UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

DANNY DAVIS,

Plaintiff,

v.

TAKEDA PHARMACEUTICALS USA, INC; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMECUETICALS INTERNATIONAL, INC.; TAKEDA DEVELOPMENT CENTER AMERICAS, INC.; and TAKEDA PHARMACEUTICAL COMPANY LIMITED,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Civil Case No. _____

COMPLAINT

Plaintiff, Danny Davis (alternatively referred to herein as "Plaintiff"), residing in Maricopa County, within the State of Arizona, by and through the undersigned attorneys, files this Complaint against Defendants Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; and Takeda Pharmaceutical Company Limited (collectively "Defendants") and for his Complaint states, upon information and belief and based upon investigation of counsel, as follows:

INTRODUCTION

1. This is a personal injury case against Defendants who were responsible for designing, developing, researching, manufacturing, testing, packaging, promoting, marketing, advertising, distributing, labeling, and/or selling a class of drugs known as proton pump

inhibitors ("PPI"s), which are prescription and over-the-counter medications referred to herein as PPIs.

2. PPIs are used to reduce acid production in order to lower the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

3. As set forth more fully herein, Plaintiff Danny Davis ingested Defendants' respective PPIs, which resulted in renal disease and serious injuries to his kidneys.

JURSIDICTION AND VALUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and the Defendants as Defendants are all incorporated and have their principal place of business in states other Plaintiff's home state of Arizona.

5. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

6. Further, a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this district. Pursuant to 28 U.S.C. § 1391, venue is proper in this district.

PLAINTIFF

7. Plaintiff, Danny Davis, a natural person and resident of Surprise, Arizona, ingested PPIs, including Prevacid between approximately May 2005 through May 2012, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs, including Prevacid, and recovery of all past, present, and

future health and medical care costs related to his renal disease and kidney related injuries and sequelae caused by his ingestion of PPIs, including Prevacid.

8. Defendant TAKEDA PHARMACEUTICALS USA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

9. Defendant TAKEDA PHARMACEUTICALS AMERICA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

10. Defendant TAKEDA DEVELOPMENT CENTER AMERICAS, INC. is an Illinois corporation which has its principal place of business at 208 South LaSalle Street, Chicago, IL 60604.

11. Defendant TAKEDA PHARMECUETICALS INTERNATIONAL, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

12. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka 540-8645.

13. On information and belief, TAKEDA PHARMACEUTICALS USA INC is either the direct or indirect owner of substantially all the stock or other ownership interests of TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED.

14. In doing the acts alleged herein, said Takeda Defendants (including TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED) were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other (hereinafter TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED are collectively referred to as "TAKEDA").

15. On information and belief, Defendants have transacted and conducted business in the State of Arizona, and/or contracted to supply goods and services within the State of Arizona, and these causes of action have arisen from the same.

16. On information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of Arizona.

17. On information and belief, at all relevant times, Defendants derived and derive substantial revenue from goods and products used in the State of Arizona and from interstate commerce.

18. On information and belief, at all relevant times, Defendants committed tortious acts within the State of Arizona causing injury within the State of Arizona, out of which act(s) these causes of action arise.

SUMMARY OF THE CASE

19. As a result of the defective nature of PPIs, persons who ingested Defendants' respective PPI products, including Plaintiff, have suffered and may continue to suffer from kidney injuries including acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

20. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs.

21. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries and sequelae.

FACTUAL ALLEGATIONS

22. Over 60 million Americans experience heartburn, a major symptom of GERD, at least once a month and some studies have suggested more than 15 million Americans experience heartburn on a daily basis.

23. About 21 million Americans used one or more prescription PPIs in 2009 accounting for nearly 20% of the drugs' global sales and earning an estimated $11 billion annually.

24. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

25. PPIs are one of the most commercially successful groups of medication in the United States. Upon information and belief, between the period of 2008 and 2013, prescription PPIs had a sale of over $50 billion with approximately 240 million units dispensed.

26. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs.

27. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article associating PPI usage with kidney injuries in *The American Journal of Medicine*, followed by years of reports from national adverse drug registries describing this association. In 1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.[1]

28. Between 1995 and 1999, Nicholas Torpey, et al. conducted a single-center retrospective analysis of renal biopsy results from 296 consecutive patients to determine the etiology of acute tubule-interstitial nephritis (TIN).[2] Acute AIN was identified in 24 (8.1%) biopsies. Eight out of 14 cases with presumed drug-related AIN could be attributed to the proton pump inhibitors omeprazole and lansoprazole.

29. Defendants knew or should have known that between 1992 and 2004 over 23 cases of biopsy-proven AIN secondary to omeprazole (Prilosec) had been reported.

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[1] Badov, D., et al. Acute Interstitial Nephritis Secondary To Omeprazole, *Nephrol Dial Transplant* (1997) 12: 2414–2416.

[2] Torpey, N., et al. *Drug-Induced Tubulo-Interstitial Nephritis Secondary To Proton Pump Inhibitors: Experience From A Single UK Renal Unit*, Nephrol. Dial. Transplant. (2004) 19: 1441–1446.

30. In 2004, Defendants knew or should have known of 8 biopsy-proven cases report from Norwich University Hospital in the United Kingdom.[3]

31. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI were causal. "Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure."[4]

32. Furthermore, in the New Zealand study, Defendants knew or should have known that twelve of the reported cases were biopsy-proven.

33. In 2006, Nimeshan Geevasinga, et al., found "evidence to incriminate all the commercially available PPIs, suggesting there is a class effect" with regard to PPI-induced AIN.[5] "Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease." This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases as two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified 18 cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional 31 cases of "biopsy proven interstitial nephritis." An additional 10 cases of "suspected interstitial nephritis," 20 cases of "unclassified acute renal failure," and 26 cases of "renal

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3 *Id*.

4 Simpson, I., et al., *PPI and Acute Interstitial Nephritis*, NEPHROLOGY (2006)11: 381-85.

5 Geevasinga, N., et al. *Proton Pump Inhibitors and Acute Interstitial Nephritis*, CLINICAL GASTROENTEROLOGY AND HEPATOLOGY, (2006)4:597-604.

impairment" were also identified. "All 5 commercially available PPIs were implicated in these cases."

34. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.[6]

35. In 2006, researchers at the Yale School of Medicine conducted a case series published in the *International Society of Nephrology's Kidney International* finding that PPI use, by way of AIN, left most patients "with some level of chronic kidney disease."

36. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs including AIN.

37. According to the petition, at the time of its filing there was "no detailed risk information on any PPI for this adverse effect."

38. In 2013, Klepser, et al. found that "patients with a renal disease diagnosis were twice as likely to have used a previous prescription for a PPI."[7] Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

39. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy.[8] Researchers further noted

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[6] Ian J. Simpson, Mark R. Marshall, Helen Pilmore, Paul Manley, Laurie Williams, Hla Thein, David Voss, *Proton pump inhibitors and acute interstitial nephritis: Report and analysis of 15 cases*, (September 29, 2006).

[7] Klepser, D., et al. Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case-Control Study, BMC NEPHROLOGY (2013) 14:150.

[8] Sampathkumar, K., et al. *Acute Interstitial Nephritis Due to Proton Pump Inhibitors*, INDIAN J. NEPHROLOGY (2013) 23(4): 304-07.

that "a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease."

40. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data in New Zealand to estimate the relative and absolute risks of acute interstitial nephritis resulting in hospitalization or death in users of PPIs.[9] The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of acute interstitial nephritis for patients currently taking PPIs.

41. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

42. The FDA noted "that the prescription PPI labeling should be consistent with regard to this risk" and that "there is reasonable evidence of a causal association."

43. In December of 2014, the labels of prescription PPIs were updated to read:

> *Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops.*

44. The FDA did not require the consistent labeling regarding risk of AIN on over-the-counter PPIs.

45. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[10] The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities

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[9] Blank, M., et al. *A Nationwide Nested Case-Control Study Indicates an Increased Risk of Acute Interstitial Nephritis with Proton Pump Inhibitor Use,* KIDNEY INTERNATIONAL (2014) 86, 837–844.

[10] Lazarus, B., et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease,* JAMA INTERN. MED., published online 11 Jan. 2016.

study (n ¼ 10,482) and the Geisinger Health System (n ¼ 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

46. "Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted hazard ratio 1.64, 95% confidence interval 1.22–2.21). The results were then validated in the Geisenger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28–1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk."[11]

47. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were

[11] See Schoenfeld, A. and Deborah Grady. *Adverse Effects Associated with Proton Pump Inhibitors*, JAMA INTERNAL MEDICINE, published online 11 Jan. 2016.

compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score–matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

48. Lazarus's data was confirmed and expanded by Yan Xie, et al.[12] Using Department of Veterans Affairs national databases to build a primary cohort of new users of PPI (n=173,321) and new users of histamine H2-receptor antagonists (H2 blockers; n=20,270), this study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

49. However, evidence of the connection of PPI's with AIN and CKD existed as early as 2007.[13] In Brewster and Perazella's review, they found that not only are PPIs "clearly associated with the development of AIN," most PPI patients they studied were "left with some level of chronic kidney disease." This CKD existed despite recovery of kidney function following PPI withdrawal. Furthermore, Härmark, et al., noted that the Netherlands Pharmacovigilance Centre Lareb received reports of AIN with the use of omeprazole,

[12] Xie, Y., et al. *Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD*, J. AM. SOC. NEPHROL. (2016) 27: ccc–ccc.

[13] Brewster, UC and MA Perazella. *Acute Kidney Injury Following Proton Pump Inhibitor Therapy*, KIDNEY INTERNATIONAL (2007) 71, 589–593.

pantoprazole, and rabeprazole, demonstrating that "AIN is a complication associated with all PPIs."[14]

50. To date, over-the-counter PPIs lack detailed risk information for AIN.

51. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD.

52. Parietal cells in the stomach lining secrete gastric juices containing hydrochloric acid to catalyze the digestion of proteins.

53. Excess acid secretion results in the formation of most ulcers in the gastroesophageal system and symptoms of heartburn and acid reflux.

54. PPIs irreversibly block the acidic hydrogen/potassium ATPase enzyme system (H+/K+ ATPase) of the gastric parietal cells, thereby halting the production of most hydrochloric acid.

55. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

56. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

57. From these findings, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis ("AIN"), a sudden kidney inflammation that can result in mild to severe problems.

[14] Härmark, L., et al. *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*, BRIT. J. OF CLIN. PHARMACOLOGY (2007) 64(6): 819-23.

58. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

59. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

60. CKD describes a slow and progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

61. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals.

62. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

63. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with PPI use.

64. Defendants concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community

against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD and ESRD.

65. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

66. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

67. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

68. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

69. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

FEDERAL REQUIREMENTS

70. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Proton Pump Inhibitors.

71. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

72. With respect to Proton Pump Inhibitors, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Proton Pump Inhibitors are adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. Proton Pump Inhibitors are adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Nexium and such deviations are not plainly stated on their labels.

c. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. Proton Pump Inhibitors do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. Proton Pump Inhibitors are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Proton Pump Inhibitors to cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took Proton Pump Inhibitors.

l. Proton Pump Inhibitors are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

m. Proton Pump Inhibitors violate 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

n. Proton Pump Inhibitors violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

o. Proton Pump Inhibitors violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

p. Proton Pump Inhibitors violate 21 CFR § 211.165 in that Nexium fails to meet established standards or specifications and any other relevant quality control criteria.

q. Proton Pump Inhibitors violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding Proton Pump Inhibitors were not followed.

r. Proton Pump Inhibitors violates 21 CFR § 310.303 in that Proton Pump Inhibitors are not safe and effective for its intended use.

s. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

t. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with Proton Pump Inhibitors as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

u. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with Proton Pump Inhibitors, and evaluating the cause of the adverse event.

v. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

w. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Proton Pump Inhibitors or otherwise received

by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

x. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

73. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under Arizona law.

FRAUDULENT CONCEALMENT

74. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with Proton Pump Inhibitors.

75. As a result of Defendants' actions, Plaintiff and physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that they had

been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
VIOLATION OF THE ARIZONA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, A.R.S. § 44-1522, et seq

76. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

77. The Plaintiff pleads this Count in the broadest sense available under law to include pleading same pursuant to all substantive law that applies to this case as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

78. The Plaintiff used Defendants' Proton Pump Inhibitors and suffered ascertainable losses as a result of the Defendants' actions in violation of the aforementioned consumer protection laws.

79. The Defendants violated the Arizona Unfair Trade Practices and Consumer Protection Law, A.R.S. §44-1522, et seq, through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Proton Pump Inhibitors.

80. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and of the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians,

the medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

81. The Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

82. The Defendants have a statutory duty to refrain from unfair trade practices in the design, development, manufacture, promotion and sale of Proton Pump Inhibitors.

83. Had the Defendants not engaged in the deceptive conduct described herein, the Plaintiff would not have purchased and/or paid for Proton Pump Inhibitors, and would not have incurred related medical costs. Specifically the Plaintiff, the Plaintiff's physicians and other Healthcare Professionals were misled by the deceptive conduct described herein.

84. The Defendants' deceptive, unconscionable, false, misleading and/or fraudulent representations and material omissions to patients, physicians and consumers, including the Plaintiff, of material facts relating to the safety of Proton Pump Inhibitors constituted unfair trade practices in violation of the state consumer protection statutes listed above.

85. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians, the

medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

86. The Defendants' conduct in connection with Proton Pump Inhibitors was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because the Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of Proton Pump Inhibitors.

87. By reason of wrongful acts engaged in by the Defendants, the Plaintiff suffered ascertainable loss and damages for which the Plaintiff is now entitled to recover.

88. As a direct and proximate result of the Defendants' wrongful conduct, the Plaintiff was damaged by paying in whole or in part for Proton Pump Inhibitors and for the Plaintiff's medical treatment. Plaintiff is now entitled to recover those damages.

89. As a direct and proximate result of the Defendants' violations of unfair trade practices, the Plaintiff sustained economic losses and other damages for which the Plaintiff is entitled to statutory and compensatory damages and attorneys' fees, in an amount to be proven at trial.

SECOND CAUSE OF ACTION
ARIZONA PRODUCTS LIABILITY ACT

90. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

91. Plaintiff's damages were caused by characteristics of Proton Pump inhibitors manufactured by the Defendants that rendered the Proton Pump Inhibitors unreasonably

dangerous after a reasonably anticipated use of the products by Plaintiff making Defendants liable to Plaintiff pursuant to A R.S. §12-681 et seq.

92. Proton Pump Inhibitors are unreasonably dangerous under the following:

a. Proton Pump Inhibitors are unreasonably dangerous in construction or composition;

b. Proton Pump Inhibitors are unreasonably dangerous in design;

c. Proton Pump Inhibitors are unreasonably dangerous because an accurate warning about the product was not provided as required;

d. Proton Pump Inhibitors are unreasonably dangerous because the products do not conform to an express warranty of the manufacturer about the product.

93. The characteristics of Proton Pump Inhibitors that render the products unreasonably dangerous existed at the time the product left the control of the manufacturers.

94. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous in design at the time the products left the manufacturers' control in that:

a. There existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and

b. The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

95. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause

damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

96. Further, Defendants, before, during, and after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

97. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that Proton Pump Inhibitors were safe, effective, fit and proper for its intended use.

98. In using Proton Pump Inhibitors, Plaintiff and his physicians relied on the skill, judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

THIRD CAUSE OF ACTION
NEGLIGENCE – MANUFACTURE

99. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

100. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of PPIs.

101. Defendants breached this duty by, among other things:

a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;

b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of PPIs and their manufacturing process so as to avoid the risk of serious harm associated with the use of PPIs; and

d. Failing to establish an adequate quality assurance program used in the manufacturing of the PPIs.

102. As a direct and proximate result of the above-described negligence in manufacture of PPIs, Plaintiff suffered Injuries and Damages.

FOURTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

103. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

104. At all relevant times, Defendants knew or should have known that PPIs were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

105. Such danger included the propensity of PPIs to cause injuries and death similar to that suffered by Plaintiff.

106. At all relevant times, Defendants also knew or reasonably should have known that the users of PPIs, including Plaintiff, would not realize or discover on their own the dangers presented by PPIs.

107. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the date of Plaintiff's use of PPIs, would have warned of the dangers presented by PPIs, or instructed on the safe use of PPIs.

108. Prior to, on, and after the date of Plaintiff's use of PPIs, Defendants had a duty to adequately warn of the dangers presented by PPIs and/or instruct on the safe use of PPIs.

109. Defendants breached these duties by failing to provide adequate warnings to Plaintiff communicating the information and dangers described above and/or providing instruction for safe use of PPIs.

110. As a direct and proximate result of Defendants' failure to warn, Plaintiff suffered Injuries and Damages.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

111. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

112. Prior to, on, and after the dates during which Plaintiff used PPIs, Defendants negligently and carelessly represented to Plaintiff, and the general public that PPIs were safe, fit, and effective for use.

113. These representations were untrue.

114. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning PPIs, to exercise reasonable care to ensure that they did not in those undertakings create unreasonable risks of personal injury to others.

115. Defendants disseminated to consumers and the medical community through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of PPIs with the intention that consumers and the medical community would rely upon that information in their decisions concerning whether to use PPIs.

116. Defendants, as medical designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that consumers and the medical community, in weighing the potential benefits and potential risks of recommending or using PPIs, would rely upon information disseminated and marketed by Defendants to them regarding the PPIs.

117. Defendants failed to exercise reasonable care to ensure that the information they disseminated to consumers and the medical community concerning the properties and effects of PPIs was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

118. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that consumers taking PPIs as recommended by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of PPIS would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, kidney injuries including acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD")

and renal failure, also known as end-stage renal disease ("ESRD"), if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

119. Defendants had a duty to promptly correct material misstatements it knew others were relying upon in ingesting PPIs.

120. Defendants failed in each of these duties by misrepresenting to Plaintiff and the medical community the safety and efficacy of PPIs and failing to correct known misstatements and misrepresentations.

121. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff suffered Injuries and Damages.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

122. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

123. Plaintiff purchased PPIs directly from Defendants.

124. At all relevant times, Defendants were a merchant of goods of the kind including Proton Pump Inhibitors.

125. At the time and place of sale, distribution, and supply of Proton Pump Inhibitors to Plaintiff, Defendants expressly represented and warranted that Proton Pump Inhibitors were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they were adequately tested.

126. At the time of Plaintiff's purchase from Defendants, PPIs were not in a merchantable condition and Defendants breached its expressed warranties, in that:

a. Proton Pump Inhibitors are unreasonably dangerous in construction or composition;

b. Proton Pump Inhibitors are unreasonably dangerous in design;

c. Proton Pump Inhibitors are unreasonably dangerous because an accurate warning about the product was not provided as required;

127. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries including but not limited to Chronic Kidney Disease, Acute Kidney Injury, Kidney Failure and related sequelae. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

128. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

129. Defendants warrant that the subject product is reasonably fit for its ordinary and intended use.

130. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, acute interstitial nephritis ("AIN"),

acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

131. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries including but not limited to Chronic Kidney Disease, Acute Kidney Injury, Kidney Failure and related sequelae. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain.

EIGHTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

132. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

133. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiff, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning PPIs, including, but not limited to, misrepresentations regarding the following topics:

a. The safety of PPIs;

b. The efficacy of PPIs;

c. The pre-market testing of PPIs;

d. The approved uses of PPIs;

134. The information Defendants distributed to the public, the medical community, and to Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

135. These materials contained false and misleading material representations, which included: that PPIs ingestion was safe and fit when used for the intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal ingestion to reduce acid production in order to lower the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

136. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of PPIs that were ingested by Plaintiff.

137. Defendants intent and purpose in making these misrepresentations was to deceived and defraud the public and medical community, including Plaintiff; to gain the confidence of the public and the medical community, including Plaintiff; to falsely assure the public and the medical community of the quality of PPIs and their fitness for use; and to induce the public and the medical community, including Plaintiff, to request, recommend, purchase, and continue to use PPIs, all in reliance on Defendants' misrepresentations.

138. The foregoing representations and omissions by Defendants were false.

139. PPIs are not safe, fit, and effective for human consumption in their intended and reasonably foreseeable manner.

140. Further, the use of PPIs is hazardous to the consumers' health, and PPIs have a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered.

141. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff was induced to, and did use PPIs, thereby causing Plaintiff to sustain severe renal disease and severe issues with his kidneys.

142. Defendants knew and had reason to know that Plaintiff, the public, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have used PPIs if the true facts regarding PPIs had not been concealed and misrepresented by Defendants.

143. Defendants had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to person who ingested PPIs.

144. At the time, Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiff ingested PPIs, Plaintiff was unaware of Defendants' misrepresentations and omissions.

145. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered Injuries and Damages.

PUNITIVE DAMAGES

146. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

147. At all times material hereto, Defendants knew or should have known that Proton Pump Inhibitors were unreasonably dangerous.

148. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Proton Pump Inhibitors.

149. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Proton Pump Inhibitors.

150. Defendants' conduct was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiff.

151. At all times material hereto, Defendants knew and recklessly disregarded the fact that Proton Pump Inhibitors have an unreasonably high rate of severe and permanent injuries including, but not limited to, acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

152. Notwithstanding the foregoing, Defendants continued to market Proton Pump Inhibitors to consumers, including Plaintiff, without disclosing the aforesaid side effects.

153. Defendants knew of the lack of warnings regarding the risk of severe and permanent injuries including, but not limited to, acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage

renal disease ("ESRD"), but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Proton Pump Inhibitors.

154. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using Proton Pump Inhibitors against its benefits.

155. Defendants' conduct is reprehensible; evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiff.

156. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

a. Awarding actual damages to the Plaintiff incidental to his purchase and use of Proton Pump Inhibitors in an amount to be determined at trial;

b. Awarding pre-judgment and post-judgment interest to the Plaintiff;

c. Awarding the costs and the expenses of this litigation to the Plaintiff;

d. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law;

e. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future; and

f. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, Danny Davis, hereby demands a trial by jury on all counts and as to all issues.

Date: December 20, 2016

__/s/_Sarah J. Showard_____

Sarah J. Showard, Esq.
(AZ State Bar No. 012350)
SHOWARD LAW FIRM, P.C.
4703 E. Camp Lowell Dr., Suite 253
Tucson, AZ 858712
Phone: (520) 622-3344
Facsimile: (520) 881-9260
sjshoward@showardlaw.com

AND

Lee Jackson (AZ Bar No. 028685)
MILSTEIN ADELMAN JACKSON FAIRCHILD & WADE, LLP
Attorney for Plaintiff
10250 Constellation Blvd., Suite 1400
Los Angeles, CA 90094
Phone: (310) 396-9600
Facsimile: (310) 396-9635
ljackson@majfw.com

PRO HAC VICE TO BE SUBMITTED

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **Danny Davis**

Defendant(s): **Takeda Pharmaceuticals USA, Inc. ; Takeda Pharmaceuticals America, Inc. ; Takeda Pharmaceuticals International, Inc. ; Takeda Development Center Americas, Inc. ; Takeda Pharmaceutical Company Limited**

County of Residence: Maricopa

County Where Claim For Relief Arose: Maricopa

County of Residence: Outside the State of Arizona

Plaintiff's Atty(s):

Sarah J. Showard
Showard Law Firm, P.C.
4703 E. Camp Lowell Dr., Ste. 253
Tucson, Arizona 85712
520-622-3344

Lee Jackson
Milstein Adelman Jackson Fairchild & Wade, LLP
10250 Constellation Blvd., Ste. 1400
Los Angeles, California 90094
310-396-9600

Defendant's Atty(s):

II. Basis of Jurisdiction: **4. Diversity (complete item III)**

III. Citizenship of Principal Parties
(Diversity Cases Only)

Plaintiff:- **1 Citizen of This State**
Defendant:- **5 Non AZ corp and Principal place of Business outside AZ**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **367 Health Care/Pharmaceutical Personal Injury Product Liability**

VI.Cause of Action: **28 U.S.C. 1332(a) Alleged personal injury from a pharmaceutical**

VII. Requested in Complaint

Class Action: **No**
Dollar Demand: **75000.00**
Jury Demand: **Yes**

VIII. This case **is not related** to another case.

Signature: /s/ Sarah J. Showard

Date: 12/20/2016

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014