UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PHILIP REINA, an individual; CATHERINE REINA, an individual; Plaintiffs, vs. MERCK & CO., INC., MERCK SHARP & DOHME CORP., Defendants.	NO. **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs PHILIP REINA and CATHERINE REINA (hereinafter "Plaintiffs"), by and through their counsel, SADAKA ASSOCIATES, LLC, allege against Defendants MERCK & CO., INC., MERCK SHARPE & DOHME, CORP., (collectively, "Defendants"), on information and belief, as follows:

PARTIES

1. Plaintiff PHILIP REINA at all times relevant to this action was and is a citizen of the state of ARIZONA.

2. Plaintiff CATHERINE REINA at all times relevant to this action was and is a citizen of the state of ARIZONA. At all times relevant to this action, Plaintiff CATHERINE REINA is the wife of Plaintiff PHILIP REINA.

3. Defendant MERCK & CO., INC. ("Merck") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. At all times relevant to this action, Merck developed, tested, designed, set specifications for, licensed,

manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Zostavax vaccine to be administered to patients throughout the United States, including New Jersey. Merck has conducted business and derived substantial revenue from within the State of New Jersey, from including, but not limited to, its business activities related to the Zostavax vaccine.

4. Defendant MERCK SHARP & DOHME CORP. is a wholly-owned subsidiary of Merck and part of the Merck family of companies. Defendant MERCK SHARP & DOHME CORP. is a corporation organized and existing under the laws of the State of New Jersey with its headquarters located at 2000 Galloping Hill Road Kenilworth, New Jersey 07033. 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 New Jersey. Defendant MERCK SHARP & DOHME has conducted business and derived substantial revenue from within the State of New Jersey, from including, but not limited to, its business activities related to the Zostavax vaccine.

5. Furthermore, at all times relevant hereto, Merck manufactured, promoted, marketed and sold the Zostavax vaccine within this district.

6. Based upon information and belief, Merck is, and was at all times relevant hereto, duly authorized to conduct business in New Jersey.

7. Based upon information and belief, at all times relevant hereto, Merck regularly conducted and solicited business within New Jersey and continues to do so.

8. Based upon information and belief, Merck, either directly or through its agents, servants and employees, does business in New Jersey, and at all times relevant hereto, has sold and distributed Zostavax in New Jersey.

9. Merck derives substantial revenue from goods used or consumed in New Jersey.

10. Based upon information and belief, Merck advertised its Zostavax vaccine to patients, doctors and hospitals in New Jersey and/or other medical facilities located in New Jersey.

11. Based on information and belief, Merck advertises or otherwise promotes its business in New Jersey.

12. Based on information and belief, Merck reasonably expects to be subject to New Jersey product liability law.

JURISDICTION

13. Plaintiffs bring their complaint under federal diversity jurisdiction, 28 U.S.C. § 1332(a) as the parties are completely diverse in citizenship and the amount in controversy exceeds $75,000.

14. This case alleges injuries sustained as a result of the Defendants' Zostavax vaccine and as such, is subject to centralized consolidation in the Eastern District of Pennsylvania, in MDL 2848.

FACTS:

15. The 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.

16. Plaintiff PHILIP REINA at all times relevant to this action was and is a citizen of the state of ARIZONA. Plaintiff PHILIP REINA was inoculated with Defendants' Zostavax vaccine in ARIZONA for routine health maintenance and for the prevention of shingles. Shortly after receiving Defendants' Zostavax vaccine Plaintiff PHILIP REINA developed a painful rash on the left side of his face, which was accompanied by blurry vision in his left eye, pain, weakness and fatigue. As a result, Plaintiff PHILIP REINA has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff CATHERINE REINA at all times relevant to this action was and is a citizen of the state of ARIZONA. At all times relevant to this action, Plaintiff CATHERINE REINA is the spouse of Plaintiff PHILIP REINA.

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

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

20. Varicella zoster is a virus that causes chickenpox.

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

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

23. 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.

24. 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.

25. 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.

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

27. 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."

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

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

29. 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.

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

31. Shingles is a reactivation of the latent VZV.

32. 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, among other things, 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.

33. 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.

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

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

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

37. 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.

38. 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.

39. 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.

40. 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. 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.

41. The prescribing information for Zostavax contains a warning that "[t]ransmission of vaccine virus may occur between vaccinees and susceptible contacts". The risk of transmission of vaccine virus is due to active viral infection in individuals receiving the Zostavax vaccine.

42. 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 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.

43. 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.

44. On February 12, 2018, the Centers for Disease Control and Prevention ("CDC") updated the Vaccine Information Statement for Zostavax by adding, *inter alia*, a warning that the live shingles vaccine can cause rash or shingles.

45. 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.

46. 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.

47. 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.

48. As a direct and proximate result of Merck's defective Zostavax vaccine, the Plaintiffs' symptoms and diagnoses have resulted in physical limitations not present prior to using Merck's product.

49. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, the Plaintiffs sustained severe and permanent personal injuries. Further, as a tragic consequence of Merck's wrongful conduct, the Plaintiffs 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. The Plaintiffs have incurred and will continue to incur medical expenses and other economic harm as a direct result of use of Zostavax.

COUNT I:
NEGLIGENCE

51. The 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 Plaintiffs, would foreseeably suffer injury as a result of Merck's failure to exercise ordinary care.

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

a. The Plaintiffs required and will continue to require healthcare and services;
b. The Plaintiffs incurred and will continue to incur medical and related expenses; and
c. The Plaintiffs 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, the Plaintiffs demand 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:
PRODUCTS LIABILITY - DESIGN DEFECT

58. The 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 the Plaintiffs' 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 Plaintiffs and other consumers.

65. The Plaintiffs' 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 Plaintiffs and other consumers. Merck is therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by the Plaintiffs' use of the product.

67. The Plaintiffs 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. Furthermore, Merck defectively manufactured the subject Zostavax vaccine such that it unreasonably increased the risk of contracting an infection from the vaccine.

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

70. As a proximate result of Merck's acts and omissions and the Plaintiffs' use of Merck's defective product, the Plaintiffs 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, the following:

a. The Plaintiffs required and will continue to require healthcare and services;
b. The Plaintiffs incurred and will continue to incur medical and related expenses; and
c. The Plaintiffs 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, the Plaintiffs demand 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

71. The 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.

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

73. 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.

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

75. 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.

76. 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.

77. 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.

78. 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 Plaintiffs and their healthcare providers, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

79. 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.

80. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert the Plaintiffs and/or their 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.

81. 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.

82. The Plaintiffs used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

83. 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.

84. The Plaintiffs did not have the same knowledge as Merck and no adequate warning was communicated to their physician(s) and/or healthcare providers.

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

86. 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.

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

88. 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.

89. 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, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

90. 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.

91. As a proximate result of Merck's acts and omissions and the Plaintiffs' use of Merck's defective product, the Plaintiffs 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. The Plaintiffs required and will continue to require healthcare and services;
b. The Plaintiffs incurred and will continue to incur medical and related expenses; and
c. The Plaintiffs 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, the Plaintiffs demand 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

92. The 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.

93. 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."

94. 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.

95. 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 Plaintiffs, when used in routinely administered dosages.

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

97. The Plaintiffs, through their 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.

98. 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.

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

WHEREFORE, the Plaintiffs demand 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

100. The 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.

101. 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.

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

103. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiffs, their 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.

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

105. 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.

106. The Plaintiffs, their 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.

107. Contrary to Merck's implied warranties, its product as used by the Plaintiffs was not of merchantable quality and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein.

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

109. 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

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

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

WHEREFORE, the Plaintiffs demand 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

111. The 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.

112. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including the Plaintiffs, 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.

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

114. After Merck became aware of the risks of Zostavax, Merck failed to communicate to the Plaintiffs and other members of the general public, that the administration of this vaccine increased the risk of viral infection.

115. 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.

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

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

118. 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.

119. The above misrepresentations were made to the Plaintiffs, as well as the general public.

120. The Plaintiffs, and their healthcare providers and physicians, justifiably relied on Merck's misrepresentations.

121. Consequently, the Plaintiffs' use of Zostavax was to his detriment as Merck's negligent misrepresentations proximately caused the plaintiffs injuries and monetary losses.

122. 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.

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

a. The Plaintiffs required and will continue to require healthcare and services;
b. The Plaintiffs incurred and will continue to incur medical and related expenses; and
c. The Plaintiffs 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, the Plaintiffs demand 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:
UNJUST ENRICHMENT

124. The 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.

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

126. The Plaintiffs paid for Merck's product for the purpose of preventing shingles.

127. Merck has accepted payment by the Plaintiffs for the purchase of their product.

128. The Plaintiffs have not received the safe and effective vaccine for which he paid.

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

WHEREFORE, the Plaintiffs demand 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 VIII:
LOSS OF CONSORTIUM

130. Plaintiff PHILIP REINA's spouse, Plaintiff CATHERINE REINA was and is at all times relevant herein the wife of Plaintiff PHILIP REINA and as such, lives and cohabitates with him.

131. By reason of the foregoing, Plaintiff PHILIP REINA's spouse, Plaintiff CATHERINE REINA has necessarily paid and has become liable to pay for medical aid, treatment and medications, and will necessarily incur further expenses of a similar nature in the future.

132. By reason of the foregoing, Plaintiff PHILIP's spouse, Plaintiff CATHERINE REINA, has been caused, presently and in the future, the loss of his wife's companionship, services, society and the ability of said Plaintiff's spouse in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs have been caused mental anguish and suffering.

WHEREFORE, the Plaintiffs demand 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgement 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 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 plaintiffs, 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 damages; and
g. Such other and further relief as this Court deems just and proper.

Respectfully Submitted,

/s/ Mark T. Sadaka
Mark T. Sadaka, Esq.,
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155 North Dean Street, Suite 4-D
Englewood, NJ 07631
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Attorneys for Plaintiffs

Dated: January 14, 2019

JS 44 (Rev. 08/16)

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

PHILIP REINA, an individual; CATHERINE REINA, an individual

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
MARK T. SADAKA, ESQ. of SADAKA ASSOCIATES LLC
155 N. DEAN STREET, SUITE 4-D, ENGLEWOOD NJ 07631
201-266-5670

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	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 840 Trademark	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	SOCIAL SECURITY	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	❒ 861 HIA (1395ff)	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 862 Black Lung (923)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 863 DIWC/DIWW (405(g))	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 864 SSID Title XVI	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 865 RSI (405(g))	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Defective pharmaceutical

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
01/14/2019

SIGNATURE OF ATTORNEY OF RECORD
/s/ Mark T. Sadaka

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.