

**IN THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ZOSTAVAX (ZOSTER VACCINE
LIVE) PRODUCTS LIABILITY
LITIGATION**

JEANETTE KELTZ,

Plaintiff,

vs.

MERCK & CO., INC. and MERCK SHARP &
DOHME CORP.,

Defendants.

MDL NO. 2848

Master Docket No.: 18-md-2848

JUDGE HARVEY BARTLE, III
DIRECT FILED COMPLAINT
PURSUANT TO PRETRIAL
ORDER NO. 22

Civil Action No.: _____

COMPLAINT

Plaintiff JEANETTE KELTZ (“Plaintiff”) files this Complaint pursuant to PTO No. 22, and is to be bound by the rights, protections and privileges and obligations of that PTO. Plaintiff states that but for the Order permitting direct filing in the Eastern District of Pennsylvania pursuant to PTO No. 22, Plaintiff would have filed this Complaint in the United States District Court for the Southern District of California (“District”). Further, in accordance with PTO No. 22, Plaintiff, hereby designates the United States District Court for the Southern District of California as the place of remand as this case may have originally been filed there.

Plaintiff, by and through her attorneys, Pendley, Baudin & Coffin, L.L.P, complains and alleges against Defendants MERCK & CO., INC. and MERCK SHARP & DOHME, CORP. (collectively, “Defendants” and/or “Merck”), on information and belief, as follows:

PARTIES

1. Plaintiff JEANETTE KELTZ (“Plaintiff”) at all times relevant to this action was and is a resident and citizen of the State of California.

2. Defendant MERCK & CO., INC. is incorporated in New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK & CO., INC. 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 the District. Merck has conducted business and derived substantial revenue within the District, including, but not limited to, its business activities related to the Zostavax vaccine.

3. Defendant MERCK SHARP & DOHME CORP. is a wholly-owned subsidiary of Defendant MERCK & CO., INC. and part of the MERCK & CO., INC. family of companies. Defendant MERCK SHARP & DOHME CORP. is incorporated in New Jersey with its headquarters located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK SHARP & DOHME CORP., 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 the District. Defendant MERCK SHARP & DOHME CORP. has conducted business and derived substantial revenue within the District, including, but not limited to, its business activities related to the Zostavax vaccine.

4. Furthermore, based upon information and belief, Merck is, and was at all times relevant hereto,

- a. duly authorized to conduct business in the District;
- b. regularly conducted and solicited business within the District and continues to do so;
- c. does business in the District, and at all times relevant hereto, has sold and distributed the Zostavax vaccine in the District;
- d. derives substantial revenue from goods used or consumed in the District;
- e. advertised its Zostavax vaccine to patients, doctors and hospitals in the District and/or other medical facilities located in the District;
- f. advertises or otherwise promotes its business in the District; and
- g. reasonably expects to be subject to the District's product liability law.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because complete diversity of citizenship exists between the Plaintiff and the Defendants.

6. Furthermore, this Court has jurisdiction and venue is appropriate over this action pursuant to Pretrial Order No. 22 (Direct Filing – Stipulated) which authorizes direct filing of cases into MDL No. 2848 in order to eliminate delays associated with transfer of cases and to promote judicial efficiency.

NO FEDERAL PREEMPTION

7. 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. 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. The Zostavax vaccine is not a vaccine listed in the Vaccine Injury Table.

FACTS

8. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the Zostavax vaccine.

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

10. Varicella zoster is a virus that causes chickenpox.

11. Once the VZV causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

12. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination.

13. 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.

14. 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.

15. 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.

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

17. 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 Postherpetic 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.”

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

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

20. 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.

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

22. Shingles is a reactivation of the latent VZV.

23. 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 to, *inter alia*, ensure the safety of this vaccine. These commitments 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.

24. 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.

25. Zostavax is a stronger, more potent version of Merck’s chickenpox vaccine, Varivax.

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

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

28. 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.

29. As of June 2016, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of serious viral infections and shingles as being caused by Zostavax.

30. 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.

31. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infections and shingles being caused by Zostavax. All that was addressed is the concern that a rash and itching might develop at the injection site. This is despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

32. The prescribing information for Zostavax contains a warning that “[t]ransmission of vaccine virus may occur between vaccinees and susceptible contacts”.

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

33. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infection, shingles, pneumonia, or possible diseases of the nervous system. This is despite the fact that Varivax, a less potent vaccine, has added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

34. 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 and acute transverse myelitis.

35. Other than postherpetic 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.

36. 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.

37. Despite this information and the potential correlation between being administered the Zostavax vaccine and within a relatively short period of time developing an infection, leading to the development of shingles or varicella-zoster virus pneumonia, Merck failed to properly

address and provide this information both to the patient and the medical providers prescribing the vaccine.

38. In October 2017, the FDA approved Shingrix – an alternative shingles vaccine manufactured by GlaxoSmithKline. Shingrix was created by extracting a glycoprotein located on the surface of the varicella zoster virus. This glycoprotein triggers the body's immune system to activate and fight against the varicella zoster virus. The glycoprotein itself, however, cannot infect the body as it is not a virus. GlaxoSmithKline added the extracted glycoprotein with an adjuvant, a substance that enhances the body's immune response to an antigen, to create Shingrix. When Shingrix enters the body, the vaccine induces an immune response that cannot directly infect the vaccinated human host nor activate dormant VZV virus. In direct contrast, Zostavax contain various mutated live strains of actual VZV virus which can directly infect the vaccinated human host and/or activate dormant VZV virus.

39. Shingrix was proven to be safe and effective to prevent shingles in over 90% of users in contrast to Zostavax's effectiveness rates that were as low as 18% in certain age groups. Shingrix was proven to stay effective in preventing shingles at least four years in contrast to Zostavax's effectiveness that waned over a five year period.

40. The safety, effectiveness, and the simple superiority of the design of Shingrix over Zostavax allowed the Center for Disease Control ("CDC") to make an unprecedented decision to recommend Shingrix over Zostavax to the general public after only a few days of Shingrix being approved by the FDA.

41. Upon information and belief, Merck possessed, or should have possessed, the knowledge to create a Shingles vaccine similarly designed as Shingrix.

CASE-SPECIFIC FACTS

42. Plaintiff at all times relevant to this action was and is a citizen of the state of California, residing and domiciled in Encinitas, California.

43. On April 13, 2017, Plaintiff was inoculated with Defendants' Zostavax vaccine at Rite Aid Pharmacy in Encinitas, California for routine health maintenance and for its intended purpose: the prevention of shingles (herpes zoster).

44. After receiving Defendants' Zostavax vaccine, on September 14, 2017, Plaintiff was diagnosed with shingles after experiencing extreme pain and an outbreak of blisters on her legs, arms and ribcage resulting in medical treatment. This outbreak lasted for at least three weeks.

45. On or about November 2, 2017, Plaintiff was diagnosed with a second shingles outbreak. On November 25, 2017, Plaintiff was diagnosed with a third outbreak of shingles after reporting to her physician with lesions on her side and a feeling like "something is biting her from inside."

46. Plaintiff continued to have reoccurring shingles outbreaks throughout the end of 2017 and throughout 2018 as a result of the Zostavax vaccine, including extreme pain and numbness in her left leg which all resulted in medical treatment. Pain and tingling sensations in her skin, as a result of Zostavax, are permanent and continue today.

47. As a direct and proximate result of Merck's Zostavax vaccine, Plaintiff's symptoms have resulted in physical limitations not present prior to using Merck's product and caused by the Zostavax vaccine. Plaintiff also experiences mental and emotional distress due to resulting physical limitations and seriousness of her condition and has suffered economic losses due to her inability to work.

48. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, Plaintiff sustained severe and disfiguring personal injuries. Further, as a

tragic consequence of Merck's wrongful conduct, Plaintiff suffered serious, progressive, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

49. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and incurred damages, including medical expenses; the loss of accumulations; and other economic and non-economic damages.

FRAUDULENT CONCEALMENT- EQUITABLE TOLLING

50. Merck committed acts of concealment (including acts and omissions) in order to prevent consumers, such as Plaintiff, from learning about the risks of injury associated with Zostavax as discussed in this Complaint.

51. The acts and omissions concealed the true risks of injury from Plaintiff and prevented him from asserting such rights. Plaintiff, while exercising reasonable diligence, could not have known of the operative facts giving rise to a cause of action until recently.

52. Due to the acts and omissions of concealment, Plaintiff was not cognizant of the facts supporting her causes of action until years after the initial injury. As such, Plaintiff's statute of limitations were tolled in light of Merck's fraudulent concealment.

53. Merck's misconduct and fraudulent concealment of the relevant facts deprived Plaintiff of vital information essential to the pursuit of the claims in this complaint, without any fault or lack of diligence on her part. Plaintiff relied on Merck's misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to inquire further and to discover Merck's tortious conduct.

EQUITABLE ESTOPPEL

54. In the alternative, Merck is estopped and may not invoke the statute of limitations

as through the fraud or concealment noted above, specifically the acts and omissions, Merck caused the Plaintiff to relax their vigilance and/or deviate from their right of inquiry into the facts as alleged in this complaint.

55. Merck induced Plaintiff to delay bringing this complaint by Merck's acts and omissions in failing to address the risk of harm discussed in this Complaint and provide this information to patients and the medical providers prescribing the vaccine, including Plaintiff and Plaintiff's prescriber.

56. Merck is and was under a continuing duty to monitor and disclose the true character, quality, and nature of Zostavax. Because of Merck's misconduct and fraudulent concealment of the true character, quality, and nature of its Zostavax, Merck is estopped from relying on any statute of limitations defense.

COUNT I:
NEGLIGENCE

57. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

58. Merck had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of Zostavax including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

59. Merck 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 knew, or should have known, that its product caused viral infections, shingles and pain throughout the body, and was therefore not safe for administration to consumers.

60. Merck failed to exercise due care in the labeling of Zostavax and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury, including viral infection, shingles, pain, resulting from its use.

61. Merck continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that Zostavax posed a serious risk of bodily harm to consumers. This is especially true given its tenuous efficacy.

62. Merck knew, or should have known, that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Merck's failure to exercise ordinary care.

63. As a direct and proximate consequence of Merck's negligence, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against 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.

COUNT II:

STRICT LIABILITY - DESIGN AND MANUFACTURING DEFECT

64. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

66. 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 designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

67. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's prescriber and/or healthcare providers, and all other consumers of the product, making the product unreasonably dangerous and defective.

68. The Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation in that when it left the hands of the manufacturers, suppliers, and distributors, the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

69. Merck's Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation because when it left the hands of Merck, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

70. At all times relevant to this action, Merck knew and had reason to know that its Zostavax vaccine was inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Merck, and when used and administered in the form manufactured and

distributed by Merck, and in the manner instructed by Merck to be used and administered to Plaintiff and other consumers.

71. Plaintiff's Zostavax prescriber and/or healthcare providers used and administered the Zostavax vaccine for the purpose intended by Merck, and in a manner normally intended to be used and administered, namely for vaccination against shingles (herpes zoster). Merck had a duty to design, create, and manufacture products that were reasonably safe and not unreasonably dangerous for their normal, common, and intended use. Merck's product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

72. Merck designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of Plaintiff and other consumers. Merck is therefore strictly liable for Plaintiff's injuries and damages sustained proximately caused by Plaintiff's use of the product.

73. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of Merck's product and/or perceive its defective dangers prior to its administration by her healthcare providers.

74. Furthermore, Merck defectively manufactured the subject Zostavax vaccine such that it unreasonably increased the risk of contracting an infection and shingles from the vaccine.

75. Merck's defective Zostavax vaccine was a substantial, proximate, and contributing factor in causing Plaintiff's injuries.

76. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against 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.

COUNT III:

PRODUCTS LIABILITY - FAILURE TO WARN

77. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

79. The Zostavax vaccine was expected to, and did, reach the intended consumers, prescribers, and persons coming in contact with the product, including Plaintiff, with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

80. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's prescriber and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous and defective.

81. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Zostavax vaccine and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product.

82. Merck's Zostavax vaccine, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Merck, was defective due to the product's inadequate warnings and instructions. Merck knew, or should have known, and should have adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, viral infection resulting in severe and recurring shingles.

83. The product was under the exclusive control of Merck and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the risk of developing a disease in the nervous system due to viral infection and shingles. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

84. Notwithstanding Merck's knowledge of the defective condition of its product, Merck failed to adequately warn the medical community and consumers of the product, including Plaintiff and her prescriber, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

85. Merck downplayed the serious and dangerous side effects of its product to encourage sales of the product; consequently, Merck placed its profits above its customers' safety.

86. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert Plaintiff and/or her prescriber and healthcare providers to the dangerous risks and reactions associated with it, including possible viral infection of the nervous system, and shingles.

87. Even though Merck knew or should have known of the risks and reactions associated with their product, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

88. Plaintiff used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

89. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Merck had knowledge of the dangerous risks and side effects of its product.

90. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to her prescriber and/or healthcare providers.

91. Merck had a continuing duty to warn consumers of its Zostavax vaccine, including Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, Merck breached its duty.

92. Although Merck knew, or should have known, of the defective nature of its Zostavax vaccine, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of its product so as to maximize

sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by its Zostavax vaccine.

93. As a direct and proximate result of Merck's failure to adequately warn or other acts and omissions of Merck described herein, Plaintiff suffered severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life.

94. Merck's failure to warn extended beyond the product's label and into other media available to Merck, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

95. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was further defective due to inadequate post-market warnings or instructions because after Merck knew, or should have known, of the risk of serious bodily harm from the administration of its Zostavax vaccine, including, but not limited to, possible viral infection and shingles, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, including Plaintiff and Plaintiff's prescriber of Zostavax, knowing the product could cause serious injury.

96. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was defective due to inadequate post-market warnings or instructions when it left Merck's control.

97. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and

- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, 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.

COUNT IV:

BREACH OF EXPRESS WARRANTY

98. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

99. 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, viral infection, shingles, pneumonia 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."

100. 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 and shingles, of which Merck had full knowledge and did not accurately or adequately warn.

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

102. Merck breached its express warranties because its product was and is defective for its intended purpose.

103. Plaintiff, through her prescriber 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.

104. 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.

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

WHEREFORE, Plaintiff demands judgment against 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.

COUNT V:
BREACH OF IMPLIED WARRANTY

106. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

107. At all times relevant to this action, Merck manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its Zostavax vaccine for use in preventing shingles.

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

109. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Plaintiff, her prescriber, and her 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.

110. Merck's representations and implied warranties were false, misleading, and inaccurate because its product was defective, and not of merchantable quality.

111. At the time Merck's product was promoted, marketed, distributed, and/or sold by Merck, Merck 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.

112. Plaintiff, her prescriber of Zostavax and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of Merck, as

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.

113. Contrary to Merck's implied warranties, its product as used by 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.

114. Merck breached its implied warranty because its product was not safely fit for its intended use and purpose.

115. Merck placed its product into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

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

WHEREFORE, Plaintiff demands judgment against 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.

COUNT VI:

NEGLIGENT MISREPRESENTATION

117. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

118. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff, the truth regarding Merck's claims that Merck's product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Merck, in fact, were false and Merck was careless or negligent in ascertaining the truth of the representations at the time Merck made the misrepresentations.

119. Merck represented and marketed Zostavax as being safe and effective.

120. After Merck became aware of the risks of Zostavax, Merck failed to communicate to Plaintiff, her prescriber, and other members of the general public, that the administration of this vaccine increased the risk of infection and shingles.

121. Merck failed to exercise ordinary care in making representations concerning its product and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce. Merck negligently and/or carelessly misrepresented and intentionally concealed 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.

122. Merck breached its duty in representing to Plaintiff, her prescriber 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.

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

124. Merck negligently misrepresented material facts about Zostavax in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Merck made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

125. The above misrepresentations were made to Plaintiff, as well as the general public.

126. Plaintiff, and her prescriber and physicians, justifiably relied on Merck's misrepresentations.

127. Consequently, Plaintiff's use of Zostavax was to her detriment as Merck's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

128. As a foreseeable, direct, and proximate result of Merck's negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Merck knew, or had reason to know, that Merck's product had not been sufficiently tested, that the product lacked adequate, accurate, and prominent warnings, and that injection with the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

129. As a direct and proximate consequence of Merck's negligent misrepresentations, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against 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.

COUNT VII:
EXEMPLARY DAMAGES

130. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

131. Defendant's conduct, as described above, was extreme and outrageous and was done with oppression and malice. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

WHEREFORE, Plaintiff demands judgment against 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/exemplary 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as alleged herein. well as:

- a. Compensatory damages for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries

sustained by Plaintiff, health and medical care costs, lost wages, together with interest and costs as provided by law;

- b. Restitution and disgorgement of profits;
- c. Reasonable attorneys' fees;
- d. The costs of these proceedings;
- e. All ascertainable economic damages;
- f. Punitive/exemplary damages; and
- g. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury.

Dated: September 5, 2019

Respectfully Submitted,



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