



community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

Throughout the time Uloric is marketed, Defendants withheld material adverse events from the public, medical community and FDA. These include, but were not limited to, unlabeled fatal and life-threatening adverse reactions Defendants knew occurred when a person used Uloric in combination with other drugs commonly used by the same patient population. In fact, the drug's package inserts encouraged co-administration of Uloric with other commonly used drugs, while denying the drug interaction or downplay the interaction. Post-marketing adverse events are consistent with the pre-approval data that went unwarned. Millions of patients, including Plaintiff, were placed at risk and harmed as a result of this misleading conduct as doctors prescribe this drug oblivious to the dangerous interactions, they have with drugs that their patients are already taking.

## **I. PARTIES**

1. At all times relevant hereto, Plaintiff James Wager was a citizen and resident of Laurel County in the state of Kentucky.
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, economic and emotional injuries, including but not limited to congestive heart failure. Based on information and belief, Plaintiff's ingestion of Uloric caused his injuries.
3. Defendant, Takeda Pharmaceutical Company Limited (hereinafter "TPC"), is a Japanese corporation, having its corporate headquarters and principal place of business in Osaka Japan. TPC is the largest pharmaceutical company in Japan. According to its annual

reports, TPC's annual sales exceeded \$15 billion.

4. Defendant, Takeda Pharmaceuticals U.S.A., Inc. (hereinafter "TPUSA."), now is, and at all times relevant to this action was, a wholly owned U.S. subsidiary of TPC. TPUSA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015, USA. TPUSA is one of the 15 largest pharmaceutical companies in the United States. According to its annual report, TPUSA's 2008 annual sales were reported to be in excess of five billion dollars. Much of Takeda's recent and current pharmaceutical sales are derived from Uloric.
5. Defendant, Takeda Pharmaceuticals America, Inc. (hereinafter "TPA"), now is, and at all times relevant to this action was, a wholly owned U.S. subsidiary of TPUSA and a U.S. commercial organization of TPC. TPA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015.
6. TPC, TPUSA and TPA will be collectively referred to as "Defendants."
7. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold in the United States the drug brand name, Uloric, which is used to lower blood uric acid levels in adults with gout.

**II. JURISDICTION AND VENUE**

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy as to the Plaintiff exceeds \$75,000 exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.
9. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. §1367.
10. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Defendants engaged in the marketing, promoting, labeling, and distribution of their product in the State of Illinois.
11. Defendants are currently transacting business from within Illinois and Cook County, Illinois, at least by maintaining offices and employees in Illinois, making and shipping into Illinois, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products, including Uloric in Illinois and Cook County, Illinois. Defendants derive substantial revenue from interstate and or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Illinois and this Judicial District.
12. Defendants have conducted business and derived substantial revenue from within Illinois and Cook County, Illinois, and has sufficient minimum contacts and intentionally avails itself of the Illinois market so as to render the exercise of jurisdiction over it by the Illinois courts consistent with the traditional notions of fair play and substantial justice.

13. Defendants, with respect to the product at issue in the case at bar, have made or performed contracts or promises substantially connected to Cook County, Illinois.
14. Therefore, this Court may exercise jurisdiction over Defendants under the laws of Illinois, the Illinois Constitution, and the Constitution of the United States.
15. At all relevant times, Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold the prescription product, Uloric® (febuxostat) in Cook County.

### **III. GENERAL ALLEGATIONS**

16. 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 the first line drug in the treatment of hyperuricemia and gout.
17. Since 1946, allopurinol has been used as a xanthine oxidase inhibitor for treatment of hyperuricemia and gout. However, in 2009, the FDA approved febuxostat as an alternative therapy for hyperuricemia and gout.
18. 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 and treatment is indicated.
19. Gout is an inflammatory arthritic disease with growing incidence. Gout was originally associated with individuals consuming a high fat diet, purine rich foods

and a relatively inactive lifestyle, but it is now considered a metabolic disorder and is linked to a variety of other disease states. In recent years, gout has been implicated in conditions such as 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.

20. Defendants submitted its New Drug Application for Uloric to Food and Drug Administration (hereinafter "FDA"), and FDA eventually approved of Uloric in February 2009. FDA's approval of the New Drug Application allowed Defendants to legally market and sell Uloric in the United States to patients, including Medicaid, Medicare and TRICARE patients. As part of the New Drug Application process, Defendants via its execution of various forms, including but not limited to FDA Form 35h, expressly and impliedly certified that it would comply with all adverse event reporting requirements, including the reporting requirements delineated in 21 C. F . R. §3 J 4.80. Accordingly, compliance with 21 C.F.R. §314.80 and the adverse event reporting obligations was a condition precedent to obtaining and maintaining FDA's approval to promote and sell Uloric to consumers.
21. Contrary to the adverse event reporting promises and certifications that Defendants had given to FDA, Defendants initiated a system to intentionally conceal a substantial number of adverse event reports and thus had no intention of complying with its certifications and promises.

22. In order to dominate the gout drug markets and to increase the sales of Uloric, Defendants misrepresented and/or concealed material facts regarding adverse events attributable to Uloric.
23. Defendants suppressed knowledge of and failed to submit full and complete Periodic Adverse Drug Experience Reports to FDA, which would have shown that there were increased 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.
24. Defendants were required to submit "Periodic Adverse Drug Experience Reports." Defendants were required to submit each adverse drug experience not reported under paragraph (c)(I)(T) of section 314.80 at quarterly intervals, for three years from the date of approval of Uloric, and then at annual intervals.
25. 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, including those with warfarin.
26. Such an interaction was to be expected since the parallel gout treatment, allopurinol, carried a drug interaction warning for warfarin, and vice versa. This is included in the package insert and warnings for allopurinol and warfarin. Both allopurinol and Uloric are members of a class of drugs used to treat elevated uric acid levels in blood plasma that leads to gout; hence, they are gout treatment agents.

Both accomplish uric acid reduction by inhibiting the enzyme xanthine oxidase. Xanthine oxidase promotes the production of uric acid, so its inhibition lowers uric acid levels in plasma. Thus, xanthine oxidase inhibitors have become a common treatment treating illnesses, like gout, caused by elevated plasma uric acid. However, as xanthine oxidase inhibitors, both Uloric and allopurinol affect other drugs that are metabolized by the xanthine oxidase enzyme, such as the immune suppressants Imuran and Purinethol. Continued ingestion of a xanthine oxidase inhibitor while also taking a drug metabolized by the xanthine oxidase enzyme results in elevated, and possibly toxic, levels of the drug not getting metabolized. This is due to the reduced xanthine oxidase available to break it down (metabolize it) and excrete it. Thus, it should be anticipated that allopurinol's interaction with drugs metabolized by xanthine oxidase would be echoed with Uloric.

27. Allopurinol interacts with most commonly prescribed medications, and since Uloric is in the same class of drugs as allopurinol, it should be expected to have the same interactions.
28. Most interactions with allopurinol were CYP450, both induction and inhibition. Similarly, the interaction with warfarin appears to be on isoform 2C9, which inhibits warfarin's metabolism, then elevates the warfarin's plasma concentration. Warfarin is an NTR (narrow therapeutic range) drug, and very small changes in plasma concentration would result in bleeding, and this was FDA's major safety concern. According to Relator Helen Ge, M.D., a former contract physician of drug safety with Defendants, Uloric acts as an inhibitor in the CYP 450 metabolism process, interfering with the other drug's metabolism, resulting in the higher plasma

concentration of co-administered drugs that share the same enzyme. When Uloric inhibited the IA2 enzyme on theophylline and methadone, and 2C8 enzyme with Imuran and methotrexate, it resulted in the deaths reported in Dr. Ge's original Uloric Disclosure Memorandum.

29. Consequently, Defendants should have done studies addressing at least six or seven major enzymes, including 1A2, 2C8 and 2 C9 on both induction and inhibition. Defendants' Uloric should have had clear documentation in the label for safe use, but Defendant failed to do such testing, leading to the deficiencies indicated in early FDA reviews.
30. Uloric's interaction with other drugs, including warfarin (Coumadin), was the subject of deficiencies observed by the FDA in Defendants' Uloric NDA. Instead of properly addressing those concerns, Defendants evaded the FDA's recommendations and proceeded to market Uloric without sufficient drug interaction warnings or studies. This has resulted in warfarin hemorrhagic bleeding incidents and a fatal methadone interaction. The pre-existing drug-drug interaction problems during the NDA may explain some of the bizarre machinations undertaken to avoid reporting post-marketing Uloric drug interactions.

**Mislabeled Recommendation to Renal Impairment Patients to Use Uloric**

31. Additionally, Uloric's original package insert at section 8.6 stated that Uloric could be used in the renal impairment patient population with mild or moderate creatine in clearance decrease. There was an insufficient basis to support this statement. The Uloric NDA disclosed three or four renal impairment reports for Uloric and two for allopurinol. The PK study for renal function only involved about 20 patients at the

- most, which was not enough data to support the claim that Uloric can be used in mild or moderate renal impairment patient population, especially since several million patients comprise this population. Subsequent Uloric phase three trials may have excluded patients who had mild or moderate renal function impairments, so that Defendants would be able to build a better safety profile to achieve approval.
32. Notwithstanding, Uloric's present advertising and website continue to assert that Uloric is superior to allopurinol because "Patients with mild to moderate kidney problems do not have to take a lower dose" of Uloric, whereas "Patients with kidney problems have to take a lower dose" of allopurinol.

**Major Cardiac Adverse Effects, Including Thromboembolic Event**

33. At the time of Uloric's original approval for marketing in the United States, Defendants had been interacting with FDA for nearly five years in an effort to obtain approval for Uloric. 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 approval was given.
34. 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.
35. In 2008, Defendants approached FDA with a new application for approval of Uloric. 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 from the data provided. 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.
36. The approval required Defendants to submit a protocol for the study in 2009, begin the trial in 2010 and have the trial completed by January 2014.
37. The post-marketing trial conducted by Defendants 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.
38. As soon as FDA was provided the data from the CARES trial, as required in the original approval of the drug, in February 2019, a black box warning was added to the label of Uloric warning of the cardiovascular risks of the drug.
39. 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.

#### **IV. PLAINTIFF SPECIFIC FACTS**

40. Upon information and belief, in 2016, 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.

41. On or about February 2017, Plaintiff experienced, among other things, a myocardial infraction that required medical treatment.
42. 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.
43. 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.
44. 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.
45. 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.
46. Plaintiff and Plaintiff's physicians foreseeably used the Defendants' Uloric, and did not misuse or alter the Uloric in an unforeseeable manner.
47. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and his/her physicians the true and significant risks associated with Uloric consumption.

48. 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.
49. As a direct result of being prescribed and consuming Uloric, Plaintiff has been severely injured, having suffered serious consequences.
50. 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.
51. Plaintiff's physicians would not have prescribed Uloric had Defendants properly disclosed the risks associated with its use.

**V.     EQUITABLE TOLLING OF STATUTE OF LIMITATIONS**

52. 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.
53. 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.
54. 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.

55. 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 I**  
**STRICT LIABILITY**

56. Plaintiff incorporates by referenced each and every preceding paragraph as though fully set forth herein.
57. At all times relevant hereto, Defendants manufactured, designed, distributed, and or sold Uloric.
58. 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.
59. 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.
60. 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.
  61. 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.
  62. The Uloric product, as distributed by Defendants, was dangerous in design at the time it left the Defendants' control.
  63. Plaintiff did not misuse or materially alter the Uloric as prescribed and dispensed to Plaintiff and used by Plaintiff.
  64. 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.
  65. 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.

66. 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.
67. Uloric was defective in manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical manufacturer.
68. The Uloric product prescribed and ingested by Decedent was unreasonably dangerous in construction and composition because it deviated in a material way from the Defendants' specifications and performance standards for the product. The dangerous, defective conditions of Uloric were not known, knowable, and/or reasonably visible to Plaintiff and /or Plaintiff's physician or discoverable upon reasonable examination.
69. 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.
70. Furthermore, a reasonable patient would conclude the possibility and seriousness of harm outweighs the benefit from its normal, intended use.
71. 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**

72. Plaintiff incorporates by referenced each and every preceding paragraph as though fully set forth herein.
73. 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.
74. 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.
75. In disregard of its aforesaid duty, Defendants were guilty of 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 Uloric 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;
- m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Uloric.

75. 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.

## **VII. 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:

76. 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.
77. 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.
78. Any other award this Court deems equitable and just.
79. Plaintiff demands a jury trial.

**DEMAND FOR JURY TRIAL**

80. Plaintiff demands trial by jury on all issues.

DATED: August 26, 2020

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