UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARY HARRELL, Plaintiff, -against- MERCK & CO., INC.; MERCK SHARP AND DOHME CORP.; and McKESSON CORP., Defendants	**Case No. _____** **JURY TRIAL DEMANDED**

COMPLAINT

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

PARTIES

1. At all times relevant to this action Plaintiff Mary Harrell was and is a citizen of the State of Georgia, and resides in Douglasville, Georgia.

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, including New Jersey. Merck has conducted and continues to conduct business in

New Jersey and derived and continues to derive substantial revenue from within New Jersey, from, including, but not limited to, its business activities related to ZOSTAVAX. Plaintiff's claims arise out of Merck's contacts with New Jersey.

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

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

7. 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. MSD has conducted and continues to conduct business in New Jersey and derived and continues to derive substantial revenue from within New Jersey, from including, but not limited to, its business activities related to ZOSTAVAX. Plaintiff's claims arise out of MSD's contacts with New Jersey.

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

9. 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 New Jersey, including to the Plaintiff and/or Plaintiff's healthcare providers. McKesson conducts business throughout the United States and regularly, continuously, and presently does business in New Jersey, including marketing, distributing, and selling ZOSTAVAX in New Jersey. McKesson derived and continues to derive substantial revenue from within New Jersey, from including, but

not limited to, its business activities related to ZOSTAVAX. Plaintiff's claims arise out of McKesson's contacts with New Jersey.

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

11. "Healthcare providers" 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

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00 exclusive of interests and costs.

13. Plaintiff is a resident and citizen of Georgia.

14. Merck and MSD are New Jersey corporations, each with its principal place of business in Kenilworth, New Jersey.

15. New Jersey has general personal jurisdiction over Merck and MSD.

16. Based upon information and belief, at all relevant times, McKesson was and is duly authorized to conduct business in New Jersey as a registered foreign corporation.

17. Defendants regularly conducted and solicited business within New Jersey and continue to do so.

18. Defendants at all relevant times sold and distributed ZOSTAVAX in New Jersey

and continue to do so.

19. Defendants derive substantial revenue from goods used or consumed in New Jersey.

20. Each Defendant engages in continuous and systematic activity in the State of New Jersey.

21. Each Defendant's continuous and system activity in the State of New Jersey and its minimum contacts within New Jersey gave rise to Plaintiff's claims.

22. Each Defendant purposefully avails itself of the privilege of conducting activities within New Jersey, thus invoking the benefits and protections of its laws, and has done so at all relevant times.

23. Each Defendant has purposefully connected itself to the state of New Jersey and has sufficient minimum contacts with the State of New Jersey such that the assertion of jurisdiction over each Defendant by New Jersey courts is reasonable and does not offend the traditional notions of fair play and substantial justice.

24. 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

25. Plaintiff incorporates by reference all prior allegations.

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

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

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

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

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

35. 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 ZOSTAVAX into the stream of commerce for use by individuals like Plaintiff and their healthcare providers.

36. As such, sufficient grounds exist 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 ZOSTAVAX.

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

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

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

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

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

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

43. 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 ZOSTAVAX throughout the United States.

44. 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 ZOSTAVAX marketing strategy and campaign.

45. 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 ZOSTAVAX "Vaccine Information Statement."

46. 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 ZOSTAVAX.

47. 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 of ZOSTAVAX into the stream of commerce to such an extent that Merck and McKesson have no separate mind(s), will or own existence in this regard.

48. 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 ZOSTAVAX for use by consumers like Plaintiff and Plaintiff's healthcare providers.

49. 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 ZOSTAVAX.

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

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

52. McKesson knew or should have known that the ZOSTAVAX 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.

53. Sufficient grounds exist to extend liability for Merck's acts and omissions to McKesson because Merck and McKesson are alter egos of each other.

54. Sufficient grounds exist to extend liability for MSD's acts and omissions to McKesson because MSD and McKesson are alter egos of each other.

55. Sufficient grounds exist to extend liability for McKesson's acts and omissions to Merck because Merck and McKesson are agents of each other.

56. Sufficient grounds exist to extend liability for McKesson's acts and omissions to MSD because MSD and McKesson are agents of each other.

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

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

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

59. Plaintiff incorporates by reference all prior allegations.

60. 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 ZOSTAVAX.

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

62. 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 use presents.

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

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

65. Each Defendant had a duty to disclose the fact that ZOSTAVAX was not safe or effective; was defective; was unreasonably dangerous; and that using ZOSTAVAX for routine health maintenance and shingles prevention carried the above-described risks.

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

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

68. Plaintiff could not reasonably have discovered the injury and/or its cause until shortly before the initiation of this action.

69. 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

70. ZOSTAVAX 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

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

72. 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.

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

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

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

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

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

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

79. 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.

80. 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.

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

ZOSTAVAX Vaccine – A Live Vaccine

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

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

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

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

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

87. 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.

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

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

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

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

92. 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."

93. 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)."

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

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

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

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

98. 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.

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

100. 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

101. 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.

102. 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]

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

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

105. 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."

106. 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.

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

108. 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.*

109. The methods utilized in the SPS are unreliable.

110. 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.

111. 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.

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

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

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

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

116. Since ZOSTAVAX's introduction in 2006, VAERS regarding ZOSTAVAX use 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.

117. As of September of 2015, VAERS received over 1,000 submissions received of serious adverse event reports regarding ZOSTAVAX, 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.

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

119. On or about November 16, 2009, ZOSTAVAX'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."

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

121. On or about August 28, 2014, ZOSTAVAX'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

122. 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)."

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

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

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

126. 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 ZOSTAVAX, 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.

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

128. 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 ZOSTAVAX 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

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

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

131. The effectiveness of ZOSTAVAX 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.

132. The effectiveness of ZOSTAVAX 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, ZOSTAVAX's effectiveness has been shown to be 4% and not statistically significant.

133. 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]

134. Merck reported that the STPS concluded that ZOSTAVAX's 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.*

135. 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]

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

137. 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]

138. 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]

139. 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]

140. 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.

141. 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.

142. 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]

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

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

145. No booster dose exists for the ZOSTAVAX vaccine.

Non-Live Alternative Zoster Vaccine

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

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

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

149. 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).

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

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

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

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

154. 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%).

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

156. 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%.

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

158. 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.

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

160. 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.

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

162. 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.

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

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

165. 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.

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

167. 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

168. Plaintiff was inoculated with ZOSTAVAX in 2013, as prescribed and/or administered by a healthcare provider at the Moncrief Army Community Hospital, located in Columbia, South Carolina for the long-term prevention of herpes zoster or shingles. At the time of Plaintiff's vaccination, Plaintiff and Plaintiff's healthcare providers relied on the warning label affixed to ZOSTAVAX, and Plaintiff relied on the information relayed through Plaintiff's healthcare provider(s) that ZOSTAVAX was an effective to permanently prevent shingles and did not carry any significant risk of adverse effect, which induced Plaintiff to be vaccinated.

169. Subsequent to Plaintiff's ZOSTAVAX inoculation, Plaintiff was treated by a healthcare provider at Tanner Medical Center at the Villa Rica Campus located in Villa Rica, Georgia for herpes zoster.

170. As a direct and proximate result of Plaintiff's use of the ZOSTAVAX vaccine, Plaintiff has and will continue suffer ongoing injuries, including but not limited to: mental and physical pain and suffering; significant medical and related expenses as a result of these injuries, including but not limited to costs for hospitalization, physician care, monitoring, treatment, medications, and supplies; diminished capacity for the enjoyment of life; diminished quality of life; increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions; and other losses and damages.

COUNT I: NEGLIGENCE
(Against all Defendants)

171. Plaintiff incorporates by reference all prior allegations.

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

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

174. 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.

175. 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.

176. Merck, MSD and McKesson had a duty to exercise ordinary and reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of ZOSTAVAX including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

177. Defendants each had a duty to warn physicians, pharmacists, medical and/or healthcare providers, including but not limited to Plaintiff's healthcare providers, of the material and significant risks of serious bodily injury and viral infection resulting from and/or associated with use of ZOSTAVAX, which Defendants knew or should have known existed.

178. 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 ZOSTAVAX, including but not limited to the decreased efficacy of ZOSTAVAX with advancing age, and ZOSTAVAX's waning efficacy post-inoculation over time to effectively zero after four years, which Defendants knew or should have known existed.

179. 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.

180. 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.

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

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

183. Defendants' failure to exercise reasonable care in the manufacture, design, marketing, labeling, and sale of ZOSTAVAX was a breach of their duty; Defendants' failure to exercise such care resulted in Plaintiff's use of ZOSTAVAX and proximately caused Plaintiff's injuries and damages and alleged herein.

184. Defendants' breach of duty was a direct and proximate cause of Plaintiff's ZOSTAVAX use, resulting in Plaintiff's injuries.

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

186. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief.

COUNT II: PRODUCTS LIABILITY - DESIGN and MANUFACTURING DEFECT
(Against all Defendants)

187. Plaintiff incorporates by reference all prior allegations.

188. Merck, MSD and McKesson designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed ZOSTAVAX.

189. Merck, MSD and McKesson 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.

190. The ZOSTAVAX vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

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

192. 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 manufacturers, suppliers, and distributors, the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

193. 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.

194. ZOSTAVAX was manufactured or designed such that it unreasonably increased the risk of contracting an infection from the vaccine.

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

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

197. Alternatively, the ZOSTAVAX vaccine with which Plaintiff was inoculated failed to perform its intended function due to a flaw in the manufacturing process 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.

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

199. 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 Defendants and when used and administered in the form manufactured and distributed by Defendants and in the manner instructed by Merck, MSD and McKesson to be used and administered to Plaintiff and other consumers.

200. 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.

201. Plaintiff's physicians and/or 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 (herpes zoster).

202. 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.

203. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered 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, together with interest, costs of suit, attorneys' fees and all such other relief.

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 designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduced into the stream of commerce ZOSTAVAX, and 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; therefore, each Defendant had a duty to warn of the risks associated with the use of ZOSTAVAX.

212. The ZOSTAVAX vaccine was under the exclusive control of Defendants.

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

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

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

217. Plaintiff was a reasonably foreseeable user of ZOSTAVAX.

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 ZOSTAVAX 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 due to viral infection.

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. ZOSTAVAX did not include warnings of its serious side effects, significantly diminishing efficacy rate, or lack of adequacy for the long-term prevention of shingles; Defendants deliberately failed to include such warnings to maximize their profits from ZOSTAVAX sales.

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 ZOSTAVAX 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 vaccine used by Plaintiff was not 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. ZOSTAVAX was unreasonably dangerous and defective because it was unaccompanied by any adequate warnings regarding its hidden and/or latent risks.

233. 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.

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

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

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 ZOSTAVAX 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 ZOSTAVAX due to inadequate warnings and instructions was a substantial, proximate, and contributing factor in causing the Plaintiff's injuries.

240. As a direct and proximate result of the defective nature of ZOSTAVAX due to inadequate warnings and instructions, Plaintiff sustained serious personal injuries and related losses and damages as alleged herein.

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

242. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive damages together with interest, costs of suit, attorneys' fees and all such other relief.

COUNT IV: BREACH OF EXPRESS WARRANTY
(Against all Defendants)

243. Plaintiff incorporates by reference all prior allegations.

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

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

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

247. The ZOSTAVAX vaccine was expected to reach and did in fact reach consumers, including Plaintiff and Plaintiff's healthcare providers, without substantial change in the condition in which it was manufactured, marketed, and sold by Defendants.

248. At all relevant times, Defendants intended that ZOSTAVAX be used in the manner that Plaintiff used it.

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

250. Plaintiff was a foreseeable user of ZOSTAVAX.

251. Plaintiff's healthcare providers were foreseeable users as prescribers and administers of ZOSTAVAX.

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

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

254. Defendants made the following express warranties regarding ZOSTAVAX:

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 ZOSTAVAX's product insert, prescribing information, patient information sheet, labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and ZOSTAVAX's regulatory submissions.

257. Members of the medical community, including Plaintiff's healthcare providers, and the public, including Plaintiff, relied upon the representations and warranties that Defendants made about the use recommendation, description, and/or dispensing of ZOSTAVAX.

258. Plaintiff justifiably relied on Defendants' express warranties about ZOSTAVAX.

259. Plaintiff's healthcare providers justifiably relied on Defendants' express warranties about ZOSTAVAX.

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

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

262. The ZOSTAVAX vaccine did not conform to these express warranties and representations because ZOSTAVAX 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.

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

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

265. As a direct and proximate result of Defendants' breach of express warranties regarding ZOSTAVAX, Plaintiff used ZOSTAVAX, and sustained injuries as alleged.

266. Defendants' breaches of their express warranties constitute violations of common law principles and N.J.S.A. § 12A:2-313, et seq.

267. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief.

COUNT V: BREACH OF IMPLIED WARRANTY
(Against all Defendants)

268. Plaintiff incorporates by reference all prior allegations.

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

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

271. Plaintiff was a foreseeable user of ZOSTAVAX.

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

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

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

275. 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.

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

277. 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 ZOSTAVAX as alleged herein.

278. Plaintiff justifiably relied on Defendants' implied warranties about ZOSTAVAX's safety and efficacy.

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

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

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

282. The ZOSTAVAX vaccine did not conform to these implied warranties because ZOSTAVAX 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.

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

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

285. As a direct and proximate result of Defendants' breach of implied warranties regarding ZOSTAVAX, Plaintiff used ZOSTAVAX and was injured as a result.

286. Defendants' breach of their implied warranties regarding the ZOSTAVAX vaccine violated N.J.S.A. § 12A:2-314, et seq.

287. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief.

COUNT VI: UNJUST ENRICHMENT
(Against all Defendants)

288. Plaintiff incorporates by reference all prior allegations.

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

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

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

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

293. McKesson accepted payment by and/or from Plaintiff's purchase of ZOSTAVAX.

294. 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.

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

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

297. 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.

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

299. Defendants are jointly and severally liable to Plaintiff for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief.

COUNT VII: PUNITIVE DAMAGES

300. The FDA has repeatedly admonished each Defendant regarding the way other drugs and medical devices are marketed to consumers and healthcare providers. Defendants have repeatedly engaged in a pattern of conduct of deliberately overstating the benefits of a drug while minimizing the risk of the drug; this practice continues even to the present time.

301. Defendants' acts were willful and malicious: each Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff, and Defendants' conduct warrants an assessment of exemplary and punitive damages.

302. Punitive damages are appropriate under all applicable law.

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:

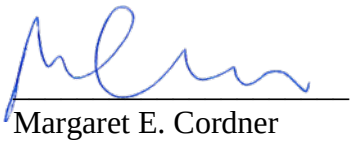
a. For general damages, including without limitation, past and future pain and suffering, past and future emotional distress, past and future loss of enjoyment of life, and other consequential damages in an amount to be proven at the time of trial;
b. For special damages in an amount to be proven at the time of trial;
c. For statutory damages in an amount to be proven at the time of trial;
d. For exemplary and punitive damages in a sufficient amount to be proven at the time of trial to punish Defendants and to deter similar conduct as alleged herein;
e. For pre-judgment and post-judgment interest on 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: July 1, 2019

Respectfully submitted,



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Attorneys for Plaintiff

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

MARY HARRELL

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Marc J. Bern & Partners LLP
60 East 42nd Street, 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

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

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

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

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

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 $

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
07/01/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

MARY HARRELL

Plaintiff

v.

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

Defendant

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: Margaret E. Cordner, Esq.
Marc J. Bern & Partners LLP
60 East 42nd Street, Suite 950
New York, NY 10165

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:

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AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

MARY HARRELL

Plaintiff

v.

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

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* MERCK SHARP and 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: Margaret E. Cordner, Esq.
Marc J. Bern & Partners LLP
60 East 42nd Street, Suite 950
New York, NY 10165

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.

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❒ 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):*

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Date: _____

_____
Server's signature

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Printed name and title

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Server's address

Additional information regarding attempted service, etc:

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AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

MARY HARRELL

Plaintiff

v.

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

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* MCKESSON CORP.
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: Margaret E. Cordner, Esq.
Marc J. Bern & Partners LLP
60 East 42nd Street, Suite 950
New York, NY 10165

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))

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❒ 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):*

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Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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