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IN RE ZOSTAVAX LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION – MIDDLESEX COUNTY MCL NO.: 629 **THIRD AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND FOR THE LAW FIRM OF MARC J. BERN & PARTNERS LLP**

Plaintiffs, by their attorneys, MARC J. BERN & PARTNERS LLP, bring this Third Amended Master Long Form Complaint as an administrative device to set forth potential claims with common factual allegations and legal bases that generally pertain to the Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP in this litigation, and that individual Plaintiffs to the Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP in this litigation may assert against Defendants in this litigation. This Complaint is the Third Amended Master Complaint filed for all Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP, and all allegations pleaded herein are deemed pleaded in any previously filed Complaint by Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP and any Short Form Complaint hereafter filed. Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP plead all Counts of this Third Amended

Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply under controlling choice of law principles, including the laws of each individual Plaintiffs' home state.

This Third Amended Master Long Complaint does not necessarily include all claims asserted in each of the transferred actions to this Court. It is anticipated that individual Plaintiffs represented by the law firm of MARC J. BERN & PARTNERS LLP will adopt this Third Amended Master Long Form Complaint and selected causes of action herein using a separate Third Amended Master Short Form Complaint. This Third Amended Master Long Form Complaint does not constitute a waiver or dismissal of any claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery and trials proceed.

Accordingly, Plaintiffs allege as follows:

INTRODUCTION

1. The ZOSTAVAX® vaccine ("ZOSTAVAX") is designed, manufactured, and marketed to prevent shingles and other zoster-related injuries indefinitely.

2. Defendants knew that ZOSTAVAX, a live-attenuated vaccine, can induce shingles and zoster-related conditions in its users, Defendants concealed this information from governmental agencies until 2014. At no time did Defendants proactively notify the medical community except to make a small-print update on the sixth page of the package insert of the product in late 2014. Defendants **never** attempted to notify the public that ZOSTAVAX was known to induce the conditions that it was supposed to prevent.

3. Since at least 2006, Defendants represented and marketed ZOSTAVAX to be 51% overall effective to prevent shingles and other zoster-related conditions indefinitely. Not

only is ZOSTAVAX only 51% effective upon perfect use at age 60 – and only if used at age 60 – the vaccine drastically wanes in efficacy after inoculation and is not effective after four years.

4. Defendants have known for over a decade that the ZOSTAVAX vaccine is far less effective than publicly advertised and represented to government agencies.

5. Defendants failed to remedy the false representations made about ZOSTAVAX and, instead, continued to intentionally omit and conceal material information from the public. In doing so, Defendants engaged in an unlawful scheme to falsify and conceal the true safety and efficacy of the ZOSTAVAX vaccine.

6. Consumers throughout the United States have purchased millions of doses of the ZOSTAVAX vaccine due to Defendants' unlawful scheme to falsify and conceal the true efficacy of the ZOSTAVAX vaccine. Defendants profited immensely from this unlawful scheme, making billions of dollars from sales of the ZOSTAVAX vaccine.

7. Plaintiffs maintain that ZOSTAVAX is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, ineffective and not fit for its intended purpose, and lacked proper warnings and instructions as to the dangers associated with its use.

PARTIES

8. Plaintiffs include women and men over the age of 50 years who were inoculated with the ZOSTAVAX® vaccine ("ZOSTAVAX").

9. Plaintiffs also include the spouses and/or intimate partners of the aforesaid Plaintiffs, Plaintiffs' children, decedent, and/or ward represented by any Plaintiffs' counsel, as well as others with standing to file claims arising from the ZOSTAVAX vaccine.

10. Plaintiffs used the ZOSTAVAX vaccine for the permanent prevention of shingles and zoster-related injuries.

11. Plaintiffs were diagnosed with shingles and/or other zoster-related injuries after and despite being inoculated with the ZOSTAVAX vaccine.

12. As a direct and proximate result of the ZOSTAVAX vaccine, Plaintiffs have and will continue to suffer ongoing injuries, including but not limited to: mental and physical pain and suffering; extensive medical care and treatment for these injuries; significant medical and related expenses as a result of these injuries, including but not limited to medical losses and costs which include care for hospitalization, physician care, monitoring, treatment, medications, and supplies; diminished capacity for the enjoyment of life; a diminished quality of life; increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions; lost wages; loss of earnings capacity; and other losses and damages as a result of shingles and other zoster-related injuries.

13. "Healthcare providers" where used hereinafter, shall refer to all pharmacists, prescribing physicians, treating physicians, persons who administered ZOSTAVAX to any Plaintiff, nurse practitioners, and any other medical professional who saw, diagnosed, treated, and or prescribed medications or vaccinations to any Plaintiffs in connection with ZOSTAVAX, shingles, zoster-related conditions, and/or the injuries alleged herein.

14. At all relevant times to this action, as further detailed herein, Defendants MERCK & CO., INC., MERCK SHARP & DOHME CORP., McKESSON CORP. (collectively, "Defendants"), and each of them, introduced into interstate commerce the ZOSTAVAX vaccine, which was to be administered to individuals and consumers throughout the United States.

15. Defendant MERCK & CO., INC. ("Merck") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

16. At all relevant times, Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine, to be administered to individuals and consumers throughout the United States.

17. Defendant MERCK SHARP & DOHME CORP. (hereinafter, "MSD"), is a wholly-owned subsidiary of Merck and part of the Merck family of companies.

18. MSD is a New Jersey corporation organized with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

19. At all relevant times, MSD, individually through its predecessors and through the actions of Merck, designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine, to be administered to individuals and consumers nationwide.

20. Defendant McKesson Corp. (hereinafter "McKesson") is a Delaware Corporation with its principal place of business at 2710 Gateway Oaks Drive, Sacramento, California 95833.

21. At all relevant times, McKesson, individually as an agent of Merck and/or MSD, packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce the ZOSTAVAX vaccine to individuals and consumers nationwide, including to the Plaintiffs.

22. At all relevant times, McKesson developed and disseminated marketing materials for ZOSTAVAX including, but not limited to, product inserts, prescribing guidelines, patient information sheets, labels, Vaccine Information Sheets, brochures, pamphlets, and other promotional materials.

JURISDICTION AND VENUE

23. Pursuant to the August 15, 2018 Order of this Court, venue in actions such as this one sharing common questions with the initially transferred actions is proper in this Court, New Jersey Superior Court, Law Division – Middlesex County, for coordinated pretrial proceedings pursuant to R. 4:38A.

24. This Court has personal jurisdiction over Merck and MSD pursuant to R. 4:4-4(a)(6) because Merck and MSD are resident corporations of the State of New Jersey.

25. This Court has personal jurisdiction over McKesson pursuant to R. 4:4-4(b)(1)(A) because McKesson conducts business in the State of New Jersey.

26. Venue is proper in this Court pursuant to R. 4:3-2 because a substantial amount of the Defendants' conduct, as alleged herein by Plaintiffs, took place throughout the State of New Jersey, including in Middlesex County.

27. Requiring Defendants to litigate these claims in New Jersey does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

28. Each Defendant systematically availed itself of the State of New Jersey by conducting regular and sustained business and engaging in substantial commerce and business activity regarding the ZOSTAVAX vaccine in New Jersey.

29. Each Defendant expected or should have expected that its acts would have consequences within the United States, and specifically in the State of New Jersey.

30. Each Defendant derived and continue to derive substantial revenue from its actions, dealings, associations, relationships, or otherwise, as described herein, from New Jersey in connection with the ZOSTAVAX vaccine.

31. Plaintiffs' claims relate to and arise from Defendants' explicit contacts and purposeful availment of the State of New Jersey because Defendants' conduct at issue in this matter as alleged herein occurred in whole or in part in the State of New Jersey.

32. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332.

33. The instant Complaint does not invoke the federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because it sets forth exclusively state law claims against the Defendants.

34. 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.

AGENCY, ALTER-EGO, VICARIOUS, SUCCESSOR, AND CO-CONSPIRATOR LIABILITY OF EACH DEFENDANT DUE TO THE RELATIONSHIPS BETWEEN MERCK, MSD, AND McKESSON

35. Plaintiffs incorporate by reference all prior allegations.

36. Each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' damages.

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

38. There exists and, at all times herein mentioned, a unity of interest in ownership between Merck and MSD.

39. Merck and MSD are not distinct corporate entities: the assets of Merck and MSD are common to both entities; Merck and MSD share and use facilities to conduct and engage in business activities; the business operations of Merck and MSD are the same; the employees and officers of Merck and MSD are largely the same people; the principal place of business of Merck and MSD is the same; the same bank accounts are used by Merck and MSD for business and other operations; Merck and MSD have no separate corporate formalities that exist or are otherwise observed.

40. No individuality and separateness exist between Merck and MSD; and any individuality and separateness between Merck and MSD that may have formerly existed has ceased.

41. As such, sufficient grounds exist for disregarding the corporate form and extending liability to MSD and Merck, for the acts of the other, through piercing the corporate veil, alter ego liability, vicarious liability, and/or successor liability.

42. Adherence to the fiction of the separate existence Merck and MSD as entities distinct from each other will permit an abuse of corporate privilege and would sanction a fraud and/or promote injustice.

43. At all times herein mentioned, the officers and/or directors of Merck and MSD mentioned or referred to herein participated in, authorized and/or directed the production and promotion of the ZOSTAVAX vaccine when they knew, or with exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that results in the injuries suffered by Plaintiffs.

44. MSD and Merck exercised, and continues to exercise, complete and domination of the finances, policy, and business practices regarding the ZOSTAVAX vaccine of McKesson to such an extent that McKesson has no separate mind, will or existence of its own.

45. The aforesaid control was used by Merck and/or MSD to negligently design, research, develop, manufacture, test, label, advertise, promote, market, sell, supply, distribute, and/or introduce into the stream of commerce ZOSTAVAX vaccine for use by individuals like Plaintiffs and their healthcare providers.

46. As such, there are sufficient grounds, in and of themselves, to extend liability to Merck and/or MSD for the acts of McKesson regarding the design, research, development, manufacture, testing, labeling, advertising, promotion, marketing, sale, supply, distribution, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine.

47. McKesson created, developed, and implemented the marketing strategy to promote and sell and distribute the ZOSTAVAX vaccine nationwide.

48. McKesson, as Merck's agent, created, developed, and implemented the marketing strategy to promote and sell and distribute the ZOSTAVAX vaccine nationwide.

49. McKesson, as MSD's agent, created, developed, and implemented the marketing strategy to promote and sell and distribute the ZOSTAVAX vaccine nationwide.

50. McKesson developed the "Vaccine Information Statement" for the ZOSTAVAX vaccine with Merck for distribution nationwide.

51. McKesson published the ZOSTAVAX "Vaccine Information Statement."

52. McKesson disseminated the ZOSTAVAX "Vaccine Information Statement."

53. Merck and/or MSD impliedly and explicitly consented to have McKesson act on Merck and/or MSD's behalf with regard to the packaging, labeling, re-packaging, marketing,

promotion, supply, distribution, sale, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine throughout the United States.

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

55. Merck and/or MSD manifested the authority of McKesson to act on Merck's and/or MSD's behalf by allowing McKesson to create, develop, publish, and disseminate the "Vaccine Information Statement" for the ZOSTAVAX vaccine.

56. Merck and/or MSD manifested the authority of McKesson to act on Merck's and/or MSD's behalf by allowing McKesson to develop, publish, and disseminate marketing and promotional materials for the ZOSTAVAX vaccine.

57. McKesson exercised, and continues to exercise, complete control, and/or equal participation in the policy and business practices of Merck and/or MSD regarding the packaging, labeling, re-packaging, marketing, promoting, supply, distribution, sale, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine to such an extent that Merck and McKesson have no separate mind(s), will or own existence in this regard.

58. The aforesaid control over Merck and MSD was used by McKesson, acting as an agent of Merck, to negligently package, label, re-package, market, promote, supply, distribute, sell, and/or introduce into the stream of commerce the ZOSTAVAX vaccine for use by patients like Plaintiffs and their healthcare providers.

59. As such, there are sufficient grounds to extend liability to Merck and/or MSD for the acts of McKesson regarding the packaging, labeling, re-packaging, marketing, promotion,

supply, distribution, sale, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine.

60. McKesson is liable for all misrepresentations made by Merck and/or MSD because McKesson is the business partner and agent of Merck and MSD.

61. McKesson knew or should have known that its misrepresentations and omissions regarding the ZOSTAVAX vaccine as alleged herein were false.

62. McKesson knew or should have known that the ZOSTAVAX vaccine that it packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce on behalf of Merck and/or MSD was not safe for human use and/or consumption.

63. As such, there are sufficient grounds to disregard the corporate form and to extend liability for Merck's acts and omissions to McKesson because Merck and McKesson are alter egos of each other.

64. As such, there are sufficient grounds to disregard the corporate form and to extend liability for MSD's acts and omissions to McKesson because MSD and McKesson are alter egos of each other.

65. As such, there are sufficient grounds to disregard the corporate form and to extend liability for Merck's acts and omissions to McKesson because Merck and McKesson are agents of each other.

66. As such, there are sufficient grounds to disregard the corporate form and to extend liability for MSD's acts and omissions to McKesson because MSD and McKesson are agents of each other.

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

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

69. "Defendants" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Merck, MSD, McKesson, and each of them.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

70. Plaintiffs incorporate by reference all prior allegations.

71. Plaintiffs bring these claims within the applicable statute of limitations because Plaintiffs and Plaintiffs' healthcare providers did not discover and could not reasonably discover the defects and unreasonably dangerous condition of the ZOSTAVAX vaccine.

72. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the ZOSTAVAX vaccine and the causal connection between these defects and Plaintiffs' injuries and damages is due to Defendants' fraudulent conduct.

73. Each Defendant's fraudulent conduct includes intentional concealment of material information from the public, and intentional misrepresentation of material information and/or downplay of the serious threat to public safety that the ZOSTAVAX vaccine presents.

74. Defendants intentionally concealed material information including but not limited to the fact that the ZOSTAVAX vaccine had not been demonstrated to be safe or effective; that the ZOSTAVAX vaccine is not effective at permanently preventing shingles or any related injuries; and that the ZOSTAVAX vaccine carried with it the serious risks and dangerous defects described herein.

75. Defendants' fraudulent conduct was directed at Plaintiffs, Plaintiffs' prescribing healthcare providers, pharmacists, the medical community, the general consuming public, and the U.S. Food and Drug Administration ("FDA").

76. Each Defendant had a duty to disclose the fact that the ZOSTAVAX vaccine was not safe or effective; was defective; was unreasonably dangerous; and that being inoculated with the ZOSTAVAX vaccine as a measure of routine health maintenance and prevention carried the above-described risks.

77. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants.

78. Plaintiffs have been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

79. Plaintiffs could not reasonably have discovered the injury and its cause until shortly before the initiation of these actions.

80. Each Defendant is estopped from relying on any statutes of limitation or repose affirmative defense by virtue of each Defendant's unclean hands, acts of fraudulent concealment, and affirmative misrepresentations and omissions of material fact.

FACTUAL BACKGROUND

81. The ZOSTAVAX vaccine was designed, developed, manufactured, marketed, distributed, and sold with the intended purpose of long-term prevention and protection against shingles and other zoster-related conditions and disease.

Shingles

82. Varicella-zoster virus ("VZV") causes chickenpox.

83. Once VZV causes chickenpox, the VZV remains inactive (dormant) in the nervous system, in the sensory neurons of dorsal root and cranial nerve ganglia, for many years.

84. When reactivated, VZV causes shingles, also known as or herpes zoster ("HZ").

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

86. VZV reactivates in aging individuals whose immune responses against VZV decline, producing shingles.

87. One in three people in the United States will develop shingles during their lifetime.

88. Approximately 99% of persons aged fifty years and older are infected with VZV. This is because nearly all of us had chickenpox as children.

89. Nearly one million cases of shingles are reported annually in the United States.

90. Shingles occurs at a rate of three to seven times higher in individuals age 50 years and older than in the rest of the population.

91. Shingles can often lead to additional complications, such as post herpetic neuralgia, which is a painful and long-lasting and recurrent neurological condition that affects nerve fibers and skin; those suffering from post-herpetic neuralgia often complain of burning pain that lasts long after the visual rash and blisters from shingles go away.

92. In addition to post herpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, ocular and neurological injuries, allodynia, cranial and motor neuron palsies, pneumonia, encephalitis, hearing loss, and death.

ZOSTAVAX Vaccine – A Live Vaccine

93. The four main types of vaccines are live-attenuated vaccines; inactivated vaccines; toxoid vaccines; and subunit, recombinant, polysaccharide, and conjugate vaccines.

94. Inactivated vaccines are vaccines that use the killed version of the germ that causes a disease.

95. Toxoid vaccines use a toxin made by the virus that causes a disease and create immunity to the parts of the virus that cause a disease instead of the germ itself.

96. Subunit, recombinant, polysaccharide, and conjugate vaccines use specific pieces of the virus – such as its protein, sugar, or capsid – and give a very strong immune response targeted to key parts of the virus because these vaccines use only specific pieces of the virus.

97. Subunit, recombinant, polysaccharide, and conjugate vaccines can also be used on almost everyone who needs them, including people with weakened immune systems and long-term health problem.

98. Live virus vaccines use a weakened (or attenuated) form of the virus that causes a disease.

99. ZOSTAVAX is a live-attenuated vaccine which contains VSV in reduced virulence.

100. One of the risks of using a live vaccine is transmission of the vaccine virus to the recipient.

101. Live-attenuated vaccines carry a serious, high risk of transmitting the live virus's disease to individuals with weakened immune systems, long-term health problems, or who have had an organ transplant.

102. Live-attenuated vaccines must be kept refrigerated before use.

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

104. Because ZOSTAVAX is a live-attenuated vaccine, it experiences potency loss during its "shelf life" – after its manufacture but before its use.

105. The ZOSTAVAX vaccine's potency loss during a shelf life of eighteen (18) to twenty (20) months is between 50% and 80%.

106. Merck and MSD knew that the end-expiry of eighteen months "is required to obtain CDC contracts" for ZOSTAVAX.

107. Merck and MSD knew that ZOSTAVAX's 18-month shelf life's potency loss "requires a significant overfill to remain portent at the end of the expiration period."

108. Merck and MSD acknowledged that "[t]his would necessitate a minimum release specification of 41,000 PFU (with a 67,000 PFU target and a 110,000 PFU maximum release potency)."

109. Live-attenuated vaccines also risk being under-attenuated (not weakened enough) or over-attenuated (weakened too much).

110. Under-attenuated vaccines carry the high risk of inducing the disease the vaccine is intended to prevent.

111. Under-attenuated live VZV has been shown to reactivate.[1]

112. Over-attenuated vaccines are not effective to offer protection against the disease the vaccine is designed to prevent.

113. Immunocompromised individuals include a wide spectrum of individuals who have, among many other circumstances, health conditions such as HIV and other conditions affecting the immune system, bone marrow transplant recipients, lymphoma and other cancers, patients in remission or otherwise who had recently been treated with chemotherapy or prednisone.

114. ZOSTAVAX is contraindicated in immunocompromised individuals because it is a "live" virus vaccine, and the risk of transmitting the disease it is intended to prevent is high.

115. Instances of zoster virus activation after ZOSTAVAX use occurs at a rate twenty-times higher in immunocompromised individuals.

116. In immunocompromised individuals, shingles will have atypical manifestations that are attributable to more severe skin legions, increased severity of pain and more diffuse involvement.

117. The vaccine virus in ZOSTAVAX is known to become dormant in nerve tissue.

118. ZOSTAVAX is manufactured from the same virus strain and by the same process used to produce Merck's chicken-pox vaccine, VARIVAX.

119. ZOSTAVAX is a highly concentrated version of Merck's chickenpox vaccine, VARIVAX, containing 14 times the dose of the attenuated live VZV virus than VARIVAX.

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

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

FDA Approval Process for Vaccines

121. Vaccines are biological products.

122. Biological products are a subset of drugs.

123. Biological products, like other drugs, are used for the treatment, prevention or cure of disease in humans.

124. However, in contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material – human, animal, or microorganism – are complex in structure, and thus are usually not fully characterized.

125. Section 351 of the Public Health Service ("PHS") Act defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, … applicable to the prevention, treatment, or cure of a disease or condition of human beings."

126. Biological products subject to the PHS Act also meet the definition of drugs under the Federal Food, Drug and Cosmetic Act ("FDC Act").

127. Biological products are licensed under section 351 of the PHS Act in addition to being under regulation under provisions of the FDC Act.

128. Current authority for the regulation of vaccines resides primarily in Section 351 of the PHS Act and specific sections of the FDC Act.

129. The FDA's Center for Biologics Evaluation and Research ("CBER") is responsible for regulating vaccines in the United States.

130. Following initial laboratory and animal testing that show that investigational use in humans is reasonably safe, biological products (like other drugs) can be studied in clinical trials in humans under an investigational new drug application ("IND") in accordance with the regulations at 21 CFR 312.

131. If the data generated by the studies demonstrate that the product is safe and effective for its intended use, the data are submitted as part of a marketing application.

132. Whereas a new drug application ("NDA") is used for drugs subject to the drug approval provisions of the FDC Act, a biologics license application ("BLA") is required for biological products subject to licensure under the PHS Act.

133. FDA approval to market a biologic is granted by issuance of a biologics license.

134. Issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product.

135. Among other things, safety and purity assessments must consider the storage and testing of cell substrates that are often used to manufacture biologics. A potency assay is required due to the complexity and heterogeneity of biologics.

136. Safety under the BLA means the relative freedom from harmful effects, direct or indirect, when a product is prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

137. Purity under the BLA means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. Purity includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

138. Potency under the BLA means the specific ability or capacity of the product, as indicated by appropriate laboratory tests, to yield a given result.

139. Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an IND application to the FDA.

140. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included are information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

141. Pre-marketing (pre-licensure) vaccine clinical trials are typically done in three phases, as is the case for any drug or biologic:

a. Initial human studies, referred to as Phase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects.

b. Phase 2 studies are dose-ranging studies and may enroll hundreds of subjects.

c. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing.

142. At any stage of the clinical or animal studies, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies, or may halt ongoing clinical studies.

143. If successful, the completion of all three phases of clinical development can be followed by the submission of a BLA.

144. The BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.[2] The BLA is regulated under 21 CFR 600 – 680.

145. A BLA is submitted by any legal person or entity who is engaged in manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards.

146. The requirements for a BLA include:

a. Applicant information
b. Product/Manufacturing information
c. Pre-clinical studies
d. Clinical studies
e. Labeling

147. To be considered, the license application must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the efficacy and safety information necessary to make a risk/benefit assessment and to recommend or oppose the approval of a vaccine. During this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.

148. Following FDA's review of a license application for a new indication, the sponsor and the FDA may present their findings to FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC"). This non-FDA expert committee comprised of scientists, physicians, biostatisticians, and a consumer representative provides advice to the FDA regarding the safety and efficacy of the vaccine for the proposed indication.

149. Vaccine approval also requires the provision of adequate product labeling to allow healthcare providers to understand the vaccine's proper use, including its potential benefits

[2] 21 CFR 601.2.

and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

150. The FDA continues to oversee the production of vaccines after the vaccine and the manufacturing processes are approved to ensure continuing safety.

151. After licensure, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product.

152. If requested by the FDA, manufacturers are required to submit to the FDA the results of their own tests for potency, safety, and purity for each vaccine lot. They may also be required to submit samples of each vaccine lot to the FDA for testing.

153. If the sponsor describes an alternative procedure which provides continued assurance of safety, purity and potency, CBER may determine that routine submission of lot release protocols, showing results of applicable tests, and samples is not necessary.

154. Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, many vaccines undergo Phase 4 studies-formal studies on a vaccine once it is on the market.

155. The government relies on the Vaccine Adverse Event Reporting System ("VAERS") to identify problems after marketing begins.

ZOSTAVAX's FDA Approval

156. In May of 2006, the FDA approved the ZOSTAVAX vaccine to be marketed and sold in the United States for the prevention of shingles in adults.

157. ZOSTAVAX was initially approved to be marked for the "the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose."[3]

158. In March 2011, ZOSTAVAX was approved for prevention of shingles in adults aged fifty (50) years of age and older.

159. The Center for Disease Control and Prevention ("CDC") does not recommend Zostavax for people aged 50 to 59 years old.

160. It is the CDC's position that, "Protection from this shingles vaccine lasts about 5 years, so adults vaccinated before they are 60 years old might not be protected later in life when the risk for shingles and its complications are greatest."

161. The clinical studies for VARIVAX, a vaccine that was already approved by the FDA, were used to support Merck's BLA to the FDA for approval of ZOSTAVAX.

162. FDA approval of the ZOSTAVAX vaccine was based, in large part, on the results of the Shingles Prevention Study ("SPS") supported by Merck.

163. On June 2, 2005, the results of the SPS were published in the *New England Journal of Medicine* in an article titled "A vaccine to prevent herpes zoster and post herpetic neuralgia in older adults,"[4] finding the following:

> 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

[3] FDA Approval Letter, May 25, 2006.

[4] Oxman MN, Levin MJ, Johnson GR, Schmader KE, Straus SE, et al. 2005. "A vaccine to prevent herpes zoster and post herpetic neuralgia in older adults." *N. Engl. J. Med.* 352(22): 2271–84.

heart failure, myocardial infarction, diabetes mellitus type 2, and major depression."[5]

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."[6]

164. Merck's SPS reported that ZOSTAVAX use reduced the incidence of postherpetic neuralgia by 66.5%.[7]

165. The methods utilized in the SPS are unreliable.

166. The methods utilized in the SPS to study and analyze the safety and efficacy of the ZOSTAVAX vaccine excluded material data regarding adverse events associated with ZOSTAVAX use, including suspected cases of shingles.

167. The approval granted by the FDA to allow the selling and marketing of the ZOSTAVAX vaccine came with certain post-marketing commitments that Merck and/or MSD agreed to complete, among other things, to ensure the safety of this vaccine. These included the following:

i. 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.

ii. An observational study using a health maintenance organization ("HMO") and 20,000 vaccinated people to

[5] *N. Engl. J.Med.* 2005; 352(22) at 2272.
[6] *Id.*
[7] *Id.*

> 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.

168. Shingles was a noted occurrence with ZOSTAVAX use during ZOSTAVAX's clinical trials.

169. ZOSTAVAX is not, and never has been, FDA-approved to be marketed or sold for the prevention of post herpetic neuralgia.

170. ZOSTAVAX is not, and never has been, FDA-approved to be marketed or sold for pain management for shingles or post herpetic neuralgia.

171. Documented adverse reactions to vaccines must be reported to the federal government in a compulsory and mandated database, VAERS.

172. Since ZOSTAVAX's introduction in 2006, VAERS regarding use of the ZOSTAVAX vaccine 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.

173. As of September of 2015, VAERS received over 1,000 submissions received of serious adverse event reports regarding the ZOSTAVAX vaccine, including but not limited to: recurrent instances of myalgia; arthralgia; lymphadenopathy; rash; actinic keratosis; severe cutaneous disease; peripheral neuropathy; cellulitis; herpes keratitis resulting in vision loss; facial paralysis; pneumonia; brain inflammation (encephalitis); and death.

174. Since its approval, the ZOSTAVAX vaccine's package insert and/or prescribing information changed several times to include additional adverse reactions and/or risks associated with ZOSTAVAX use.

175. On or about November 16, 2009, the ZOSTAVAX vaccine's package insert, patient information sheet, and prescribing information was changed to include the following risks: "injection site rash, injection site urticaria, arthralgia, and myalgia."

176. On or about July 13, 2011, CBER approved MSD's proposed changes to the package insert to amend Section 6.2 of the ZOSTAVAX vaccine's package insert, which lists "VZV Rashes Following Vaccination," to include the term "'varicella' referring to the 2 rashes previously identified as varicella-like."

177. On or about August 28, 2014, the ZOSTAVAX vaccine's Package Insert and prescribing information was approved for change to include: "infections and infestations: Herpes zoster (vaccine strain)" under Section 6.3 ("Post-Marketing Experience"), which lists adverse reactions identified during post-marking use of ZOSTAVAX,[8] and to add "Shingles" in the "What are the possible side effects of ZOSTAVAX?" section.

178. On or about February 17, 2016, the prescribing information for ZOSTAVAX was changed to add the following risk: "Eye Disorders: necrotizing retinitis (patients of immunosuppressive therapy)."

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

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

181. The vaccine virus in ZOSTAVAX is known to become dormant in nerve tissue.

[8] All versions of the ZOSTAVAX vaccine's Package Insert, Section 6.3, expressly state that "Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to the vaccine" implying that no causal relationship should be drawn from the list of reactions identified therein.

182. The CDC states that live-attenuated virus vaccines should not be administered within four weeks of each other. Commonly administered live-vaccines, all of which are in the category of live-attenuated vaccinations posing potential interactions if administered too closely in time with the ZOSTAVAX vaccine, include: Measles, Mumps and Rubella vaccine ("MMR"); Rotavirus vaccine; Vaccina vaccine; and the Influenza Vaccine ("Flumist"). Receiving any of these vaccines too closely together can decrease the efficacy of the ZOSTAVAX vaccine.

183. Being inoculated with the ZOSTAVAX vaccine too closely in time to the pneumococcal vaccine ("P23") is known to reduce the immune system's response to the ZOSTAVAX vaccine.

184. While the prescribing information furnished with ZOSTAVAX mentions decreased efficacy with the pneumococcal vaccine, as of the present, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine does not adequately, if at all, address the potential risk of interactions between ZOSTAVAX and other common vaccinations, such as the Flumist influenza vaccination.

Vaccine Efficacy of ZOSTAVAX

185. Consumers and patients used the ZOSTAVAX vaccine with the intention to have permanent protection from herpes zoster based on Defendants' representations.

186. Merck's study, the SPS, found that ZOSTAVAX was overall 51% effective at preventing shingles in adults aged 60 years and older.

187. The effectiveness of the ZOSTAVAX vaccine decreases with advancing age: the SPS results showed that ZOSTAVAX was 41% effective in adults aged 70 through 79 years and only 18% effective in adults aged 80 years and older.

188. The effectiveness of the ZOSTAVAX vaccine rapidly decreases over time after inoculation: its effectiveness four years post-inoculation has been reported to be as low as 19% effective,[9] and after eight years post-inoculation, the ZOSTAVAX vaccine's effectiveness has been shown to be 4% and not statistically significant.

189. In 2012, the results of Merck's Short-Term Persistence Substudy ("STPS") were evaluated, utilizing Merck's selective "case determination" in its method, and Merck reported that ZOSTAVAX's efficacy after four or more years post-inoculation decreased from 51% to 39.6%, "although the differences were not statistically significant." [10]

190. Merck reported that the STPS concluded that ZOSTAVAX's vaccine efficacy was "statistically significant for the incidence of HZ and the HZ burden of illness through year 5" with its efficacy uncertain beyond that point.[11]

191. In 2015, Merck's post-FDA approval Long-Term Persistence Substudy ("LTPS") regarding ZOSTAVAX showed that its efficacy after four or more years post-inoculation was as low as 21%.[12]

192. Merck's LTPS nonetheless reported that ZOSTAVAX's "statistically significant ***vaccine efficacy for incidence of HZ persisted***" for eight years post-vaccination.[13]

193. In 2016, a CDC-funded retrospective cohort study showed that the ZOSTAVAX vaccine's efficacy four or more years post-inoculation was approximately 24%, rendering it useless to prevent shingles at that time.[14]

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[9] Izurieta, HS, et al. (2017). "Effectiveness and Duration of Protection Provided by the Live-attenuated Herpes Zoster Vaccine in the Medicare Population Ages 65 Years and Older." *Clin Infect Dis.* 2017 Mar 15;64(6):785-793.
[10] Schmader KE (2012). "Persistence of the efficacy of zoster vaccine in the shingles prevention study and the short-term persistence substudy." *Clin Infect Dis.* 2012 Nov 15; 55(10):1320-8.
[11] *Id.*
[12] Morrison, VA, et al. (2015). "Long-term persistence of zoster vaccine efficacy." *Clin Infect Dis.* 2015 Mar 15;60(6):900-9.
[13] *Id.* (emphasis added).

194. In 2017, Merck's own retrospective cohort study found that the ZOSTAVAX vaccine's efficacy four or more years post-inoculation was as low as 34% in 60 to 69-year-old adults and 29% in 70 to 79-year-old adults.[15]

195. Merck's retrospective cohort study's 2017 results reported that ZOSTAVAX's vaccine efficacy waned from 47.2% in the second year after vaccination "more gradually through year eight" – at which point Merck reported that its efficacy was found to be 31.8%.[16]

196. In 2017, an FDA-funded retrospective cohort study showed that the ZOSTAVAX vaccine's efficacy four years post-inoculation was much lower than Merck's findings: after four years, ZOSTAVAX's efficacy was only 19%, rendering it useless to prevent shingles at that time.[17]

197. The CDC published, in its updates on its recommendations for use of the herpes zoster vaccine, that the ZOSTAVAX vaccine wanes in efficacy within five years, having almost no remaining preventative effects after seven years.

198. The CDC does not recommend ZOSTAVAX for people aged 50 to 59 years old because "[p]rotection from this shingles vaccine lasts about 5 years, so adults vaccinated before they are 60 years old might not be protected later in life when the risk for shingles and its complications are greatest."[18]

199. The instructions for use and information regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended.

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[14] Tseng, HF, et al. (2016). "Declining Effectiveness of Herpes Zoster Vaccine in Adults Aged ≥60 Years." *J Infect Dis*. 2016 Jun 15; 213(12):1872-5.

[15] Baxter, R., et al. (2018). "Long-Term Effectiveness of the Live Zoster Vaccine in Preventing Shingles: A Cohort Study." *Am J Epidemiol.* 2018 Jan 1;187(1):161-169.

[16] *Id.*

[17] Izurieta, HS, et al. (2017). "Effectiveness and Duration of Protection Provided by the Live-attenuated Herpes Zoster Vaccine in the Medicare Population Ages 65 Years and Older." *Clin Infect Dis.* 2017 Mar 15;64(6):785-793.

[18] June 18, 2018 CDC Update, "Shingles Zostavax Vaccination – What You Should Know." (https://www.cdc.gov/vaccines/vpd/shingles/public/zostavax/index.html) (last visited September 13, 2018).

200. The instructions for use and information regarding the ZOSTAVAX vaccine does not recommend its users, consumers, patients administrators, or prescribers to re-vaccinate for the prevention of adult shingles.

201. No booster dose exists for the ZOSTAVAX vaccine.

Non-Live Alternative Zoster Vaccine

202. The methods of producing a non-live-attenuated zoster vaccine were available and known to Merck and MSD since at least 1982.

203. Merck has held multiple patents for methods of producing non-live VZV/shingles vaccines since 1984.

204. Since at least 1999, Merck knew that non-live zoster vaccines are as effective as a live-attenuated virus zoster vaccine.

205. Non-live zoster vaccines also maintain efficacy post-inoculation.

206. Unlike the live-attenuated zoster vaccine ZOSTAVAX, a non-live-attenuated zoster vaccine is safe and effective for use in even immunocompromised patients.

207. Non-live-attenuated vaccines carry no risk of transmission of the virus to their users.

208. Non-live zoster vaccines carry no risk of reactivating the VZV virus and inducing shingles after inoculation.

209. As early as 2004, Merck conducted studies using a heat-inactivated VZV vaccine that was found to significantly reduce the risk of herpes zoster.

210. The proportion of subjects in Merck's heat-inactivated formulations of zoster vaccine studies that reported systemic adverse experience was higher in recipients of the live attenuated vaccine (51.2%) than the heat-inactivated vaccine (40%).

211. Merck conducted studies on immunocompromised individuals using an inactivated shingles vaccine.[19]

212. In February 2017, Merck announced the results of one of its inactivated VZV vaccine studies on immunocompromised subjects (Study NCT01229267) ("First Phase 3 Trial"), which found that the inactivated vaccine reduced the incidence of confirmed herpes zoster cases by an estimated 64%.

213. Merck's First Phase 3 Trial's results showed a reduction of other herpes zoster complications by an estimated 73.5%.

214. Because Merck's First Phase 3 Trial's subjects are immunocompromised, they were at a six times greater risk of developing shingles than the general population.

215. ZOSTAVAX, however, is not indicated in immunocompromised individuals because ZOSTAVAX is a live-attenuated vaccine.

216. Shingrix which was recently approved by the FDA for the prevention of shingles in adults 50 years and older is a non-live vaccine which is much more effective at preventing shingles, and also considered likely safe to administer to immunocompromised individuals.

217. Shingrix is administered as a two-dose vaccine series.

218. Shingrix is overall 97.2% effective; 96.6% in persons aged 50 to 59 years; 97.4% for persons aged 60 to 69; and 97.9% for persons aged 70 years and older.

219. Vaccine efficacy for Shingrix in subjects aged 50 years and older was 93.1% four years post-vaccination.

220. Vaccine efficacy for Shingrix in subjects who received Shingrix at the age of 70 years or older is 85.1% four years post-vaccination.

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[19] "A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy." June 30, 2015.

221. On October 25, 2017, the Advisory Community on Immunization Practices ("ACIP") voted in favor of three recommendations for the use of Shingrix for the prevention of shingles.

222. The CDC adopted these recommendations, issuing a public advisory statement that for adult shingles prevention, "Shingrix is the preferred vaccine, over Zostavax. . ."[20]

223. The CDC recommends that all healthy adults 50 years and older receive Shingrix "even if in the past you . . . received Zostavax."[21]

COUNT I: VIOLATION OF THE NEW JERSEY PRODUCT LIABILITY ACT
(Against all Defendants)

224. Plaintiffs incorporate by reference all prior allegations.

225. Pursuant to N.J.S.A. 2A:58-C, *et seq.*, (New Jersey Products Liability Act) Plaintiffs assert all claims and causes of action against Defendants, including but not limited to, negligence, breach of implied warranty of merchantability, breach of implied warranty of fitness, strict liability, failure to warn and/or inadequate warning on theories of both negligence and strict liability, all claims and causes of action pertaining to the design, manufacture, sale and distribution of the defective Zostavax vaccine which was not reasonably fit, suitable, or safe for their intended purpose because it was defectively designed, manufactured and/or failed to contain adequate warnings.

226. Merck is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

227. MSD is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

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[20] August 3, 2018 CDC Update, "Shingles Zostavax Vaccination – What You Should Know." (https://www.cdc.gov/shingles/vaccination.html) (last visited September 13, 2018).

[21] August 22, 2018 CDC Update, "Shingles Zostavax Vaccination – What You Should Know." (https://www.cdc.gov/vaccines/vpd/shingles/public/shingrix/index.html) (last visited September 13, 2018).

228. McKesson is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

229. Merck is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

230. MSD is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

231. McKesson is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

232. Merck and/or MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine.

233. McKesson, individually as an agent of Merck and/or MSD, packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce the ZOSTAVAX vaccine to consumers nationwide, and including for ultimate use by Plaintiffs.

A. PRODUCTS LIABILITY - DEFECTIVE DESIGN
(Against all Defendants)

234. Plaintiffs incorporate by reference all prior allegations.

235. MSD is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

236. McKesson is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

237. McKesson is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

238. The ZOSTAVAX vaccine was intended to prevent and provide long-term protection against shingles and zoster-related conditions.

239. Defendants placed the ZOSTAVAX vaccine into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

240. Defendants put the ZOSTAVAX vaccine into the stream of commerce for use by Plaintiffs' healthcare providers.

241. Plaintiffs were reasonably foreseeable users of the ZOSTAVAX vaccine.

242. The ZOSTAVAX vaccine was expected to, and did, reach Plaintiffs and Plaintiffs' healthcare providers with no substantial change in the condition in which Defendants put the product into the stream of commerce.

243. The ZOSTAVAX vaccine was administered to Plaintiffs for its intended purpose of prevention and long-term protection against shingles and zoster-related conditions.

244. Plaintiffs' healthcare providers used and administered the ZOSTAVAX vaccine to Plaintiffs in the manner normally intended to be used and administered.

245. The ZOSTAVAX vaccine failed to perform as intended.

246. The ZOSTAVAX vaccine did not prevent and provide long-term protection against shingles and zoster-related conditions to Plaintiffs.

247. Plaintiffs contracted shingles and/or zoster-related conditions after, and despite, being inoculated with ZOSTAVAX.

248. The ZOSTAVAX vaccine with which Plaintiffs were inoculated failed to perform its intended function due to its defective design, as evident by Plaintiffs' injuries.

249. Defendants put the ZOSTAVAX vaccine into the stream of commerce in a defective condition for use by the Plaintiffs' healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

250. The ZOSTAVAX vaccine, as put into the stream of commerce by Defendants, was defective in its design and formulation because when it left the hands of the Defendants the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

251. The ZOSTAVAX vaccine, as put into the stream of commerce by Defendants, was defective in its design and formulation because when it left the hands of Defendants the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

252. Defendants had a duty to design, research, develop, manufacture, test, label, advertise, promote, market, sell, supply, distribute, and/or introduce into the stream of commerce a product that was reasonably safe and not unreasonably dangerous for its normal, common, and intended use.

253. The ZOSTAVAX vaccine was not reasonably fit, suitable, or safe for its anticipated use.

254. Reasonable and safer alternative designs existed and could have been utilized by Defendants for prevention and long-term protection against shingles.

255. Reasonably prudent designers, developers, manufacturers, advertisers, promoters, marketers, sellers, suppliers, and/or distributors would not have placed the product – the ZOSTAVAX vaccine – in the stream of commerce with knowledge of its design flaws.

256. Merck, MSD, and McKesson put into the stream of commerce a defective product – the ZOSTAVAX vaccine – that created an unreasonable risk of serious harm to the health, safety, and well-being of the Plaintiffs and other consumers.

257. The utility of the ZOSTAVAX vaccine did not outweigh the risk inherent in the product as designed.

258. Defendants knew or should have known that the ZOSTAVAX vaccine's defective design existed when the product was manufactured.

259. Plaintiffs and Plaintiffs' healthcare providers could not, by the exercise of reasonable care, discover the defective design or condition of the ZOSTAVAX vaccine and/or perceive its defects prior to its administration to Plaintiffs.

260. As a direct and proximate result of the defective design of the ZOSTAVAX vaccine with which Plaintiffs were inoculated, Plaintiffs sustained serious personal injuries and related losses including serious physical injury and impairment; mental anguish; pain and suffering; loss of enjoyment of life; diminished capacity for the enjoyment of life; a diminished quality of life; loss of care, comfort, and consortium; lost wages; diminished ability to work; medical and related expenses; economic damages; and other losses and damages.

261. As a direct and proximate result of the defective design of the ZOSTAVAX vaccine with which Plaintiffs were inoculated, Plaintiffs will continue to suffer such harm, damages, economic damages, and other losses in the future.

262. The defective design of ZOSTAVAX vaccine was a substantial, proximate, and contributing factor in causing the Plaintiffs' injuries.

263. Merck, MSD, and McKesson are each therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by Plaintiffs' use of the ZOSTAVAX vaccine pursuant to N.J.S.A. § 2A:58C-2 ("...c. was designed in a defective manner.").

264. Defendants are jointly and severally liable to Plaintiffs for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

B. PRODUCTS LIABILITY – MANUFACTURING DEFECT
(Against all Defendants)

265. Plaintiffs incorporate by reference all prior allegations.

266. Merck is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

267. MSD is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

268. McKesson is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

269. Merck is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

270. MSD is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

271. McKesson is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

272. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine.

273. McKesson packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce the ZOSTAVAX vaccine to consumers, including Plaintiffs and Plaintiffs' healthcare providers, and independently created marketing materials for ZOSTAVAX.

274. The ZOSTAVAX vaccine was intended to prevent and provide long-term protection against shingles and zoster-related conditions.

275. Defendants placed the ZOSTAVAX vaccine into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

276. The ZOSTAVAX vaccine was put into the stream of commerce by Defendants for use by Plaintiffs' physicians and/or healthcare providers.

277. Plaintiffs were reasonably foreseeable users of the ZOSTAVAX vaccine.

278. The ZOSTAVAX vaccine was expected to, and did, reach Plaintiffs and Plaintiffs' healthcare providers with no substantial change in the condition in which the product was put into the stream of commerce by Defendants.

279. The ZOSTAVAX vaccine was administered to Plaintiffs for its intended purpose of prevention and long-term protection against shingles and zoster-related conditions.

280. Plaintiffs' healthcare providers used and administered the ZOSTAVAX vaccine to Plaintiffs in the manner normally intended to be used and administered.

281. The ZOSTAVAX vaccine failed to perform as intended.

282. The ZOSTAVAX vaccine did not prevent and provide long-term protection against shingles and zoster-related conditions.

283. Plaintiffs contracted shingles and other zoster-related conditions after, and despite, being inoculated with ZOSTAVAX.

284. The ZOSTAVAX vaccine with which Plaintiffs were inoculated failed to perform its intended function due to a flaw in the manufacturing process, as evident by Plaintiffs' injuries.

285. The ZOSTAVAX vaccine with which Plaintiffs were inoculated was defective in its manufacture because the product deviated from its manufacturing standards when it came off the production line.

286. The ZOSTAVAX vaccine with which Plaintiffs were inoculated failed to perform in its intended manner due to some flaw in its fabrication process.

287. The ZOSTAVAX vaccine with which Plaintiffs were inoculated failed to perform in its intended manner due to a mistake in the manufacturing process.

288. The ZOSTAVAX vaccine with which Plaintiffs were inoculated were not manufactured and/or processed pursuant to its specifications.

289. The ZOSTAVAX vaccine, as constructed, deviated from any such specifications or design.

290. There was an unreasonable risk that the ZOSTAVAX vaccine would not perform safely and effectively for the purpose for which it was intended, which is the prevention and long-term protection against shingles and zoster-related conditions.

291. Plaintiffs and Plaintiffs' healthcare providers could not, by the exercise of reasonable care, discover the defective condition of the ZOSTAVAX vaccine and/or perceive its defects prior to its administration to Plaintiffs.

292. As a direct and proximate result of Plaintiffs' reasonably anticipated use of ZOSTAVAX as designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce

by Defendants, Plaintiffs suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

293. As a direct and proximate result of manufacturing defect of the ZOSTAVAX vaccine with which Plaintiffs were inoculated, Plaintiffs sustained serious personal injuries and related losses including serious physical injury and impairment; mental anguish; pain and suffering; loss of enjoyment of life; diminished capacity for the enjoyment of life; a diminished quality of life; loss of care, comfort, and consortium; lost wages; diminished ability to work; medical and related expenses; economic damages; and other losses and damages.

294. As a direct and proximate result of the manufacturing defect of the ZOSTAVAX vaccine with which Plaintiffs were inoculated, Plaintiffs will continue to suffer such harm, damages, economic damages, and other losses in the future.

295. The defective manufacture of ZOSTAVAX vaccine was a substantial, proximate, and contributing factor in causing the Plaintiffs' injuries.

296. Merck, MSD, and McKesson are each therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by their use of the ZOSTAVAX vaccine pursuant to N.J.S.A. § 2A:58C-2 ("...a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae....").

297. Defendants are jointly and severally liable to Plaintiffs for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

C. PRODUCTS LIABILITY – FAILURE TO WARN
(Against all Defendants)

298. Plaintiffs incorporate by reference all prior allegations.

299. Merck is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

300. MSD is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

301. McKesson is a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, including prescription drugs and vaccines.

302. Merck is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

303. MSD is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

304. McKesson is held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

305. Merck and MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine.

306. McKesson, individually and as an agent of Merck and MSD, packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce the ZOSTAVAX vaccine to consumers, including Plaintiffs and Plaintiffs' healthcare providers, and independently created marketing materials for ZOSTAVAX.

307. In the course of same, Defendants directly advertised, marketed, and/or promoted the product to the FDA, healthcare professionals, and consumers, including the Plaintiffs, Plaintiffs' healthcare providers, and persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the ZOSTAVAX vaccine.

308. The ZOSTAVAX vaccine was under the exclusive control of Merck, MSD, and/or McKesson.

309. The ZOSTAVAX vaccine was defective at the time it left Defendants' control because the vaccine failed to include adequate warnings, instructions, and directions relating to the dangerous risks associated with the use of ZOSTAVAX to prevent shingles.

310. The ZOSTAVAX vaccine was intended to prevent and provide long-term protection against shingles and zoster-related conditions.

311. Defendants placed the ZOSTAVAX vaccine into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

312. Defendants put the ZOSTAVAX vaccine into the stream of commerce for use by Plaintiffs' healthcare providers.

313. Plaintiffs were reasonably foreseeable users of the ZOSTAVAX vaccine.

314. The ZOSTAVAX vaccine was expected to, and did, reach Plaintiffs and Plaintiffs' healthcare providers with no substantial change in the condition in which Defendants put the product into the stream of commerce.

315. The ZOSTAVAX vaccine was administered to Plaintiffs for its intended purpose of prevention and long-term protection against shingles and zoster-related conditions.

316. Plaintiffs' healthcare providers used and administered the ZOSTAVAX vaccine to Plaintiffs in the manner normally intended to be used and administered.

317. The ZOSTAVAX vaccine was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their healthcare providers of such risks.

318. Defendants failed to provide adequate warnings to healthcare providers and users, including Plaintiffs and Plaintiffs' healthcare providers, of the increased risk of developing severe and permanent injuries, including, but not limited to, the risk of contracting shingles and suffering from zoster-related injuries associated with ZOSTAVAX due to viral infection.

319. The ZOSTAVAX vaccine was unaccompanied by appropriate and adequate warnings regarding the risk of developing severe and permanent injuries, including, but not limited to, the risk of contracting shingles and suffering from zoster-related injuries known to Defendants to be associated with ZOSTAVAX due to viral infection.

320. The warnings and prescribing information for ZOSTAVAX did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

321. Defendants failed to provide adequate warnings to healthcare providers and users, including Plaintiffs and Plaintiffs' healthcare providers, of the waning efficacy of ZOSTAVAX over time post-inoculation, or that it would not be effective at all four years after vaccination.

322. The ZOSTAVAX vaccine did not include warnings of its serious side effects, significantly diminishing efficacy rate, or lack of adequacy for long-term prevention of shingles to maximize the Defendants' profits from the ZOSTAVAX vaccine.

323. The ZOSTAVAX vaccine was defective due to inadequate post-marketing warnings or instructions:

a. After Defendants knew or should have known of the risk of serious bodily harm from the use of ZOSTAVAX, Defendants failed to provide an adequate warning to the product's users, consumers, and/or their healthcare providers about that risk of serious bodily harm.

b. After Defendants knew or should have known of the decreasing efficacy of the ZOSTAVAX vaccine with advancing age and over time post-inoculation, Defendants failed to provide an adequate warning to the product's users, consumers, and/or their healthcare

providers that the product was not effective for its intended purpose after four years post-inoculation.

324. Healthcare providers and consumers, including Plaintiffs and Plaintiffs' healthcare providers, neither knew nor had reason to know at the time of their use of ZOSTAVAX of the existence of the aforementioned defects.

325. Ordinary consumers would not have recognized the potential risks or side effects of which Defendants failed to include appropriate warnings, and of which Defendants concealed.

326. The ZOSTAVAX used by Plaintiffs were neither misused nor materially altered.

327. Defendants are strictly liable to Plaintiffs because Defendants sold a product that is unreasonably dangerous and for failed to provide an adequate warning or instructions with the that product – the ZOSTAVAX vaccine.

328. Defendants are therefore strictly liable because of their following acts and/or omissions:

a. Failing to adequately and correctly warn the Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare communities of the dangers of ZOSTAVAX for its intended users;

b. Failing to adequately and correctly warn the Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare communities of the risk of contracting shingles and suffering from zoster-related injuries from ZOSTAVAX use;

c. Failing to adequately and correctly warn the Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare communities that the efficacy of ZOSTAVAX decreases with advancing age;

d. Failing to adequately and correctly warn the Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare communities that the efficacy of ZOSTAVAX wanes significantly over time post-inoculation, to near-zero after four years;

e. Failing to disclose their knowledge that ZOSTAVAX's established side effects in adults include reactivation of VZV to actually cause shingles;

f. Failing to disclose their knowledge that ZOSTAVAX's established efficacy in adults decreases drastically with advancing age;

g. Failing to disclose their knowledge that ZOSTAVAX's established efficacy wanes significantly over time after vaccination, to near-zero after four years;

h. Failing to disclose reports of shingles associated with ZOSTAVAX use to providers and consumers;

i. Failing to disclose reports of zoster-related conditions and injuries associated with ZOSTAVAX use to providers and consumers;

j. Failing to correct the misrepresentation that ZOSTAVAX is safe and effective for long-term prevention and protection against shingles and zoster-related injuries;

k. Failing to correct the misrepresentation that ZOSTAVAX is a safe and effective vaccine for preventing post herpetic neuralgia; and

l. Failing to correct the misrepresentation that ZOSTAVAX is a safe and effective vaccine to diminish the incidence and burden of post herpetic neuralgia in consumers who are vaccinated with ZOSTAVAX and subsequently contract shingles.

329. Had Plaintiffs and Plaintiffs' healthcare providers been adequately warned of the increased risk of contracting shingles and suffering from zoster-related injuries associated with ZOSTAVAX, Plaintiffs would not have used ZOSTAVAX.

330. Had Plaintiffs not used ZOSTAVAX, Plaintiffs would not have suffered the injuries and damages as described herein.

331. Plaintiffs and Plaintiffs' healthcare providers could not, by the exercise of reasonable care, discover the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions and/or perceive its hidden, unknown, and unreasonably dangerous risks prior to its administration to Plaintiffs.

332. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions, Plaintiffs' healthcare providers prescribed

and/or administered the ZOSTAVAX vaccine to Plaintiffs.

333. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions, Plaintiffs used ZOSTAVAX.

334. As a direct and proximate result of Plaintiffs' reasonably anticipated use of ZOSTAVAX as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiffs suffered the serious injuries as alleged herein.

335. The defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions was a substantial, proximate, and contributing factor in causing the Plaintiffs' injuries.

336. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions, Plaintiffs sustained serious personal injuries and related losses including serious physical injury and impairment; mental anguish; pain and suffering; loss of enjoyment of life; diminished capacity for the enjoyment of life; a diminished quality of life; loss of care, comfort, and consortium; lost wages; diminished ability to work; medical and related expenses; economic damages; and other losses and damages.

337. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions, Plaintiffs will continue to suffer such harm, damages, economic damages, and other losses in the future.

338. Merck, MSD, and McKesson are each therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by their use of the ZOSTAVAX vaccine pursuant to N.J.S.A. § 2A:58C-2 ("...b. failed to contain adequate warnings or instructions....")

339. Defendants are jointly and severally liable to Plaintiffs for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys'

fees and all such other relief as the Court deems proper.

D. PRODUCT LIABILITY – BREACH OF IMPLIED WARRANTY
(Against all Defendants)

340. Plaintiffs incorporate by reference all prior allegations.

341. At all times relevant and material, Merck and/or MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine.

342. At all times relevant and material, McKesson, individually as an agent of Merck and/or MSD, packaged, labeled, re-packaged, marketed, promoted, supplied, distributed, sold, and/or introduced into the stream of commerce the ZOSTAVAX vaccine nationwide.

343. At all relevant and material times, Defendants were sellers who typically deal with pharmaceutical products, drugs, and vaccines similar to ZOSTAVAX.

344. Defendants were aware that consumers, including Plaintiffs, would use the ZOSTAVAX vaccine to prevent shingles.

345. Plaintiffs were foreseeable users of the ZOSTAVAX vaccine.

346. Plaintiffs were at all relevant times in privity with Defendants.

347. Plaintiffs' healthcare providers were at all relevant times in privity with Defendants.

348. The ZOSTAVAX vaccine was expected to reach and did in fact reach consumers, including Plaintiffs, without substantial changes in the condition in which the vaccine was manufactured and sold by Defendants.

349. At all relevant times, Defendants intended that the ZOSTAVAX vaccine be used in the manner that Plaintiffs herein in fact used the vaccine, and Defendants impliedly warranted the ZOSTAVAX vaccine was:

a. of merchantable quality;

b. fit for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions;

c. safe for its intended purpose and did not carry the hidden and inherent risk of serious physical injury;

d. adequately tested and was of fair and average quality for which it was marketed and sold;

e. effective for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions and would protect its users against shingles for life;

f. effective for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions and would protect its users against shingles regardless of the user's age at the time of inoculation; and

g. would comply with Defendants' express warranties regarding the ZOSTAVAX vaccine as alleged herein.

350. Plaintiffs justifiably relied on Defendants' implied warranties about the ZOSTAVAX vaccine's safety and efficacy.

351. Plaintiffs' healthcare providers justifiably relied on Defendants' implied warranties about the ZOSTAVAX vaccine's safety and efficacy.

352. In reliance on Defendants' implied warranties, Plaintiffs used the ZOSTAVAX vaccine as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

353. In reliance on Defendants' implied warranties, Plaintiffs' healthcare providers prescribed and administered the ZOSTAVAX vaccine to Plaintiffs in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

354. Defendants breached the implied warranties they made to Plaintiffs and Plaintiffs' healthcare providers with respect to the ZOSTAVAX vaccine.

355. The ZOSTAVAX vaccine was **not** of merchantable quality.

356. The ZOSTAVAX vaccine was **not** fit for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions because it decreases in efficacy significantly post-inoculation to zero after four years.

357. The ZOSTAVAX vaccine was **not** safe for its intended purpose because it carries the hidden and inherent risk of serious physical injury.

358. The ZOSTAVAX vaccine was **not** adequately tested prior to being marketed and sold by Defendants because the study methods used for FDA approval were unreliable.

359. The ZOSTAVAX vaccine was **not** of fair and average quality for which it was marketed and sold.

360. The ZOSTAVAX vaccine would **not** protect its users against shingles for life.

361. The ZOSTAVAX vaccine does **not** protect its users against shingles regardless of the user's age at the time of inoculation.

362. The ZOSTAVAX vaccine did **not** comply with Defendants' express warranties regarding the ZOSTAVAX vaccine as alleged herein.

363. At the time of making such implied warranties, Defendants knew or should have known that the ZOSTAVAX vaccine did not conform to these implied warranties because the ZOSTAVAX vaccine was not safe and had numerous serious side effects of which Defendants did not accurately warn or instruct and it was not as effective as promoted.

364. As a direct and proximate result of the Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine's fitness and quality for its intended use, Plaintiffs used the ZOSTAVAX vaccine and were injured as a result.

365. Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine makes them liable under New Jersey's Product Liability Act. *See* N.J.S.A. § 2A:58-C, *et*

seq.

366. As a direct and proximate result of Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine, Plaintiffs sustained serious personal injuries and related losses including serious physical injury and impairment; mental anguish; pain and suffering; loss of enjoyment of life; diminished capacity for the enjoyment of life; a diminished quality of life; loss of care, comfort, and consortium; lost wages; diminished ability to work; medical and related expenses; economic damages; and other losses and damages.

367. As a direct and proximate result of the Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine, Plaintiffs will continue to suffer such harm, damages, economic damages, and other losses in the future.

368. Defendants are jointly and severally liable to Plaintiffs for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II: BREACH OF EXPRESS WARRANTY
(Against Merck and MSD)

369. Plaintiffs incorporate by reference all prior allegations.

370. At all times relevant and material, Merck and/or MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce the ZOSTAVAX vaccine.

371. At all relevant times, Merck and/or MSD were aware that consumers, including Plaintiffs, would use the ZOSTAVAX vaccination.

372. At all relevant times, Merck and/or MSD were aware that the medical community, including Plaintiffs' healthcare providers, would prescribe, recommend, and administer the ZOSTAVAX vaccine.

373. At all relevant times, Merck and/or MSD intended that the ZOSTAVAX vaccine be used in the manner that Plaintiffs in fact used the ZOSTAVAX vaccine.

374. At all relevant times, Merck and/or MSD intended that the ZOSTAVAX vaccine be prescribed, recommended, and administered in the manner that Plaintiffs' healthcare providers in fact prescribed, recommended, and administered the ZOSTAVAX vaccine to Plaintiffs.

375. Plaintiffs were foreseeable users of the ZOSTAVAX vaccine.

376. Plaintiffs' healthcare providers were foreseeable users – as prescribers and administers – of the ZOSTAVAX vaccine.

377. Plaintiffs were at all times in privity with Merck.

378. Plaintiffs were at all times in privity with MSD.

379. Plaintiffs' healthcare providers were at all relevant times in privity with Merck.

380. Plaintiffs' healthcare providers were at all relevant times in privity with MSD.

381. The ZOSTAVAX vaccines were expected to reach and did in fact reach consumers, including Plaintiffs and Plaintiffs' healthcare providers, without substantial change in the condition in which they were manufactured, marketed, and sold by Merck and/or MSD.

382. Merck and/or MSD made the following express warranties regarding the ZOSTAVAX vaccine:

a) that it was safe and fit for use by consumers;
b) that it was of merchantable quality;
c) that its side effects were minimal;
d) that it was adequately tested and fit for its intended use;
e) that it was effective for the long-term prevention and protection against shingles and zoster-related conditions;

f) that it was effective to prevent and protect against shingles and zoster-related conditions for the duration of its users' lifetime;

g) that its efficacy did not decrease over time post-inoculation;

h) that its efficacy was the same regardless of its users' age at the time of inoculation;

i) that it was effective for long-term prevention and protection against post-herpetic neuralgia;

j) that it lessened the burden of post-herpetic neuralgia in individuals who develop shingles;

k) that it lessened the incidence of post-herpetic neuralgia in individuals who develop shingles;

l) that it effectively managed pain associated with post-herpetic neuralgia;

m) that it effectively managed and/or lessened pain associated with shingles;

n) that it was approved for managing and/or lessening pain associated with shingles and/or post-herpetic neuralgia; and

o) that it was approved for prevention and protection against post-herpetic neuralgia.

383. Merck's and/or MSD's representations and warranties, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

384. Merck and/or MSD made its express warranties to Plaintiffs and Plaintiffs' healthcare providers through the ZOSTAVAX vaccine's product insert, prescribing information, patient information sheet, labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and the ZOSTAVAX vaccine's regulatory submissions.

385. Members of the medical community, including Plaintiffs' healthcare providers, and the public, including Plaintiffs, relied upon the representations and warranties that Merck

and/or MSD made about the use recommendation, description, and/or dispensing of the ZOSTAVAX vaccine.

386. Plaintiffs justifiably relied on the express warranties made by Merck and/or MSD about the ZOSTAVAX vaccine.

387. Plaintiffs' healthcare providers justifiably relied on the express warranties made by Merck and/or MSD about the ZOSTAVAX vaccine.

388. In reliance on the express warranties made by Merck and/or MSD, Plaintiffs herein used the ZOSTAVAX vaccine as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

389. In reliance on the express warranties made by Merck and/or MSD, Plaintiffs' healthcare providers herein prescribed and administered the ZOSTAVAX vaccine to Plaintiffs in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

390. In reliance on the express warranties made by Merck and/or MSD, Plaintiffs were inoculated with the ZOSTAVAX vaccine in the foreseeable manner normally intended, manufactured, recommended, promoted, and marketed by Defendants.

391. Merck and/or MSD breached the express warranties made to Plaintiffs and Plaintiffs' healthcare providers with respect to the ZOSTAVAX vaccine.

392. The ZOSTAVAX vaccine was **not** safe or fit for its intended purpose because it carries the hidden and inherent risk of serious physical side effects and injuries, including transmission of viral infection and reactivating VZV and causing shingles.

393. The ZOSTAVAX vaccine was **not** of merchantable quality.

394. The ZOSTAVAX vaccine contained serious side effects causing serious risk of physical injury.

395. The ZOSTAVAX vaccine was **not** adequately tested prior to being marketed and sold by Defendants because the study methods used for FDA approval were unreliable.

396. The ZOSTAVAX vaccine was **not** safe or fit for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions because it decreases in efficacy significantly post-inoculation to zero after four years.

397. The ZOSTAVAX vaccine would **not** protect its users against shingles for life.

398. The ZOSTAVAX vaccine was **not** safe or fit for its intended purpose of long-term prevention and protection against shingles and zoster-related conditions because it decreases in efficacy significantly post-inoculation to zero after four years.

399. The ZOSTAVAX vaccine does **not** protect its users against shingles regardless of the user's age at the time of inoculation; its efficacy decreases with advancing age.

400. The ZOSTAVAX vaccine has not been shown to be effective for long-term prevention and protection against post-herpetic neuralgia; for lessening the burden or incidence of post-herpetic neuralgia in individuals who develop shingles; or for lessening or managing the pain associated with shingles or post-herpetic neuralgia.

401. The ZOSTAVAX vaccine is **not**, and has never been, approved for long-term prevention and protection against post-herpetic neuralgia.

402. The ZOSTAVAX vaccine is **not**, and has never been, approved to lessen the burden or incidence of post-herpetic neuralgia in individuals who develop shingles.

403. The ZOSTAVAX vaccine is **not**, and has never been, approved for managing and/or lessening pain associated with shingles and/or post-herpetic neuralgia.

404. Merck and/or MSD fraudulently withheld and concealed information about the substantial risks of viral infection that could result in serious injury and/or death associated with using the ZOSTAVAX vaccine.

405. Merck and/or MSD fraudulently concealed information regarding the true efficacy of the ZOSTAVAX vaccine from Plaintiffs and Plaintiffs' healthcare providers.

406. At the time of making such express warranties, Merck and/or MSD knew or should have known that the ZOSTAVAX vaccine did not conform to these express warranties and representations because the ZOSTAVAX vaccine was not safe and had numerous serious side effects, many of which Merck and/or MSD did not accurately warn or instruct.

407. As a direct and proximate result of Merck's and/or MSD's breach of their express warranties regarding the ZOSTAVAX vaccine, Plaintiffs used the ZOSTAVAX vaccine and were injured as a result.

408. Merck's and/or MSD's breaches of their express warranties constitute violations of common law principles and the following statutory provisions: N.J. Stat. Ann. §§ 12A:2-313(1)(a) to 12a:2-313(1)(c).

409. As a direct and proximate result of Merck's and/or MSD's breach of their express warranties regarding the ZOSTAVAX vaccine, Plaintiffs sustained serious personal injuries and related losses including serious physical injury and impairment; mental anguish; pain and suffering; loss of enjoyment of life; diminished capacity for the enjoyment of life; a diminished quality of life; loss of care, comfort, and consortium; lost wages; diminished ability to work; medical and related expenses; economic damages; and other losses and damages.

410. As a direct and proximate result of Merck's and/or MSD's breach of their express warranties regarding the ZOSTAVAX vaccine, Plaintiffs will continue to suffer such harm, damages, economic damages, and other losses in the future.

411. Merck and/or MSD are jointly and severally liable to Plaintiffs for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiffs demand judgment against the Merck and MSD and each of them, individually, jointly, and severally; 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; and any and all such other relief as the Court deems just and proper; and further, demand a trial by jury of all issues so triable.

COUNT III: SURVIVAL ACTION

412. Plaintiffs incorporate by reference all prior allegations as though set forth fully at length herein.

413. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the law of the Plaintiffs' resident State or Plaintiffs' Decedents' resident states or New Jersey.

414. Plaintiffs bring this claim on behalf of Plaintiffs' Decedents' Estate under applicable state statutory and/or common laws.

415. Plaintiffs have standing to bring this survival action under applicable state law.

416. As a direct and proximate cause of the aforesaid, Plaintiffs' Decedents was caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of Plaintiffs Decedent's death.

417. As a direct and proximate result of the conduct of Defendants, Plaintiffs' Decedents, prior to Plaintiffs' Decedents' death, was obligated to spend various sums of money to treat Plaintiffs Decedent's injuries, which debts have been assumed by the Estate.

418. As a direct and proximate result of the aforesaid, Plaintiffs' Decedents suffered a loss of earnings and earning capacity.

419. Plaintiffs' Decedents' spouses or heirs, including domestic partners, as Administrators or beneficiaries of the Estate of the Plaintiffs' Decedents, bring the claim on behalf of the estate for damages under applicable statutory and/or common laws, and in Plaintiffs' Decedents' own right.

420. By reason of the foregoing, Defendants are jointly and severally liable to the Estate of Plaintiffs' Decedents for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiffs demand judgment against the Defendants, and each of them, individually, jointly, and severally; 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; and any and all such other relief as the Court deems just and proper; and further, demand a trial by jury of all issues so triable.

COUNT IV: WRONGFUL DEATH

421. Plaintiffs incorporate by reference all prior allegations as though set forth fully at length herein.

422. Plaintiffs bring this claim on behalf of the estate and for the benefit of the Plaintiffs' Decedents' lawful beneficiaries.

423. Plaintiffs have standing to bring this wrongful death action under all applicable state law.

424. Plaintiffs' Decedents died as a result of the Defendants' conduct and/or the defective nature of ZOSTAVAX as alleged herein, and is survived by various family members, named and unnamed.

425. As a direct and proximate result of Defendants' conduct and/or the defective nature of ZOSTAVAX as alleged herein, Plaintiffs' Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses, and bodily injury resulting in death.

426. As a direct and proximate cause of the conduct of Defendants, Plaintiffs' Decedents' beneficiaries have incurred hospital, nursing and medical expenses, funeral expenses, and estate administration expenses as a result of Plaintiffs' Decedents' death.

427. Defendants' wrongful conduct and/or the defective nature of ZOSTAVAX as alleged herein has proximately caused Plaintiffs' Decedents' heirs to suffer the loss of Plaintiffs Decedent's companionship, services, society, marital association, love, consortium and all other damages allowed under state statutes and laws.

428. Plaintiffs bring these claims on behalf of Plaintiffs' Decedents' lawful beneficiaries for these damages and for all pecuniary losses under applicable state statutory and/or common laws.

429. Plaintiffs' Decedents' estate representative further pleads all wrongful death damages allowed by statue in the state or states in which the causes of action accrued.

430. By reason of the foregoing, Defendants are jointly and severally liable to the Estate of Plaintiffs' Decedents for compensatory and other damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiffs demand judgment against the Defendants, and each of them, individually, jointly, and severally; 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; and any and all such other relief as the Court deems just and proper; and further, demand a trial by jury of all issues so triable.

WHEREFORE, Plaintiffs pray for judgment against Defendants, as follows:

a. For general damages in an amount to be proven at the time of trial;
b. For special damages in an amount to be proven at the time of trial;
c. For statutory damages as set forth above, in an amount to be proven at the time of trial;
d. For pre-judgment and post-judgment interest on the above general and special damages;
e. For costs of this suit and attorneys' fees; and
f. All other relief that this Court deems necessary, proper, and just.

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: 
MARGARET E. CORDNER
For the Firm

Dated: January 24, 2020

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: _____
MARGARET E. CORDNER
For the Firm

Dated: January 24, 2020

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Margaret E. Cordner, Esq. is hereby designated as trial counsel in this matter.

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: _____
MARGARET E. CORDNER
For the Firm

Dated: January 24, 2020

CERTIFICATION PURSUANT TO R. 4:5-1

Plaintiffs upon information and belief are not aware of any pending or contemplated action. Further, upon information and belief, Plaintiffs are not aware of any other party who should be joined in this action.

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: _____
MARGARET E. CORDNER
For the Firm

Dated: January 24, 2020