UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VENUS CALVERT and JASON CALVERT, Plaintiffs, v. MERCK & CO., INC. and MERCK SHARP & DOHME CORP. Defendants.	C.A. No.: JURY TRIAL DEMANDED

COMPLAINT

I. COMMON ALLEGATIONS

Plaintiffs, VENUS CALVERT and JASON CALVERT, by and through their attorneys NAPOLI SHKOLNIK, LLC, alleges as follows:

JURISDICTION AND VENUE

1. This Court has personal jurisdiction over the Defendants based on Diversity of Citizenship pursuant to 28 U.S.C. Section 1332(a)(1), and the amount in controversy is well in excess of the jurisdictional limit of $75,000.

2. At all times relevant hereto, plaintiffs were and are residents of the State of Washington State.

3. Defendant Merck & Co., Inc. is a New Jersey Corporation with its principle place of business at 1 Merck Drive, Whitehouse Station, NJ 08889.

4. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co, Inc. and also a New Jersey Corporation. Merck Sharp & Dohme Corp. transacts business at 126 E Lincoln Ave, Rahway, NJ 07065.

5. Merck & Co., Inc. and Merck Sharp & Dohme Corp. are hereinafter collectively referred to as Merck.

6. At all times relevant to this lawsuit, Merck was engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting and/or selling, either directly or indirectly through third parties, the Zostavax vaccine.

7. Every single action leading up to this lawsuit occurred in Washington State.

8. Based upon information and belief, Merck is, and was at all times relevant hereto, duly authorized to conduct business in Washington State as a registered foreign corporation.

9. Based upon information and belief, at all times relevant hereto, Merck regularly conducted and solicited business within Washington State and continues to do so.

10. Based upon information and belief, Merck, either directly or through its agents, servants and employees, does business in Washington State, and at all times relevant hereto, has sold and distributed the Zostavax vaccine in Washington State.

11. Merck derives substantial revenue from goods used or consumed in Washington State.

12. Based on information and belief, Merck advertised its Zostavax vaccine to patients, doctors and hospitals in Washington State and/or other medical facilities located in Washington State.

13. Based on information and belief, Merck advertises or otherwise promotes its business in Washington State.

14. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiffs 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.

FACTS

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

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

17. Varicella zoster is a virus that causes chickenpox.

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

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

20. 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.

21. 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.

22. 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.

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

24. 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."

25. A risk of using a live virus vaccine is that it is not weakened enough or "under-attenuated".

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

27. 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.

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

29. Shingles is a reactivation of the latent VZV.

30. 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.

31. 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.

32. Zostavax is a stronger, more potent version of Merck's chickenpox vaccine, Varivax.

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

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

35. 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.

36. As of July 2012, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of viral infection.

37. 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.

38. 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. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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 postvaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

44. 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.

45. On or about April 6, 2012, Plaintiff, VENUS CALVERT, received the Zostavax vaccine for its intended purpose: the prevention of shingles.

46. As a direct result of the vaccine, Plaintiff suffered from a Shingles outbreak, in addition to chronic pain, rash and lesions to various parts of her body.

47. Plaintiff did not have a Shingles outbreak until June 17, 2017.

48. As a direct result of the vaccine, Plaintiff, VENUS CALVERT, suffered mental and emotional distress due to resulting physical limitations and seriousness of her condition.

49. 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.

50. Plaintiffs have incurred medical expenses and other economic harm as a direct result of use of Zostavax.

FIRST CAUSE OF ACTION
NEGLIGENCE

51. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

52. 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.

53. 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 infection, and was therefore not safe for administration to consumers.

54. 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, resulting from its use.

55. 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.

56. Merck knew, or should have known, that consumers, such as the Plaintiff, VENUS CALVERT, suffered the aforesaid injuries as a result of Merck's failure to exercise ordinary care.

57. As a direct and proximate consequence of Merck's negligence, 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.

WHEREFORE, Plaintiffs demand judgment against the Defendants and request compensatory damages for 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.

SECOND CAUSE OF ACTION
DESIGN DEFECT

58. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

60. 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.

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

62. 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.

63. 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.

64. 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 the Plaintiff, VENUS CALVERT, and other consumers.

65. Plaintiff's physicians 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.

66. 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 the Plaintiff and other consumers. Merck

is therefore strictly liable for the Plaintiff injuries and damages sustained proximately caused by his use of the product.

67. 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 his physicians and/or healthcare providers.

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

69. As a proximate result of Merck's acts and omissions, the Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for his injuries described in this Complaint, 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.

WHEREFORE, Plaintiffs demand judgment against the Defendants, and request compensatory damages for 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.

THIRD CAUSE OF ACTION
FAILURE TO WARN

70. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

72. 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.

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

74. 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.

75. 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 adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, viral infection, resulting in shingles, postherpetic neuralgia, or other diseases of the nervous system.

76. 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. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

77. 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 the Plaintiff and his healthcare providers, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

78. 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.

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

80. 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.

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

82. 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.

83. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to his physicians and/or healthcare providers.

84. Merck had a continuing duty to warn consumers of its Zostavax vaccine, including the 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.

85. 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.

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

87. 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.

88. Upon information and belief, the Zostavax vaccine 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, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

89. 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.

90. As a proximate result of Merck's acts and omissions and the 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, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical bills and other expenses, and other losses and damages.

WHEREFORE, Plaintiffs demand judgment against the Defendants, 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.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

91. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

92. 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, 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."

93. 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.

94. 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.

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

96. Plaintiff, through his 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.

97. 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.

98. 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, Plaintiffs demand judgment against the Defendants 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.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

99. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

100. 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.

101. Merck knew of the intended use of its 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.

102. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiff, his physicians, and his 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.

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

104. 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.

105. Plaintiff, his physicians 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.

106. Contrary to Merck's implied warranties, its product 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.

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

108. 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 the Plaintiff without substantial change in the condition in which it was manufactured and sold.

109. 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 his injuries described herein.

WHEREFORE, Plaintiffs, demand judgment against the Defendants and request compensatory damages for 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
UNJUST ENRICHMENT

110. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

111. Merck is and at all times was the manufacturer, seller, and/or supplier of the shingles vaccine, Zostavax.

112. Plaintiff paid for Merck's product for the purpose of preventing shingles.

113. Merck has accepted payment by Plaintiff for the purchase of their product.

114. Plaintiff had not received the safe and effective vaccine for which he paid.

115. 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.

WHEREFORE, plaintiffs demand 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.

NINTH CAUSE OF ACTION
LOSS OF CONSORTIUM

116. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

117. Plaintiff, JASON CALVERT, was at all times relevant hereto the spouse of Plaintiff, and as such, lived and cohabitated with her.

118. By reason of the foregoing, Plaintiff, JASON CALVERT, has incurred significant

expenses for medical care and will continue to be economically and emotionally harmed in the future.

119. By reason of the foregoing, Plaintiffs were caused to suffer, and Plaintiffs will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

120. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

WHEREFORE, plaintiffs demand judgment against the defendants herein on all causes of action in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over his causes of action alleged herein, together with interest, costs and the disbursements of this action, with interest from June 17, 2017.

NAPOLI SHKOLNIK, LLC

By: /s/ Nicholas R. Farnolo
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ATTORNEY FOR PLAINTIFF

Dated: July 21, 2019

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Venus Calvert and Jason Calvert

(b) County of Residence of First Listed Plaintiff Clark, WA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Napoli Shkolnik, PLLC, Nicholas R. Farnolo, Esq.; 400 Broadhollow Rd Suite 305, Melville, NY 11747 - Phone: 212-397-1000

DEFENDANTS

Merck & Co.,Inc. and Merck Sharp & Dohme Corp.

County of Residence of First Listed Defendant Union, 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
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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. sec. 1332(a)(1)

Brief description of cause:
Diversity of Citizenship

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 500,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 07/21/2019

SIGNATURE OF ATTORNEY OF RECORD /s/ Nicholas R. Farnolo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If 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. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
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 statue.

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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

VENUS CLAVERT and JASON CALVERT

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Merck & Co., Inc.
1 Merck Drive,
Whitehouse Station, NJ 08889
and
Merck Sharp & Dohme Corp.
2000 Galloping Hill Road,
Kenilworth, NJ 07033

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Nicholas Farnolo, Esq.
Napoli Shkolnik, PLLC
400 Broadhollow Rd.
Suite 305
Melville, NY 11747

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: