiovascular mortality were higher with

febuxostat than with allopurinol.

24. As soon as FDA was provided the data from the CARES trial, as required in the original approval of the drug, FDA required Defendants include a Black Box warning to the label of Uloric warning of the cardiovascular risks of the drug. The warning was added to the febuxostat label in February, 2019.

25. At no time prior to February, 2019 was a Black Box warning regarding cardiovascular risks present on the warning label. Upon information and belief, at no time prior to 2018 when the results of CARES were provided to FDA, did Defendants seek to add additional warning about the cardiovascular risks of the drug.

PLAINTIFF SPECIFIC FACTS

26. Upon information and belief, in 2014, Plaintiff's treating medical physician prescribed Uloric to Plaintiff due to Plaintiff's medically diagnosed gout condition. Defendants represented Uloric to be an appropriate and suitable product for such purposes.

27. On or about September 27, 2017, Plaintiff experienced a Stroke that required medical treatment.

28. As a result of Defendants' actions and inactions, Plaintiff was injured due to Uloric, which caused Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

29. Defendants ignored reports from patients and health care providers throughout the United States of Uloric's failure to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff, and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out Uloric's design as the cause of the injuries, Defendants continued to market Uloric as a safer

and more effective prescriptive drug as compared to other available alternative treatment for hyperuricemia and gout.

30. Defendants did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, of the adverse effect or defects in Uloric despite Defendants' knowledge that it had failed due to the described defects.

31. Defendants' Uloric was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to take Uloric.

32. Plaintiff and Plaintiff's physicians foreseeably used the Defendants' Uloric, and did not misuse, or alter the Uloric in an unforeseeable manner.

33. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and his/her physicians the true and significant risks associated with Uloric consumption.

34. As a result of Defendants' actions, Plaintiff and his/her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

35. As a direct result of being prescribed and consuming Uloric, Plainitff has been permanently and severely injured, having suffered serious consequences.

36. Plaintiff, as a direct and proximate result of Uloric, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, along with economic loss due to medical expenses and living-related expenses due to his new lifestyle.

37. Plaintiff's physicians would not have prescribed Uloric had Defendants properly disclosed the risks associated with its use.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

38. Defendants failed to disclose a known defect and affirmatively misrepresented that Uloric was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Uloric. Neither Plaintiff nor the prescribing physician had knowledge that Defendants were engaged in the wrongdoing alleged herein.

39. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Uloric, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

40. Thus, because Defendants fraudulently concealed the defective nature of Uloric and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

41. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Uloric caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of acts indicating to a reasonable person that Plaintiff was the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

COUNT 1
STRICT LIABILITY

42. Plaintiff incorporates by referenced each and every preceding paragraph as though fully set forth herein.

43. At all times relevant hereto, Defendants manufactured, designed, distributed, and/or sold Uloric.

44. At all times relevant hereto, the dangerous propensities of Uloric were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

45. The Uloric product as distributed by Defendants was a defective and unreasonably dangerous product, as Defendants failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular the common, foreseeable and intended use of Uloric to lower blood uric acid levels in adults with gout.

46. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendants' Uloric product was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent injuries. Defendants further failed to inform and/or warn Plaintiff and Plaintiff's treating physician with respect to the selection of appropriate candidates to receive Defendants' Uloric product.

47. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician as to the risks of the Defendants' Uloric product. To the contrary, Defendants withheld information from Plaintiff and Plaintiff's physician regarding the true risks related to prescribing the Uloric product.

48. The Uloric product, as distributed by Defendants, was dangerous in design at the time

it left the Defendants' control.

49. Plaintiff did not misuse or materially alter the Uloric as prescribed and dispensed to Plaintiff and used by Plaintiff.

50. At the time the Uloric product left Defendants' control, there existed feasible and suitable alternative design for the treatment of hyperuricemia and gout that was capable of preventing Plaintiff's damages.

51. When compared to other feasible alternatives, the Uloric product greatly results in a much higher risk of injuries and side effects. Other feasible alternative designs exist which do not present the same frequency and severity of risks.

52. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Uloric in a defective and dangerous condition, as described above, to Plaintiff.

53. The Uloric received by Plaintiff did not perform safely as an ordinary consumer would have expected it to perform when used in a reasonably foreseeable way.

54. Furthermore, a reasonable patient would conclude the possibility and seriousness of harm outweighs the benefit from it's normal, intended use.

55. As a direct, foreseeable and proximate result of Defendants' defective Uloric product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products. Plaintiff has suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

COUNT II
NEGLIGENCE

56. Plaintiff incorporates by referenced each and every preceding paragraph as though fully set forth herein.

57. At all times relevant hereto, it was the duty of Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of Uloric.

58. Defendants failed to exercise ordinary care in the manufacture, sale, labeling, and marketing Uloric in that Defendants know or should have known that Uloric created a high risk of unreasonable harm to Plaintiffs and other users.

59. In disregard of its duty, Defendants committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Uloric without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Uloric while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Uloric;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Uloric was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Uloric was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative hyperuricemia and gout products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety

precautions to those persons to whom it was reasonably foreseeable would use Uloric;

g. Advertising, marketing, and recommending the use of Uloric, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Uloric;

h. Representing that Uloric was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative hyperuricemia and gout products were available for use for the purpose for which Uloric was manufactured;

j. Continuing to manufacture and sell Uloric with the knowledge that Uloric was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Uloric so as to avoid the risk of serious harm associated with the use of Uloric. Failing to design and manufacture Uioric so as to ensure the drug was at least as safe and effective as other similar products;

l. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Uloric and that use of Uloric created a high risk of severe injuries; and

m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Uloric.

60. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at lengthy herein, and prays judgment in his favor and against

the Defendant awarding the following:

1. A monetary award, sufficient to compensate plaintiff for the following categories of damages:

    a. General damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

    b. Past, present, and future damages for costs of medical and rehabilitative treatment and care for Plaintiff;

    c. Past wage loss and future loss of earning capacity.

2. Plaintiff's cost of this action, together with interest on past and future special and general damage amounts from the date of injury at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and such other and further relief as the Court deems equitable and just.

3. Any other award this Court deems equitable and just.

4. Plaintiff demands a jury trial.

Date: July 14, 2020

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