
COMPLAINT

COME NOW, Plaintiff JANE BODA, by and through her attorneys, MARC J. BERN & PARTNERS, LLP, who complain and allege against Defendants, MERCK & CO., INC., MERCK SHARP & DOHME CORP., (hereinafter, “MERCK”) and MCKESSON CORP., and each of them (collectively, “Defendants”), on information and belief, as follows:

INTRODUCTION

1. Plaintiff brings this action for personal injuries and damages suffered as a direct and proximate result of being inoculated with the unreasonably dangerous vaccine, ZOSTAVAX, intended for the prevention of shingles as manufactured by Defendants.

3. The subject of the present matter is the ZOSTAVAX vaccine, intended for the prevention of the shingles virus. At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the ZOSTAVAX vaccine to be administered to patients throughout the United States, including Wisconsin.

4. Plaintiff’s claims for damages all relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the faulty ZOSTAVAX vaccine.

5. The Defendants' vaccine that is the subject of this action reached and was administered to Plaintiff, through her physicians, without substantial change in condition from the time the vaccine left Defendants' possession.

6. Plaintiff JANE BODA her physicians, and pharmacists used the ZOSTAVAX vaccine in the manner in which it was intended.

7. Defendants are solely responsible for any alleged design, manufacture or information defect the ZOSTAVAX vaccine may contain.

8. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect regarding its ZOSTAVAX vaccine.

9. Plaintiff JANE BODA was influenced by, affected by, or otherwise caused to use and consent to being inoculated with the Defendants' ZOSTAVAX vaccine as a result of virtually uniform and/or identical information provided, as well as representations and material omissions made by Defendants MERCK, MERCK SHARP & DOHME, and MCKESSON, as set forth herein. This information emanated from the same source, MERCK, and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were received by or otherwise exposed to Plaintiff JANE BODA and her health care providers and pharmacies was the same and include, but are not limited to, the following:

- a. The ZOSTAVAX vaccine applications submitted to and relied by the FDA to obtain a biologics license and for clearance to commercially market.
- b. Product information, instructions for use and other labeling materials provided with the ZOSTAVAX vaccine.
- c. Marketing and promotional materials made available and provided by Defendants' marketing departments to Plaintiff's health care providers, including, but not limited to:
- d. Patient brochures provided by Defendants' sales representatives in person,
- e. Training seminars hosted by MERCK,

- f. CME (Continuing Medical Education) materials created, authored and/or provided by Defendants.
- g. Information supplied at Professional Conferences at booths hosted or manned by MERCK or their Key Opinion Leaders.
- h. Representations and informational packets made and provided by Defendants' marketing and sales departments through their sales representatives to each Plaintiff's physicians during in-office visits or meetings with said physicians and by pharmacists at the places where they go regularly to obtain other medications.
- i. Defendants' online websites that provided the same specific information on the ZOSTAVAX vaccine, including product description, indications for use, instructions for use, and ordering information.

10. Plaintiff, JANE BODA, was urged by her health care providers through the North Fond du Lac Clinic to be inoculated with the ZOSTAVAX vaccine for the prevention of adult shingles, which they were informed by said providers was a dangerous condition.

11. Plaintiff JANE BODA experienced injuries because of the same defects with the ZOSTAVAX, which were known or knowable to Defendants, at all relevant times, but negligently, recklessly, and intentionally withheld from Plaintiff and her health care providers, as set forth herein.

JURISDICTION AND VENUE

12. Plaintiff is a resident and citizen of Wisconsin.

13. Defendants MERCK and MSD (herein after "MERCK Defendants") are New Jersey corporations, each with principal places of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly through related entities, the vaccination ZOSTAVAX.

14. Upon information and belief Defendants MERCK and MSD expressly and/or impliedly assume the liabilities and obligations of Schering-Plough ("MSD") and named Defendants for the injuries and damages alleged herein as a result of Plaintiff's use of the ZOSTAVAX vaccine.

15. Defendant McKESSON is a California corporation with principal place of business in Sacramento.

16. This Court has subject-matter jurisdiction over the action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000.00 exclusive of interests and costs.

17. Venue in this district is appropriate under 28 U.S.C. § 1391 in that a substantial portion of the events giving rise to the claim occurred in this judicial district, and related cases before this Court are active.

PARTIES

18. At all times relevant to this action, Plaintiff JANE BODA has resided at N5537 Seven Hill Road, Fond Du Lac, Wisconsin 54937.

19. At all relevant times to this action, as further detailed herein, Defendants MERCK & CO., MERCK SHARP & DOHME, and MCKEESON CORP., and each of them, were engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, packaging, processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce and into the State of Wisconsin, either directly or indirectly through third parties or related entities, the ZOSTAVAX vaccine, which was to be administered to patients throughout the United States, including Wisconsin, and including the ZOSTAVAX vaccine, as given to Plaintiff JANE BODA, and derived substantial income from doing business in Wisconsin.

20. Defendant MERCK & CO., INC. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, MERCK researched, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and sold the ZOSTAVAX vaccine to be administered to patients throughout the United States, including Wisconsin. MERCK has conducted business and derived substantial revenue from within the State of Wisconsin, from including, but not limited to, its business activities related to the ZOSTAVAX vaccine.

21. Defendant MERCK SHARP & DOHME CORP., is a wholly-owned subsidiary of Defendant MERCK and part of the MERCK family of companies. MERCK SHARP & DOHME CORP. is a corporation organized and existing under the laws of the State of New Jersey with its headquarters located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, through the actions of its wholly-owned subsidiary, MERCK, or, based on information and belief, its own actions, MERCK, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the ZOSTAVAX vaccine to be administered to patients throughout the United States, including Wisconsin. MERCK has conducted business and derived substantial revenue from within the State of Wisconsin, from including, but not limited to, its business activities related to the ZOSTAVAX vaccine.

22. Defendant MCKESSON CORP. (hereinafter "MCKESSON") is a Delaware Corporation with its principal place of business at 2710 Gateway Oaks Drive, Sacramento, California. At all relevant times, MCKESSON was in the business of manufacturing, labeling, selling, marketing, packaging, re-packaging, and distributing the ZOSTAVAX vaccine, on information and belief, the ZOSTAVAX vaccine administered to the Plaintiff. Defendant does business throughout the United States and in the State of Wisconsin, and regularly, continuously, and presently does business with this judicial district, including manufacturing, marketing, selling and distributing the ZOSTAVAX vaccine.

23. Affiliates have provided MERCK with support in the development and distribution of the ZOSTAVAX vaccine. MCKESSON acts as such affiliate and does regularly, and continuously conduct business throughout the State of Wisconsin, including this judicial district.

24. Based upon information and belief, MERCK is, and was at all times relevant hereto, duly authorized to conduct business in Wisconsin as a registered foreign corporation.

25. Based upon information and belief, at all times relevant hereto, MERCK regularly conducted and solicited business within Wisconsin and continues to do so.

26. Based upon information and belief, MERCK, either directly or through its agents, servants and employees, does business in Wisconsin, and at all times relevant hereto, has sold and distributed the ZOSTAVAX vaccine in Wisconsin.

27. MERCK derives substantial revenue from goods used or consumed in Wisconsin.

28. Based on information and belief, MERCK aggressively advertised its ZOSTAVAX vaccine to patients, doctors and hospitals in Wisconsin and/or other medical facilities located throughout Wisconsin.

29. Based on information and belief, MERCK advertises or otherwise promotes its business in Wisconsin.

30. Plaintiff is informed and believes, and thereon alleges that, at all times herein mentioned, and each of them, were and are corporations organized and existing under the laws of the State of Wisconsin or the laws of some state or foreign jurisdiction; that each of the said defendants were and are authorized to do and are doing business in the State of Wisconsin and regularly conducted business in the State of Wisconsin.

ALTER-EGO, VICARIOUS AND SUCCESSOR LIABILITY, AND PIERCING THE CORPORATE VEIL AS A RESULT OF THE RELATIONSHIPS BETWEEN MERCK, MERCK SHARP & DOHME, MCKESSON CORP.

31. Plaintiff incorporate by reference all prior allegations.

32. At all relevant times, Merck, MSD, and McKesson were agents, servants, partners, aiders and abettors, co-conspirators and/or joint venturers, and were all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to each other, knowing their collective conduct would foreseeably cause harm to Plaintiff.

33. At all relevant times, Merck, MSD, and McKesson were engaged in the business of, or were successors in interest to, entities in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling the ZOSTAVAX vaccine for use by Plaintiff, her health care providers, and pharmacists. As such, each of these Defendants is individually, as well as jointly and severally, liable to Plaintiff for their damages.

34. Plaintiff would not have an adequate remedy if Merck, MSD, and McKesson were not named parties in this action.

35. A unity of interest in ownership between Merck and MSD exists or existed at all relevant times, such that any individuality and separateness between Merck and MSD has ceased and Merck and MSD are alter-egos of the other. Adherence to the fiction of the separate existence of Merck and MSD as entities distinct from each other will permit an abuse of corporate privilege and would sanction a fraud and/or promote injustice. Sufficient grounds exist to disregard the corporate form and extend liability to MSD and Merck for the other's acts through piercing the corporate veil.

36. MSD and Merck exercised, and continues to exercise, complete and domination of the finances, policy, and business practices regarding the ZOSTAVAX vaccine of McKesson to such an extent that McKesson has no separate minds, wills or existences of its own.

37. Merck and/or MSD used the aforesaid control over McKesson to research, design, formulate, compound, test, manufacture, produce, process, assemble, inspect, distribute, market, label, promote, package, prescribe, and/or advertise, and sell the ZOSTAVAX vaccine for use by consumers like Plaintiff, and Plaintiff's health care providers and pharmacists.

38. McKesson exercised, and continues to exercise, complete control, and/or equal participation in the policy and business practices of Merck and/or MSD regarding the production, promotion, packaging, advertising, distribution, and selling of the ZOSTAVAX vaccine to such an extent that Merck, MSD, and McKesson have no separate mind, will or own existence in this regard.

39. McKesson used its aforesaid control over Merck and MSD, acting as an agent of Merck, to research, process, assemble, inspect, distribute, market, label, promote, package, advertise, and/or sell the ZOSTAVAX vaccine for use by consumers like Plaintiff, their health care providers, and pharmacists.

40. McKesson, individually and as Merck's agent, developed and implemented the marketing strategy to promote and sell and distribute the ZOSTAVAX vaccine nationwide, including in Wisconsin.

41. McKesson developed the "Vaccine Information Statement" for the ZOSTAVAX vaccine with Merck, and published and disseminated the ZOSTAVAX "Vaccine Information Statement" nationwide, including in Wisconsin.

42. Merck and/or MSD impliedly and explicitly consented to have McKesson act on Merck and/or MSD's behalf with regard to the creation, implementation, marketing, distribution, and wide

dissemination of the marketing materials for the ZOSTAVAX vaccine and the product itself nationwide, including in Wisconsin.

43. Merck and MSD manifested McKesson's authority to act on their behalf by allowing McKesson to create, develop, and implement the marketing strategy and campaign for the ZOSTAVAX vaccine.

44. Merck and MSD manifested McKesson's authority to act on their behalf by allowing McKesson to develop, publish, and disseminate the "Vaccine Information Statement" for the ZOSTAVAX vaccine, and/or to develop, publish, and disseminate marketing and promotional materials for the ZOSTAVAX vaccine.

45. McKesson, Merck, and MSD are liable for all acts and omissions made by each other because of their alter-ego, business partner, or agency relationship.

46. "Merck" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors-in-interest including but not limited to Schering-Plough Corporation, successors, assigns, officers, directors, employees, agents and representatives of Merck, MSD, and each of them.

47. "MSD" where used hereinafter, shall include and refer to all predecessor(s)-in-interest including but not limited to Schering Plough Corporation, successor(s)-in-interest, assigns, officers, directors, employees, agents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and/or representatives of MSD.

48. "Defendants" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Merck, MSD, McKesson, collectively.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OF REPOSE

49. Plaintiff's action was filed within the applicable statute of limitations for her claims because Plaintiff, and her healthcare professionals, did not discover, and could not reasonably discover, the defects and unreasonably dangerous propensities of the ZOSTAVAX vaccine.

50. Plaintiff's ignorance of the defective and unreasonably dangerous nature of the ZOSTAVAX vaccine and the causal connection between these defects and Plaintiff's injuries and damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

51. Defendants' acts and omissions include intentional concealment from Plaintiff, prescribing healthcare professionals, pharmacists, and the general consuming public and the FDA of material information that the ZOSTAVAX vaccine had not been demonstrated to be safe or effective for its intended purpose.

52. Defendants are estopped from relying on any statutes of limitation or repose by unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

53. The ZOSTAVAX vaccine was designed, developed, marketed, and sold with the intended purpose of long-term prevention of herpes zoster, or shingles.

54. Herpes zoster, or shingles, is caused by the varicella zoster virus (VZV). VZV also causes chickenpox. Once the VZV causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

55. Shingles results from reactivation of the latent VZV, and afflicts nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients. The incidence and severity of shingles increases as people age.

56. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

GENERAL FACTUAL BACKGROUND

57. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiff from filing this Complaint.

- a. Pursuant to §11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table.
- b. The ZOSTAVAX vaccine is not a vaccine listed in the Vaccine Injury Table. At all times hereinafter mentioned, MERCK designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the ZOSTAVAX vaccine.

58. ZOSTAVAX was designed, developed, marketed, and sold with the intended purpose of preventing shingles, which is caused by the varicella zoster virus (VZV).

59. Varicella zoster is a virus that causes chickenpox.

60. Once the varicella zoster virus causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

61. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome.

62. When reactivated, varicella zoster replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

63. In May of 2006, the U.S. Food and Drug Administration (“FDA”) approved the ZOSTAVAX vaccine to be marketed and sold in the United States by MERCK.

64. ZOSTAVAX was initially indicated for the “the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose.” FDA Approval Letter, May 25, 2006.

65. FDA approval was based in large part on the results of the Shingles Prevention Study (SPS) supported by MERCK.

66. The results of the SPS were published in the New England Journal of Medicine on June 2, 2005. The paper was titled “A Vaccine to Prevent Herpes Zoster and Post-herpetic Neuralgia in Older Adults”. N. Engl. J. Med. 2005; 352(22):2271-84.

- a. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox. The incidence and severity of shingles increases as people age.
- b. As further described in this paper, “[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient’s quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression.” N. Engl. J. Med. 2005; 352(22) at 2272.
- c. The ZOSTAVAX vaccine is essentially the same vaccine as that used for chickenpox, except significantly stronger.
- d. ZOSTAVAX contains live VZV. The virulence of the virus is reduced or “attenuated.” Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.
- e. ZOSTAVAX is developed from a live attenuated version of the Oka/MERCK VZV vaccine strain.
- f. One of the paper’s more significant findings was “[t]he greater number of early cases of herpes zoster in the placebo group, as compared with the vaccine group, and the fact that no vaccine virus DNA was detected, indicate that the vaccine did not cause or induce herpes zoster.”

67. A risk of using a live virus vaccine is that it is not weakened enough or “under-attenuated.”

68. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.

69. Under-attenuated live VZV has been shown to reactivate. Leggiadro, R. J. (2000). “Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children.” The Pediatric Infectious Disease Journal, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). Nature Medicine, 6(4), 451–454.

70. Once injected, attenuated live virus has been shown to recombine into more virulent strains causing disease.

71. Shingles is a reactivation of the latent VZV, that afflicts in nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients.

72. The approval granted by the FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that MERCK agreed to complete, among other things, to insure the safety of this vaccine. These included the following:

- a. A randomized, placebo-controlled safety study to assess the rates of serious adverse events in 6,000 people receiving the vaccine as compared to 6,000 who receive a placebo.
- b. An observational study using a health maintenance organization (HMO) and 20,000 vaccinated people to address safety issues in the course of clinical practice. This study is specifically to detect “potential safety signals following administration of ZOSTAVAX.” This study was to be submitted to the FDA by December 2008.

73. Since the publication of the SPS in the New England Journal of Medicine, there have been questions raised regarding the safety of ZOSTAVAX vaccine in scientific and medical journals.

74. ZOSTAVAX is a stronger, more potent version of MERCK’s chickenpox vaccine, Varivax.

75. Varivax contains a minimum of 1,350 PFU (plaque-forming units) of the virus while ZOSTAVAX contains a minimum of 19,400 PFU.

76. In the clinical studies evaluating ZOSTAVAX, more than 90% of the vaccinated subjects received 32,300 PFU.

77. MERCK added several adverse reactions to its package insert/prescribing information since Varivax was approved:

- a. The biological system in which the most adverse reactions were added was the nervous system.

- b. Added reactions include: encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barré syndrome, Bell's palsy, ataxia, non-febrile seizures, aseptic meningitis, dizziness, and paresthesia.
- c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

78. As the date of Plaintiff JANE BODA's vaccination, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine contain no clear reference to the potential risk of neurologic disorders, including debilitating post-herpetic neuralgia.

79. Individuals with compromised immune systems should not receive a live virus vaccine because those individuals can develop the disease that the vaccine is designed to prevent.

80. Instances of zoster virus activation occurs at a rate twenty-times higher in immunocompromised patients. Immunocompromised patients encompass a wide spectrum of health conditions ranging from HIV, lymphoma and other cancers, bone marrow transplant recipients, or patients in remission or otherwise who had recently been treated with chemotherapy or prednisone. For those who may be immunocompromised, the shingles will have atypical manifestations that are attributable to more severe skin lesions, increased severity of pain and more diffuse involvement.

81. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for ZOSTAVAX, did not adequately, if at all, address the risk of viral infection or neurological interference. All that was addressed was the concern that a rash and itching might develop at the injection site. This was despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

82. The prescribing information for ZOSTAVAX contains a warning that "[t]ransmission of vaccine virus may occur between vaccines and susceptible contacts."

- a. The risk of transmission of vaccine virus is due to active viral infection in individuals receiving the ZOSTAVAX vaccine.

83. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for ZOSTAVAX, did not adequately, if at all, address the risk of viral infection or possible diseases of the nervous system. This was despite the fact that Varivax, a less potent vaccine, had added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

84. Since ZOSTAVAX's introduction in 2006, Vaccine Adverse Event Reports ("VAERS") appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis.

85. Documented adverse reactions to vaccines must be reported to the federal government in a compulsory and mandated database, the Vaccine Adverse Event Reporting System ("VAERS"). As of September of 2015, there had been 1,111 submissions received of serious adverse event reports regarding the Zoster vaccine, including 36 deaths. These reports included depicting recurrent instances of: myalgia; arthralgia; lymphadenopathy; rash; actinic keratosis; severe cutaneous disease; peripheral neuropathy; cellulitis; herpes keratitis and retinal necrosis resulting in vision loss; facial paralysis; pneumonia; brain inflammation (encephalitis); and death.

86. Other than post-herpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, allodynia, cranial and motor neuron palsies, pneumonia, encephalitis, visual impairment, hearing loss, and death.

87. Since the live vaccine ZOSTAVAX was a mere amplification of the virus already disseminated and widely distributed in their Varivax (chickenpox) vaccine, it was likely more cost effective to mass produce this duplicative vaccine rather than to allocate resources and funding to the testing and FDA clearance of a non-live vaccine alternative.

88. MERCK had knowledge that a non-live vaccine was an effective and preferential way to prevent shingles, but it maximized Defendants' profits to pursue a less safe live-attenuated vaccine with the strain of the virus already cleared for market (in Varivax), and to abandon prior patents or research on non-live alternatives.

89. The Center for Disease Control and Prevention ("CDC") publishes that the ZOSTAVAX vaccine wanes in efficacy within five years, having almost no remaining preventative effects after seven years.

90. The instructions and information published by MERCK regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccinate. Patients who received the ZOSTAVAX vaccine do so with the

intention to have long-term protection from herpes zoster, although even upon perfect use, the efficacy of the vaccine will decrease significantly after four years.

91. Additionally, unlike ZOSTAVAX, protein-based vaccine alternatives are safe and effective even in immunocompromised patients. Non-live or inactivated vaccines carry no risk of reactivation inducing shingles after inoculation and are not known to cause post-herpetic neuralgia. Unlike ZOSTAVAX, non-live vaccines also maintain efficacy, with 88% lower risk to develop shingles after four years than ZOSTAVAX, which diminishes in efficacy steadily with time.

92. MERCK knew, or should have known, that the pharmaceutical efficacy and overall safety and benefit of a non-live, inactivated, or protein based vaccine, is a safer alternative to the ZOSTAVAX vaccine. The existence of safer alternatives to shingles-preventative care which is widely known to the scientific community has been tested in clinical trials alongside ZOSTAVAX comparing efficacy and shows that such dangers of ZOSTAVAX were known or discoverable, as was a safer and more effective alternative. MERCK cannot claim that risks or alternatives were “scientifically undiscoverable” in the context of a state-of-the-art defense.

93. It follows that given the increased risk of viral infection due to vaccination, such complications are also possible complications of ZOSTAVAX. It also follows that post-vaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

94. Despite this information and the potential correlation between being administered the ZOSTAVAX vaccine and developing an infection within a relatively short period of time, leading to the development of shingles or varicella-zoster virus pneumonia, MERCK failed to properly address and provide this information both to patients and the medical providers prescribing the vaccine.

95. As a direct result of the vaccine, Plaintiff suffered, is suffering and/or will continue to suffer from mental and emotional distress due to resulting physical limitations and seriousness of her condition and irreversible blindness.

96. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of ZOSTAVAX, Plaintiff sustained severe and permanent personal injuries. Further, as a tragic consequence of MERCK's wrongful conduct, Plaintiff suffered serious, progressive, permanent, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

97. Plaintiff has incurred and will continue to incur medical expenses and other economic harm as a direct result of use of ZOSTAVAX.

PLAINTIFF SPECIFIC FACTS

98. Plaintiff JANE BODA was inoculated with Defendants' ZOSTSVAX vaccine on or about November 8, 2011, administered by David Krueger at North Fond du Lac Clinic - North, located in North Fond du Lac, Wisconsin. The vaccine was ordered by Douglas Fownes, M.D., and recommended for routine adult health maintenance and for the prevention of shingles and post-herpetic neuralgia.

99. The ZOSTAVAX vaccine not did function as intended, and JANE BODA subsequently suffered from a long series of resilient herpes zoster outbreaks, which inevitably resulted in neurological interference and painful post-herpetic neuralgia that has been resistant to all therapies.

100. On or about June 27, 2016, JANE BODA was treated by Mark A. Whitmore, M.D. at Fond du Lac Regional Clinic Mail, Agnesians HealthCare in Fond du Lac for a blistering vesicular eruption, which was diagnosed as severe herpes zoster, or shingles. On or about June 30, 2017, JANE BODA was further treated at Fond du Lac Regional Clinic for uncontrolled symptoms of shingles outbreaks. JANE BODA sought subsequent treatment on or about July 27, 2016 for severe and unrelenting pain and shingles outbreaks, at which time she was diagnosed with post-herpetic neuralgia: a chronic condition of pain and nerve damage secondary to zoster infections. Throughout 2016 and 2017, JANE BODA required continuous care to treat severe symptoms of neuralgia and hypersensitivity in the areas where zoster infections had been present.

101. JANE BODA has been prescribed Gabapentin, Promethazine, and Imipramine in increasing dosages for management of her excruciating pain and neurologic interference. Plaintiff has also been treated with Morphine therapy in attempts to curb her pain.

102. As a proximate result of her zoster infections and resulting post-herpetic neuralgia, Plaintiff JANE BODA experienced significant weight loss and decreased ability to live a normal life because of her chronic pain.

103. As a direct and proximate result of these malfunctions, Plaintiff JANE BODA suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JANE BODA has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

FIRST CAUSE OF ACTION: NEGLIGENCE

104. Plaintiff incorporates by reference all prior allegations.

105. The ZOSTAVAX vaccine contains live Oka/Merck VZV vaccine strain. The virulence of the virus is reduced or “attenuated.” Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

106. A risk of using a live-attenuated virus vaccine is that it is not weakened enough or “under-attenuated”. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent. Under-attenuated live VZV has been shown to reactivate.¹ Once injected, attenuated live virus vaccines have been shown to recombine into more virulent strains causing disease.

107. ZOSTAVAX vaccine, at its peak if injected at age 60, was at best 51%.

108. The ZOSTAVAX vaccine wanes in efficacy to near zero after four years post-inoculation.

109. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

110. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

111. Merck and MSD each had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiff, to manufacture to design, manufacture, process, package, label, market, promote, distribute, and sell a product that was safe and effective for its normal, common, and intended purpose.

112. McKesson had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiff, to package, label, market, promote, distribute, and sell a product that was safe and effective for its normal, common, and intended purpose.

113. Merck, MSD, and McKesson each directly advertised or marketed the ZOSTAVAX vaccine to consumers or persons responsible for consumers, including the Plaintiff and the prescribers and/or administrators of the ZOSTAVAX vaccine, and therefore each Defendant had a duty to warn of the risks associated with the use of the product or unreasonable inherently dangerous propensities of ZOSTAVAX that are not obvious in the contemplated use of the product.

114. By negligently and/or wantonly failing to adequately warn of the dangers of the use of the product, each Defendant breached its duty.

115. In May 2006, the U.S. Food and Drug Administration (“FDA”) approved the ZOSTAVAX vaccine to be marketed and sold in the United States by Merck.

116. ZOSTAVAX was initially indicated for the “the prevention of herpes zoster in individuals 60 years of age and older when administered as a single-dose.”²

117. FDA approval of the ZOSTAVAX vaccine was based in large part on the results of the Shingles Prevention Study (“SPS”) supported by Merck and/or MSD.

¹ Leggiadro, R. J. (2000). “Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children.” *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

² FDA Approval Letter, May 25, 2006.

118. The results of the SPS were published in the *New England Journal of Medicine* on June 2, 2005. The paper was titled “A Vaccine to Prevent Herpes Zoster and post-herpetic Neuralgia in Older Adults”. *N. Engl. J. Med.* 2005; 352(22):2271-84.

119. FDA approval to allow the selling and marketing of the ZOSTAVAX vaccine in 2006 came with certain post-marketing commitments that Merck and/or MSD agreed to complete, among other things, to insure the safety of the ZOSTAVAX vaccine.

120. Since ZOSTAVAX’s introduction in 2006, a significant number of various adverse effects, including but not limited to shingles, were reported to Merck and MSD during the post-marketing commitments made by Merck and MSD for the FDA approval of ZOSTAVAX in 2006.

121. Since ZOSTAVAX’s introduction in 2006, Vaccine Adverse Event Reports (“VAERS”) appeared in significant numbers documenting numerous adverse effects, including, but not limited to, shingles and shingles-related injuries.

122. Despite having knowledge of this information, Defendants failed to provide this information to patients and medical providers who prescribe and administer the ZOSTAVAX vaccine.

123. At all relevant times, the ZOSTAVAX vaccine’s patient information sheet, its label, and its prescribing information did not adequately address the risk of viral infection or possible diseases of the nervous system associated with the use of the product, or of its waning efficacy to near zero four years after inoculation.

124. The ZOSTAVAX vaccine’s patient information sheet only addressed the concern that a rash and itching might develop at the injection site. The ZOSTAVAX vaccine’s patient information sheet failed to notify its readers that shingles was a noted occurrence during the product’s clinical trials.

125. When Plaintiff were inoculated with ZOSTAVAX, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine lacked an adequate and conspicuous reference to the potential risk of viral infection.

126. When Plaintiff were inoculated with ZOSTAVAX, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine lacked an adequate and conspicuous warning that its efficacy waned to near zero after four years post-inoculation.

127. Merck, MSD, and McKesson failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of ZOSTAVAX because Merck and MSD knew, or should have known, that the ZOSTAVAX vaccine carried the serious risk of causing viral infection and was therefore not unreasonably dangerous to its consumers.

128. Merck, MSD, and McKesson failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of ZOSTAVAX because Merck, MSD, and McKesson knew, or should have known, that the ZOSTAVAX vaccine was not effective for long-term prevention of shingles in adults over 60 years of age.

129. The ZOSTAVAX vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck, MSD, and McKesson was unreasonably and inherently dangerous due the risks associated with its use, was more dangerous than expected by the ordinary consumer, and those dangers were not known or obvious to any other party except Defendants (each of them). Merck, MSD, and McKesson breached their duty of reasonable care by selling the unreasonably dangerous ZOSTAVAX vaccine.

130. Merck, MSD, and McKesson failed to issue to consumers and/or their healthcare providers adequate warnings or disclosures, through labels or other means, regarding the actual efficacy of the ZOSTAVAX vaccine and the risks of serious bodily injury, including viral infection, resulting from use of the ZOSTAVAX vaccine. Merck, MSD, and McKesson's failure was a breach of their duty of reasonable care.

131. Reasonably prudent manufacturers, distributors, suppliers, and/or sellers would not have placed the ZOSTAVAX vaccine in the stream of commerce with knowledge of its inherent, hidden, and unreasonably dangerous risks.

132. Merck and MSD continued to manufacture, market, and sell the ZOSTAVAX vaccine despite the knowledge, whether direct or ascertained with reasonable care, that ZOSTAVAX was not effective for its purpose and that it posed serious risk of bodily harm to consumers.

133. Merck and MSD continued to manufacture, market, and sell the ZOSTAVAX vaccine despite the knowledge that its efficacy waned significantly over time, and was effectively worthless after four years post-inoculation.

134. McKesson continued to label, package, market, promote, distribute, and sell the ZOSTAVAX vaccine without adequate instructions or warnings despite the knowledge, whether direct or ascertained with reasonable care, that ZOSTAVAX was not effective for its purpose and that it posed a serious risk of bodily harm to consumers.

135. Merck, MSD, and McKesson breached their duty of reasonable care by continuing to sell the unreasonably dangerous ZOSTAVAX vaccine without adequate disclosures despite having actual or constructive knowledge of its associated risks and lack of efficacy.

136. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term

prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off and did not maintain the efficacy for intended purpose.

137. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine, a live-attenuated virus.

138. As a direct and proximate result of the breach of care by Merck, MSD, and McKesson, Plaintiff suffered severe and permanent personal injuries, including significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

139. As a direct and proximate result of the breach of care by Merck, MSD, and McKesson, Plaintiff suffered, are suffering, and/or will continue to suffer from mental and emotional distress due to resulting physical limitations and seriousness of their physical condition. Plaintiff have incurred and will incur medical expenses and other economic harm.

SECOND CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

140. Plaintiff incorporates by reference all prior allegations.

141. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

142. Patients who received the ZOSTAVAX vaccine do so with the intention to have long-term protection from herpes zoster.

143. Herpes zoster, or shingles, is caused by the varicella zoster virus (VZV).

144. VZV also causes chickenpox. Once the VZV causes chickenpox, the virus remains inactive or dormant in the nervous system for many years.

145. Shingles results from reactivation of the latent VZV, and afflicts nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients. The incidence and severity of shingles increases as people age.

146. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

147. The ZOSTAVAX vaccine contains live Oka/Merck VZV vaccine strain. The virulence of the virus is reduced or “attenuated.” Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

148. A risk of using a live-attenuated virus vaccine is that it is not weakened enough or “under-attenuated”. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent. Under-attenuated live VZV has been shown to reactivate.³ Once injected, attenuated live virus vaccines have been shown to recombine into more virulent strains causing disease.

149. ZOSTAVAX vaccine, at its peak if injected at age 60, was at best 51%.

150. The ZOSTAVAX vaccine waned in efficacy to near zero after four years post-inoculation.

151. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

³ Leggiadro, R. J. (2000). “Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children.” *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

152. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

153. At all relevant times, Defendants, each of them, placed the ZOSTAVAX vaccine into the stream of commerce with full knowledge that it would reach consumers such as Plaintiff.

154. The ZOSTAVAX vaccine was expected to, and did, reach the intended consumers, and the persons administering it with no substantial change in the condition in which the product was designed, produced, and manufactured by Merck and MSD and sold, distributed, labeled, and marketed by Merck, MSD, and McKesson.

155. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD, and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson was defective in design and formulation because when it left the hands of Merck, MSD, and McKesson: ZOSTAVAX was unreasonably dangerous; the product was more dangerous than expected by the ordinary consumer; the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product; and/or the product's inherent dangers were not known or obvious to any other party except Defendants (each of them).

156. The ZOSTAVAX vaccine was inherently dangerous because it is used for long-term prevention of shingles.

157. At all relevant times, Merck, MSD, and McKesson knew and had reason to know that the ZOSTAVAX vaccine was inherently defective and unreasonably dangerous as designed and formulated, and when used and administered in the form and in the manner instructed by Defendants to be used and administered.

158. Merck, as a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, knew or should have known of a safer and more effective alternative vaccine for shingles prevention, in the form of a non-live or inactivated vaccine strain.

159. MSD, as a leading designer and manufacturer of pharmaceutical products, knew or should have known of a safer and more effective alternative vaccine for shingles prevention, in the form of a non-live or inactivated vaccine strain.

160. McKesson, as a leading manufacturer, marketer, distributor, and seller of pharmaceutical products, and specifically a leading marketer, distributor of the ZOSTAVAX vaccine, knew or should have known of a safer and more effective alternative vaccine for shingles prevention, in the form of a non-live or inactivated vaccine strain.

161. Merck and MSD knew that a non-live vaccine for herpes zoster prevention existed at the time when Plaintiff were each administered the ZOSTAVAX vaccine. Merck owned the patent of a non-live zoster vaccine alternative, and chose to continue using the Oka/Merck VZV vaccine strain and let the non-live vaccine patent lapse.

162. Protein-based vaccine alternatives are safer and more effective than the live-attenuated ZOSTAVAX vaccine even in immunocompromised patients.

163. Non-live vaccines carry no risk of reactivation inducing shingles after inoculation.

164. Unlike ZOSTAVAX, the non-live zoster vaccine maintains its efficacy, with 88% lower risk to develop shingles after four years. ZOSTAVAX diminishes in efficacy steadily with time to zero after four years.

165. Merck, MSD, and McKesson knew or should have known that there were widely-publicized and economically feasible alternative designs to the ZOSTAVAX vaccine itself, and methods to prescribe the ZOSTAVAX vaccine, to boost its long-term efficacy.

166. Merck, MSD, and McKesson knew, or should have known, that the pharmaceutical efficacy and overall safety and benefit of a protein-based zoster vaccine is a safer alternative to the ZOSTAVAX vaccine.

167. The alternative zoster vaccines were scientifically discoverable to Defendants in the context of the state-of-the-art defense. ZOSTAVAX's dangers were known or discoverable, as was a safer and more effective alternative to ZOSTAVAX.

168. Safer alternative vaccines to ZOSTAVAX for the long-term prevention of shingles which are widely known to the scientific community exist. An alternative zoster vaccine has been tested in clinical trials alongside the ZOSTAVAX vaccine comparing their efficacy. These studies show that the alternative vaccine was more effective, and safer, than ZOSTAVAX.

169. An alternative design of the ZOSTAVAX vaccine, such as an inactivated, non-live, or protein-based vaccine, would have eliminated the possibility of inducing shingles, and would have prevented the injury suffered by Plaintiff.

170. Alternatively, Merck, MSD, and McKesson knew or should have known that there were widely-publicized and economically feasible methods to "de-activate" the ZOSTAVAX vaccine strain, for example using heat or gamma-radiation, to eliminate the possibility of re-activating the virus upon being inoculated, as occurred in Plaintiff.

171. The ZOSTAVAX vaccine's instructions, labeling, and packaging did not alert potential ZOSTAVAX vaccine consumers or administrators or prescribers of the product of its decreased efficacy over time.

172. The instructions and information published by Merck, MSD, and McKesson regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccine.

173. It was reasonably foreseeable that consumers of the ZOSTAVAX vaccine would fail to offer long-term prevention of shingles to consumers such as Plaintiff, and that consumers including Plaintiff would contract herpes zoster despite being inoculated with the ZOSTAVAX vaccine that was intended to prevent it.

174. Alternatively, it was reasonably foreseeable that consumers of the ZOSTAVAX vaccine, including Plaintiff, would contract the vaccine-strain of herpes zoster after being inoculated with the ZOSTAVAX vaccine.

175. The ZOSTAVAX vaccine was defective in its design and/or manufacture because Plaintiff used it for the purpose intended and in a manner normally used and they still suffered from shingles.

176. Alternatively, the ZOSTAVAX vaccine was defective in its design and/or manufacture because Plaintiff used it for the purpose intended and in a manner normally used and they contracted shingles as a result.

177. Merck and MSD knew, or should have known, that consumers, such as the Plaintiff, would foreseeably suffer injury because of the design and/or manufacture of the ZOSTAVAX vaccine. McKesson knew, or should have known, that consumers, such as Plaintiff, to whom it marketed and distributed the ZOSTAVAX vaccine, would suffer serious injury because of the design and/or manufacture of the ZOSTAVAX vaccine.

178. Plaintiff's physicians and/or healthcare providers used and administered the ZOSTAVAX vaccine for the purpose intended by Merck, MSD, and McKesson, and in a manner normally intended to be used and administered.

179. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of the ZOSTAVAX vaccine and/or perceive its defective dangers prior to its administration by her physicians and/or healthcare providers.

180. Plaintiff, their physicians, and their pharmacists used the ZOSTAVAX vaccine in the manner in which it was intended.

181. The ZOSTAVAX vaccine did not serve its intended purpose.

182. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

183. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

184. As a direct and proximate result of the ZOSTAVAX vaccine's defective design, Plaintiff sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

THIRD CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

185. Plaintiff incorporates by reference all prior allegations.

186. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

187. Patients who received the ZOSTAVAX vaccine do so with the intention to have long-term protection from herpes zoster.

188. Herpes zoster, or shingles, is caused by the varicella zoster virus (VZV).

189. VZV also causes chickenpox. Once the VZV causes chickenpox, the virus remains inactive or dormant in the nervous system for many years.

190. Shingles results from reactivation of the latent VZV, and afflicts nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients. The incidence and severity of shingles increases as people age.

191. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

192. The ZOSTAVAX vaccine contains live Oka/Merck VZV vaccine strain. The virulence of the virus is reduced or “attenuated.” Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

193. A risk of using a live-attenuated virus vaccine is that it is not weakened enough or “under-attenuated”. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent. Under-attenuated live VZV has been shown to reactivate.⁴ Once injected, attenuated live virus vaccines have been shown to recombine into more virulent strains causing disease.

194. ZOSTAVAX vaccine, at its peak if injected at age 60, was at best 51%.

195. The ZOSTAVAX vaccine waned in efficacy to near zero after four years post-inoculation.

196. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

⁴ Leggiadro, R. J. (2000). “Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children.” *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

197. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

198. Merck, as a manufacturer, marketer, and distributor of pharmaceutical products, is held to the level of knowledge of an expert in the field. At all relevant times, Merck had knowledge of the dangerous risks and side effects of the ZOSTAVAX vaccine. At all relevant times, Merck had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.

199. MSD, as a designer and manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field. At all relevant times, MSD had knowledge of the dangerous risks and side effects of the ZOSTAVAX vaccine. At all relevant times, MSD had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.

200. McKesson, as a leading manufacturer, marketer, and distributor of pharmaceutical products, and specifically a leading marketer and distributor of the ZOSTAVAX vaccine at all relevant times is held to the level of knowledge of an expert in the field. At all relevant times, McKesson had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.

201. Plaintiff and their healthcare providers and physicians did not have the same knowledge as Defendants, and no adequate warning was communicated to Plaintiff's physicians and/or healthcare providers.

202. At all relevant times, Defendants, each of them, placed the ZOSTAVAX vaccine into the stream of commerce with full knowledge that it would reach consumers such as Plaintiff who would become inoculated with the vaccine.

203. The ZOSTAVAX vaccine was under the exclusive control of Merck, MSD, and McKesson.

204. The ZOSTAVAX vaccine was defective when it left the possession of Merck, MSD, and McKesson, in that it contained inadequate warnings and instructions to alert the Plaintiff and/or Plaintiff's healthcare providers that the ZOSTAVAX vaccine created a risk of serious and dangerous side effects, including but not limited to viral infection resulting in shingles.

205. The ZOSTAVAX vaccine was defective when it left the possession of Merck, MSD, and McKesson, in that it contained insufficient warnings or disclosure to alert the Plaintiff and/or Plaintiff's healthcare providers to the actual efficacy of the product over time.

206. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson was defective because when it left the hands of Merck, MSD, and McKesson, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer, and those dangers were not known or obvious to any other party except Defendants (each of them).

207. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson, was defective due to inadequate warnings or instructions regarding the inherent, hidden, and unreasonable dangers of the product.

208. The ZOSTAVAX vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which the product was sold by Merck, MSD, and McKesson.

209. The risk of inducing shingles was a side-effect that was reasonably foreseeable to Defendants, each of them.

210. The risk of inducing shingles, the very condition ZOSTAVAX was intended to prevent, was a risk that was not obvious to a consumer of the vaccine, such as Plaintiff, or a prescriber or administrator of the vaccine following the indications of the product's label, prescribing instructions, or instructions for use.

211. When Plaintiff was vaccinated with ZOSTAVAX on the date of vaccination, the ZOSTAVAX vaccine lacked adequate and conspicuous warning that that the live vaccine could re-activate a serious strain of the herpes zoster virus.

212. The waning efficacy of the ZOSTAVAX vaccine over after inoculation, to effectively zero after four years, is not obvious to a consumer of the vaccine, such as Plaintiff, or a prescriber or administrator of the vaccine following the indications of the label, prescribing instructions, or instructions for use.

213. Patients who received the ZOSTAVAX vaccine do so with the intention to have long-term protection from herpes zoster.

214. Even upon perfect use, the efficacy of the vaccine will decrease significantly after four years. Merck, MSD, and McKesson each knew the rate at which the ZOSTAVAX vaccine's efficacy declined.

215. The Center for Disease Control ("CDC") published that the ZOSTAVAX vaccine wanes significantly in efficacy within five years, having almost no remaining preventative effects after seven years. This information is not included on any labeling or packaging literature to alert potential ZOSTAVAX vaccine consumers or administrators or prescribers of its decreased efficacy over time.

216. The instructions and information published and provided by Merck, MSD, and McKesson regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccine.

217. The instructions and warnings that accompanied the ZOSTAVAX vaccine were inadequate in light of the generally recognized and prevailing scientific and medical knowledge at the time of its manufacture and sale.

218. Upon information and belief, the ZOSTAVAX vaccine as manufactured by Merck and/or MSD, and marketed, distributed, and sold by Merck, MSD, and McKesson, was further defective due to inadequate post-market warnings or instructions.

219. When Plaintiff was vaccinated with ZOSTAVAX, the ZOSTAVAX vaccine lacked adequate and conspicuous warning or disclosures that the efficacy rate of the ZOSTAVAX vaccine would be effectively zero after four years.

220. If the Plaintiff was equipped with the knowledge of the unreasonably dangerous risks associated with the ZOSTAVAX vaccine, Plaintiff would not have purchased it and agreed to have it injected into her body.

221. If the Plaintiff's physicians, pharmacists, or healthcare providers were equipped with the unreasonably dangerous risks associated with the ZOSTAVAX vaccine, they would not have recommended, prescribed, purchased, or administered it to the Plaintiff.

222. If the Plaintiff was equipped with the knowledge of the efficacy of the ZOSTAVAX vaccine over time, including the rate at which its efficacy wanes, Plaintiff would not have purchased it and agreed to have it injected into her body.

223. If the Plaintiff's physicians, pharmacists, or healthcare providers were equipped with the knowledge of the efficacy of the ZOSTAVAX vaccine over time, including the rate at which its efficacy wanes, they would not have recommended, prescribed, purchased, or administered it to the Plaintiff for the long-term prevention of shingles.

224. When Plaintiff was vaccinated with ZOSTAVAX, the ZOSTAVAX vaccine was administered and used as intended.

225. Plaintiff has suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

226. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

227. The herpes zoster viral strain is most effectively treated and can be curbed with antivirals only during the initial stages of viral outbreak. If the window of treatment is missed, patients are often unable to treat the virus, or in the alternative, the virus persists with longer duration even after antiviral therapies.

228. If the Plaintiff and her health care providers were equipped with the knowledge of the true efficacy of the ZOSTAVAX vaccine (which wanes to nearly zero with time), Plaintiff and her healthcare providers would have been able to more effectively treat and curb the serious symptoms of zoster virus upon onset, at which time Plaintiff reasonably believed she were immune because of her use of ZOSTAVAX.

229. As a proximate result of the ZOSTAVAX vaccine's defectiveness through inadequate warnings, and the Plaintiff's use of the defective product, Plaintiff suffered serious physical injuries including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the

enjoyment of life, diminished quality of life, and incurred medical bills and other expenses, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

FOURTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

230. Plaintiff incorporates by reference all prior allegations.

231. MERCK, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that its ZOSTAVAX vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, severe shingles and post-herpetic neuralgia, and was adequately tested and fit for its intended use.

- a. Specifically, MERCK stated that "ZOSTAVAX is a vaccine that is used for adults 60 years of age or older to prevent shingles (also known as zoster)."
- b. MERCK also stated that "ZOSTAVAX works by helping your immune system protect you from getting shingles."
- c. MERCK, in the SPS paper, stated that "...the vaccine did not cause or induce herpes zoster."

232. At the time of making such express warranties, MERCK knew and/or should have known that its ZOSTAVAX vaccine did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which MERCK had full knowledge and did not accurately or adequately warn.

233. The ZOSTAVAX vaccine manufactured and sold by MERCK did not conform to these representations because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as the Plaintiff, when used in routinely administered dosages.

234. MERCK breached its express warranties because its product was and is defective for its intended purpose.

235. Plaintiff, through her physicians and/or other healthcare providers, did rely on MERCK's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

236. Members of the medical community, including physicians and other healthcare professionals, relied upon MERCK's representations and express warranties in connection with the use recommendation, description, and dispensing of MERCK's ZOSTAVAX vaccine.

237. As a foreseeable, direct, and proximate result of the breach of the express warranties, the Plaintiff suffered severe and permanent personal injuries, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

FIFTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

238. Plaintiff incorporates by reference all prior allegations.

239. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

240. Herpes zoster, or shingles, is caused by the varicella zoster virus (VZV).

241. VZV also causes chickenpox. Once the VZV causes chickenpox, the virus remains inactive or dormant in the nervous system for many years.

242. Shingles results from reactivation of the latent VZV, and afflicts nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients. The incidence and severity of shingles increases as people age.

243. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

244. The ZOSTAVAX vaccine contains live Oka/Merck VZV vaccine strain. The virulence of the virus is reduced or “attenuated.” Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

245. A risk of using a live-attenuated virus vaccine is that it is not weakened enough or “under-attenuated”. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent. Under-attenuated live VZV has been shown to reactivate.⁵ Once injected, attenuated live virus vaccines have been shown to recombine into more virulent strains causing disease.

246. ZOSTAVAX vaccine, at its peak if injected at age 60, was at best 51%.

⁵ Leggiadro, R. J. (2000). “Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children.” *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

247. The ZOSTAVAX vaccine waned in efficacy to near zero after four years post-inoculation.

248. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

249. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

250. Merck and MSD, through their officers, directors, agents (including distributor McKesson), representatives, and written literature and packaging, and written and media advertisements, expressly warranted that the ZOSTAVAX vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

251. Merck, MSD, and McKesson, through their officers, directors, agents, representatives, and through written literature and packaging, and written and media advertisements, expressly warranted that its ZOSTAVAX vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

252. Merck and MSD warranted that "...the vaccine did not cause or induce herpes zoster."

253. The ZOSTAVAX vaccine did not conform to the warranties made by Merck and MSD because it could and did induce shingles.

254. At the time of making such express warranties, Merck and MSD knew that the ZOSTAVAX vaccine could induce herpes zoster.

255. Additionally, Merck, MSD, and McKesson, each of them, through their officers, directors, agents, representatives, and through written literature and packaging, and written and media advertisements, represented that:

- a. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it.
- b. That serious adverse effects were experienced by less than 1% of individuals in the ZOSTAVAX vaccine's clinical trials and studies.
- c. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults – and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults.
- d. That ZOSTAVAX was a “well-studied vaccine.”
- e. That ZOSTAVAX “significantly reduced” the risk of developing shingles compared with placebo.”
- f. That ZOSTAVAX would benefit its users “in the *prevention of long-term nerve pain from shingles* (post-herpetic neuralgia) *can be primarily attributed to the vaccine's effect on the prevention of shingles.*” (emphasis added).
- g. That the efficacy of ZOSTAVAX is 51% for everyone.
- h. That the efficacy of ZOSTAVAX did not diminish over time after vaccination.
- i. That the immunity provided by ZOSTAVAX was unlimited.
- j. That the immunity provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated.
- k. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles.
- l. That ZOSTAVAX was safe.
- m. That ZOSTAVAX was effective.

256. The ZOSTAVAX vaccine did not conform to the warranties made by Merck, MSD, and McKesson because it caused serious injury, including shingles, to consumers such as the Plaintiff when used in routinely administered dosages.

257. The ZOSTAVAX vaccine did not conform to the warranties made by Merck, MSD, and McKesson because it was not effective for the long-term prevention of shingles – it was not effective at all after four years.

258. The ZOSTAVAX vaccine did not conform to the warranties made by Merck, MSD, and McKesson because its efficacy was not the same for all of its users – its peak efficacy rate of 51% was only in users that are 60 years of age.

259. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew and/or should have known that the ZOSTAVAX vaccine did not conform to the express warranties and representations:

260. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine was associated with numerous serious side effects, including the possibility of viral infection.

261. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine waned in efficacy – to effectively zero – after four years post-inoculation.

262. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine was only 51% effective at its peak, if the user was inoculated at age 60.

263. Merck, MSD, and McKesson breached each of their express warranties.

264. Plaintiff, through Plaintiff's physicians and/or other healthcare providers, did rely on the express warranties made by Merck, MSD, and McKesson regarding the safety and efficacy of the ZOSTAVAX vaccine in purchasing, administering, and using the product.

265. Members of the medical community, including physicians and other healthcare professionals, relied upon each Defendants' representations and express warranties in connection with the use recommendation, description, and dispensing of the ZOSTAVAX vaccine.

266. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

267. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

268. As a foreseeable, direct, and proximate result of the breach of the express warranties by Merck, MSD, and McKesson, the Plaintiff contracted herpes zoster, resulting in the Plaintiff suffering serious physical injuries including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, diminished quality of life, and incurred medical bills and other expenses, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

SIXTH CAUSE OF ACTION:
FRAUDULANT MISREPRESENTATION

269. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

270. At all relevant times, as set forth, Defendants, and each of them, engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing,

preparing, compounding, assembling, packaging, processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce the ZOSTAVAX vaccine

271. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

272. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

Merck and MSD

273. At all times relevant to this action, Merck and MSD manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold the ZOSTAVAX vaccine for its intended use for the long-term prevention of shingles.

274. Merck and MSD knew of the intended use of the ZOSTAVAX vaccine at the time Merck marketed, sold, and distributed its product for use by the Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

275. Merck and MSD impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiff's, their physicians, and their healthcare providers, that ZOSTAVAX vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

276. Merck's and MSD's representations and implied warranties were false, misleading, and inaccurate because the ZOSTAVAX vaccine was not safe or effective for its intended purpose, and was not of merchantable quality.

277. At the time the ZOSTAVAX vaccine was promoted, marketed, distributed, and/or sold by Merck and MSD, Merck and MSD knew of the use for which it was intended and impliedly warranted its product to be of merchantable quality and safe and fit for such use.

278. Plaintiff, her physicians, and her healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of Merck and MSD, as the manufacturer, developer, distributor, and seller of the ZOSTAVAX vaccine, as to whether it was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was manufactured and sold.

279. Contrary to Merck and MSD's implied warranties, the ZOSTAVAX vaccine as used by the Plaintiff, was not of merchantable quality and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein and was not effective for the long-term prevention of shingles.

280. Merck and MSD breached their implied warranties because the ZOSTAVAX vaccine was not fit for its intended use and purpose.

281. Merck and MSD placed the ZOSTAVAX vaccine into the stream of commerce in its condition, and the product was expected to and did reach the Plaintiff without substantial change in the condition in which it was manufactured and sold.

282. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

283. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

284. As a foreseeable, direct and proximate result of Merck's and MSD's acts and omissions and Plaintiff's use of the ZOSTAVAX vaccine, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described herein.

McKesson

285. At all times relevant to this action, McKesson, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its ZOSTAVAX vaccine for its intended use for the long-term prevention of shingles.

286. McKesson knew of the intended use of the ZOSTAVAX vaccine at the time McKesson marketed, sold, and distributed the ZOSTAVAX vaccine for use by the Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

287. McKesson impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiff, their physicians, and their healthcare providers, that ZOSTAVAX vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

288. McKesson's representations and implied warranties were false, misleading, and inaccurate because the ZOSTAVAX vaccine was not safe or fit for its intended use and was not of merchantable quality.

289. At the time the ZOSTAVAX vaccine was promoted, marketed, distributed, and/or sold by McKesson, McKesson knew of the use for which it was intended and impliedly warranted its product to be of merchantable quality and safe and fit for such use.

290. Plaintiff and her physicians and healthcare providers reasonably relied on the superior skill and judgment of McKesson, as marketer, distributor, and seller of the ZOSTAVAX vaccine, as to

whether it was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was sold.

291. Contrary to McKesson's implied warranties, the ZOSTAVAX vaccine as used by the Plaintiff was not safe or fit for its intended use because the product was unreasonably dangerous as described herein and was not effective for the long-term prevention of shingles.

292. McKesson breached its implied warranty because the ZOSTAVAX vaccine was not fit for its intended use and purpose.

293. McKesson placed the ZOSTAVAX vaccine into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the product was expected to and did reach the Plaintiff without substantial change in the condition in which it was sold.

294. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

295. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

296. As a foreseeable, direct and proximate result of McKesson's acts and omissions and Plaintiff use of the ZOSTAVAX vaccine, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described herein.

SEVENTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

297. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

Merck and MSD

298. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

299. Merck and MSD had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff, the truth regarding its claims that the ZOSTAVAX vaccine had been tested and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.

300. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, Merck and MSD widely disseminated the following material representations of material fact regarding the safety and efficacy of the ZOSTAVAX vaccine directly to consumers, including Plaintiff, in its advertising and promotional campaign using television and radio commercials on broadcast television, cable television and other national media outlets; print advertisements run in magazines targeted, journals, and newspapers towards consumers and prescribers including national newspapers such as the New York Times, Washington Post, USA Today; posters and other signage in pharmacies where consumers bought their prescription drugs, including Plaintiff's pharmacy; product handouts and brochures; its own website; and other ZOSTAVAX marketing materials:

- a. That ZOSTAVAX did not cause or induce shingles.
- b. That adult shingles causes pain in almost every instance.
- c. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it.

- d. That the ZOSTAVAX vaccine was approved to treat the pain associated with shingles.
- e. That serious adverse effects were experienced by less than 1% of individuals in the ZOSTAVAX vaccine's clinical trials and studies.
- f. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults – and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults.
- g. That “[t]here is no way to predict when the varicella-zoster virus (VZV) will reactivate or who will develop zoster.”
- h. That ZOSTAVAX was a “well-studied vaccine.”
- i. That ZOSTAVAX “significantly reduced” the risk of developing shingles compared with placebo.”
- j. That ZOSTAVAX would benefit its users the *prevention of long-term nerve pain from shingles* (post-herpetic neuralgia) *can be primarily attributed to the vaccine's effect on the prevention of shingles.*” (emphasis added).
- k. That the efficacy of ZOSTAVAX is 51% for everyone.
- l. That the efficacy of ZOSTAVAX did not diminish over time after vaccination.
- m. That the immunity provided by ZOSTAVAX was unlimited.
- n. That the immunity provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated.
- o. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles.
- p. That ZOSTAVAX was safe.
- q. That ZOSTAVAX was effective.

301. Prior to being inoculated with ZOSTAVAX, Plaintiff read, saw, and/or heard Merck's and MSD's representations through Merck's and MSD's direct-to-consumer advertisements.

302. Prior to being inoculated with ZOSTAVAX, Plaintiff's healthcare providers read, saw, and/or heard Merck's and MSD's representations through Merck's and MSD's advertisements, and publications in medical journals, visits from ZOSTAVAX sales representatives.

303. On or about November 8, 2011, when Plaintiff received the ZOSTAVAX vaccination, Plaintiff and/or her healthcare providers read or saw these representations on the ZOSTAVAX vaccine label or prescribing information.

304. Each of these representations is false.

305. Merck and MSD believed these misrepresentations to be true.

306. Merck and MSD were careless or negligent by failing to ascertain the truth of these representations at the time it made them.

307. Alternatively, Merck and MSD negligently misrepresented material facts about ZOSTAVAX when they knew or reasonably should have known of the falsity of such misrepresentations.

308. Alternatively, Merck and MSD made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

309. The above misrepresentations were made to Plaintiff, Plaintiff's physicians and/or pharmacists, the medical community, as well as the general public.

310. Merck and MSD negligently and/or carelessly misrepresented the truth regarding the high risk of the product's unreasonable, dangerous and adverse side effects associated with the administration, use, and injection of the product.

311. Merck and MSD breached their duty by representing to the Plaintiff, Plaintiff's physicians and healthcare providers, and the medical community that Merck's product did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

312. Merck and MSD failed to warn the Plaintiff and other consumers, of the defective condition of ZOSTAVAX, as manufactured and/or supplied by Merck and/or MSD.

313. On or about November 8, 2011, the date of Plaintiff's vaccination, Plaintiff relied on the warning label affixed to ZOSTAVAX, and the information relayed through her healthcare provider that ZOSTAVAX was an effective in preventing shingles on a permanent basis, and did not carry any significant risk of adverse effect, which induced her to be vaccinated.

314. Alternatively, Plaintiff's healthcare providers relied on the warning label affixed to the ZOSTAVAX vaccine and believed that it was effective in preventing shingles on a long-term or permanent basis and that it did not carry any significant risk of adverse effect.

315. Merck and MSD intended to induce the Plaintiff to rely on the misrepresentations so that Plaintiff would purchase and use ZOSTAVAX, for Merck's and MSD's own financial gain.

316. Alternatively, Merck and MSD intended to induce Plaintiff's physicians and healthcare providers to rely on the misrepresentations and prescribe, recommend, and/or administer the ZOSTAVAX vaccine to consumers and patients such as Plaintiff, for Merck's own financial gain.

317. Plaintiff and Plaintiff's healthcare providers, pharmacists and physicians, justifiably relied on Merck's and MSD's misrepresentations.

318. If Merck and MSD had given Plaintiff adequate and appropriate information regarding the risk of serious infection after ZOSTAVAX injection and the waning efficacy of ZOSTAVAX to near-zero four years after inoculation, Plaintiff would not have used ZOSTAVAX for the long-term prevention of shingles because the unreasonable risk of serious infection accompanying ZOSTAVAX use is outweighed by its minimal efficacy.

319. If Merck and MSD had given Plaintiff's healthcare providers and physicians adequate and appropriate information regarding the risk of serious infection after ZOSTAVAX injection and the waning efficacy of ZOSTAVAX to near-zero four years after inoculation, Plaintiff's physicians would not have prescribed or administered ZOSTAVAX to Plaintiff for the long-term prevention of shingles because the unreasonable risk of serious infection accompanying ZOSTAVAX use is outweighed by its minimal efficacy.

320. Consequently, Plaintiff's use of ZOSTAVAX was to Plaintiff's own detriment as Merck's and MSD's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

321. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

322. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

323. As a direct and proximate consequence of Merck's and MSD's negligent misrepresentations, the Plaintiff has sustained serious personal injuries including physical pain and suffering, mental anguish, diminished capacity for the enjoyment of life, diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

McKesson

324. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

325. McKesson had a duty to accurately and truthfully represent to the medical community, state governments, and U.S. consumers, including Plaintiff, the truth regarding its claims that the ZOSTAVAX vaccine had been tested and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.

326. McKesson disseminated the following material representations of material fact regarding the safety and efficacy of the ZOSTAVAX vaccine directly to consumers, including Plaintiff, in its advertising and promotional campaign using television and radio commercials on broadcast television,

cable television and other national media outlets; print advertisements run in magazines targeted, journals, and newspapers towards consumers and prescribers including national newspapers such as the New York Times, Washington Post, USA Today; posters and other signage in pharmacies where consumers bought their prescription drugs, including Plaintiff's pharmacy; product handouts and brochures; its own website; and other ZOSTAVAX marketing materials: that ZOSTAVAX as being safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.

327. Prior to being inoculated with ZOSTAVAX, Plaintiff read, saw, and/or heard McKesson's representations through McKesson's direct-to-consumer advertisements.

328. Prior to being inoculated with ZOSTAVAX, Plaintiff's healthcare providers read, saw, and/or heard McKesson's representations through McKesson's advertisements and visits from ZOSTAVAX sales representatives.

329. On or about the date of Plaintiff's vaccination, Plaintiff and/or her healthcare providers read or saw these representations on the ZOSTAVAX vaccine label or prescribing information.

330. McKesson's representations were false.

331. McKesson was careless or negligent because it failed to ascertain the truth of its statements. McKesson should have known its misrepresentations were false.

332. Alternatively, McKesson knew its misrepresentations were false.

333. McKesson was aware of the risks and efficacy over time of ZOSTAVAX.

334. McKesson failed to communicate to the Plaintiff, Plaintiff's healthcare providers, and other members of the general public, that the administration of this vaccine increased the risk of viral infection, or that the ZOSTAVAX vaccine would not remain effective past four years.

335. McKesson breached its duty in representing to the Plaintiff, Plaintiff's physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients, and that ZOSTAVAX was effective for the long-term prevention of shingles.

336. The above misrepresentations were made to Plaintiff, Plaintiff's physicians and/or pharmacists, the medical community at the time Plaintiff was prescribed ZOSTAVAX.

337. Upon information and belief, McKesson created or published the warning label affixed to the ZOSTAVAX vaccine that was given to Plaintiff on the dates of her vaccination.

338. Upon information or belief, McKesson distributed or sold the ZOSTAVAX vaccine with its warning label that was given to Plaintiff.

339. On or about the respective dates of their ZOSTAVAX vaccination(s), Plaintiff relied on the warning label affixed to ZOSTAVAX, and the information relayed through their healthcare provider that ZOSTAVAX was an effective in preventing shingles on a permanent basis, and did not carry any significant risk of adverse effect, which induced her to be vaccinated.

340. Alternatively, Plaintiff's healthcare providers relied on the warning label affixed to the ZOSTAVAX vaccine and believed that it was effective in preventing shingles on a long-term or permanent basis and that it did not carry any significant risk of adverse effect.

341. McKesson intended to induce the Plaintiff's to rely on the misrepresentations so that Plaintiff would purchase and use ZOSTAVAX, for McKesson's own financial gain.

342. Alternatively, McKesson intended to induce Plaintiff's physicians and healthcare providers to rely on the misrepresentations and prescribe, recommend, and/or administer the ZOSTAVAX vaccine to consumers and patients such as Plaintiff's, for McKesson's own financial gain.

343. Plaintiff and Plaintiff's healthcare providers, pharmacists and physicians, justifiably relied on McKesson's misrepresentations.

344. If McKesson had given Plaintiff's adequate and appropriate information regarding the risk of serious infection after ZOSTAVAX injection and the waning efficacy of ZOSTAVAX to near-zero four years after inoculation, Plaintiff's would not have used ZOSTAVAX for the long-term prevention of shingles because the unreasonable risk of serious infection accompanying ZOSTAVAX use is outweighed by its minimal efficacy.

345. If McKesson had given Plaintiff's healthcare providers adequate and appropriate information regarding the risk of serious infection after ZOSTAVAX injection and the waning efficacy of ZOSTAVAX to near-zero four years after inoculation, Plaintiff's health care providers would not have prescribed or administered ZOSTAVAX to Plaintiff for the long-term prevention of shingles because the unreasonable risk of serious infection accompanying ZOSTAVAX use is outweighed by its minimal efficacy.

346. Plaintiff and Plaintiff's healthcare providers, pharmacists and physicians, justifiably relied on McKesson's misrepresentations.

347. Consequently, Plaintiff's use of ZOSTAVAX was to Plaintiff's own detriment.

348. Plaintiff suffered from shingles, and its related painful and persistent physical injuries and damages (including incurable neuralgia), despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

349. Alternatively, Plaintiff suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

350. As a direct and proximate consequence of McKesson's negligent misrepresentations, Plaintiff contracted a serious strain of herpes zoster virus, and sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against MERCK, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

EIGHTH CAUSE OF ACTION: UNJUST ENRICHMENT

351. Plaintiff incorporates by reference all prior allegations.

352. Merck and MSD are and at all times were the manufacturer, seller, and/or supplier of the shingles vaccine, ZOSTAVAX.

353. McKesson is and at all times was the marketer, promoter, packager, labeler, distributor, and seller of the shingles vaccine, ZOSTAVAX.

354. Plaintiff paid for the ZOSTAVAX vaccine for the long-term prevention of shingles.

355. Merck has accepted payment by Plaintiff for the purchase of the ZOSTAVAX vaccine.

356. Alternatively, MSD has accepted payment by Plaintiff for the purchase of the ZOSTAVAX vaccine.

357. Alternatively, McKesson has accepted payment by Plaintiff for the purchase of the ZOSTAVAX vaccine.

358. Plaintiff have suffered from shingles, and its related painful and persistent physical injuries and damages, despite being inoculated with the ZOSTAVAX vaccine which was intended for long-term prevention of shingles. Plaintiff contracted shingles because ZOSTAVAX wore off.

359. Alternatively, Plaintiff have suffered from shingles, its painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.

360. Plaintiff has not received the safe and effective vaccine for which Plaintiff paid.

361. It would be inequitable for Merck to keep this money if Plaintiff did not in fact receive safe and effective treatment for the prevention of shingles.

362. Alternatively, it would be inequitable for MSD to keep this money if Plaintiff did not in fact receive safe and effective treatment for the prevention of shingles. Alternatively, it would be inequitable for McKesson to keep this money if Plaintiff did not in fact receive safe and effective treatment for the prevention of shingles.

WHEREFORE, Plaintiff demands judgment against MERCK, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

NINTH CAUSE OF ACTION:
VIOLATION OF DECEPTIVE TRADE PRACTICES ACT

363. Plaintiff incorporates by reference all prior allegations and further alleges:

364. Plaintiff bring this cause of action pursuant to Wisconsin Statutes § 100.18.

365. Wisconsin Statutes § 100.18 provides that unfair competition shall mean and include untrue, deceptive, or misleading advertisements, announcements, statements, or representations in conjunction with any transaction.

366. The acts and practices described above were and are likely to mislead members of the general public like the Plaintiff and therefore constitute unfair business practices within the meaning of Wisconsin Statutes § 100.18. The acts of untrue and misleading advertising set forth in the presiding paragraphs are incorporated by reference and are, by definition, violations of Wisconsin Statutes § 100.18. This conduct includes, but is not limited to:

- a. Fear-driven advertisement campaigns meant to scare adults into asking their medical providers about the ZOSTAVAX Vaccine. See: "MERCK hopes ominous new ZOSTAVAX ad can scare up adult vaccination rates.", Carly Helfand, FiercePharma, November 21, 2016.
- b. Representing that ZOSTAVAX was safe, fit, and effective for human consumption; knowing that said representations were false, and concealing, that ZOSTAVAX had a serious propensity to cause users;
- c. Engaging in advertising programs designed to create the image, impression, and belief by consumers and physicians that ZOSTAVAX was safe for human consumption and would not interfere with daily life, even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;
- d. Purposefully downplaying and understating the health hazards and risks associated with ZOSTAVAX.
- e. Marketing and promoting ZOSTAVAX in a careless and reckless manner despite knowing the dangers propensities of the vaccine; and
- f. Issuing promotional literature and commercials deceiving potential users of ZOSTAVAX by playing on the fears of the public, overstating the benefits of ZOSTAVAX, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of ZOSTAVAX.

367. These practices constitute unlawful, unfair, and fraudulent business acts or practices, within the meaning of Wisconsin's Deceptive Trade Practices Act and consumer fraud statutes, codified

in Wisconsin Statutes § 100.18, as well as unfair, deceptive, untrue, and misleading advertising prohibited by Wisconsin Statutes § 100.18.

368. The unlawful, unfair, and fraudulent business practices of Defendants described above present a continuing threat to members of the public like the Plaintiff in that Defendants continue to engage in the conduct described therein.

369. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars in ill-gotten gains from the sale and prescription of ZOSTAVAX in Wisconsin, sold in large part because of the acts and omissions described herein.

370. Pursuant to Wisconsin Statutes § 100.18, seeks an order of this Court compelling Defendants to provide restitution and injunctive relief calling for Defendants, and each of them, to cease unfair business practices in the future.

WHEREFORE, Plaintiff demands judgment against MERCK, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

PUNITIVE DAMAGES ALLEGATIONS

371. Plaintiff, incorporates by reference all prior allegations.

372. At all times material hereto, Defendants knew or should have known that the ZOSTAVAX vaccines were unreasonably dangerous with respect to the risk of inducing herpes zoster, post-herpetic neuralgia, nerve damage, infections and other serious conditions.

373. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of the ZOSTAVAX vaccine.

374. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of its ZOSTAVAX vaccine. Data establishes that the failure rates the vaccine are and were much higher than

what Defendants have in the past and currently continue to publish to the medical community and members of the public.

375. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiff. Defendants had actual knowledge of the dangers presented by the ZOSTAVAX vaccine, yet consciously failed to act reasonably to inform or warn Plaintiff, their physicians, or the public at large of these dangers. Defendants consciously failed to establish and maintain an adequate quality and post-market surveillance system.

376. At all times material hereto, Defendants knew and recklessly disregarded the fact that the ZOSTAVAX vaccines have an unreasonably high rate of inducing herpes zoster, post-herpetic neuralgia, nerve damage, infections and other serious conditions.

377. Notwithstanding the foregoing, Defendants continued to market the ZOSTAVAX vaccine aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

378. Defendants knew of the ZOSTAVAX vaccine's lack of warnings regarding the risk of inducing herpes zoster, post-herpetic neuralgia, nerve damage, infections and other serious conditions, 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 the ZOSTAVAX vaccine.

379. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using the ZOSTAVAX vaccine against its benefits.

380. 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.

381. 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 DAMAGES

WHEREFORE, Plaintiff demands judgment against Defendants for:

- a. General (non-economic) damages, including, without limitation, past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and other consequential damages as allowed by law;
- b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;
- c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;
- d. Costs of suit;
- e. Prejudgment interest as allowed by law;
- f. Post-judgment interest at the highest applicable statutory or common law rate from the date of judgment until satisfaction of judgment; and

- g. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff, demand a trial by jury on all triable issues.

Dated: May 1, 2018

Respectfully submitted,

/s/ Shawn Sassaman
Wisconsin Bar No.: 76321
Marc J. Bern & Partners, LLP
101 West Elm Street, Suite 215
Conshohocken, Pennsylvania 19428
Tel: (212) 702-5000
Fax: (212) 818-0164

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.)

Place an "X" in the appropriate box (required): Green Bay Division Milwaukee Division

I. (a) PLAINTIFFS

Jane Boda

(b) County of Residence of First Listed Plaintiff **Fon du Lac County, WI**
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
MARC J. BERN & PARTNERS LLP
101 West Elm Street, Suite 215
Conshohocken, PA 19428

DEFENDANTS

Merck & Co., Inc.; Merck Sharp & Dohme Corp.; and McKesson Corporation

County of Residence of First Listed Defendant **Union County, NJ**
(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 checked="" 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 type="checkbox"/> 2	<input checked="" type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input 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)

Click here for: [Nature of Suit Code Descriptions.](#)

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	PERSONAL INJURY <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	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <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 LABOR <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 IMMIGRATION <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 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <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)) FEDERAL TAX SUITS <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"/> 376 Qui Tam (31 USC 3729(a)) <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
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS			
<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	<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	Habeas Corpus: <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 Other: <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 - Transfer
- 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332

Brief description of cause:
Product liability causing personal injury

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND \$** 1,000,000.00 **CHECK YES only if demanded in complaint: JURY DEMAND:** Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE **Lynn S. Adelman** DOCKET NUMBER **2:18-cv-00020-LA**

DATE **05/01/2018** SIGNATURE OF ATTORNEY OF RECORD **/s/ Shawn M. Sassaman**

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING FEE _____ 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
- (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
- (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" 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 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- 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.