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JORJA BENTLEY	:	COURT OF COMMON PLEAS
	:	PHILADELPHIA COUNTY
Plaintiff,	:	
	:	
vs.	:	OCTOBER TERM 2016
	:	
MERCK & CO., INC.	:	NO. 004102
	:	
and	:	
	:	
MERCK SHARP & DOHME CORP.	:	
	:	
and	:	
	:	
ANN REDFIELD, MSN, RN	:	
	:	
Defendants.	:	

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOU LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias, de plazo al partir de la fecha de la demanda y la notification. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su

persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIEN ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

PHILADELPHIA BAR ASSOCIATION
Lawyer's Referral & Information Service
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	:	
Defendants.	:	

COMPLAINT

Plaintiff, Jorja Bentley, by and through her counsel, alleges as follows:

PARTIES

1. Plaintiff, Jorja Bentley currently resides at P.O. Box 19852, Reno, Nevada.
2. Merck & Co., Inc. is a New Jersey Corporation with its principle place of business at 1 Merck Drive, Whitehouse Station, NJ 08889.
3. 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.

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

5. 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.

6. Ann Redfield, MSN, RN, formerly known as Ann R. Sweet, MSN, RN, upon information and belief, worked with Merck's Clinical Safety and Risk Management Department as part of the "vaccine team" at Merck West Point, located at 770 Sumneytown Pike, West Point, PA 19486. Defendant Redfield acted at all times pertinent hereto within the scope of her employment and/or at times beyond the scope of her employment.

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

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

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

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

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

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

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

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 post-vaccination 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 November 4, 2014, plaintiff Jorja Bentley received the Zostavax vaccine for its intended purpose: the prevention of shingles.

46. Within 24-hours of receiving the vaccine, she developed a headache, dizziness and blurred vision.

47. As a direct result of the vaccine, Plaintiff suffered, is suffering and/or will continue to suffer from injuries to her right eye, elevated blood pressure, headaches and dizziness.

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

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

COUNT I
NEGLIGENCE

51. Plaintiff repeats, reiterates, and realleges 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, 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, Jorja Bentley 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, Plaintiff, Jorja Bentley demands 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.

COUNT II
DESIGN DEFECT

58. Plaintiff repeats, reiterates, and realleges 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 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's injuries and damages sustained proximately caused by her use of the product.

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

COUNT III
FAILURE TO WARN

70. Plaintiff repeats, reiterates, and realleges 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 her 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 Jorja Bentley did not have the same knowledge as Merck and no adequate warning was communicated to her 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, Jorja Bentley 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, Plaintiff, Jorja Bentley demands 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.

COUNT IV
BREACH OF EXPRESS WARRANTY

91. Plaintiff repeats, reiterates, and realleges 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 her physicians and/or other healthcare providers, did rely on Merck's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

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, Plaintiff, Jorja Bentley demands 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.

COUNT V
BREACH OF IMPLIED WARRANTY

99. Plaintiff repeats, reiterates, and realleges 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, her physicians, and her healthcare providers, that Zostavax vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

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, her 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 her injuries described herein.

WHEREFORE, Plaintiff, Jorja Bentley demands 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.

COUNT VI
FRAUDULENT MISREPRESENTATION

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

111. Merck, by and through its agents and employees such as named Defendant Ann Redfield and other such employees as will be added following discovery, intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and consumers, including the Plaintiff and her health care providers, that its Zostavax vaccine had been adequately tested in clinical trials and was found to be safe and effective.

112. Merck knew or believed at the time it made its fraudulent misrepresentations, that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of its Zostavax vaccine. Merck made its fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of their product, such as Jorja Bentley.

113. Merck's fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, the Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase Merck's product.

114. Merck's fraudulent misrepresentations intentionally concealed the following material information:

- a. Merck represented through its labeling, advertising, marketing material, advertisements, and packaging that Zostavax had been tested and was found to be safe and effective for preventing shingles;
- b. Merck represented that Zostavax did not cause or induce shingles;
- c. Merck knowingly omitted in the packaging for this product that the Zostavax vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases;
- d. Merck represented that Zostavax was safe, when, indeed, it was not.
- e. Defendant Ann Redfield, MSN, RN, working with part of the "vaccine team" as part of Merck's Clinical Safety and Risk Management Department, wrote the comment section for Merck's WAES adverse experience reports.
- f. Defendant Redfield also worked as the "process owner" of Merck's Varicella Zoster Vaccine Identification Program. In this capacity, Defendant Redfield drafted documents presented to the Merck employees who interacted directly with healthcare providers who recommend, prescribe, and dispense Zostavax. In addition, Defendant Redfield gave presentations to Merck's field personnel, which was the sales force of Merck employees who interacted directly with healthcare providers.

- g. Upon information and belief, Defendant Redfield acted within the scope of her employment when she excluded or otherwise ignored reports of meningitis caused by vaccine-strain herpes zoster and assisted Merck in communicating this false information to sales representatives and then healthcare providers. In the alternative, based upon information and belief, Defendant Redfield acted beyond the scope of her employment when she misrepresented key safety information, such as excluding or otherwise ignoring reports of meningitis caused by vaccine-strain herpes zoster in her communications to Merck, who in turn communicated this false information to sales representatives and then health care providers.

115. Merck and Defendant Redfield were under a duty to disclose to the Plaintiff and her physicians and healthcare providers, the defective design and formulation of its product, which design and formulation heightened the risk of suffering the injuries, diseases, and maladies more specifically described in this Complaint.

116. Merck and Defendant Redfield had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous injuries and damages to persons who used the product.

117. The intentional concealment and omissions of material fact concerning the safety of the Zostavax vaccine was undertaken purposefully, willfully, wantonly, fraudulently by Defendants Merck and Redfield, with intent to mislead, with reckless disregard for the health and safety of the Plaintiff and to induce Plaintiffs physicians and healthcare providers to purchase, prescribe, administer and/or dispense Merck's product; and to mislead plaintiff into reliance upon Merck's fraudulent misrepresentations to use Merck's product as a safe and effective vaccine.

118. At the time Defendants made these misrepresentations, including Merck through its various officers, directors, agents, representatives, and employees, and at the times the

Plaintiff was administered Merck's product, Plaintiff was unaware of Defendants' falsehoods, and reasonably believed them to be true.

119. Defendants knew and had reason to know that the product was at great risk of causing serious personal injury to users of the product, and that the product was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given by Merck.

120. In reliance upon Defendants' false and fraudulent misrepresentations, through her physicians and healthcare providers, the Plaintiff was induced to, and did, reasonably rely upon Defendants' misrepresentations regarding the safety and efficacy of Merck's product, thereby sustaining severe and permanent personal injuries and damages. Defendants knew and had reason to know that Jorja Bentley, her physicians and her healthcare providers, in using Merck's product, did not have the ability to determine the true facts intentionally concealed by Defendants, and would not have used the product if the true facts regarding the product had been known by Plaintiff, her physicians, and her healthcare providers.

121. As a result of Merck's research and testing or lack thereof, Merck willfully, wrongfully, and intentionally distributed false information including, but not limited to, assuring the Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that Merck's product was safe for use. As a result of Merck's research and testing, or lack thereof, Merck intentionally omitted, concealed, and suppressed from the medical community, Plaintiff, and other consumers the true results of Merck's studies and research, which revealed the true risks of serious harm associated with the use of the product.

122. Merck had a duty when disseminating information to the public to provide truthful information, and a parallel duty not to deceive the public, the Plaintiff, her healthcare providers and physicians, and the FDA.

123. The information distributed by Merck to the public, including the Plaintiff, the medical community, and the FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of Merck's product.

124. Merck recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of its product to the public at large, and the Plaintiff, Jorja Bentley in particular, for the purpose of influencing the sales of a product known by Merck to be dangerous and defective.

125. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and purposefully.

126. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, Plaintiff, Jorja Bentley was caused to suffer the serious and dangerous side effects as are more specifically described in this Complaint.

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

WHEREFORE, Plaintiff, Jorja Bentley demands 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.

COUNT VII
NEGLIGENT MISREPRESENTATION

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

129. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff, Jorja Bentley, 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.

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

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

132. 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.

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

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

135. 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.

136. The above misrepresentations were made to Plaintiff, Jorja Bentley, as well as the general public.

137. Plaintiff, Jorja Bentley, and her healthcare providers and physicians, justifiably relied on Merck's misrepresentations.

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

139. 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.

140. As a direct and proximate consequence of Merck's negligent misrepresentations, the Plaintiff sustained serious personal injuries and related losses including mental anguish,

physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

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.

COUNT VIII
UNJUST ENRICHMENT

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

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

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

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

153. Plaintiff, Jorja Bentley, has not received the safe and effective vaccine for which she paid.

154. It would be inequitable for Merck to keep this money if Plaintiff, Jorja Bentley, 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.

BERN CAPPELLI, LLP

Dated: February 22, 2016

By: /s/ Shawn M. Sassaman
Shawn M. Sassaman, Esquire
I.D. #76321
101 West Elm Street, Suite 630
Conshohocken, PA 19428
(610) 941-4444

Attorney for Plaintiff

VERIFICATION

I, Shawn M. Sassaman, Esquire being duly sworn according to law, depose and say that I am the attorney for the Plaintiff, that I make this pleading on her behalf, that she is unavailable to execute a Verification so as to enable timely filing of Plaintiff's Complaint and the facts set forth in the foregoing Complaint are true and correct to the best of counsel's knowledge, information and belief.

This Verification is made pursuant to Pa. R.C.P. 1024 and is based on interviews, conferences, reports, records and other investigatory material in the file.

DATE: February 22, 2017

/s/ Shawn M. Sassaman
SHAWN M. SASSAMAN
Attorney for Plaintiff

CERTIFICATE OF SERVICE

I, Shawn M. Sassaman, attorney for the Plaintiff, hereby certify that a true and correct copy of the Plaintiff's Complaint was served on all parties of record via the Court's electronic distribution service on the date noted below. A copy of the Complaint was served on Ann Redfield, RN via First Class Mail.

DATE: February 22, 2017

/s/ Shawn M. Sassaman
SHAWN M. SASSAMAN
Attorney for Plaintiff