**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF FLORIDA**
**PENSACOLA DIVISION**

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| MARGARET BRATINA,<br><br>Plaintiff,<br><br>-against-<br><br>MERCK & CO., INC.;<br>MERCK SHARP AND DOHME CORP.; and<br>McKESSON CORP.,<br><br>Defendants | CIVIL ACTION NO.<br><br>**JURY TRIAL DEMANDED** |

## COMPLAINT

Plaintiff, by and through the undersigned attorneys, alleges as follows:

## PARTIES

1. At all times relevant to this action Plaintiff Margaret Bratina was and is a citizen of the State of Florida.

2. 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.

3. 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.

4. 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 consumers throughout the United States.

5. "Merck" shall include and 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.

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

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

8. 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 consumers throughout the United States.

9. "MSD" 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.

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

11. 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 consumers nationwide, including to the Plaintiff and/or Plaintiff's healthcare providers.

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

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

## JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 as to the claims of the Plaintiff.

15. Complete diversity exists between all named parties in this action.

16. The amount in controversy alleged by Plaintiff exceeds seventy-five thousand dollars ($75,000.00).

17. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiff from filing this Complaint:

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

18. Plaintiff incorporates by reference all prior allegations.

19. Each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

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

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

22. 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 observed.

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

24. 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.

25. 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.

26. 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 Plaintiff.

27. 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.

28. 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 Plaintiff and Plaintiff's healthcare providers.

29. 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.

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

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

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

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

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

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

36. 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.

37. 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.

38. 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.

39. 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.

40. 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/or MSD and McKesson have no separate mind(s), will or own existence in this regard.

41. McKesson used the aforesaid control over Merck and MSD, acting as an agent of Merck and MSD, 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 consumers like Plaintiff and Plaintiff's healthcare providers.

42. As such, sufficient grounds exist 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.

43. 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 was not safe for human use and/or consumption.

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

45. McKesson knew or should have known that the misrepresentations and omissions regarding the ZOSTAVAX vaccine Merck, MSD, and it made as alleged herein were false.

46. As such, sufficient grounds exist to extend liability for Merck's acts and omissions to McKesson because Merck and McKesson are alter egos of each other.

47. As such, sufficient grounds exist to extend liability for MSD's acts and omissions to McKesson because MSD and McKesson are alter egos of each other.

48. As such, sufficient grounds exist to extend liability for Merck's acts and omissions to McKesson because Merck and McKesson are agents of each other.

49. As such, sufficient grounds exist to extend liability for MSD's acts and omissions to McKesson because MSD and McKesson are agents of each other.

**ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

50. Plaintiff incorporates by reference all prior allegations.

51. Plaintiff brings these claims within the applicable statute of limitations because Plaintiff and Plaintiff's healthcare providers did not discover and could not reasonably discover the defects and unreasonably dangerous condition of the ZOSTAVAX vaccine.

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

53. 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.

54. 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.

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

56. 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.

57. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants.

58. Plaintiff has been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Plaintiff's part.

59. Any applicable statute of limitations has been tolled because Plaintiff could not

reasonably have discovered the injury and/or its cause until shortly before this action was filed.

60. 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

61. 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

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

63. 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.

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

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

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

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

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

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

70. 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.

71. 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.

72. 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, visual impairment, hearing loss, and death.

**ZOSTAVAX Vaccine – A Live Vaccine**

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

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

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

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

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

78. 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.

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

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

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

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

83. 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."

84. 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)."

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

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

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

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

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

[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.

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

91. 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.

**ZOSTAVAX's FDA Approval**

92. 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.

93. 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."[2]

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

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

96. 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."

97. 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.

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

99. Merck's SPS reported that ZOSTAVAX use reduced the incidence of postherpetic neuralgia by 66.5%.[3]

[2] FDA Approval Letter, May 25, 2006.
[3] *Id.*

100. The methods utilized in the SPS are unreliable.

101. 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.

102. 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 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.

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

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

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

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

107. 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.

108. 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.

109. 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.

110. 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."

111. 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."

112. 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,[4] and to add "Shingles" in the "What are the possible side effects of ZOSTAVAX?" section.

[4] 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

113. 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)."

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

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

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

117. 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.

118. 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.

119. 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.

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frequency or establish a causal relationship to the vaccine" implying that no causal relationship should be drawn from the list of reactions identified therein.

**Vaccine Efficacy of ZOSTAVAX**

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

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

122. 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.

123. 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,[5] and after eight years post-inoculation, the ZOSTAVAX vaccine's effectiveness has been shown to be 4% and not statistically significant.

124. 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." [6]

125. 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.[7]

[5] 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.
[6] 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.
[7] *Id.*

126. 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%.[8]

127. Merck's LTPS nonetheless reported that ZOSTAVAX's "statistically significant ***vaccine efficacy for incidence of HZ persisted***" for eight years post-vaccination.[9]

128. 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.[10]

129. 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.[11]

130. 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%.[12]

131. 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.[13]

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[8] Morrison, VA, et al. (2015). "Long-term persistence of zoster vaccine efficacy." *Clin Infect Dis.* 2015 Mar 15;60(6):900-9.
[9] *Id.* (emphasis added).
[10] 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.
[11] 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.
[12] *Id.*
[13] 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.

132. 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.

133. 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."[14]

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

135. 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.

136. No booster dose exists for the ZOSTAVAX vaccine.

**Non-Live Alternative Zoster Vaccine**

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

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

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

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

[14] 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).

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

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

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

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

145. 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%).

146. Merck conducted studies on immunocompromised individuals using an inactivated shingles vaccine.[15]

147. 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%.

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

149. 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.

[15] "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.

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

151. 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.

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

153. 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.

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

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

156. 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.

157. The CDC adopted these recommendations, issuing a public advisory statement that for adult shingles prevention, "Shingrix is the preferred vaccine, over Zostavax. . ."[16]

158. The CDC recommends that all healthy adults 50 years and older receive Shingrix "even if in the past you . . . received Zostavax."[17]

[16] August 3, 2018 CDC Update, "Shingles Zostavax Vaccination – What You Should Know." (https://www.cdc.gov/shingles/vaccination.html) (last visited September 13, 2018).
[17] 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).

## PLAINTIFF-SPECIFIC FACTS

159. Plaintiff, Margaret Bratina, at all times relevant to this action was and is a citizen of the State of Florida, and resides in Pensacola, Florida.

160. On or about May 14, 2014, Plaintiff was inoculated with the ZOSTAVAX vaccine at Publix Pharmacy located in Pensacola, Florida as recommended for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries.

161. Subsequent to Plaintiff's ZOSTAVAX inoculation, Plaintiff was treated by the Sacred Heart Medical Group located in Pensacola, Florida for herpes zoster.

162. Plaintiff was treated for continuing pain and was diagnosed with postherpetic neuralgia.

163. As a direct and proximate result of the ZOSTAVAX vaccine, Plaintiff has and will continue 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 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; and other losses and damages; and will continue to suffer such losses, and damages in the future.

## COUNT I: NEGLIGENCE
**(Against all Defendants)**

164. Plaintiff incorporates by reference all prior allegations.

165. Merck, MSD, and McKesson are a leading designers, manufacturers, marketers, and distributors of pharmaceutical products, including prescription drugs and vaccines.

166. Merck, MSD, and McKesson are held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

167. 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.

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

169. Merck and MSD had a duty to exercise reasonable care in 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, including the duty to take all reasonable steps necessary to introduce into the stream of commerce a product that was not defective and unreasonably dangerous to its consumers and users.

170. McKesson had a duty, independently and as an agent of Merck and/or MSD, to exercise reasonable care in the packaging, labeling, re-packaging, marketing, promotion, supply, distribution, sale, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine, including the duty to take all reasonable steps necessary to introduce into the stream of commerce a product that was not defective and unreasonably dangerous to its consumers and users.

171. Defendants each had a duty to warn physicians, pharmacists, medical and/or healthcare providers, including but not limited to Plaintiffs' healthcare providers, of the significant risks associated with use of the ZOSTAVAX vaccine, including but not limited to the material and

significant risk of serious bodily injury and viral infection resulting from its use, which Defendants knew or should have known existed.

172. Defendants each had a duty to warn physicians, pharmacists, medical and/or healthcare providers, including but not limited to Plaintiffs' healthcare providers, of the potential hazards of the ZOSTAVAX vaccine, including but not limited to the decreased efficacy of the ZOSTAVAX vaccine with advancing age, and the ZOSTAVAX vaccine's waning efficacy post-inoculation over time to effectively zero after four years, which Defendants knew or should have known existed.

173. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of ZOSTAVAX because Defendants knew, or should have known, that ZOSTAVAX caused viral infection, and was therefore not safe for administration to consumers.

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

175. Defendants continued to manufacture, market, and sell the product despite the knowledge – whether direct or ascertained with reasonable care – that ZOSTAVAX posed a serious risk of bodily harm to consumers.

176. Defendants knew or should have known that consumers, such as the Plaintiffs, would use the vaccine in the way it was intended and foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care in the design, research, development, manufacture, testing, labeling, advertisement, promotion, marketing, sale, supply, distribution, and/or introduction into the stream of commerce of the ZOSTAVAX vaccine.

177. Defendants breached their duty of care by putting into the stream of commerce the ZOSTAVAX vaccine, which was a product that was not safe or effective for its purpose – long-term prevention of shingles without adverse risk of serious side effects or injury.

178. Defendants breached their duty of care by putting into the stream of commerce the ZOSTAVAX vaccine without providing any warnings about the serious risks of physical harm or the hazards associated with the lack of efficacy of the ZOSTAVAX vaccine.

179. Defendants' breach of duty was a direct and proximate cause of Plaintiff's inoculation with ZOSTAVAX, resulting in Plaintiff's injuries.

180. Defendants' breach of duty was a substantially contributing factor to Plaintiffs' injuries as alleged herein.

181. Plaintiff has suffered damages as a direct and proximate result of Defendants' failure to exercise ordinary care.

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

183. As a direct and proximate consequence of Defendants' negligence, Plaintiff sustained serious personal injuries and related losses as alleged herein, and Defendants are liable to Plaintiff for Plaintiff's resulting damages.

184. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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: PRODUCTS LIABILITY - DESIGN and MANUFACTURING DEFECT**
**(Against all Defendants)**

185. Plaintiff incorporates by reference all prior allegations.

186. Merck, MSD, and McKesson are a leading designers, manufacturers, marketers, and distributors of pharmaceutical products, including prescription drugs and vaccines.

187. Merck, MSD, and McKesson are held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

188. 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.

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

190. Defendants had a duty to design, create, manufacture, market, distribute, and sell a product that was reasonably safe and not unreasonably dangerous for its normal, common, and intended use.

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

192. Plaintiff's healthcare providers used and administered the ZOSTAVAX vaccine for the purpose intended by Defendants, and in a manner normally intended to be used and administered, namely for the long-term vaccination against shingles.

193. 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.

194. Defendants placed into the stream of commerce a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of Plaintiff, Plaintiff's healthcare providers, and other consumers.

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

196. The ZOSTAVAX vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and formulation in that when it left the hands of the Defendants because the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

197. The ZOSTAVAX vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in 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.

198. At all times relevant to this action, Defendants knew and had reason to know that the ZOSTAVAX vaccine was inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Merck and MSD and when used and administered in the form manufactured and distributed by all Defendants and in the manner instructed by all Defendants to be used and administered to Plaintiff and other consumers.

199. ZOSTAVAX was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized.

200. Reasonably prudent manufacturers and distributors would not have placed the product in the stream of commerce with knowledge of these design flaws.

201. Alternatively, the ZOSTAVAX vaccine with which Plaintiff was inoculated failed to perform its intended function due to a flaw in the manufacturing process, as evident by Plaintiff's injuries, because: the product deviated from its manufacturing standards when it came off the production line; failed to perform in its intended manner due to some flaw in its fabrication process; was not manufactured and/or processed pursuant to its specifications; and/or, as constructed, deviated from any such specifications or design.

202. Reasonably prudent manufacturers and distributors would not have placed the product in the stream of commerce with knowledge of these manufacturing flaws.

203. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of ZOSTAVAX and/or perceived its defective dangers prior to its administration by Plaintiff's healthcare providers.

204. The defective ZOSTAVAX vaccine was a substantial, proximate, and contributing factor in causing Plaintiff's injuries.

205. As a proximate result of the defective design and/or manufacture of ZOSTAVAX, and Plaintiff's use of ZOSTAVAX, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for the injuries as alleged herein.

206. Defendants are therefore strictly liable for the Plaintiff's injuries and damages sustained proximately caused by Plaintiff's use of the product.

207. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 III: PRODUCTS LIABILITY – FAILURE TO WARN
**(Against all Defendants)**

208. Plaintiff incorporates by reference all prior allegations.

209. Merck, MSD and McKesson are leading designers, manufacturers, marketers, and distributors of pharmaceutical products, including prescription drugs and vaccines.

210. Merck, MSD and McKesson are held to the standard of an expert in the field of vaccine design, manufacture, and marketing.

211. Defendants directly advertised, marketed, and/or promoted the product to the FDA, healthcare professionals, and consumers, including the Plaintiff, Plaintiff's 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.

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

213. 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.

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

215. 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.

216. Defendants put the ZOSTAVAX vaccine into the stream of commerce for use by Plaintiff's healthcare providers.

217. Plaintiff was a reasonably foreseeable user of the ZOSTAVAX vaccine.

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

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

220. Plaintiff's healthcare providers used and administered the ZOSTAVAX vaccine to Plaintiff in the manner normally intended to be used and administered.

221. 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.

222. Defendants failed to provide adequate warnings to healthcare providers and users, including Plaintiff and Plaintiff's 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.

223. 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 use.

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

225. Defendants failed to provide adequate warnings to healthcare providers and users, including Plaintiff and Plaintiff's 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.

226. 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.

227. 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.

228. Healthcare providers and consumers, including Plaintiff and Plaintiff's healthcare providers, neither knew nor had reason to know at the time of Plaintiff's use of ZOSTAVAX of the existence of the aforementioned facts about ZOSTAVAX.

229. Ordinary consumers would not have recognized the potential risks or side effects of which Defendants failed to appropriately warn, and of which Defendants concealed.

230. The ZOSTAVAX used by Plaintiff was neither misused nor materially altered.

231. Defendants failed to adequately and correctly warn the Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare communities of:

a. the dangers of ZOSTAVAX for its intended users;

b. the risk of contracting shingles and suffering from zoster-related injuries from ZOSTAVAX use;

c. the efficacy of ZOSTAVAX decreases with advancing age;

d. the efficacy of ZOSTAVAX wanes significantly over time post-inoculation, to near-zero after four years;

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

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

g. their knowledge that ZOSTAVAX's established efficacy wanes

significantly over time after vaccination, to near-zero after four years;

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

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

j. that ZOSTAVAX is not safe and effective for long-term prevention and protection against shingles and zoster-related injuries;

k. that ZOSTAVAX is not a safe and effective vaccine for preventing post herpetic neuralgia; and

l. that ZOSTAVAX is not 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.

232. The ZOSTAVAX vaccine was unreasonably dangerous and defective because it was unaccompanied by any adequate warnings regarding its hidden and/or latent risks.

233. Plaintiff and Plaintiff's 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 Plaintiff.

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

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

236. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine due to inadequate warnings and instructions, Plaintiff's healthcare providers prescribed and/or administered the ZOSTAVAX vaccine to Plaintiff.

237. As a direct and proximate result of the defective nature of the ZOSTAVAX vaccine

due to inadequate warnings and instructions, Plaintiff used ZOSTAVAX.

238. As a direct and proximate result of Plaintiff's reasonably anticipated use of ZOSTAVAX, Plaintiff suffered the serious injuries as alleged herein.

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

240. Defendants are each therefore strictly liable for the Plaintiff's injuries and damages sustained proximately caused by Plaintiff's use of the ZOSTAVAX vaccine.

241. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 IV: BREACH OF EXPRESS WARRANTY**
**(Against all Defendants)**

242. Plaintiff incorporates by reference all prior allegations.

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

244. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the ZOSTAVAX vaccination.

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

246. At all relevant times, Defendants were aware that the medical community, including Plaintiff's healthcare providers, would prescribe, recommend, and administer the ZOSTAVAX vaccine.

247. At all relevant times, Defendants intended that the ZOSTAVAX vaccine be used in the manner that Plaintiff in fact used the ZOSTAVAX vaccine.

248. At all relevant times, Defendants intended that the ZOSTAVAX vaccine be prescribed, recommended, and administered in the manner that Plaintiff's healthcare providers prescribed, recommended, and administered the ZOSTAVAX vaccine to Plaintiff.

249. Plaintiff was a foreseeable user of the ZOSTAVAX vaccine.

250. Plaintiff's healthcare providers were foreseeable users as prescribers and administers of the ZOSTAVAX vaccine.

251. Plaintiff was at all times in privity with Defendants.

252. Plaintiff's healthcare providers were at all relevant times in privity with Defendants.

253. The ZOSTAVAX vaccines were expected to reach and did in fact reach consumers, including Plaintiff and Plaintiff's healthcare providers, without substantial change in the condition in which they were manufactured, marketed, and sold by Defendants.

254. At all relevant times, Defendants 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.

255. Defendants' representations and warranties, as alleged above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good (ZOSTAVAX) and became part of the basis of the bargain creating an express warranty that ZOSTAVAX would conform to these affirmations of fact or promises.

256. Defendants made their express warranties to Plaintiff and Plaintiff's 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.

257. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' express warranties about the ZOSTAVAX vaccine.

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

259. In reliance on Defendants' express warranties, Plaintiff's healthcare providers prescribed and administered the ZOSTAVAX vaccine to Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

260. The ZOSTAVAX vaccine did not conform to these express warranties and representations because the ZOSTAVAX vaccine was not safe; had numerous serious side effects, many of which Defendants did not accurately warn or instruct; was not effective to prevent shingles permanently; was not effective to prevent shingles or zoster-related conditions at all after four years post-inoculation; was not approved to manage shingles-related pain; and was not approved to prevent or lessen the burden of post-herpetic neuralgia.

261. Defendants thus breached the express warranties they made to Plaintiff and Plaintiff's healthcare providers with respect to the ZOSTAVAX vaccine.

262. As a direct and proximate result of Defendants' breach of express warranties regarding the ZOSTAVAX vaccine, Plaintiff used ZOSTAVAX, sustaining injuries as alleged.

263. Defendants' breaches of their express warranties constitute violations of common law principles and N.Y. U.C.C. Law § 2-313, et seq.

264. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 V: BREACH OF IMPLIED WARRANTY**
**(Against all Defendants)**

265. Plaintiff incorporates by reference all prior allegations.

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

267. At all relevant and material times, Defendants were aware that consumers, including Plaintiff, would use the ZOSTAVAX vaccine to prevent shingles.

268. Plaintiff was a foreseeable user of the ZOSTAVAX vaccine.'

269. Plaintiff's healthcare providers were foreseeable users as prescribers and administers of the ZOSTAVAX vaccine.

270. Plaintiff was at all relevant times in privity with Defendants.

271. Plaintiff's healthcare providers were at all relevant times in privity with Defendants.

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

273. At all relevant times, Defendants intended that the ZOSTAVAX vaccine be used in the manner that Plaintiff herein in fact used the vaccine.

274. At all relevant times, Defendants impliedly warranted that ZOSTAVAX 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.

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

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

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

278. The ZOSTAVAX vaccine did not conform to these implied warranties because the ZOSTAVAX vaccine was not safe, had numerous serious side effects of which Defendants did not adequately warn, and it was not effective for long-term or permanent shingles prevention.

279. Defendants thus breached the implied warranties they made to Plaintiff and Plaintiff's healthcare providers with respect to the ZOSTAVAX vaccine.

280. As a direct and proximate result of Defendants' breach of implied warranties regarding the ZOSTAVAX vaccine, Plaintiff used ZOSTAVAX and sustained injuries as alleged.

281. Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine violated N.Y. U.C.C. Law § 2-314, et seq.

282. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 VI: FRAUDULENT MISREPRESENTATION
**(Against all Defendants)**

283. Plaintiff incorporates by reference all prior allegations.

**Merck and MSD**

284. Merck and MSD are leading designers, manufacturers, marketers, and distributors of pharmaceutical products, including prescription drugs and vaccines.

285. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, Merck and MSD represented the following material information to the public:

a. That ZOSTAVAX was safe;

b. That ZOSTAVAX was effective for its intended purpose;

c. That ZOSTAVAX was a "well-studied vaccine";

d. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles;

e. That ZOSTAVAX would benefit its users "in the ***prevention of long-term nerve pain from shingles*** (post-herpetic neuralgia) ***can be primarily attributed to the vaccine's effect on the prevention of shingles***" (emphasis added);

f. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it;

g. That the ZOSTAVAX vaccine was approved to treat the pain associated with shingles;

h. That the ZOSTAVAX vaccine was indicated to prevent post-herpetic neuralgia;

i. That the ZOSTAVAX vaccine reduces the burden and incidence of post-herpetic neuralgia in patients who are vaccinated with ZOSTAVAX and subsequently develop shingles;

j. That the ZOSTAVAX vaccine was approved to prevent post-herpetic neuralgia and manage the pain associated with it;

k. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults – and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults;

l. That ZOSTAVAX "significantly reduced" the risk of developing shingles compared with placebo";

m. That ZOSTAVAX was effective in preventing shingles and post-herpetic neuralgia to consumers over the age of 50;

n. That the efficacy of ZOSTAVAX did not diminish over time after vaccination;

o. That the immunity provided by ZOSTAVAX was unlimited, giving its users permanent and lifetime prevention against shingles and post-herpetic neuralgia;

p. That the immunity against shingles provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated;

q. That the efficacy of ZOSTAVAX is 51% for everyone;

r. That "[t]here is no way to predict when the varicella-zoster virus (VZV) will reactivate or who will develop zoster";

s. That ZOSTAVAX did not actually cause shingles; and

t. That the ZOSTAVAX vaccine did *not* induce serious side effects (such as shingles, post-herpetic neuralgia, retinal necrosis, keratitis and acute myelitis);

286. These representations are false.

287. Merck and MSD made the aforesaid representations through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.

288. Merck and MSD made the aforesaid representations to healthcare providers and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in medical journals that healthcare providers throughout the United States in person, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work, subscribed, received, and read in 2006.

289. Merck and MSD made the aforesaid representations to healthcare providers and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the American Journal of Health-System Pharmacy in 2006. Healthcare providers throughout the United States, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work, subscribed, received, and read these ZOSTAVAX journal ads in 2006.

290. Merck and MSD made the aforesaid representations to healthcare providers and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the Journal of the

American Geriatrics Association in 2007. Healthcare providers throughout the United States, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work, subscribed, received, and read these ZOSTAVAX journal ads in 2007.

291. Merck and MSD made the aforesaid representations to healthcare providers and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the medical journal American Family Physician in 2007. Healthcare providers throughout the United States, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work, subscribed, received, and read these ZOSTAVAX journal ads in 2007.

292. Merck and MSD made the aforesaid statements to the public, including directly to consumers, Plaintiff, Plaintiff's healthcare providers, and the medical community through the May 26, 2006 video news release for the ZOSTAVAX vaccine.

293. The May 26, 2006 video news release for the ZOSTAVAX vaccine was disseminated through broadcast television, cable television, national newspapers such as the New York Times, Washington Post, USA Today, and other national media outlets.

294. In May 2006, Merck and MSD made the ZOSTAVAX video news release available to broadcast media (including broadcast television, cable television, and other national media outlines) via satellite feed, electronic feed, and videocassette. The broadcast media then disseminated Merck's and MSD's ZOSTAVAX video news release to the public, including directly to consumers, and to the medical community.

295. In June 2006, Merck and MSD made the ZOSTAVAX video news release available to broadcast media (including broadcast television, cable television, and other national media outlines) via satellite feed, electronic feed, and videocassette. The broadcast media then

disseminated Merck's and MSD's ZOSTAVAX video news release to the public, including directly to consumers, Plaintiff, Plaintiff's healthcare providers, and the medical community.

296. From 2006 until 2014, Merck and MSD represented to the public, including directly to consumers, Plaintiff, Plaintiff's healthcare providers, and the medical community, that ZOSTAVAX did not cause or induce shingles through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.

297. Since 2006, Merck and MSD represented to the medical community, to the public, Plaintiff, Plaintiff's healthcare providers, and directly to consumers that known adverse effects associated with ZOSTAVAX use were no more serious that a "rash" through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.

298. Merck's employee Melissa Lore disseminated information available on the labeling of ZOSTAVAX, as it was administered to Plaintiff. The labeling contained misleading information, such as the efficacy and safety of ZOSTAVAX as a preventative measure for shingles, particularly that it was not known to cause or induce post-herpetic neuralgia, shingles, or other complications suffered by Plaintiff.

299. Merck's website includes information that the ZOSTAVAX vaccine prevents the reactivation of the zoster virus to effectively prevent shingles.

300. David Gutsch, M.D. ("Gutsch"), is currently the Executive Director, Vaccines Regulatory, for Merck and MSD.

301. From 2005 through 2017, Gutsch gave presentations to Merck's, MSD's, and McKesson's field personnel, and the ZOSTAVAX sales force, who interacted directly with healthcare providers.

302. During his presentations from 2005 through 2017, Gutsch instructed the ZOSTAVAX field personnel and sales force who interacted directly with healthcare providers to represent to healthcare providers: that ZOSTAVAX was effective indefinitely after a single administration; that ZOSTAVAX did not cause shingles; that ZOSTAVAX was safe and effective for the long-term prevention of shingles and zoster-related injuries; that ZOSTAVAX was effective to treat pain and post-herpetic neuralgia associated with shingles.

303. The ZOSTAVAX sales force relayed Gutsch's misinformation directly to Plaintiff's healthcare providers though in-person office visits, over the telephone, and during lunches and dinners.

304. In May 2006, Mark Feinberg, M.D., Ph.D., was the vice president of policy, public health and medical affairs of Merck Vaccines.

305. In May 2006, Dr. Feinberg stated that shingles is an "often painful disease in older adults."

306. Since May 2006, Merck and MSD heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to prevent post-herpetic neuralgia.

307. Since May 2006, Merck and MSD heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to lessen the burden of post-herpetic neuralgia in individuals with shingles.

308. Since May 2006, Merck and MSD heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to manage the pain associated with shingles or post-herpetic neuralgia.

**Presentations and Meetings**

309. From 2006 until 2017, Merck's and MSD's professional representatives met healthcare providers throughout the United States in person, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work.

310. During these meetings, Merck's and MSD's professional representatives represented to said healthcare providers: that ZOSTAVAX was effective for the long-term prevention of shingles and zoster-related injuries; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster; and that ZOSTAVAX lessened the incidence and burden of post-herpetic neuralgia if a patient did get shingles after being vaccinated.

311. From 2006 through 2017, Merck and MSD represented to the medical community, including to Plaintiff's healthcare providers, through seminars that the effect of time since vaccination on ZOSTAVAX's vaccine efficacy is not statistically significant.

312. On October 2008, Dr. M. Levin, acting on behalf of Merck and MSD, presented at the Annual ICAAC/IDSA Annual Meeting in Washington, DC, and represented that "protection [from shingles] persists for up to 7 years." Medical professionals in academia, government, and private practice attended this meeting. This information reached Plaintiff's healthcare providers directly or through word of mouth from their peers.

313. Plaintiff's healthcare providers received Dr. M. Levin's representations made in October 2008 regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and relied upon these representations.

314. On October 23, 2010, Dr. M. Levin, acting on behalf of Merck and MSD, presented at the 48th Annual ICAAC/IDSA 46th Annual Meeting in Washington, DC, and represented that "protection [from shingles] persists for up to 7 years." Medical professionals in academia, government, and private practice attended this meeting. This information reached Plaintiff's healthcare providers directly or through word of mouth from their peers.

315. Plaintiff's healthcare providers received Dr. M. Levin's representations made on October 23, 2010 regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and relied upon these representations.

316. On May 18, 2011, Merck represented that "The effect of time since vaccination on VE [vaccine efficacy] (waning effect) is not statistically significant" in a presentation regarding the "Persistence of Zoster Vaccine Efficacy" at the Society of Clinical Trials ("SCT") Annual Meeting in Vancouver, BC Canada. Medical professionals in academia, government, and private practice attended this SCT Annual Meetings. This information reached Plaintiff's healthcare providers directly or through word of mouth from their peers.

317. Plaintiff's healthcare providers received these representations made by Merck and MSD in the May 18, 2011 SCT Annual Meeting regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and relied upon these representations.

318. From 2006 until 2017, Merck's and MSD's professional representatives met healthcare providers throughout the United States in person, including Plaintiff's healthcare providers at the medical facilities where Plaintiff's healthcare providers work.

319. Merck's and MSD's professional representatives represented to said healthcare providers that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.

320. Between 2006 and 2017, Merck and MSD, through sales representatives and through agents' word-of-mouth recommendations, specifically made oral representations to Plaintiff's healthcare providers that ZOSTAVAX's efficacy rate was "between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered."

321. Between 2006 and 2017, Plaintiff's healthcare providers relied upon Merck's and MSD's representations that ZOSTAVAX's efficacy rate was between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff as a result regardless of each Plaintiff's age at the time of ZOSTAVAX use.

322. Merck's and MSD's representations were false: the maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration. ZOSTAVAX's efficacy rate continually declines after age 60.

323. Between 2006 and 2017, Merck and MSD, through sales representatives and through agents' word-of-mouth recommendations, specifically made oral representations to Plaintiff's healthcare providers that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation."

324. Between 2006 and 2017, Plaintiff's healthcare providers relied upon Merck's and MSD's representations that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation" and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff as a result regardless of Plaintiff's age at the time of administration of ZOSTAVAX.

325. Merck's and MSD's representations were false: ZOSTAVAX's efficacy rate declines to almost zero four years post-inoculation.

326. From 2006 until 2017, Merck and MSD held convention panels that were attended by physicians throughout the United States in person, including Plaintiff's healthcare providers.

327. During these convention panels, Merck and MSD represented that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not

decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.

328. Plaintiff's healthcare providers attended Merck's and MSD's convention panels regarding ZOSTAVAX and heard and received Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and relied upon these representations.

329. Plaintiff's healthcare providers heard and received Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof through word-of-mouth from their peers and relied upon these representations.

330. Plaintiff's healthcare providers relied upon Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff as a result.

**Advertisements**

331. From 2012 until 2017, Merck and MSD broadcasted numerous television commercials on public television and cable television promoting ZOSTAVAX, wherein actors and/or celebrities spoke in detail about how painful shingles is.

332. In 2017, Patrick Bergstedt, head of global marketing for Merck, admitted that Merck promoted ZOSTAVAX using "scare tactics" to increase the rate of ZOSTAVAX vaccination in adults and consumers.

**Bradshaw Ad**

333. In 2014, Merck and MSD ran numerous television commercials broadcasted on public television promoting ZOSTAVAX featuring former football quarterback Terry Bradshaw ("Bradshaw Ad"), wherein Bradshaw spoke in detail about how painful shingles is.

334. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiff and Plaintiff's healthcare providers, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.

335. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiff and Plaintiff's healthcare providers, that ZOSTAVAX was intended for long-term prevention of pain caused by shingles.

336. Plaintiff saw the Bradshaw Ad.

337. Plaintiff was influenced by and relied upon the Bradshaw Ad and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

338. Plaintiff's healthcare providers saw the Bradshaw Ad.

339. Plaintiff's healthcare providers were influenced by and relied upon the Bradshaw Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for long-term prevention of shingles as a result.

**Day 7 with Shingles Ad**

340. From 2015 through 2017, Merck and MSD ran television commercials broadcasted on public television and cable television promoting ZOSTAVAX that depicted a person struggling through a day at an office job because of shingles pain ("Day #7 with Shingles Ad").

341. The Day #7 with Shingles Ad showed graphic depictions of blistering skin and described the pain associated with shingles, representing to its viewers, including Plaintiff and Plaintiff's healthcare providers, that shingles always causes pain in every patient.

342. The Day #7 with Shingles Ad represented to the viewing public and consumers, including Plaintiff and Plaintiff's healthcare providers, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.

343. Plaintiff saw the Day #7 with Shingles Ad.

344. Plaintiff was influenced by and relied upon the Day #7 with Shingles Ad and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

345. Plaintiff's healthcare providers saw the Day #7 with Shingles Ad.

346. Plaintiff's healthcare providers were influenced by and relied upon the Day #7 with Shingles Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for long-term prevention of shingles as a result.

**Day 18 with Shingles Ad**

347. From 2015 through 2017, Merck and MSD ran television commercials broadcasted on public television promoting ZOSTAVAX that showing a person who gives up on a game of golf because of shingles pain. ("Day #18 with Shingles Ad").

348. The Day #18 with Shingles Ad showed graphic depictions of blistering skin and depicted the person suffering from shingles failing to bend down without experiencing strong pain.

349. The Day #18 with Shingles Ad showed graphic depictions of blistering skin and described the pain associated with shingles, representing to its viewers, including Plaintiff and Plaintiff's healthcare providers, that shingles always causes pain in every patient.

350. The Day #18 with Shingles Ad depicted the actor posing as a shingles sufferer, who states: “After almost three weeks, I just really wanted to give it a shot.”

351. The Day #18 with Shingles Ad represented to its viewers, including Plaintiff and Plaintiff’s healthcare providers, that the blisters caused by shingles lasts at least three weeks.

352. The Day #18 with Shingles Ad represented to its viewers, including Plaintiff and Plaintiff’s healthcare providers, that the pain caused by shingles lasts at least three weeks.

353. The Day #18 with Shingles Ad informed its viewers: “If you had chicken pox, the shingles virus is already inside you.”

354. Plaintiff saw the Day #18 with Shingles Ad.

355. Plaintiff was influenced by and relied upon the Day #18 with Shingles Ad and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

356. Plaintiff’s healthcare providers saw the Day #18 with Shingles Ad.

357. Plaintiff’s healthcare providers were influenced by and relied upon the Day #18 with Shingles Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for long-term prevention of shingles as a result.

**Linda Ad**

358. Beginning in September 2016 through 2017, Merck and MSD ran television commercials broadcasted on public television promoting ZOSTAVAX, featuring a woman swimming alone in a pool while a voice-over represents to its viewers that “shingles virus [has] been lurking inside you since you had the chicken pox . . . [and] can surface anytime as a painful, blistering rash. One in three people will get me in their lifetime . . .will it be you?" (“Linda Ad”).

359. The Linda Ad represented to the viewing public and consumers, including Plaintiff and Plaintiff's healthcare providers, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.

360. Plaintiff saw the Linda Ad.

361. Plaintiff was influenced by and relied upon the Linda Ad and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

362. Plaintiff's healthcare providers saw the Linda Ad with Shingles Ad.

363. Plaintiff's healthcare providers were influenced by and relied upon the Linda Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff's for long-term prevention of shingles as a result.

**Print Advertisements**

364. Beginning in September 2016 to present date, Merck and MSD published the ZOSTAVAX vaccine's print advertisements, which ran in magazines targeting 50-year-olds, showing graphic photos of a rash associated with shingles ("Print Ads").

365. The Print Ads showed graphic photos of a rash associated with shingles and represented to their viewers and/or readers, including but not limited to Plaintiff and Plaintiff's healthcare providers, that shingles always causes pain in every patient.

366. Plaintiff saw the Print Ads in magazines.

367. Plaintiff was influenced by and relied upon the Print Ads in magazines and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

368. Plaintiff's healthcare providers saw the Print Ads.

369. Plaintiff's healthcare providers were influenced by and relied upon the Print Ads and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for long-term prevention of shingles as a result.

**Falsity and Materiality of Merck and MSD's Representations**

370. Merck and MSD's representations were false as alleged in ¶¶ 289-373.

371. The ZOSTAVAX vaccine can cause the chickenpox virus to reactivate and cause shingles upon its administration.

372. ZOSTAVAX is not effective indefinitely after a single administration.

373. ZOSTAVAX's efficacy four years after vaccination is zero.

374. ZOSTAVAX's efficacy four years after vaccination is statistically the same as zero.

375. ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.

376. Merck and MSD knew that ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.

377. Merck's and MSD's representations that "the effect of time since vaccination on [ZOSTAVAX's] vaccine efficacy is not statistically significant are false.

378. Merck's and MSD's representations that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation" were false: ZOSTAVAX efficacy rate declines to almost zero four years post-inoculation.

379. Merck's and MSD's representations that ZOSTAVAX's efficacy rate was "between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered" were false: the maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration. ZOSTAVAX's efficacy rate continually declines after age 60.

380. Merck's and MSD's false representations, as alleged in ¶¶ 289-373, were material.

381. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 289-373, relied upon these representations that ZOSTAVAX was effective to prevent shingles after a single shot and understood those representations to indicate that a single shot of ZOSTAVAX would prevent shingles indefinitely.

382. Plaintiff's healthcare providers, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 289-373, relied upon these representations that ZOSTAVAX was effective to prevent shingles after a single shot and understood those representations to indicate that a single shot of ZOSTAVAX would prevent shingles indefinitely.

383. Shingles is not always accompanied by pain.

384. Shingles is not always accompanied by painful blisters or blistering rash.

385. Merck's and MSD's false representations, as alleged in ¶¶ 289-373, were misleading.

386. ZOSTAVAX is not, and has never been, approved to treat pain associated with shingles.

387. ZOSTAVAX is not, and has never been, approved to prevent post-herpetic neuralgia.

388. ZOSTAVAX is not, and has never been, approved to lessen the ***incidence*** of post-herpetic neuralgia if a patient did get shingles after being vaccinated.

389. ZOSTAVAX is not, and has never been, approved to lessen the ***burden*** of post-herpetic neuralgia if a patient did get shingles after being vaccinated.

390. Merck's and MSD's representations that ZOSTAVAX is ***highly effective*** in preventing shingles and shingles pain were misleading.

391. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 289-373, does not equate a vaccine with the ***highest*** efficacy rate of 51% if vaccinated at age 60 with "highly effective."

392. Plaintiff's healthcare providers, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 289-373, do not equate a vaccine with the ***highest*** efficacy rate of 51% if vaccinated at age 60 with "highly effective."

**Knowledge that the Representations Were False and Misleading**

393. Merck and MSD had the duty to disclose to Plaintiff and Plaintiff's healthcare providers of the defective nature of the ZOSTAVAX vaccine that Merck and MSD manufactured, marketed, distributed, and sold to them.

394. Merck and MSD had the duty to warn the Plaintiff and Plaintiff's healthcare providers of the ineffective nature of the vaccine and the heightened the risk of suffering the injuries, diseases, and maladies associated with use of the ZOSTAVAX vaccine, and that Plaintiff suffered as a result as alleged.

395. Merck and MSD knew or believed at the time they made false representations about the ZOSTAVAX vaccine that the representations were false.

396. Merck and MSD knew or believed at the time it made false representations about the ZOSTAVAX vaccine that the false representations were material.

397. Merck and MSD knew or believed at the time they made false representations about the ZOSTAVAX vaccine that the representations were misleading.

398. Merck and MSD knew or believed at the time they made false representations about the ZOSTAVAX vaccine that the representations and misleading and would likely deceive any

consumer into believing that ZOSTAVAX was safe and effective to prevent shingles and pain associated with shingles indefinitely after a single shot.

399. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine carried the serious risks of physical harm to its users, including viral infection, shingles, and shingles-related conditions, because it could reactivate the VZV virus.

400. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and zoster-related injuries and would not effective at all after four years post-inoculation.

401. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.

402. Merck's and MSD's own research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine; the true risks of serious harm including viral infection, shingles and shingles-related conditions, and other injuries associated with the use of the ZOSTAVAX vaccine; and the true efficacy of the ZOSTAVAX vaccine.

403. Merck and MSD intentionally misrepresented facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiff's and Plaintiff's healthcare providers to rely upon Merck's and MSD's misrepresentations to recommend, prescribe, purchase, and use the ZOSTAVAX vaccine as an effective vaccine for the long-term prevention of shingles and zoster-related injuries, and to purchase and use the ZOSTAVAX vaccine as a result – for Merck's and MSD's own financial gain.

404. Merck and MSD intentionally misrepresented material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers such as Plaintiff's and Plaintiff's

healthcare providers to rely upon Merck's and MSD's misrepresentations and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles and purchase the product – for Merck's and MSD's own financial gain and to the Plaintiff's detriment.

405. Merck and MSD intentionally misrepresented facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to mislead Plaintiff, Plaintiff's healthcare providers, consumers, and the public.

**Detrimental Reliance**

406. At the time Merck and MSD made these misrepresentations, and at the times that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff was unaware of the representations' falsehoods, and reasonably believed them to be true.

407. At the time Merck and MSD misrepresented material facts, and at the time that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff was unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain, and would lessen the frequency of post-herpetic neuralgia occurrence and post-herpetic neuralgia-associated pain.

408. At the time Merck and MSD made these misrepresentations, and at the time that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff's healthcare providers were unaware of the representations' falsehoods, and reasonably believed them to be true.

409. At the time Merck and MSD misrepresented material facts, and at the time that the Plaintiff were administered the ZOSTAVAX vaccine, Plaintiff's healthcare providers was unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-

related injuries, and zoster-related pain, and would lessen the frequency of post-herpetic neuralgia occurrence and post-herpetic neuralgia-associated pain.

410. Merck and MSD knew and had reason to know that consumers, including the Plaintiff and Plaintiff's healthcare providers and physicians that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, ***did not have the ability to determine the true facts*** regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally misrepresented and concealed.

411. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine, its efficacy, and its propensity to cause serious and dangerous injuries and damages to persons who used the product.

412. Plaintiff would not have purchased and used the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.

413. Plaintiff's healthcare providers would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.

414. Plaintiff reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain.

415. Because Plaintiff reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles, zoster-related injuries, and pain, Plaintiff sustained severe and permanent personal injuries and damages.

416. Plaintiff's healthcare providers reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiff for the long-term prevention of shingles, zoster-related injuries, zoster-related pain, post-herpetic neuralgia occurrence, and post-herpetic neuralgia-associated pain.

417. Because Plaintiff's healthcare providers reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine for the long-term prevention of shingles, zoster-related injuries, and pain, Plaintiff sustained severe and permanent personal injuries and damages.

418. Merck's and MSD's false representations regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard for the health and safety of the public, its consumers, and the Plaintiff.

419. Merck's and MSD's false representations regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.

420. As a direct and proximate consequence of Merck's and MSD's fraudulent misrepresentations, Plaintiff sustained serious personal injuries and related losses as alleged.

**McKesson**

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

422. 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 Plaintiff.

423. Since 2006, McKesson made representations of material fact about ZOSTAVAX, including the following:

a. That ZOSTAVAX was safe;

b. That ZOSTAVAX was effective for its intended purpose;

c. That ZOSTAVAX was a "well-studied vaccine";

d. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles;

e. That ZOSTAVAX would benefit its users "in the ***prevention of long-term nerve pain from shingles*** (post-herpetic neuralgia) ***can be primarily attributed to the vaccine's effect on the prevention of shingles***" (emphasis added);

f. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it;

g. That the ZOSTAVAX vaccine was approved to treat the pain associated with shingles;

h. That the ZOSTAVAX vaccine was indicated to prevent post-herpetic neuralgia;

i. That the ZOSTAVAX vaccine reduces the burden and incidence of post-herpetic neuralgia in patients who are vaccinated with ZOSTAVAX and subsequently develop shingles;

j. That the ZOSTAVAX vaccine was approved to prevent post-herpetic neuralgia and manage the pain associated with it;

k. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults – and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults;

l. That ZOSTAVAX "significantly reduced" the risk of developing shingles compared with placebo";

m. That ZOSTAVAX was effective in preventing shingles and post-herpetic neuralgia to consumers over the age of 50;

n. That the efficacy of ZOSTAVAX did not diminish over time after vaccination;

o. That the immunity provided by ZOSTAVAX was unlimited, giving its users permanent and lifetime prevention against shingles and post-herpetic neuralgia;

p. That the immunity against shingles provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated;

q. That the efficacy of ZOSTAVAX is 51% for everyone;

r. That "[t]here is no way to predict when the varicella-zoster virus (VZV) will reactivate or who will develop zoster";

s. That ZOSTAVAX did not actually cause shingles; and

t. That the ZOSTAVAX vaccine did *not* induce serious side effects (such as shingles, post-herpetic neuralgia, retinal necrosis, keratitis and acute myelitis).

424. Each of these representations is false.

425. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, McKesson widely disseminated these material representations of material fact regarding the safety and efficacy of the ZOSTAVAX vaccine directly to consumers, including Plaintiff and Plaintiff's healthcare providers, in its advertising and promotional campaign using television and radio commercials on broadcast television, cable television and other national media outlets; print advertisements run in magazines targeted, journals, and newspapers towards consumers and prescribers including national newspapers such as the New York Times, Washington Post, USA Today; posters and other signage in pharmacies where consumers bought their prescription drugs, including Plaintiff's pharmacies; product handouts and brochures; its own website; materials provided to each Plaintiff's State Department of Health; materials provided to insurance companies for dissemination to policyholders and consumers, including Plaintiff; and other ZOSTAVAX marketing materials.

426. Since May 2006, McKesson heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to prevent post-herpetic neuralgia.

427. Since May 2006, McKesson heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to lessen the burden of post-herpetic neuralgia in individuals who develop shingles.

428. Since May 2006, McKesson heavily promoted ZOSTAVAX for the off-label use of ZOSTAVAX to lessen or manage the pain associated with shingles or post-herpetic neuralgia.

429. McKesson had the duty to disclose to Plaintiff and Plaintiff's healthcare providers of the defective nature of the ZOSTAVAX vaccine that McKesson marketed, distributed, and sold to them.

430. McKesson had the duty to warn the Plaintiff and Plaintiff's healthcare providers of the ineffective nature of the vaccine and the heightened the risk of suffering the injuries, diseases, and maladies associated with use of the ZOSTAVAX vaccine, and that Plaintiff suffered as a result as alleged.

431. McKesson knew and had reason to know that the ZOSTAVAX vaccine carried the serious risks of physical harm to its users, including viral infection, shingles, and shingles-related conditions, because it could reactivate the VZV virus.

432. McKesson knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and zoster-related injuries and would not effective at all after four years post-inoculation.

433. McKesson knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.

434. Merck's and MSD's own research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine; the true risks of serious harm including viral infection,

shingles and shingles-related conditions, and other injuries associated with the use of the ZOSTAVAX vaccine; and the true efficacy of the ZOSTAVAX vaccine.

435. McKesson knew or should have known the results of Merck's and MSD's own testing of the ZOSTAVAX vaccine.

436. McKesson knew or believed at the time it made false representations about the ZOSTAVAX vaccine that the representations were false.

437. McKesson knew or believed at the time it made false representations about the ZOSTAVAX vaccine that the false representations were material.

438. McKesson knew or believed at the time it made false representations about the ZOSTAVAX vaccine that the false representations were misleading.

439. McKesson intentionally misrepresented facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiff and Plaintiff's healthcare providers to rely upon McKesson's misrepresentations to recommend, prescribe, purchase, and use the ZOSTAVAX vaccine as an effective vaccine for the long-term prevention of shingles and zoster-related injuries, and to purchase and use the ZOSTAVAX vaccine as a result – for McKesson's own financial gain, to the Plaintiff's detriment.

440. At the time McKesson made these misrepresentations, and at the times that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff was unaware of the representations' falsehoods, and reasonably believed them to be true.

441. At the time McKesson misrepresented material facts, and at the time that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff was unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-related injuries, and pain.

442. At the time McKesson made these misrepresentations, and at the times that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff's healthcare providers were unaware of the representations' falsehoods, and reasonably believed them to be true.

443. At the time McKesson misrepresented material facts, and at the time that the Plaintiff were administered the ZOSTAVAX vaccine, Plaintiff's healthcare providers was unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-related injuries, pain, and would lessen the frequency of post-herpetic neuralgia occurrence and post-herpetic neuralgia-associated pain.

444. McKesson knew and had reason to know that consumers, including the Plaintiff and Plaintiff's healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, ***did not have the ability to determine the true facts*** regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally misrepresented.

445. McKesson knew that the Defendants named herein had sole access to material facts concerning the ZOSTAVAX vaccine, its efficacy, and its propensity to cause serious and dangerous injuries and damages to persons who used the product.

446. Plaintiff would not have purchased and used the ZOSTAVAX vaccine if Plaintiff knew the true facts regarding its safety and efficacy.

447. Plaintiff's healthcare providers would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine to Plaintiff if they knew the true facts regarding its safety and efficacy.

448. Plaintiff reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and was induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain.

449. Because Plaintiff reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain, Plaintiff sustained severe and permanent personal injuries and damages.

450. Plaintiff's healthcare providers reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiff for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain.

451. Because Plaintiff's healthcare providers reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiff for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain, Plaintiff sustained severe and permanent personal injuries and damages.

452. McKesson made its fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of the ZOSTAVAX vaccine, such as Plaintiff.

453. McKesson's false representations regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.

454. As a foreseeable, direct, and proximate result of McKesson's fraudulent misrepresentations, Plaintiff suffered the serious injuries alleged herein.

455. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 VII: FRAUDULENT CONCEALMENT**
**(Against all Defendants)**

456. Plaintiff incorporates by reference all prior allegations.

**Merck and MSD**

457. Merck and MSD are leading designers, manufacturers, marketers, and distributors of pharmaceutical products, including prescription drugs and vaccines.

458. Merck and MSD had the duty to disclose to the Plaintiff and Plaintiff's healthcare providers of the defective design and formulation of the ZOSTAVAX vaccine, which heightened the risk of suffering the injuries, diseases, and maladies that Plaintiff suffered as a result as alleged.

459. Merck and MSD were also under a duty to warn the Plaintiff and Plaintiff's healthcare providers of the ineffective nature of the vaccine and the heightened the risk of suffering the injuries, diseases, and maladies associated with use of the ZOSTAVAX vaccine, and that Plaintiff suffered as a result as alleged.

460. Since June 2006 and during all relevant times, ZOSTAVAX vaccine's television commercials, radio commercials, and print advertisements were published and run in magazines targeting 50-year-old-and-older adults, and in broadcast television, cable television, mainstream radio, and other broadcast media outlets, as alleged in ¶¶ 335-373.

461. From 2006 until present date, Merck and MSD intentionally concealed the following material information from ZOSTAVAX vaccine's label, ZOSTAVAX's marketing materials, and in representations made by Merck and MSD as alleged in ¶¶ 289-373, 464:

a) The ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases including shingles and post herpetic neuralgia;

b) That the ZOSTAVAX vaccine can reactivate the VZV virus and cause shingles;

c) The effect of time since vaccination on ZOSTAVAX's efficacy;

d) That the ZOSTAVAX vaccine's efficacy rate wanes significantly over time post-inoculation, to near-zero after four years;

e) That the ZOSTAVAX vaccine's highest efficacy rate is 51%, and only upon perfect use, at age 60;

f) That the ZOSTAVAX vaccine's efficacy rate decreases significantly with advancing age;

g) ZOSTAVAX is not, and has never been, approved to treat pain associated with shingles;

h) ZOSTAVAX is not, and has never been, approved to prevent post-herpetic neuralgia;

i) ZOSTAVAX is not, and has never been, approved to lessen the incidence and burden of post-herpetic neuralgia if a patient did get shingles after being vaccinated; and

j) ZOSTAVAX is not effective indefinitely after a single administration.

462. Each of these facts are material.

463. Plaintiff saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373.

464. Plaintiff's healthcare providers saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 289-373.

465. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, did not know that ZOSTAVAX could reactivate the VZV virus and actually cause shingles.

466. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, did not know that ZOSTAVAX could reactivate the VZV virus and actually cause shingles.

467. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, did not know that the highest efficacy rate of ZOSTAVAX was 51% upon perfect use at age 60.

468. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, did not know that the highest efficacy rate of ZOSTAVAX was 51% upon perfect use at age 60.

469. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, did not know that the efficacy rate of ZOSTAVAX decreased with advancing age.

470. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, did not know that the efficacy rate of ZOSTAVAX decreased with advancing age.

471. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, did not know that the efficacy rate waned significantly over time post-inoculation to near-zero after four years.

472. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, did not know that the efficacy rate waned significantly over time post-inoculation to near-zero after four years.

473. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, relied on those representations and understood that they indicated that ZOSTAVAX would prevent shingles indefinitely.

474. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, relied on those representations and understood that they indicated that ZOSTAVAX would prevent shingles indefinitely.

475. Plaintiff, who saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373, relied on those representations and understood that they indicated that ZOSTAVAX would NOT reactive VZV and actually cause shingles.

476. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, relied on those representations and understood that they indicated that ZOSTAVAX would NOT reactive VZV and actually cause shingles.

477. Plaintiff was influenced by and relied on saw and/or read the representations made by Merck and MSD as alleged in ¶¶ 335-373 and was induced to use ZOSTAVAX for long-term prevention of shingles as a result.

478. Plaintiff's healthcare providers, who saw, read, or otherwise received the representations made by Merck and MSD as alleged in ¶¶ 289-373, were influenced by and relied these representations and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for long-term prevention of shingles as a result.

479. Jill Bradley was Merck's Director of Marketing Communications.

480. On June 13, 2006, Nancy Chamberlin, Pharm. D., Regulatory Review Officer, APLB, submitted a memorandum to Jill Bradley, Merck's Director of Marketing Communications,

regarding the APLB's label review of ZOSTAVAX and stating APLB's position regarding Merck's ZOSTAVAX label:

> "We disagree with your proposal to omit the warning for vaccination with a live attenuated virus and precautionary statement regarding the theoretical risk of transmitting the vaccine virus to varicella-susceptible individuals. Omission of these would make your promotional pieces lacking in appropriate fair balance risk information that needs to be conveyed with every promotional material."

481. On June 13, 2006, Bradley decided, on behalf of Merck and MSD and in the scope of her employment with Merck and MSD, to intentionally omit the aforesaid warnings associated with the vaccination of a live attenuated virus for the 2006 ZOSTAVAX label.

482. On June 13, 2006, when Merck and MSD decided to omit information on the 2006 ZOSTAVAX vaccine's label, Bradley knew and/or had reason to know the risks associated with the vaccination of a live attenuated virus was material information that would be relied upon by the medical community, including Plaintiff's healthcare providers, and by Plaintiff.

483. On or about June 13, 2006, Merck and MSD knew or had reason to know that the ZOSTAVAX vaccine's label omitted statements about the cardiac events; the warnings and precautions of using a live virus vaccine; and the need to avoid close contact (including household contacts) with someone who may be pregnant and has not had chickenpox or been vaccinated against chickenpox, or someone who has problems with their immune system.

484. On or about June 13, 2006, Merck and MSD knew or had reason to know that the ZOSTAVAX vaccine's label omitted a warning regarding vaccination with a live attenuated virus and also lacked a precautionary statement regarding the theoretical risk of transmitting the vaccine virus to varicella-susceptible individuals.

485. From June 13, 2006, Merck and MSD intentionally omitted material facts from the ZOSTAVAX label and while marketing and selling the ZOSTAVAX vaccine.

486. Merck and MSD knowingly omitted in the packaging for the ZOSTAVAX vaccine that the ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases.

**Detrimental Reliance by Plaintiff and Plaintiff's Healthcare Providers**

487. Merck and MSD knew or believed at the time it intentionally omitted and concealed material facts, as alleged in ¶¶ 462-490, about the ZOSTAVAX vaccine that the facts omitted and concealed were material.

488. At the time Merck and MSD intentionally omitted and concealed material facts, and at the times that the Plaintiff were administered the ZOSTAVAX vaccine, Plaintiff and Plaintiff's healthcare providers were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain.

489. Plaintiff would not have purchased and/or used the ZOSTAVAX vaccine if Plaintiff knew the true facts regarding its safety and efficacy.

490. Plaintiff's healthcare providers would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine to Plaintiff if they knew the true facts regarding its safety and efficacy.

491. Merck and MSD intentionally omitted and/or concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers, including Plaintiff and Plaintiff's healthcare providers, to rely upon Merck's and MSD's misrepresentations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles and zoster-

related injuries, and to purchase and use the ZOSTAVAX vaccine as a result – for Merck's and MSD's own financial gain and to Plaintiff's detriment.

492. Merck and MSD knew and had reason to know that Plaintiff and Plaintiff's healthcare providers did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that Merck and MSD intentionally omitted and concealed.

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

494. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine created great risk of causing serious personal injury to the users of the ZOSTAVAX vaccine.

495. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.

496. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and zoster-related injuries and would not effective at all after four years post-inoculation.

497. Merck's and MSD's own research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine; the true risks of serious harm including viral infection, shingles and shingles-related conditions, and other injuries associated with the use of the ZOSTAVAX vaccine; and the true efficacy of the ZOSTAVAX vaccine.

498. Plaintiff justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose.

499. Plaintiff's healthcare providers justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose.

500. Because Plaintiff justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose, Plaintiff was induced to purchase and use the ZOSTAVAX vaccine.

501. Because Plaintiff's healthcare providers justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose, Plaintiff's healthcare providers were induced to prescribe, purchase, and administer the ZOSTAVAX vaccine to Plaintiff.

502. Because Plaintiff justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and was induced to use ZOSTAVAX as a result, Plaintiff suffered serious injuries as alleged herein.

503. Because Plaintiff's healthcare providers justifiably relied on the representations made by Merck and MSD, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, which induced Plaintiff's healthcare providers to prescribed and/or administer the ZOSTAVAX vaccine to Plaintiff as a result, Plaintiff suffered serious injuries as alleged herein.

504. Merck's and MSD's intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly,

purposefully, and with reckless disregard and depraved indifference for the health and safety of the public, its consumers, and the Plaintiff.

505. Merck's and MSD's intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.

506. As a direct and proximate consequence of Merck's and MSD's fraudulent concealment, Plaintiff sustained serious personal injuries and related losses as alleged herein.

**McKesson**

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

508. McKesson had the duty to disclose to the Plaintiff and Plaintiff's healthcare providers of the defective design and formulation of the ZOSTAVAX vaccine that it sold to them, which heightened the risk of suffering the injuries, diseases, and maladies that Plaintiff suffered as a result as alleged.

509. McKesson was also under a duty to warn the Plaintiff and Plaintiff's healthcare providers of the ineffective nature of the vaccine and the heightened the risk of suffering the injuries, diseases, and maladies associated with use of the ZOSTAVAX vaccine, and that Plaintiff suffered as a result as alleged.

510. From 2006 until present date, McKesson intentionally omitted material facts from the ZOSTAVAX package insert, prescribing information, and label, and while marketing and selling the ZOSTAVAX vaccine.

511. From 2006 until present date, McKesson intentionally concealed the following material information from ZOSTAVAX vaccine's label, package insert, prescribing information,

ZOSTAVAX's marketing materials, and in representations made by McKesson as alleged in ¶¶ 426-458:

k) The ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases including shingles and post herpetic neuralgia;

l) That the ZOSTAVAX vaccine can reactivate the VZV virus and cause shingles;

m) The effect of time since vaccination on ZOSTAVAX's efficacy;

n) That the ZOSTAVAX vaccine's efficacy rate wanes significantly over time post-inoculation, to near-zero after four years;

o) That the ZOSTAVAX vaccine's highest efficacy rate is 51%, and only upon perfect use, at age 60;

p) That the ZOSTAVAX vaccine's efficacy rate decreases significantly with advancing age;

q) ZOSTAVAX is not, and has never been, approved to treat pain associated with shingles;

r) ZOSTAVAX is not, and has never been, approved to prevent post-herpetic neuralgia;

s) ZOSTAVAX is not, and has never been, approved to lessen the incidence and burden of post-herpetic neuralgia if a patient did get shingles after being vaccinated; and

t) ZOSTAVAX is not effective indefinitely after a single administration.

512. Each of these facts are material.

513. On or about June 13, 2006, McKesson knew or had reason to know that the ZOSTAVAX vaccine's package insert, prescribing information, and label omitted statements about the warnings and precautions of using a live virus vaccine and the need to avoid close contact (including household contacts) with someone who may be pregnant and has not had chickenpox or been vaccinated against chickenpox, or someone who has problems with their immune system.

514. On or about June 13, 2006, McKesson knew or had reason to know that the ZOSTAVAX vaccine's package insert, prescribing information, and label omitted a warning

regarding vaccination with a live attenuated virus and also lacked a precautionary statement regarding the theoretical risk of transmitting the vaccine virus to varicella-susceptible individuals.

515. McKesson knew or believed at the time it intentionally omitted and concealed material facts about the ZOSTAVAX vaccine that the facts omitted and concealed were material.

516. McKesson, with Merck and MSD, had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous injuries and damages to persons who used the product.

517. McKesson knew and had reason to know that the ZOSTAVAX vaccine created great risk of causing serious personal injury to the users of the ZOSTAVAX vaccine, including but not limited to the risk of causing shingles and other related conditions.

518. McKesson knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.

519. McKesson knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and zoster-related injuries and would not effective at all after four years post-inoculation.

520. Merck's and MSD's own research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine; the true risks of serious harm including viral infection, shingles and shingles-related conditions, and other injuries associated with the use of the ZOSTAVAX vaccine; and the true efficacy of the ZOSTAVAX vaccine.

521. McKesson knew or should have known the results of Merck's and MSD's research and testing of the ZOSTAVAX vaccine that revealed the true safety, risks of serious harm and injury, and actual efficacy of the ZOSTAVAX vaccine.

522. McKesson intentionally omitted and/or concealed facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers, including Plaintiff and Plaintiff's healthcare providers, to rely upon McKesson's misrepresentations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles and zoster-related injuries, and to purchase and use the ZOSTAVAX vaccine as a result – for McKesson's own financial gain and to Plaintiff's detriment.

523. Plaintiff was influenced by and relied on McKesson's representations, which omitted and intentionally concealed material facts about the ZOSTAVAX vaccine and was induced to use ZOSTAVAX for permanent prevention of shingles as a result.

524. Plaintiff's healthcare providers were influenced by and relied on McKesson's representations, which omitted and intentionally concealed material facts about the ZOSTAVAX vaccine, and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiff for permanent prevention of shingles as a result.

525. At the time McKesson intentionally omitted and concealed material facts, and at the times that the Plaintiff was administered the ZOSTAVAX vaccine, Plaintiff and Plaintiff's healthcare providers were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles, zoster-related injuries, and zoster-related pain.

526. Plaintiff would not have purchased and used the ZOSTAVAX vaccine if Plaintiff knew the true facts regarding its safety and efficacy.

527. Plaintiff's healthcare providers would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.

528. McKesson knew and had reason to know that consumers, including the Plaintiff and Plaintiff's healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.

529. Plaintiff's healthcare providers justifiably relied on the representations made by McKesson, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose.

530. Because Plaintiff's healthcare providers justifiably relied on the representations made by McKesson, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose, Plaintiff's healthcare providers was induced to prescribe, purchase, and administer the ZOSTAVAX vaccine to Plaintiff.

531. Plaintiff's healthcare providers would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine to Plaintiff if they knew the true facts regarding its safety and efficacy.

532. Plaintiff justifiably relied on the representations made by McKesson, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose.

533. Because Plaintiff justifiably relied on the representations made by McKesson, which intentionally omitted and concealed material facts about the ZOSTAVAX vaccine, and reasonably believed that the product was safe and effective for its intended purpose, Plaintiffs were induced to purchase and use the ZOSTAVAX vaccine.

534. Because Plaintiff justifiably relied on McKesson and was induced to use ZOSTAVAX, Plaintiff suffered serious injuries as alleged herein.

535. Because Plaintiff's healthcare providers justifiably relied on McKesson, which induced Plaintiff's healthcare providers to prescribed and/or administer the ZOSTAVAX vaccine to Plaintiff, Plaintiff suffered serious injuries as alleged herein.

536. McKesson's intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard and depraved indifference for the health and safety of the public, its consumers, and the Plaintiff.

537. McKesson's intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.

538. As a foreseeable, direct, and proximate result of McKesson's fraudulent concealment, Plaintiff suffered the serious injuries alleged herein.

539. As a direct and proximate result of Defendants' fraudulent concealment of material facts regarding the ZOSTAVAX vaccine, Plaintiff sustained injuries as alleged herein.

540. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 VIII: NEGLIGENT MISREPRESENTATION
**(Against all Defendants)**

541. Plaintiff incorporate by reference all prior allegations.

### Merck and MSD

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

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

544. 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.

545. Merck and MSD each had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff and Plaintiff's healthcare providers, the truth regarding their claims that the ZOSTAVAX vaccine had been tested, and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.

546. Merck and MSD had the duty to disclose to Plaintiff and Plaintiff's healthcare providers of the defective nature of the ZOSTAVAX vaccine that Merck and MSD manufactured, marketed, distributed, and sold to them.

547. Merck and MSD had the duty to disclose to the Plaintiff and Plaintiff's physicians and healthcare providers of the defective design and formulation of the ZOSTAVAX vaccine, which heightened the risk of suffering the injuries, diseases, and maladies that Plaintiff suffered as a result as alleged.

548. Merck and MSD failed to warn the Plaintiff, Plaintiff's healthcare providers, the medical community, and other consumers of the defective condition of ZOSTAVAX.

549. Merck and MSD failed to disclose to the Plaintiff, Plaintiff's healthcare providers, and other members of the general public that the administration of this vaccine increased the risk of viral infection.

550. Merck and MSD failed to disclose to the Plaintiff, Plaintiff's healthcare providers healthcare providers, and other members of the general public that administration of the ZOSTAVAX vaccine would not prevent or protect against shingles or zoster-related conditions or disease after four years post-inoculation.

551. Merck and MSD represented and marketed ZOSTAVAX as being safe and effective. Plaintiff incorporate by reference and re-alleges Plaintiff's allegations in ¶¶ 289-396, *supra*, as to Merck and MSD's misrepresentations.

552. Merck's and MSD's representations were made to Plaintiff, Plaintiff's healthcare providers, the medical community, as well as the general public.

553. Merck and MSD intentionally represented these facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to induce Plaintiff, Plaintiff's healthcare providers, consumers, and the public, to rely on these misrepresentations and prescribe, recommend, administer, purchase, and use ZOSTAVAX – for Merck's and MSD's financial gain.

554. These representations made by Merck and MSD were, in fact, false.

555. Merck and MSD failed to exercise ordinary care in making false representations concerning the ZOSTAVAX vaccine and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.

556. Merck and MSD knew, or had reason to know, that the ZOSTAVAX vaccine had not been sufficiently tested; that the ZOSTAVAX vaccine lacked adequate, accurate, and prominent warnings; that use of the ZOSTAVAX vaccine created a high risk of adverse health effects, had higher than acceptable risks of harm to users, had higher than reported and represented risks of adverse side effects such as those specifically described herein; and that the ZOSTAVAX

vaccine was not effective for the long-term or permanent prevention and protection against shingles and other zoster-related conditions and disease.

557. Merck and MSD misrepresented material facts about ZOSTAVAX when Merck and MSD knew or reasonably should have known of the falsity of such misrepresentations.

558. Merck and MSD made such material misrepresentations about ZOSTAVAX without exercising reasonable care to ascertain the accuracy of these representations.

559. Merck and MSD were careless or negligent by failing to ascertain the truth of their representations at the time Merck and MSD made them.

560. Merck and MSD each breached their duty by representing to the Plaintiff, Plaintiff's healthcare providers, and the medical community that the ZOSTAVAX vaccine's use did **not** carry the serious and increased risk of viral infection, such as those suffered by Plaintiff and other similarly situated consumers.

561. Merck and MSD each breached their duty by representing to the Plaintiff, Plaintiff's healthcare providers, and the medical community that the ZOSTAVAX vaccine was effective for permanent prevention and protection against shingles and zoster-related injuries.

562. Plaintiff and Plaintiff's healthcare providers justifiably relied on Merck's and MSD's misrepresentations.

563. If Plaintiff knew the actual risk of viral infection associated with ZOSTAVAX use and that ZOSTAVAX was not effective for permanent prevention and protection against shingles and zoster-related injuries, Plaintiff would not have purchased or used the ZOSTAVAX vaccine.

564. If Plaintiff's healthcare providers knew the actual risk of viral infection associated with ZOSTAVAX use and that ZOSTAVAX was not effective for permanent prevention and

protection against shingles and zoster-related injuries, Plaintiff's healthcare providers would not have recommended, prescribed, and/or administered the ZOSTAVAX vaccine to Plaintiff.

565. As a foreseeable, direct, and proximate result of Plaintiff's and Plaintiff's healthcare providers' justifiable reliance on Merck's and MSD's negligent misrepresentations as set forth herein, Plaintiff were inoculated with ZOSTAVAX.

566. As a foreseeable, direct, and proximate result of Plaintiff's use of ZOSTAVAX, Plaintiff sustained injuries and monetary losses as alleged herein.

567. Consequently, Plaintiff's use of ZOSTAVAX was to Plaintiff's own detriment.

568. As a direct and proximate consequence of Merck's and MSD's breach of duty and the negligent misrepresentations of material facts they made regarding the ZOSTAVAX vaccine, Plaintiff sustained serious personal injuries and related losses as alleged herein.

**McKesson**

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

570. 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, and including for ultimate use by Plaintiff.

571. McKesson had a duty to accurately and truthfully represent to the medical community, the FDA, and consumers, including Plaintiff and Plaintiff's healthcare providers, the truth regarding its claims that the ZOSTAVAX vaccine had been tested, and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.

572. McKesson had the duty to disclose to Plaintiff and Plaintiff's healthcare providers of the defective nature of the ZOSTAVAX vaccine that McKesson marketed, distributed, and sold to them.

573. McKesson had the duty to disclose to the Plaintiff and Plaintiff's healthcare providers of the defective design and formulation of the ZOSTAVAX vaccine, which heightened the risk of suffering the injuries, diseases, and maladies that Plaintiff suffered as a result as alleged.

574. McKesson failed to warn the Plaintiff, Plaintiff's healthcare providers, the medical community, and other consumers of the defective condition of ZOSTAVAX.

575. McKesson failed to disclose to the Plaintiff, Plaintiff's healthcare providers, and other members of the general public that the administration of this vaccine increased the risk of viral infection.

576. McKesson failed to disclose to the Plaintiff, Plaintiff's healthcare providers, and other members of the general public that administration of the ZOSTAVAX vaccine would not prevent or protect against shingles or zoster-related conditions after four years post-inoculation.

577. McKesson represented and marketed ZOSTAVAX as being safe and effective. Plaintiff incorporates by reference and re-allege Plaintiff' allegations in ¶¶ 426-458, *supra*, as to McKesson's misrepresentations.

578. McKesson's representations were made to Plaintiff, Plaintiff' healthcare providers, the medical community, as well as the general public.

579. McKesson intentionally represented these facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to induce consumers, including Plaintiff and Plaintiff's healthcare providers, to rely on these misrepresentations and prescribe, recommend, administer, purchase, and use ZOSTAVAX – for McKesson's financial gain.

580. These representations made by McKesson were false.

581. McKesson failed to exercise ordinary care in making representations concerning the ZOSTAVAX vaccine and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.

582. McKesson knew, or had reason to know, that the ZOSTAVAX vaccine had not been sufficiently tested; that the ZOSTAVAX vaccine lacked adequate, accurate, and prominent warnings; that use of the ZOSTAVAX vaccine created a high risk of adverse health effects, had higher than acceptable risks of harm to users, had higher than reported and represented risks of adverse side effects such as those specifically described herein; and that the ZOSTAVAX vaccine was not effective for the long-term or permanent prevention and protection against shingles and other zoster-related conditions and disease.

583. McKesson misrepresented material facts about ZOSTAVAX when McKesson knew or reasonably should have known of the falsity of such misrepresentations.

584. McKesson made such material misrepresentations about ZOSTAVAX without exercising reasonable care to ascertain the accuracy of these representations.

585. McKesson was careless or negligent by failing to ascertain the truth of its representations at the time McKesson made them.

586. McKesson breached its duty by representing to the Plaintiff, Plaintiff's healthcare providers, and the medical community that the ZOSTAVAX vaccine's use did **not** carry the serious and increased risk of viral infection, such as those suffered by Plaintiff and other similarly situated consumers.

587. McKesson breached its duty by representing to the Plaintiff, Plaintiff's healthcare providers, and the medical community that the ZOSTAVAX vaccine was effective for permanent prevention and protection against shingles and zoster-related injuries.

588. Plaintiff and Plaintiff's healthcare providers justifiably relied on McKesson's misrepresentations.

589. If Plaintiff knew the actual risk of viral infection associated with ZOSTAVAX use and that ZOSTAVAX was not effective for permanent prevention and protection against shingles and zoster-related injuries, Plaintiff would not have purchased or used the ZOSTAVAX vaccine.

590. If Plaintiff's healthcare providers knew the actual risk of viral infection associated with ZOSTAVAX use and that ZOSTAVAX was not effective for permanent prevention and protection against shingles and zoster-related injuries, Plaintiff's healthcare providers would not have recommended, prescribed, and/or administered the ZOSTAVAX vaccine to Plaintiff.

591. As a foreseeable, direct, and proximate result of Plaintiff' and Plaintiff's healthcare providers' justifiable reliance on McKesson's negligent misrepresentations as set forth herein, Plaintiff were inoculated with ZOSTAVAX.

592. As a foreseeable, direct, and proximate result of Plaintiff's use of ZOSTAVAX, Plaintiff sustained injuries and monetary losses as alleged herein.

593. Consequently, Plaintiff's use of ZOSTAVAX was to Plaintiff's own detriment.

594. As a direct and proximate consequence of McKesson's breach of its duty and the negligent misrepresentations of material facts it made regarding the ZOSTAVAX vaccine, Plaintiff sustained serious personal injuries and related losses as alleged herein.

595. As a direct and proximate result of each Defendants' breach of its duty and the negligent misrepresentations of material facts they made regarding the ZOSTAVAX vaccine,

Plaintiff 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; medical and related expenses; economic damages; and other losses and damages; and will continue to suffer such harm, damages, and other losses in the future.

596. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 IX: CONSUMER FRAUD**
**(Against all Defendants)**

597. Plaintiff incorporates by reference all prior allegations.

598. Defendants designed, manufactured, sold, distributed, supplied, marketed, and/or promoted the ZOSTAVAX vaccine, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and/or sold by Defendants.

599. Defendants introduced into the stream of commerce the ZOSTAVAX vaccine which was defective and unreasonably dangerous to consumers, including Plaintiff.

600. Defendants had a duty to accurately and truthfully represent to the medical community, the FDA, and consumers, including Plaintiff and Plaintiff's healthcare providers, the truth regarding the claims they made regarding the ZOSTAVAX vaccine.

601. Defendants published information and represented that the ZOSTAVAX vaccine was safe and effective for use as directed and marketed it accordingly, as alleged in ¶¶ 289-424, 426-458 and incorporated herein, in, *inter alia*, literature provided to physicians, patients, and pharmacies, the websites they presently maintain, and the information disseminated on large-scale

marketing and advertising campaigns including but not limited to the television commercials broadcasted throughout the nation and throughout New York.

602. Defendants omitted and/or intentionally concealed material facts regarding the ZOSTAVAX vaccine, as alleged in ¶¶ 289-424, 426-458 and incorporated herein.

603. Defendants' acts and omissions were consumer-oriented.

604. The misrepresentations made by Defendants, in fact, were false.

605. Defendants' false representations were materially misleading.

606. Defendants negligently, carelessly, and/or intentionally misrepresented the truth regarding: 1) the high risk of ZOSTAVAX's unreasonable, dangerous, and adverse side effects associated with its use; 2) the efficacy of ZOSTAVAX, including the effect of time and the user's age on its efficacy post-inoculation; 3) off-label and unapproved uses for ZOSTAVAX.

607. Defendants negligently, carelessly, and/or intentionally omitted or concealed the truth regarding: 1) the high risk of ZOSTAVAX's unreasonable, dangerous, and adverse side effects associated with its use; and 2) the efficacy of ZOSTAVAX, including the effect of time and the user's age on its efficacy post-inoculation.

608. After Defendants became aware of the increased and unreasonable risks of the ZOSTAVAX vaccine, Defendants failed to communicate to the Plaintiff, Plaintiff's healthcare providers, and other consumers, that the administration of this vaccine increased the risk of viral infection, post herpetic neuralgia, and other serious conditions.

609. Defendants' misrepresentations and omissions were deceptive.

610. Because Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' misrepresentations of material facts and were unable to independently ascertain the

material facts omitted or concealed by Defendants regarding ZOSTAVAX, Plaintiff used ZOSTAVAX and suffered injuries as alleged.

611. Protection of Florida consumers is codified in the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

612. Commercial behavior that constitutes "unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce" is unlawful pursuant to the FDUTPA, and a consumer who suffered a loss because of this conduct may bring an action for damages.

613. At all relevant times, Merck, MSD, and McKesson engaged in continuous and pointed commercial marketing activity and introduced the ZOSTAVAX vaccine heavily into the stream of commerce within Florida and to Florida consumers.

614. At all relevant times, Merck, MSD, and McKesson engaged in a distribution and sales strategy within the state of Florida intending to reach Florida consumers, including Plaintiff.

615. At all relevant times, the ZOSTAVAX vaccine's aggressive marketing campaign, containing advertising techniques that evaded divulging the known serious risks and warnings to consumers, including Plaintiff, was unconscionable commercial behavior and is impermissible under the FDUTPA.

616. Defendants violated the FDUTPA by making false representations of material fact regarding ZOSTAVX and concealing material facts regarding ZOSTAVAX to consumers, with the intent to induce the sale and distribution of the vaccine for profit within Florida.

617. The information about ZOSTAVAX that Defendants disseminated, including via the advertising campaigns targeted at Florida consumers, do not accurately portray or warn about

the efficacy or substantial propensity of serious risks associated with its use, thus deceptively misleading consumers in a material aspect in violation of the FDUTPA.

618. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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 X: LOSS OF CONSORTIUM**
**(Against all Defendants)**

619. Plaintiff incorporates by reference all prior allegations.

620. At all relevant times hereto, where applicable, Plaintiff has and/or had a spouse (hereafter referred to as "Spouse Plaintiff") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Plaintiff's injuries from ZOSTAVAX.

621. For the reasons set forth herein, Spouse Plaintiff and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

622. For the reasons set forth herein, Spouse Plaintiff and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

623. For Spouse Plaintiff, Plaintiff alleges that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

624. Spouse Plaintiff and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

625. As a direct and proximate result of the conduct of Defendants, Plaintiff, Spouse Plaintiff, and/or Family Member Plaintiffs suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

626. As a direct and proximate result of the aforesaid and including the observance of the suffering and physical deterioration of Plaintiff, Spouse Plaintiff and/or Family Member Plaintiffs have and will continue to suffer permanent and ongoing psychological damage, which may require future psychological and medical treatment.

627. As a direct and proximate result of Defendants' negligence, strict liability, and wrongful conduct, Spouse Plaintiff and/or Family Member Plaintiffs have been deprived of the society, love, affection, companionship, care, and services of Plaintiff.

628. As a direct and proximate result of Defendants' negligence, strict liability, and wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages.

629. Spouse Plaintiff and/or Family Member Plaintiffs of Plaintiff are entitled to recovery for said losses pursuant to all applicable law.

630. Defendants are liable to Spouse Plaintiff and/or Family Member Plaintiffs, jointly and severally, for all general, special, and equitable relief to which Spouse Plaintiff and/or Family Member Plaintiffs are entitled by law 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 XI: UNJUST ENRICHMENT
**(Against all Defendants)**

631. Plaintiff incorporates by reference all prior allegations.

632. Merck and MSD are and at all times were the designers, developers, manufacturers, sellers, and/or suppliers of the ZOSTAVAX vaccine.

633. McKesson is and at all times was the promoter, marketer, packager, labeler, distributer, and seller of the ZOSTAVAX vaccine, and the creator of marketing content to maximize profits of the ZOSTAVAX vaccine on the market.

634. Plaintiff paid for the ZOSTAVAX vaccine to obtain a safe and effective form of long-term prevention and protection against shingles and zoster-related injuries.

635. Merck and MSD accepted payment by and/or from Plaintiff from Plaintiff's purchase of the ZOSTAVAX vaccine.

636. McKesson accepted payment by and/or from Plaintiff from Plaintiff's purchase of the ZOSTAVAX vaccine.

637. Plaintiff has not received the safe and effective form of long-term prevention and protection against shingles and zoster-related injuries for which Plaintiff paid.

638. Instead, Plaintiff suffered from shingles and/or other zoster-related injuries despite having been inoculated with the ZOSTAVAX vaccine.

639. Defendants profited and experienced financial gain from Plaintiff's use of ZOSTAVAX at the Plaintiff's expense and detriment.

640. It would be inequitable for Defendants to keep this money if Plaintiff did not in fact receive safe and effective treatment form of long-term prevention and protection against shingles and zoster-related injuries for which Plaintiff paid.

641. Defendants should not be able to keep the money paid by Plaintiff for the ZOSTAVAX vaccine.

642. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive 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.

**PRAYER FOR RELIEF**

WHEREFORE Plaintiff prays for relief and judgment against each of the Defendants as appropriate to each cause of action alleged as follows:

a. For general damages, including without limitation, past and future pain and suffering, past and future emotional distress, past and future loss of enjoyment of life, and other consequential damages as allowed by law 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; including without limitation, past and future pain and suffering, past and future emotional distress, past and future loss of enjoyment of life, and other consequential damages as allowed by law 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 exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;
e. For pre-judgment and post-judgment interest on the above general and special damages;
f. For costs of this suit and attorneys' fees; and
g. All other relief that this Court deems necessary, proper, and just.

**DEMAND FOR JURY TRIAL**

Plaintiff demands trial by jury of all claims so triable.

Dated: February 5, 2019

Respectfully submitted,

/s/ Carmen A. DeGisi
Carmen A. DeGisi, Esq.
Marc J. Bern & Partners LLP
101 West Elm Street, Suite 215
Conshohocken, PA 19428
Tel: (610) 941-9880
Fax: (610) 941-1088
Email: cdegisi@bernllp.com
*Attorneys for Plaintiffs*

JS 44 (Rev. 06/17)

# CIVIL COVER SHEET

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

## I. (a) PLAINTIFFS

Margaret Bratina

**(b)** County of Residence of First Listed Plaintiff Escambia
*(EXCEPT IN U.S. PLAINTIFF CASES)*

**(c)** Attorneys *(Firm Name, Address, and Telephone Number)*
Marc J. Bern & Partners LLP
60 E. 42nd St., Suite 950
New York, NY 10165

## DEFENDANTS

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

County of Residence of First Listed Defendant Union, NJ
*(IN U.S. PLAINTIFF CASES ONLY)*

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

## II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

## III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

*(For Diversity Cases Only)*

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

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

Click here for: Nature of Suit Code Descriptions.

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

**TORTS**

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

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

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

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

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

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

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

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

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

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

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

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

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

**PRISONER PETITIONS**

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

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

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

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

## VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability

## VII. REQUESTED IN COMPLAINT:

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

**DEMAND $** 1,000,000.00

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

## VIII. RELATED CASE(S) IF ANY

*(See instructions):*

JUDGE Harvey Bartle III DOCKET NUMBER 2:18-MD-02848

DATE 02/05/2019

SIGNATURE OF ATTORNEY OF RECORD /s/ Carmen De Gisi

**FOR OFFICE USE ONLY**

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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

# UNITED STATES DISTRICT COURT

for the

Northern District of Florida

MARGARET BRATINA

*Plaintiff(s)*

v.

MERCK & CO., INC.;
MERCK SHARP AND DOHME CORP.; and
McKESSON CORP.,

*Defendant(s)*

Civil Action No.

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)* Merck & Co., Inc.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Carmen A. DeGisi, Esq.
Marc J. Bern & Partners LLP
101 West Elm Street, Suite 215
Conshocken, PA 19428

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
*Server's signature*

_____
*Printed name and title*

_____
*Server's address*

Additional information regarding attempted service, etc:

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

# UNITED STATES DISTRICT COURT

for the

Northern District of Florida

MARGARET BRATINA

*Plaintiff(s)*

v.

MERCK & CO., INC.;
MERCK SHARP AND DOHME CORP.; and
McKESSON CORP.,

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Merck Sharp & Dohme Corp.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Carmen A. DeGisi, Esq.
Marc J. Bern & Partners LLP
101 West Elm Street, Suite 215
Conshocken, PA 19428

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
*Server's signature*

_____
*Printed name and title*

_____
*Server's address*

Additional information regarding attempted service, etc:

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

# UNITED STATES DISTRICT COURT

for the

Northern District of Florida

MARGARET BRATINA

*Plaintiff(s)*

v.

MERCK & CO., INC.;
MERCK SHARP AND DOHME CORP.; and
McKESSON CORP.

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* McKesson Corporation
2710 Gateway Oaks Drive
Sacramento, CA 95833

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Carmen A. De Gisi, Esq.
Marc J. Bern & Partners LLP
101 West Elm Street, Suite 215
Conshocken, PA 19428

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
*Server's signature*

_____
*Printed name and title*

_____
*Server's address*

Additional information regarding attempted service, etc: