

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
ST LOUIS DIVISION

DAWN MOONEY, INDIVIDUALLY, AS  
AN HEIR AT LAW OF RUTH NASH,  
DECEASED, AND ON BEHALF OF ALL  
HEIRS AT LAW OF RUTH NASH,  
DECEASED

Plaintiff,

v.

MERCK SHARP & DOHME CORP., and  
DOES 1-100

Defendants.

Cause No. 4:13-cv-598

**COMPLAINT FOR DAMAGES**

JURY TRIAL DEMANDED

COMES NOW Plaintiff and complains and alleges against Defendants Merck Sharp & Dohme Corp., and Does 1 through 100, and each of them as follows:

GENERAL ALLEGATIONS

1. Plaintiff, Dawn Mooney, Individually, as an Heir at Law of Ruth Nash, deceased, and on Behalf of All Heirs at Law of Ruth Nash, deceased (“Plaintiff”), by and through her attorneys, brings this action for personal injuries and wrongful death suffered as a proximate result of Ruth Nash (“Decedent”) being prescribed and ingesting the defective and unreasonably dangerous prescription drug Januvia (sitagliptin phosphate) (the “Drug”), prescription medications used to help lower blood sugar levels in adults with diabetes mellitus type 2, which at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendant Merck Sharp & Dohme Corp., (hereinafter the “Merck” for Januvia); and Does 1 through 100 (collectively, the “Doe Defendants” for either of Januvia) (the Merck and the Doe Defendants collectively are the “Defendants”).

2. The true names or capacities whether individual, corporate or otherwise, of the Doe Defendants 1 through 100, inclusive, are unknown to Plaintiff who therefore, sues said Defendants by such fictitious names. Plaintiff believes and alleges that each of the Defendants

designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff and Decedent as alleged herein.

3. At all times herein mentioned, each of the Defendants, inclusive of the Doe Defendants, was the agent, servant, partner, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.

4. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendant, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

5. The injuries and damages to Plaintiff and Decedent were caused by the wrongful acts, omissions, and fraudulent representations of Defendants, many of which occurred within the State of Missouri.

6. At all times herein mentioned, Defendants were each engaged in the business of, or were successors in interest to, entities engaged in the business of research, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the Drug.

7. At all times herein mentioned Defendants were each authorized to do or otherwise engaged in business within the State of Missouri and did in fact supply the aforementioned products within the State of Missouri and elsewhere.

8. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of the Drug when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Drug, and thereby actively participated in the tortious conduct which resulted in the physical injuries described herein.

#### JURISDICTION AND VENUE

9. Jurisdiction is proper in this court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiffs and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars (\$75,000.00), exclusive of interest and costs.

10. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of Missouri, have committed a tort in whole or in part in the State of Missouri, and have continuing contacts with the State of Missouri.

11. In addition, venue of this case is proper in the Eastern District of Missouri pursuant to 28 U.S.C. § 1391(b)(1) because all Defendants are residents of this state.

12. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Eastern District of Missouri.

#### PLAINTIFF

13. Plaintiff Dawn Mooney is a natural person currently residing in Elsberry, Missouri. Plaintiff is the surviving adult child and Heir at Law of Ruth Nash, deceased (the "Decedent"), who was a resident of St. Louis, Missouri at the time Decedent ingested the Drug, was diagnosed with pancreatic cancer, and ultimately died of said cancer. As Plaintiff herein, Dawn Mooney is bringing Plaintiff's individual claims, including Plaintiff's claim for the wrongful death of the Decedent, and the claims of the estate.

14. Decedent was prescribed and used the Drug beginning on or about April 29, 2011 and continued said use through at December 2011. On or about December 6, 2011,

Decedent suffered severe physical, economic and emotional injuries as a result of said Drug, including but not limited to Decedent's being diagnosed with pancreatic cancer. Plaintiff and Decedent were unaware that Decedent's injuries were caused by the Drug until within two years of the filing of this complaint.

#### DEFENDANTS

15. Merck Sharp & Dohme Corp. ("Merck") is a New Jersey corporation, which has its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100 USA. Merck may be served at CT Corporation System, 120 South Central Ave., Clayton, MO 63105. Merck has conducted business and derived substantial revenue from within the State of Missouri.

#### FACTUAL ALLEGATIONS

16. This is an action for injuries and damages suffered by Plaintiff and Decedent as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Drug.

17. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold the Drug as prescriptions that, along with diet and exercise, are designed to help lower blood sugar levels in adults with type 2 diabetes.

18. According to the American Diabetes Association, "Type 2 diabetes is the most common form of diabetes. Millions of Americans have been diagnosed with type 2 diabetes. [...] In type 2 diabetes, either the body does not produce enough insulin or the cells ignore the insulin. Insulin is necessary for the body to be able to use glucose for energy. When you eat food, the body breaks down all of the sugars and starches into glucose, which is the basic fuel for the cells in the body. Insulin takes the sugar from the blood into the cells. When glucose builds up in the blood instead of going into cells, it can lead to diabetes complications."<sup>1</sup>

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<sup>1</sup> <http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2>

19. Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels or ‘hyperglycemia’, which is the hallmark of the condition.

20. Diabetes remains the most frequent cause of blindness, amputations and dialysis worldwide.<sup>2</sup> With the current estimate of more than 350 million patients worldwide<sup>3</sup> it is considered to be one of the major health challenges of the 21<sup>st</sup> century.

21. Januvia is supposed to help prevent these diabetic complications.

22. Januvia is a member of a recently approved class of therapeutic agents for the treatment of type 2 diabetes, dipeptidyl peptidase-4 (DDP-4) inhibitors. As with other Drug in it’s class, Januvia exerts its actions through potentiation of incretin receptor signaling. Incretins are gut-derived hormones, principally GLP-1 and glucose-dependent insulintropic peptide (GIP), that are secreted at low basal levels in the fasting state.

23. Januvia was approved by the Food and Drug Administration (“FDA”) on or about October 16, 2006 “as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as monotherapy and in combination with metformin or a PPAR $\gamma$  agonist (e.g., thiazolidinediones) when diet and exercise plus the single agent do not provide adequate glycemic control.”<sup>4</sup>

24. Following FDA approval, Januvia was launched by Defendants in North America in 2006.

25. Januvia is the first in a new class of Drug that inhibit the proteolytic activity of dipeptidyl peptidase-4 (DDP-4), thereby potentiating the action of endogenous glucoregulatory peptides, known as incretins.<sup>5</sup>

26. In February 2010, concerns were published regarding the GLP-1 Drug and the

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<sup>2</sup> ID

<sup>3</sup> IDF Diabetes atlas, <http://www.idf.org/diabetesatlas/5e/diabetes>.

<sup>4</sup> [http://www.accessdata.fda.gov/Drugatfda\\_docs/appletter/2006/021995s000ltr.pdf](http://www.accessdata.fda.gov/Drugatfda_docs/appletter/2006/021995s000ltr.pdf)

<sup>5</sup> Drucker D, Easley Continuing, Kirkpatrick P. Sitagliptin. Nature Reviews Drug Discovery. Feb. 2007. 6:109-10.

DDP-4 inhibitors, including Januvia, and their potential linkage with pancreatic cancer.

27. Writing in DIABETES CARE, Butler *et al.* published *GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You*<sup>6</sup> wherein they wrote, “History has taught us that enthusiasm for new classes of Drug, heavily promoted by the pharmaceutical companies that market them, can obscure the caution that should be exercised when the long-term consequences are unknown. Of perhaps greatest concern in the case of the GLP-1–based Drug, including GLP-1 agonists and dipeptidyl peptidase-4 (DDP-4) inhibitors, is preliminary evidence to suggest the potential risks of asymptomatic chronic pancreatitis and, with time, pancreatic cancer.”

28. In addition, these researchers wrote, “However, in the context of a new class of medical therapy, the proverb ‘What you do not know cannot hurt you’ clearly does not apply. We feel that enough preliminary evidence has accumulated to suggest that there is a plausible risk that long-term recipients of GLP-1–based therapy may develop asymptomatic chronic pancreatitis (Fig. 1), and worse, subsequently a minority of individuals treated by this class of Drug may develop pancreatic cancer.”

29. In February 2011, the journal Gastroenterology published on-line the work of Elashoff *et al.*<sup>7</sup> titled, *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*.

30. These researchers used the FDA Adverse Event Reporting System (AERS) with the primary goal of their analysis being to assess the association between treatment with Januvia (and similar Drug) and an adverse event report of pancreatitis, where the Drug were listed as the primary suspect associated with a pancreatitis report in the database. A secondary goal was to examine the FDA AERS database for reported pancreatic or thyroid

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<sup>6</sup> Butler PC, Dry D, Elashoff D. GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You Diabetes Care February 2010 33:453-455.

<sup>7</sup> Elashoff M, Matveyenko AV, Gier B, Elashoff R & Butler PC Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies. Gastroenterology (2011) 141:150-156.

cancer associated with use of Januvia and similar Drug, with various other anti-diabetic Drug used as controls. Metformin was not used as a control drug because it has been reported to decrease the risk of pancreatic cancer.

31. These researchers reported that pancreatitis, inflammation of the pancreas, was >6-fold more frequently reported in patients prescribed Januvia. This association was statistically significant.

32. Because pancreatitis is a known risk factor for pancreatic cancer,<sup>8</sup> Elashoff *et al.* evaluated the reported rates of pancreatic cancer with Januvia (and similar Drug) compared to control events relative to Avandia (rosiglitazone).

33. The reported event rate for pancreatic cancer was 2.7-fold greater with Januvia than other therapies.

34. Because pancreatitis acts as a risk factor for subsequent pancreatic cancer through the mechanisms of chronic inflammation and increased cell turnover,<sup>9</sup> it is not unforeseen that there is a progressive increased risk of pancreatic cancer with prolonged exposure to the Drug.

35. These researchers noted that the potential to increase the risk of cancer might be expected to occur by “permitting declaration of tumors previously held in check by an intact immune system” as has been published by others within the world’s medical literature.

36. On May 13, 2011, the Arzneimittelkommission der deutschen Ärzteschaft (Drug Commission of the German Medical Association - AkdÄ) published *Pancreatic cancers associated with exenatide (Byetta ®)* on its website.<sup>10</sup> Byetta is a diabetes drug that acts like Januvia.

37. The manufacturers of Januvia have suggested that the most likely reason for the

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<sup>8</sup> Rebours V, Boutron-Ruault MC, Schnee M, et al. The natural history of hereditary pancreatitis: a national series. *Gut* 2009;58: 97–103.

<sup>9</sup> Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic carcinogenesis. *Lab Invest* 2009;89:489–497.

<sup>10</sup> <http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513.html>

apparent association between the use of these Drug and acute pancreatitis is the increased risk of pancreatitis in patients with type 2 diabetes.<sup>11</sup>

38. However, recent animal studies showing pancreatitis as a consequence of GLP-1 mimetic therapy challenge that assumption and lead to the conclusion that asymptomatic chronic pancreatitis is an adverse effect of GLP-1-based treatment.<sup>12,13</sup>

39. GLP-1 receptors are abundantly expressed in the pancreas, and Januvia therapy has been shown to lead to increased pancreatic ductal replication, acinar to ductal metaplasia or cellular change, and, less commonly, acute pancreatitis in a rat model of type 2 diabetes.<sup>14</sup>

40. Increased ductal turnover and acinar to ductal metaplasia are both well-established characteristics of chronic pancreatitis in humans.<sup>15</sup>

41. It has also been suggested that immunomodulatory effects of DDP-4 inhibition might increase risk for all cancers.<sup>16,17</sup>

42. Butler *et al.*<sup>18</sup> also reported that human and rodent pancreases contain numerous GLP-1 receptors in areas in which cancer is thought to originate, and mice that are genetically predisposed to pancreatic cancer develop the disease more quickly than usual in response to

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<sup>11</sup> Monami M, Lamanna C, Marchionni N, Mannucci E. Rosiglitazone and risk of cancer: a meta-analysis of randomized clinical trials. *Diabetes Care* 2008;31:1455–1460.

<sup>12</sup> Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, interactions with metformin. *Diabetes* 2009;58: 1604–1615.

<sup>13</sup> Nachnani JS, Bulchandani DG, Nookala A, et al. Biochemical and histological effects of exendin-4 (exenatide) on the rat pancreas. *Diabetologia* 2009;58:1604–1615.

<sup>14</sup> Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, interactions with metformin. *Diabetes* 2009;58: 1604–1615.

<sup>15</sup> Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic carcinogenesis. *Lab Invest* 2009;89:489– 497.

<sup>16</sup> Havre PA, Abe M, Urasaki Y, et al. The role of CD26/dipeptidyl peptidase IV in cancer. *Front Biosci* 2008;13:1634–1645.

<sup>17</sup> Matteucci E, Giampietro O. Dipeptidyl peptidase-4 (CD26): knowing the function before inhibiting the enzyme. *Curr Med Chem* 2009;16:2943–2951.

<sup>18</sup> Gier B, Matveyenko AV, Kirakossian D, et al. Chronic GLP-1 Receptor Activation by Exendin-4 Induces Expansion of Pancreatic Duct Glands in Rats and Accelerates Formation of Dysplastic Lesions and Chronic Pancreatitis in the KrasG12D Mouse Model. *Diabetes* May 2012 vol. 61 no. 5 1250-1262

Byetta.

43. In April 2012, Public Citizen, a non-profit consumer-advocacy organization based in Washington DC, sent a petition to the FDA to withdraw another drug in the GLP-1 class, Victoza (liraglutide) from the market.

44. Dr. Sidney Wolfe, director of the health and research group at Public Citizen, said at that time, “We don’t just go after Drug casually...(W)e only go after Drug when there is clear evidence of unique dangers or risks, and when there is no evidence of a unique clinical advantage.”

45. Dr. Wolfe said at the time that his concern extends to other diabetes Drug that alter the GLP-1 pathway, which would include Januvia.

46. As a result of the defective nature of Januvia, persons who were prescribed and ingested Januvia for even a brief period of time, including Decedent herein, were at increased risk for developing life-threatening pancreatic cancer. Once that cancer spreads, a patient stands just a 1.8% chance of surviving for longer than five years.

47. Due to the flawed formulation of Januvia, it increases the risk of pancreatic cancer in those diabetic patients to whom it is prescribed.

48. Defendants concealed their knowledge that Januvia can cause life threatening pancreatic cancer from Decedent, other consumers, the general public, and the medical community. Indeed, the manufacturer of Januvia does not even mention ‘pancreatic cancer’ in their drug’s respective product inserts.

49. Specifically, the Defendants did not adequately inform consumers and the prescribing medical community about the risks of pancreatic cancer associated with Januvia usage, nor did Defendants warn or otherwise advise physicians to institute monitoring procedures looking for the first signs of changes within the pancreas.

50. The current warnings for the Drug are simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff and Decedent herein.

51. Even if the warnings were sufficient, which Plaintiff strongly denies, Januvia still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of the Drug. Other drugs to treat diabetes are available. Januvia is quite simply too dangerous and defective as formulated. The Defendants should withdraw Januvia from the market.

52. Defendants willfully, wantonly, and with malice withheld the knowledge of increased risk of pancreatic cancer in users of Januvia to prevent any chances of their product's registration being delayed or rejected by FDA.

53. As the manufacturer and distributor of Januvia, Defendants knew or should have known that the Drug's usage was associated with pancreatic cancer.

54. With the knowledge of the true relationship between use of Januvia and pancreatic cancer, rather than taking steps to pull the Drug off the market or provide strong warnings, Defendants promoted and continue to promote Januvia as a safe and effective treatment for adults with type 2 diabetes.

55. Januvia is one of the top selling Drug in the country, and further, Januvia is one of Merck's best sellers with \$919 million in sales the first quarter of 2012 alone.<sup>19</sup>

56. While Defendants have enjoyed great financial success from their blockbuster Drug, they continue to place American citizens at risk of developing deadly pancreatic cancer.

57. Consumers, including Decedent, who have used Januvia for treatment of their type 2 diabetes had several alternative safer products available to treat their condition and have not been adequately warned about the significant risks and lack of benefits associated with Januvia therapy.

58. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and Decedent's physicians the true and significant risks associated with Januvia use.

59. As a result of Defendants' actions, Decedent and Decedent's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence

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<sup>19</sup> Merck 2012 Januvia Product Insert

that Decedent would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Decedent's Januvia use was the direct and proximate result of Defendants' conduct.

60. At all times relevant hereto, the Defendants have directly marketed and distributed the Drug to the medical community.

61. At all times relevant hereto, the Defendants have directly marketed the Drug to the consuming public throughout the United States, including the Decedent, herein.

62. Defendants departed from and failed to meet requirements of laws, regulations and class and product specific requirements including failing to undertake adequate post approval marketing studies on safety of the Drug as dictated by good pharmaceutical science standards.

63. Defendants both over-promoted the Drug and under-warned about their risks, including:

- a. in print advertising;
- b. on their websites and blogs;
- c. advertised to users that use of the Drug was "safe" whereas it was not and Defendants knew or should have know it was not; and
- d. promoted the Drug to doctors, clinics and users as safer than (or as safe as) other diabetes Drug.

64. Defendants did not perform adequate safety testing on the Drug as required by good pharmaceutical science practice.

65. Defendants failed to provide proper and full information as to the safety of the Drug.

66. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied the Drug to the purchaser.

67. Defendants have never sought to enlarge their warnings to include a warning about pancreatic cancer risks associated with the use of the Drug.

68. Instead, Defendants marketed (and continue to market) the Drug as having a low risk of side effects and continue to minimize the Drug's deadly side effects.

69. Manufacturers such as the Defendants, herein, are required to have systems in place to collect and analyze any complaints they receive from doctors and hospitals about their products.

70. Defendants did not timely apprise the F.D.A., the public, nor treating physicians of the defect(s) in Defendants' Drug, despite Defendants' knowledge that injuries had occurred and had been reported to Defendants due to the above-described defects.

71. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that the Drug was of such a nature that they were not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

72. Decedent and Decedent's prescribing health care providers were unaware of the true degree and incidence of pancreatic cancer associated with the use of the Drug and would have used and prescribed other methods for diabetes control if they had been so informed.

73. Decedent suffered from severe and personal injuries, which were permanent and lasting in nature, including death, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications.

74. As a direct and proximate result of the aforesaid conduct of Defendants and each of them as set forth hereinafter, Decedent suffered injuries, including but not limited to pancreatic cancer, which resulted in his death and damages to Decedent and Plaintiff in a sum in excess of the jurisdictional limits of the Court.

75. As a direct and proximate result of the aforesaid conduct of the Defendants, and each of them, Decedent was compelled to incur obligations for physicians, surgeons, nurses, hospital care, medicine, hospices, x-rays, medical supplies, and other medical treatment, the

true and exact amount thereof being unknown to Plaintiff at this time, and Plaintiff prays leave to amend this complaint accordingly when the true and exact cost thereof is ascertained.

76. As a further direct and proximate result of the said conduct of the Defendants, and each of them, Decedent suffered a loss of income, wages, profits and commissions, a diminishment of earning potential, and other pecuniary losses, the full nature and extent of which are not yet known to Plaintiff; and leave is requested to amend this complaint to conform to proof at the time of trial.

77. By reasons of the premises, Plaintiff and Decedent have been caused great pain and suffering.

#### STATEMENT OF DECEDENT'S INJURIES

78. On or about April 29, 2011 Decedent was prescribed and began taking Januvia upon direction of his physician for long-term maintenance of Type II diabetes, and Decedent continued to take Januvia until at least December 2011.

79. As a direct result of the ingestion of Januvia, the Decedent was diagnosed with pancreatic cancer on or about December 6, 2011. Had Decedent and/or Decedent's physician been properly warned by Defendants regarding the risk of pancreatic cancer from usage of these prescription medications, Decedent's physician would have not prescribed the Drug and Decedent would never had ingested these prescription medications.

80. As a direct result of being prescribed the Drug for this period of time, Decedent was permanently and severely injured, having suffered serious consequences from Decedent's usage of the Drug, including but not limited to, the development of pancreatic cancer, which led to his untimely death on September 25, 2012.

81. Decedent, as a direct and proximate result of his Januvia use, suffered severe mental and physical pain and suffering prior to his death, along with economic loss.

82. As a proximate result of Defendants' acts and omissions, Decedent suffered the injuries described hereinabove due to his ingestion of the Drug. Plaintiff accordingly seeks damages associated with these injuries.

83. Decedent would not have used the Drug had Defendants properly disclosed the risks associated with their use.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

84. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

85. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and are now, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Januvia at issue in this lawsuit. The Januvia manufactured by Defendants reached Decedent without substantial changes and were ingested as directed. The Drug were defective and unreasonably dangerous when they entered into the stream of commerce and when used by Decedent.

86. The Decedent was administered the Drug for their intended purposes.

87. The Decedent could not have discovered any defect in the Drug through the exercise of care.

88. Defendants, as manufacturers of pharmaceutical Drug, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Januvia were incomplete and inadequate.

89. Decedent did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Decedent or to Decedent's treating physicians. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous or incomplete.

90. Defendants had a continuing duty to provide consumers, including Decedent, and Decedent's physicians with warnings and other clinically relevant information and data

regarding the risks and dangers associated with the Drug, as it became or could have become available to Defendants.

91. Defendants marketed, promoted, distributed and sold unreasonably dangerous and defective prescription Drug, Januvia, to health care providers empowered to prescribe and dispense the Drug to consumers, including Decedent, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of the Drug, which resulted in injury to Decedent and ultimately the death of Decedent.

92. Despite the fact that Defendants knew or should have known that the Drug caused unreasonable and dangerous side effects, they continued to promote and market the Drug without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

93. Defendants knew or should have known that consumers, Decedent specifically, would foreseeably and needlessly suffer injury or death as a result of Defendants' failures.

94. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Decedent and to Decedent's intermediary physicians, in at least the following ways:

- a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Decedent and Decedent's physicians to the dangerous risks of the Drug including, among other things, their tendency to increase the risk of, and/or cause, the development of pancreatic cancer;
- b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, pancreatic cancer; and
- c. Defendants continued to aggressively promote and sell the Drug even after they knew or should have known of the unreasonable risks of developing pancreatic

cancer from ingestion of the Drug.

95. Defendants had an obligation to provide Decedent and Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drug, and/or that there existed safer and more or equally effective alternative drug products.

96. By failing to provide Decedent and Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drug, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

97. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Decedent and the public.

98. Defendants' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered the Drug misbranded.

99. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to the Drug and suffered the injuries and damages set forth hereinabove.

## COUNT II

### STRICT PRODUCTS LIABILITY - DESIGN DEFECT

100. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

101. Defendants are the manufacturers, designers, distributors, sellers and suppliers of the Drug, who sold The Drug in the course of business.

102. The Drug manufactured, designed, sold, marketed, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

103. The Drug administered to Plaintiff was defective in design or formulation in the following respects:

- a. When it left the hands of the Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;
- b. Any benefit of these Drug were outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;
- c. The dosages and/or formulation of the Drug sold by the Defendants was unreasonably dangerous;
- d. There are no patients for whom the benefits of the Drug outweighed the risks;
- e. The subject product was not made in accordance with the Defendants' specifications or performance standards;
- f. There are no patients for whom the Drug is a safer and more efficacious drug than other drug products in its class; and/or
- g. There were safer alternatives that did not carry the same risks and dangers that Defendants' the Drug had.

104. The Drug administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.

105. The foreseeable risks associated with the design or formulation of the Drug include, but are not limited to, the fact that the design or formulation of The Drug is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

106. The defective and unreasonably dangerous design and marketing of The Drug was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case.

107. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of The Drug, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering.

108. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

### COUNT III

#### NEGLIGENCE

109. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

110. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of the Drug into the stream of commerce, including a duty to ensure that the products did not cause users to suffer from unreasonable, dangerous side effects.

111. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of the Drug into interstate commerce in that Defendants knew or should have known that the Drug created a high risk of unreasonable, dangerous side effects, including causing and increasing the risk of developing pancreatic cancer.

112. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of the Drug.

113. Despite the fact that Defendants knew or should have known that the Drug caused unreasonable, dangerous side effects, Defendants continued to market the Drug to consumers including Decedent.

114. Defendants knew or should have known that consumers such as Decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

115. Defendants willfully and deliberately failed to avoid those consequences, and in

doing so, Defendants acted with a conscious disregard of the safety of Decedent as alleged previously.

116. As a proximate and legal result of Defendants' negligence, Plaintiff and Decedent were caused to suffer the herein described injuries and damages.

#### COUNT IV

##### BREACH OF IMPLIED WARRANTY

117. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

118. At all times mentioned in this Complaint, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold the Drug, and prior to the time they was prescribed to Decedent, Defendants impliedly warranted to Decedent, and Decedent's physicians and healthcare providers, that the Drug were of merchantable quality and safe for the use for which they were intended.

119. Decedent and Decedent's physicians and healthcare providers relied on the skill and judgment of the Defendants in using and prescribing the Drug.

120. The products were unsafe for their intended use, and they were not of merchantable quality, as warranted by Defendants, in that the Drug had very dangerous propensities when put to their intended use and would cause severe injury (or death) to the user. The Drug were unaccompanied by adequate warnings of their dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

121. As a proximate and legal result of the defective and unreasonably dangerous condition of the Drug manufactured and supplied by Defendants, Decedent was caused to suffer the herein described injuries and damages.

122. After Plaintiff was made aware or otherwise came to believe that the injuries discussed herein were a result of the Drug, notice was duly given to Defendants of the breach of said warranty.

COUNT V

BREACH OF EXPRESS WARRANTY

123. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

124. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the Drug was expressly warranted to be safe for use by Decedent, and other members of the general public.

125. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Drug were to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. The Drug were unaccompanied by adequate warnings of their dangerous propensities that were either known or knowable at the time of distribution.

126. Decedent and Decedent's physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using the Drug. The warranty and representations were untrue in that the products were unsafe and, therefore, unsuited for the use for which they was intended. The Drug could and did thereby cause Decedent to suffer the herein described injuries and damages.

127. As soon as the true nature of the products and the fact that the warranty and representations were false were ascertained, Defendants were notified of the breach of said warranty.

COUNT VI

NEGLIGENT MISREPRESENTATION

128. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

129. Defendants owed a duty in all of their several undertakings, including the communication of information concerning the Drug, to exercise reasonable care to ensure that

they did not, in those undertakings, create unreasonable risks of personal injury to others.

130. Defendants disseminated information to physicians concerning the properties and effects of the Drug, with the intent and expectation that physicians would rely on that information in their decisions regarding the prescribing of drug therapy for their patients.

131. Alternatively or in addition, when Defendants disseminated information to physicians concerning the properties and effects of the Drug, they should have realized, in the exercise of due care to avoid causing personal injury to others, that physicians would reasonably rely on that information in their decisions concerning the prescription of drug therapy for their patients.

132. By uniformly honored custom and practice, the label for a prescription drug product, whether name brand or generic, as it is distributed to pharmacies for dispensing to patients, per the prescriptions of their physicians, accompanies or is placed on or in the package from which the drug is to be dispensed.

133. A drug company will generally distribute to physicians the labels for a name brand prescription drug product along with samples of the product, when it is being introduced to the market, and disseminate the content of the labels (i.e., the product labeling) to physicians through publication of the drug's monograph in the PDR, and otherwise communicate information regarding the drug through advertising, distribution of promotional materials, sales presentations by company sales representatives, group sales presentations, and sponsored publications and seminar speakers.

134. Defendants disseminated false information, as referenced above, to physicians and the medical community and to their patients with knowledge that the information was false or in conscious disregard of its truth or falsity.

135. Defendants disseminated the false information, as referenced above, to physicians, the medical community and their patients with the intention to deceive physicians and their patients and to induce the physicians to prescribe the Drug.

136. Alternatively or in addition, Defendants failed to exercise reasonable care to

ensure that the information disseminated to physicians concerning the properties and effects of the Drug were accurate and not misleading, Defendants failed to exercise reasonable care to insure that accurate and not misleading information was disseminated to physicians concerning the properties and effects of the Drug by failing to publish or disseminate current and accurate information.

137. Defendants expected or should have expected that patients taking the Drug, pursuant to prescriptions written or issued in reliance on false information, would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to the Drug.

138. As a proximate and foreseeable result of this dissemination to physicians, by Defendants consciously or negligently disseminating false information, the Decedent suffered grievous bodily injury, and ultimately death, and consequent economic and other loss, as described above, when Decedent's physicians, in reasonable reliance upon the negligently inaccurate, misleading and otherwise false information disseminated by these defendants, and reasonably but unjustifiably believing the information to be true, prescribed for the Decedent the Drug.

139. As a result of the foregoing negligent misrepresentations by Defendants, and each of them, the Decedent was caused to suffer the herein described injuries and damages.

## COUNT VII

### FRAUDULENT CONCEALMENT

140. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

141. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Decedent and to Decedent's physicians, the true facts concerning the Drug, that is, that the Drug were dangerous and defective, and likely to cause serious health consequences to users, including the injuries as described in this Complaint.

142. Defendants concealed important facts from Decedent and from Decedent's physicians and healthcare providers which facts include, but are not limited to, the fact that

Defendants:

- a. Failed to disclose any connection between use of the Drug and the development of pancreatic cancer;
- b. Did not inform prescribers and users of studies related to use of the Drug and the development of pancreatic cancer, and
- c. Concealed from prescribers and users that numerous adverse events have been reported linking use of the Drug to pancreatic cancer.

143. At all times mentioned in this Complaint, Defendants made affirmative representations to Decedent and Decedent's prescribing physicians prior to the day the Drug were first prescribed to Decedent that the Drug were safe as set forth above while concealing the material facts set forth herein.

144. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Decedent and to Decedent's physicians and healthcare providers the true facts concerning the Drug, which facts include, but are not limited to, the fact that the Drug were dangerous and likely to cause serious health consequences to users, including pancreatic cancer and death.

145. At all times mentioned in this Complaint, Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Decedent's physicians, and therefore from Decedent, with the intent to defraud as alleged herein.

146. At all times mentioned in this Complaint, neither Decedent nor Decedent's physicians or healthcare providers were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did, that is, that the Drug would not have been prescribed as part of Decedent's treatment and Decedent would not have been injured as a result.

147. Had Decedent been informed of the deaths and serious injury adverse reports associated with the Drug usage, Decedent would have immediately discontinued the Drug or never taken the Drug in the first instance.

148. As a proximate result of the concealment or suppression of the facts set forth above, Decedent and Decedent's physicians and healthcare providers reasonably relied on Defendants' deception and, Decedent was prescribed the Drug and subsequently sustained injuries and damages as set forth in this Complaint. Defendants' concealment was a substantial factor in causing the injuries described herein.

149. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiff, for the sake of example and by way of punishing said defendants, seeks punitive damages according to proof.

150. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Decedent was caused to suffer the herein described injuries and damages.

#### COUNT VIII

##### LOSS OF CONSORTIUM

151. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

163. Plaintiff, Dawn Mooney, was at all times relevant hereto the child of the Decedent.

164. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of her mother's companionship and society, and accordingly, the Plaintiff has been caused great mental anguish.

#### COUNT IX

##### PUNITIVE DAMAGES

165. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

166. Although Defendants knew or recklessly disregarded the fact that the Drug cause debilitating and potentially lethal side effects, Defendants continued to market the Drug to consumers, including Decedent, without disclosing these side effects when there were safer alternative methods for treating type 2 diabetes.

167. Defendants knew of the Drug' defective nature, as set forth herein, but continued to design, manufacture, market, and sell them so as to maximize sales and profits at the expense of the health and safety of the public, including Decedent, in conscious and/or negligent disregard of the foreseeable harm caused by the Drug.

168. Defendants intentionally concealed or recklessly failed to disclose to the public, including Decedent, the potentially life-threatening side effects of the Drug to ensure their continued and increased sales. Defendants failed to provide warnings that would have dissuaded physicians from prescribing the Drug and consumers from purchasing and consuming the Drug, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming the Drug.

169. The aforementioned conduct of Defendants was willful and wanton and was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff prays for relief as follows:

1. Actual damages as alleged, jointly and/or severally against Defendants, in excess of \$75,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Wrongful death;
5. Burial and funeral expenses;
6. Loss of companionship and society;
7. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of \$75,000.00;
8. Interest on the judgment at the highest legal rate from the date of judgment until

- collected;
9. Attorneys' fees, expenses, and costs of this action; and
10. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

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

DESIGNATION OF PLACE OF TRIAL

Plaintiff hereby designates Kansas City, Kansas as the place of trial.

Dated: March 29, 2013

Respectfully submitted,

**WAGSTAFF & CARTMELL LLP**

/s/ Thomas J. Preuss

Thomas P. Cartmell (Missouri Bar No. 45366)

Thomas J. Preuss (Missouri Bar No. 54923)

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And

Ryan L. Thompson (*Pro Hac Vice* application anticipated)

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*Attorneys for Plaintiff*



## CIVIL COVER SHEET

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

**I. (a) PLAINTIFFS**

Dawn Mooney, Individually, as an Heir at Law of Ruth Nash, Deceased  
and on Behalf of all Heirs at Law of Ruth Nash, Deceased

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

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

Thomas J. Preuss, Wagstaff & Cartmell LLP, 4740 Grand Ave., Suite 300,  
Kansas City, MO 64112, 816-701-1168

**DEFENDANTS**

Merck Sharp & Dohme Corp.

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

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

Attorneys (If Known)

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

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

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

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation

**VI. CAUSE OF ACTION**

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

**28 US Section 1332**

Brief description of cause:

**Personal injury; product liability.**

**VII. REQUESTED IN COMPLAINT:**

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

**DEMAND \$**

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

03/29/2013

/s/ Thomas J. Preuss

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

# INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
  - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
  - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
- United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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

for the



Defendant

Civil Action No.

Signature of Clerk or Deputy Clerk

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* Merck Sharp & Dohme Corp  
was received by me on *(date)* \_\_\_\_\_ .

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_ , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_ , who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

☐ I returned the summons unexecuted because \_\_\_\_\_ ; or

☐ Other *(specify)*: \_\_\_\_\_ .

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0 \_\_\_\_\_ .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: