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Attorneys for Plaintiffs

CARMEN SENF, an individual;
DEBRA SMITH, an individual;
BARBARA COOK, an individual;
DEBRA MARTIN, an individual;
RUDOLPH IANNACI, an individual;
BONNIE PHILLIPS, an individual;
GARY ARNOLD, an individual;
KEN NICOLL, an individual;
DUANE WHITING, an individual;
REA MULLER, an individual;
GARY BRADY, an individual;
PAM WATSON, an individual;
VIRGINIA BROWN, an individual;
DOTTIE SHEARIN, an individual; and
EMMA R. NEAL, an individual,

Plaintiffs,

v.

MERCK & CO., INC., a corporation;
MERCK SHARPE & DOHME CORP.,
a corporation; **McKESSON CORP**.,
a corporation; **ANN REDFIELD, R.N.**,
an individual,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO.: _____

CIVIL ACTION

COMPLAINT & DEMAND FOR JURY TRIAL

COMPLAINT

COME NOW, Plaintiffs by and through their attorneys, MARC J. BERN & PARTNERS, LLP, who complain and allege against Defendants MERCK & CO., INC., (hereinafter,

"Merck"), MERCK SHARPE & DOHME, CORP., McKESSON CORP., and ANN REDFIELD, MSN, R.N., and each of them (collectively, "Defendants"), on information and belief, alleges as follows.

INTRODUCTION

1. Plaintiffs bring this action for personal injuries and damages suffered as a direct and proximate result of being inoculated with the unreasonably dangerous vaccine, ZOSTAVAX, intended for the prevention of shingles as manufactured by Defendants.

2. The subject of the present matter is the ZOSTAVAX vaccine, intended for the prevention of herpes zoster; the shingles virus. At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the ZOSTAVAX vaccine to be administered to patients throughout the United States, including New Jersey.

3. All named Plaintiffs' claims for damages relate to Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the faulty ZOSTAVAX vaccine.

4. The Defendants' vaccine that is the subject of this action reached and was administered to all Plaintiffs, by and through their physicians, medical facilities and pharmacies without substantial change in condition from the time they left Defendants' possession.

5. Plaintiffs, their physicians, and their pharmacists used the ZOSTAVAX vaccine in the manner in which it was intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect the ZOSTAVAX vaccine may contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect regarding its ZOSTAVAX vaccine.

PARTIES

8. Plaintiff CARMEN SENF at all times relevant to this action was and is a citizen of the State of North Dakota, residing in West Fargo. CARMEN SENF was inoculated with Defendants' ZOSTAVAX vaccine on or about October 17, 2012 at the Sanford Medical Center, located in Fargo, North Dakota, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused CARMEN SENF to contract a persistent strain of herpes zoster with extensive complications. On or about October 28, 2013, CARMEN SENF was treated by Matthew J. Nelsen, M.D. at Sanford Medical Center for the onset of a blistering vesicular outbreak accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles. On or about November 1, 2013, CARMEN SENF was treated again at Sanford Medical Center for ongoing and worsening symptoms, particularly as they affected her face. CARMEN SENF was then diagnosed with the condition of Trigeminal Neuralgia, secondary to shingles. On or about October 22, 2014, CARMEN SENF sought treatment from Eudeniu Vuntean, M.D. for worsening facial pain attributable to the shingles which caused her facial paralysis, pain in her eyes, and trouble chewing and eating. On or about June 3, 2015, CARMEN SENF underwent additional treatment by Matthew J. Nelsen, M.D. for new and worsening shingles outbreaks. CARMEN SENF was also treated by Ronald J. Borowicz, M.D. on or about June 6, 2015, who affirmed the diagnosis of severe shingles. Subsequently, on or about October 14, 2015, CARMEN SENF was treated by neurologist Ronald J. Borowicz for continued facial pain, which was diagnosed as chronic trigeminal neuralgia on the left side, secondary to herpes zoster infections. On or about

November 12, 2015, CARMEN SENF was treated by Douglas J. Hushka in the Emergency Department of Sanford Medical Center – Fargo Hospital for severe migraines. CARMEN SENF was then diagnosed with additional herpes zoster infections with visual disturbance and chronic migraines caused by her trigeminal neuralgia. Throughout her extended treatment of these conditions, CARMEN SENF has been prescribed Acyclovir, Gabapentin, Tegretol, Norco, and Tramadol for management of her excruciating symptoms. As a direct and proximate result of the defect of Defendants' ZOSTAVAX vaccine, Plaintiff CARMEN SENF suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CARMEN SENF has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff DEBRA SMITH at all times relevant to this action was and is a citizen of the State of Missouri, residing in Jefferson City. DEBRA SMITH was inoculated with Defendants' ZOSTAVAX vaccine on or about April 11, 2012, at East End Drug, located in Jefferson City, Missouri, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused DEBRA SMITH to contract a persistent strain of herpes zoster. On or about November 27, 2012, DEBRA SMITH was treated by Kenneth E. Schafermeyer, D.O. at Primary Care Medicine, P.C. for the onset of a painful vesicular rash accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff DEBRA SMITH suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DEBRA SMITH

has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff BARBARA COOK at all times relevant to this action was and is a citizen of the State of Pennsylvania, residing in Scranton. BARBARA COOK was inoculated with Defendants' ZOSTAVAX vaccine on or about April 6, 2014, at the Price Chopper Pharmacy, located in Scranton, Pennsylvania, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused BARBARA COOK to contract a persistent strain of herpes zoster. On or about July 22, 2016, BARBARA COOK was treated by Michael Jonathon Fox, M.D. at Geisinger Medical Group for blistering vesicular outbreaks, which were diagnosed as severe shingles. BABRARA COOK has been prescribed Acyclovir for management of her painful condition. As a direct and proximate result of these malfunctions, Plaintiff BARBARA COOK suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BARBARA COOK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff DEBRA MARTIN at all times relevant to this action was and is a citizen of the State of Mississippi, residing in McComb. DEBRA MARTIN was inoculated with Defendants' ZOSTAVAX vaccine on or about March 3, 2008, administered by James Brock, Jr. M.D., as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused DEBRA MARTIN to contract a persistent strain of herpes zoster. On or about March 12, 2016, DEBRA MARTIN was treated by Jackie E. Brister, FNP for the onset of a blistering vesicular rash accompanied by

weakened immune symptoms and interference with her vision, which was diagnosed as herpes zoster, or shingles with ocular involvement. DEBRA MARTIN was referred to a specialist and was treated at Kebert Eye Clinic for the shingles that had spread to her eyes. DEBRA MARTIN has been prescribed Valcyclovir for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff DEBRA MARTIN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DEBRA MARTIN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff RUDOLPH IANNACI at all times relevant to this action was and is a citizen of the State of Florida, residing in Naples. RUDOLPH IANNACI was inoculated with Defendants' ZOSTAVAX vaccine on or about February 29, 2013 at the Walgreens Pharmacy, located in Naples, Florida, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused RUDOLPH IANNACI to contract a persistent strain of herpes zoster. On or about July 29, 2013, RUDOLPH IANNACI was treated by Anthony Deluca, M.D. of Wall Family Medical Clinic, located in Sea Girt, New Jersey for the onset of a painful vesicular outbreak accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. RUDOLPH IANNACI has been prescribed Acyclovir for management of his painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff RUDOLPH IANNACI suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUDOLPH IANNACI has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff GARY ARNOLD at all times relevant to this action was and is a citizen of the State of Michigan, residing in Remus. GARY ARNOLD was inoculated with Defendants' ZOSTAVAX vaccine on or about April 11, 2012 at the Walgreens Pharmacy as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused GARY ARNOLD to contract a persistent and chronic strain of herpes zoster. On or about December 16, 2016, GARY ARNOLD was treated by Dr. Julie Boss, D.O. of Boss & Crew Eye Associated for a blistering vesicular outbreak which has spread to the eyes and was then diagnosed as herpes zoster, or shingles with ophthalmic interference. GARY ARNOLD was treated again by Julie Boss, D.O. for ongoing and worsening symptoms of blisters forming on the eyes and forehead. GARY ARNOLD was prescribed Acyclovir to help manage his recurrent symptoms. As a direct and proximate result of these malfunctions, Plaintiff GARY ARNOLD suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff GARY ARNOLD has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

12. Plaintiff BONNIE PHILLIPS at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Cumberland Gap. BONNIE PHILLIPS was inoculated with Defendants' ZOSTAVAX vaccine on or about April 4, 2013, administered at the Lincoln memorial University Medical Clinic located in in Harrogate, Tennessee, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused BONNIE PHILLIPS to contract a persistent and chronic strain of herpes zoster. On or about April 4, 2016, BONNIE PHILLIPS

was treated by Tariq Mirza, M.D. at the Middlesboro ARH Hospital Emergency Department for a painful and blistering vesicular outbreak, which was diagnosed as herpes zoster, or shingles. BONNIE PHILLIPS was prescribed Hydrocodone, Acyclovir, and Norco to help manage her symptoms. As a direct and proximate result of these malfunctions, Plaintiff BONNIE PHILLIPS suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BONNIE PHILLIPS has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

13. Plaintiff KEN NICOLL at all times relevant to this action was and is a citizen of the State of Denver, Colorado. KEN NICOLL was inoculated with Defendants' ZOSTAVAX vaccine on or about October 3, 2014, prescribed by Todd D. Larson, and administered at Keiser Permanente Colorado, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused KEN NICOLL to contract a persistent strain of herpes zoster. One week later, on or about November 11, 2014, , KEN NICOLL was treated at the Saint Joseph Hospital ER Department for severe headaches, floaters in the eye, and pain, which was diagnosed by William Bentley, M.D. as herpes zoster eruptions causing headaches and other interference. On or about November 20, 2015, KEN NICOLL was treated by Todd D. Larson, M.D. for ongoing and worsening symptoms of vesicular outbreaks, which were diagnosed as additional herpes zoster infections. On or about April 15, 2015, KEN NICOLL was treated by Roger M. Weiss, D.O. at Keiser Permanente Colorado for severe residual pain, which was diagnosed as post-herpetic neuralgia. KEN NICOLL has been prescribed Acyclovir, Nortriptyline and Gabapentin for management of his painful symptoms. The subsequent medications required to treat KEN NICOLL's recurrent

shingles have resulted in memory loss and other cognitive issues that affect his daily life. As a direct and proximate result of these malfunctions, Plaintiff KEN NICOLL suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff KEN NICOLL has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

14. Plaintiff DUANE WHITING all times relevant to this action was and is a citizen of the State of Minnesota, residing in Coon Rapids. DUANE WHITING was inoculated with Defendants' ZOSTAVAX vaccine on or about February, 19, 2009 at the Minneapolis VA HCS, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused DUANE WHITING to contract a persistent and chronic strain of herpes zoster. On or about January 31, 2017, DUANE WHITING was treated by Shannah M. Brent, RN, BSN, for a blistering vesicular outbreak which has spread to the eyes and was then diagnosed as herpes zoster. On or about February 8, 2017, DUANE WHITING was treated by Shannah M. Brent for ongoing and worsening symptoms of shingles. On or about February 8, 2017, DUANE WHITING was treated at the Urgent Care Clinic for unbearable shingles pain and was prescribed pain medication. On or about February 13, 2017, DUANE WHITING sought subsequent treatment from Elizabeth Bachorik, MSN, ANP-C, for treatment of his recurrent and painful symptoms. DUANE WHITING has been prescribed Valtrex, Gabapentin, and Vicodin to help manage his recurrent symptoms. As a direct and proximate result of these malfunctions, Plaintiff DUANE WHITING suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result,

Plaintiff DUANE WHITING has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

15. Plaintiff REA MULLER all times relevant to this action was and is a citizen of the State of Louisiana, residing in Luling. REA MULLER was inoculated with Defendants' ZOSTAVAX vaccine on or about August 2, 2012 at the Walgreens Pharmacy, located in Boute, Louisiana, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused REA MULLER to contract a persistent and chronic strain of herpes zoster. On or about June 2, 2013, REA MULLER was treated by Osei Prempeh, M.D. at the Urgent Care Clinic for a blistering vesicular outbreak which was then diagnosed as herpes zoster. REA MULLER has been prescribed Valtrex, Tramadol, and Lidocaine topical cream for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff REA MULLER suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff REA MULLER has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

16. Plaintiff GARY BRADY at all times relevant to this action was and is a citizen of the State of Oregon, residing in Portland. GARY BRADY was inoculated with Defendants' ZOSTAVAX vaccine on or about September 24, 2014 at the VA Hospital, located in Portland, Oregon, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused GARY BRADY to contract a persistent strain of herpes zoster. On or about December 27, 2014, GARY BRADY was treated at the Portland VA Clinic for a blistering vesicular outbreak, which was diagnosed as herpes

zoster, or shingles. On or about December 30, 2014, GARY BRADY was treated in the Emergency Department of the Portland VA Hospital for ongoing and worsening symptoms of shingles accompanied by excruciating pain. GARY BRADY was diagnosed with post-herpetic neuralgia. On or about July 13, 2015, GARY BRADY was treated by Somnath Saha, M.D. at the Portland VA Clinic for new and worsening outbreak symptoms and nerve pain, and the diagnoses of shingles and post-herpetic neuralgia was affirmed and all ongoing prescription regiments were doubled in strength. GARY BRADY has been prescribed Valcyclovir, Gabapentin, and Capsaicin cream for treatment of his painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff GARY BRADY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff GARY BRADY has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

17. Plaintiff PAM WATSON at all times relevant to this action was and is a citizen of the State of New Hampshire, residing in Errol. PAM WATSON was inoculated with Defendants' ZOSTAVAX vaccine on or about March 2, 2014 at the Rite Aid Pharmacy, located in Colebrook, New Hampshire, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused PAM WATSON to contract a persistent strain of herpes zoster. On or about December 19, 2015, PAM WATSON was treated by Heidi Root, M.D. at Upper Connecticut Valley Hospital Emergency Room for a painful vesicular eruption, which was diagnosed as herpes zoster, or shingles. PAM WATSON has been prescribed Gabapentin for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff PAM WATSON suffered painful injuries

and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff PAM WATSON has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

18. Plaintiff VIRGINIA BROWN at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Louisville. VIRGINIA BROWN was inoculated with Defendants' ZOSTAVAX vaccine in 2012, administered by Dr. Henry Bynum, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused VIRGINIA BROWN to contract a persistent strain of herpes zoster. During 2013, VIRGINIA BROWN was treated by Dr. Lawrence D. Loehle, M.D. for a vesicular eruption, which was diagnosed as herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff VIRGINIA BROWN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VIRGINIA BROWN has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

19. Plaintiff DOTTIE SHEARIN at all times relevant to this action was and is a citizen of the State of North Carolina, residing in Rocky Mount. DOTTIE SHEARIN was inoculated with Defendants' ZOSTAVAX vaccine on or about March 19, 2010 at the Rite Aid Pharmacy, located in Rocky Mount, North Carolina, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused DOTTIE SHEARIN to contract a persistent strain of herpes zoster. On or about March 15, 2013, DOTTIE SHEARIN was treated by Dr. David R. Dirks, for a blistering vesicular outbreak, which was diagnosed as herpes zoster, or shingles. DOTTIE SHEARIN has

been prescribed Acyclovir for treatment of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff DOTTIE SHEARIN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DOTTIE SHEARIN has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

20. Plaintiff EMMA R. NEAL at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Florence. EMMA R. NEAL was inoculated with Defendants' ZOSTAVAX vaccine on or about February 8, 2010 at St. Elizabeth Health Care – Florence, located in Florence, Kentucky, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused EMMA R. NEAL to contract a persistent strain of herpes zoster. On or about July 8, 2016, EMMA R. NEAL was treated by Jared J. Patton, PA-C at St. Elizabeth Health for a blistering vesicular outbreak, which was diagnosed as herpes zoster, or shingles. EMMA R. NEAL has been prescribed Acyclovir and Lipoderm for treatment of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff EMMA R. NEAL suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff EMMA R. NEAL has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

21. At all relevant times to this action, as further detailed herein, Defendants MERCK & CO., MERCK SHARPE & DOHME, McKESSON CORP., and ANN REDFIELD, DOES and each of them, were engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, packaging,

processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce and into the State of New Jersey, either directly or indirectly through third parties or related entities, the ZOSTAVAX vaccine, which was to be administered to patients throughout the United States, including New Jersey.

8. Defendant Merck & Co., is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Merck researched, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and sold the ZOSTAVAX vaccine to be administered to patients throughout the United States, including New Jersey. Merck has conducted business and derived substantial revenue from within the State of New Jersey, from including, but not limited to, its business activities related to the ZOSTAVAX vaccine.

22. Defendant Merck Sharp & Dohme Corp., is a wholly-owned subsidiary of Defendant Merck and part of the Merck family of companies. Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the State of New Jersey with its headquarters located at 126 E. Lincoln Ave. Rahway, New Jersey. At all times relevant to this action, through the actions of its wholly-owned subsidiary, Merck, or, based on information and belief, its own actions, Merck, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the ZOSTAVAX vaccine to be administered to patients throughout the United States, including New Jersey. Merck has conducted business and derived substantial revenue from within the State of New Jersey, from including, but not limited to, its business activities related to the ZOSTAVAX vaccine.

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

24. Defendant McKesson Corporation (hereinafter "McKesson") is a Delaware Corporation with its principal place of business at One Post Street, San Francisco, California, 94104. At all relevant rimes, McKesson was in the business of manufacturing, labeling, selling, marketing, packaging, re-packaging, and distributing the ZOSTAVAX vaccine, on information and belief, the ZOSTAVAX vaccine administered to the Plaintiffs. Defendant does business throughout the United States and in the State of California, and regularly, continuously, and presently does business with this judicial district, including manufacturing, marketing, selling and distributing the ZOSTAVAX vaccine.

25. Affiliates have provided Merck with support in the development and distribution of the ZOSTAVAX vaccine. McKesson Corporation acts as such affiliate and does regularly, and continuously conduct business throughout the State of New Jersey, including this judicial district.

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

15. Based on information and belief, Merck advertised its ZOSTAVAX vaccine to patients, doctors and hospitals in New Jersey and/or other medical facilities located throughout New Jersey.

16. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to N.J. 4:28-1(a)(2) which allows permissive joinder of parties if feasible for claims that are similarly situated. In the present Complaint all Plaintiffs' claims arise from a common nucleus of fact and joinder is not prejudicial and is conducive to efficiency of based on commonality. Plaintiffs assert a right to relief in respect of or arising out of the same transaction, occurrence, or common nucleus, series of transactions or occurrences, and questions of law and fact common to all such Plaintiffs will arise in the action.

17. Plaintiffs were influenced by, affected by, or otherwise caused to use and consent to being inoculated with the Defendants' ZOSTAVAX vaccine as a result of virtually uniform and/or identical information provided, as well as representations and material omissions made by Defendants Merck, Merck Sharpe & Dohme, McKesson, and Ann Redfield, and DOES 1 through 50, as set forth herein. This information emanated from the same source, Merck, and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were received by or otherwise exposed to Plaintiffs and their health care providers and pharmacies was the same and include, but are not limited to, the following:

a. The ZOSTAVAX vaccine applications submitted to and relied by the FDA for clearance to commercially market.
b. Product information, instructions for use and other labeling materials provided with the ZOSTAVAX vaccine.
c. Marketing and promotional materials made available and provided by Defendants' marketing departments to Plaintiffs' health care providers, including, but not limited to:
    i. Patient brochures provided by Defendants' sales representatives in person,
    ii. Training seminars hosted by Merck,

iii. CME (Continuing Medical Education) materials created, authored and/or provided by Defendants.

iv. Information supplied at Professional Conferences at booths hosted or manned by Merck or their Key Opinion Leaders.

d. Representations and informational packets made and provided by Defendants' marketing and sales departments through their sales representatives to each implanting physician of Plaintiffs' during in-office visits or meetings with said physicians and by pharmacists at the places where they go regularly to obtain other medications.

e. Defendants' online websites that provided the same specific information on the ZOSTAVAX vaccine, including product description, indications for use, instructions for use, and ordering information.

f. The indications for use were the same or substantially similar in each Plaintiff's situation, as set forth herein. The Plaintiffs were each urged by their health care providers or pharmacists to get inoculated with the ZOSTAVAX vaccine for the prevention of adult shingles, which they were informed by said providers was a dangerous condition.

g. Plaintiffs experienced injuries because of the same defects with the ZOSTAVAX, which were known or knowable to Defendants, at all relevant times, but negligently, recklessly, and intentionally withheld from Plaintiffs and their health care providers, as set forth herein.

JURISDICTION AND VENUE

18. This action is brought by Plaintiffs, each of them resident citizens of the State of New Jersey, pursuant to N.J. R. 4: 4 -3(a)(1).

19. This Court has personal jurisdiction over Defendants, Merck & Co., Merck Sharpe & Dohme pursuant to N.J. R. 4: 4-3(a)(6) , as resident corporations of the State of

New Jersey, and over Ann Redfield and McKesson as registered agents of Merck, conducting business in the State of New Jersey.

20. Venue is proper in this Court pursuant to R. 4: 3-2 because venue is deemed proper in the Superior Court in the county in which cause of action arose, or where any party to the action resides. Further, pursuant to R. 4: 3-2(b) a corporation is deemed to reside in any county in which its registered office is located or in any county in which is it actually doing business. Defendants Merck and Merck Sharp & Dohme are situated and incorporated in New Jersey. Further, a substantial amount of the defendants' conduct, as alleged herein by Plaintiffs took place in Atlantic County.

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

22. Moreover, all of the defendants systematically availed themselves of the State of New Jersey by conducting regular and sustained business and engaging in substantial commerce and business activity in New Jersey, including without limitation researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, and/or introducing into interstate commerce in the State of New Jersey, either directly or indirectly, its products, including ZOSTAVAX vaccine. Defendants, and each of them, expected or should have expected that their acts would have consequences within the United States, specifically, in the State of New Jersey; Defendants, and each of them, derived and, based on information and belief, some if not all continue to derive substantial revenue from their actions, dealings, associations, relationships, or otherwise, as described herein, in connection with the ZOSTAVAX vaccine.

23. Each of the above-named Plaintiff's claims arise from and relate to Defendants' purposeful avail of the State of New Jersey because resident Defendants'

wrongful conduct in researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, ZOSTAVAX vaccines took place, in whole or in part, in the State of New Jersey. Therefore, the claims of New Jersey Plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of New Jersey. Further and independently, McKesson Corporation consented to jurisdiction in the State of New Jersey by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

24. The instant Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

ALTER-EGO, VICARIOUS AND SUCCESSOR LIABILITY, AND PIERCING THE CORPORATE VEIL AS A RESULT OF THE RELATIONSHIPS BETWEEN MERCK, MERCK SHARPE & DOHME, McKESSON CORP., AND ANN REDFIELD

25. Plaintiffs incorporate by reference all prior allegations.

26. At all times herein mentioned, Defendants Merck, Merck Sharp & Dohme, McKesson and Ann Redfield were agents, servants, partners, aiders and abettors, co-conspirators and/or joint venturers, and were all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture

and rendered substantial assistance and encouragement to each other, knowing their collective conduct constituted a breach of duty owed to Plaintiffs.

27. There exists and, at all times herein mentioned, a unity of interest in ownership between Defendants Merck, Merck Sharp & Dohme and Ann Redfield such that any individuality and separateness between them has ceased and these particular Defendants are alter egos. Adherence to the fiction of the separate existence of these particular Defendants as entities distinct from each other will permit an abuse of corporate privilege and would sanction a fraud and/or promote injustice.

28. At all times herein mentioned, Merck, Merck Sharp & Dohme, McKesson, and Ann Redfield, and each of them, were engaged in the business of, or were successors in interest to, entities in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling the ZOSTAVAX vaccine for use by Plaintiffs, their health care providers, and pharmacists. As such, each of these particular Defendants is individually, as well as jointly and severally, liable to Plaintiffs for their damages.

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

30. Plaintiffs, would not have an adequate remedy if Defendants Merck Sharp & Dohme and Ann Redfield were not a named party in this action.

31. Defendant Merck Sharp & Dohme and Ann Redfield exercised, and continues to exercise, complete and domination of the finances, policy, and business practices of

Defendant Merck to such an extent that Defendants Merck, Sharpe & Dohme and McKesson have no separate minds, wills or existences of its own.

32. The aforesaid control was used by Defendant Merck to negligently research, design, formulate, compound, test, manufacture, produce, process, assemble, inspect, distribute, market, label, promote, package, prescribe, and/or advertise, and sell ZOSTAVAX vaccine for use by patients like Plaintiffs, their health care providers, and their pharmacists.

33. As such, there are sufficient grounds, in and of themselves, for disregarding the corporate form and extending liability to Defendants Merck Sharp & Dohme and McKesson through piercing the corporate veil.

34. 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, successors, assigns, officers, directors, employees, agents and representatives of Merck, Merck Sharp & Dohme, and Ann Redfield and each of them.

35. "Defendants" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Merck, Merck Sharp & Dohme, and Ann Redfield, and DOES 1 through 50, and each of them.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

36. Plaintiffs, incorporate by reference all prior allegations.

37. Plaintiffs, are within the applicable statute of limitations for their claims because Plaintiffs, and their health care professionals, did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of the ZOSTAVAX vaccine.

38. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the ZOSTAVAX vaccine and the causal connection between these defects and each Plaintiff's

injuries and damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

39. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

40. Such conduct includes intentional concealment from Plaintiffs, prescribing health care professionals, pharmacists, and the general consuming public and the FDA of material information that ZOSTAVAX had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described herein.

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

FACTUAL BACKGROUND

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

a. Pursuant to §11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table.

b. The ZOSTAVAX vaccine is not a vaccine listed in the Vaccine Injury Table. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the ZOSTAVAX vaccine.

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

44. Varicella zoster is a virus that causes chickenpox.

45. Once the varicella zoster virus causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

46. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infection of sensory nerve ganglion and the peripheral nerve and its branches persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatome.

47. When reactivated, varicella zoster replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

48. In May of 2006, the U.S. Food and Drug Administration ("FDA") approved the ZOSTAVAX vaccine to be marketed and sold in the United States by Merck.

49. ZOSTAVAX was initially indicated for the "the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose." FDA Approval Letter, May 25, 2006.

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

51. The results of the SPS were published in the *New England Journal of Medicine* on June 2, 2005. The paper was titled "A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults". *N. Engl. J. Med.* 2005; 352(22):2271-84.

a. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox. The incidence and severity of shingles increases as people age.

b. As further described in this paper, "[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient's quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression." *N. Engl. J.Med.* 2005; 352(22) at 2272.

c. The ZOSTAVAX vaccine is essentially the same vaccine as that used for chickenpox, except significantly stronger.

d. ZOSTAVAX contains live VZV. The virulence of the virus is reduced or "attenuated." Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

e. ZOSTAVAX is developed from a live attenuated version of the Oka/Merck VZV vaccine strain.

f. One of the paper's more significant findings was "[t]he greater number of early cases of herpes zoster in the placebo group, as compared with the vaccine group, and the fact that no vaccine virus DNA was detected, indicate that the vaccine did not cause or induce herpes zoster."

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

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

54. Under-attenuated live VZV has been shown to reactivate. Leggiadro, R. J. (2000). "Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children." *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

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

56. Shingles is a reactivation of the latent VZV, that afflicts in nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients.

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

a. A randomized, placebo-controlled safety study to assess the rates of serious adverse events in 6,000 people receiving the vaccine as compared to 6,000 who receive a placebo.

b. An observational study using a health maintenance organization (HMO) and 20,000 vaccinated people to address safety issues in the course of clinical practice. This study is specifically to detect "potential safety signals following administration of ZOSTAVAX." This study was to be submitted to the FDA by December 2008.

58. Since the publication of the SPS in the *New England Journal of Medicine*, there have been questions raised regarding the safety of ZOSTAVAX vaccine in scientific and medical journals.

59. ZOSTAVAX is a stronger, more potent version of Merck's chickenpox vaccine, Varivax.

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

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

62. Merck added several adverse reactions to its package insert/prescribing information since Varivax was approved.

a. The biological system in which the most adverse reactions were added was the nervous system.

b. Added reactions include: encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barré syndrome, Bell's palsy, ataxia, non-febrile seizures, aseptic meningitis, dizziness, and paresthesia.

c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

63. As of July 2012, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine contain no clear reference to the potential risk of viral infection.

64. Individuals with compromised immune systems should not receive a live virus vaccine because those individuals can develop the disease that the vaccine is designed to prevent.

65. Instances of zoster virus activation occurs at a rate twenty times higher in immunocompromised patients. Immunocompromised patients encompass a wide spectrum of health conditions ranging from HIV, lymphoma and other cancers, bone marrow transplant recipients, or patients in remission or otherwise who had recently been treated with chemotherapy or prednisone. For those who may be immunocompromised, the shingles will have atypical manifestations that are attributable to more severe skin legions, increased severity of pain and more diffuse involvement.

66. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for ZOSTAVAX, did not adequately, if at all, address the risk of viral infection. All that was addressed was the concern that a rash and itching might develop at the injection site. This was despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

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

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

68. Being inoculated with the zoster vaccine too closely to the pneumococcal vaccine ("P23') is known to reduce the immune system's response to the zoster vaccine. Additionally, the CDC states that live-virus attenuated vaccines should not be administered

within four weeks of each other. Commonly administered live-vaccines include: Measles, Mumps and Rubella vaccine (MMR); Rotavirus vaccine; Vaccina vaccine; and the Influenza Vaccine ("Flumist:) are all in the category of potential interactions with the ZOSTAVAX vaccine. Receiving any two of these vaccines too closely together can decrease the efficacy of the zoster vaccine. While the prescribing information furnished by Merck 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.

69. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for ZOSTAVAX, did not adequately, if at all, address the risk of viral infection or possible diseases of the nervous system. This was despite the fact that Varivax, a less potent vaccine, had added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

70. Since ZOSTAVAX's introduction in 2006, Vaccine Adverse Event Reports ("VAERS") appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis.

71. Documented adverse reactions to vaccines must be reported to the federal government in a compulsory and mandated database, the Vaccine Adverse Event Reporting System ("VAERS".) As of September of 2015, there had been 1,111 submissions received of serious adverse event reports regarding the Zoster vaccine, including 36 deaths. These reports included depicting recurrent instances of: myalgia; arthralgia; lymphadenopathy; rash; actinic keratosis; severe cutaneous disease; peripheral neuropathy; cellulitis; herpes keratis resulting in vision loss; facial paralysis; pneumonia; brain inflammation (encephalitis); and death.

72. Other than postherpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, allodynia, cranial and motor neuron palsies, pneumonia, encephalitis, visual impairment, hearing loss, and death.

73. GlaxoSmithKline has produced an alternative shingles vaccine, called Shingrix, which was submitted for approval by the FDA in October of 2016, with expected approval in 2017. Unlike ZOSTAVAX, which injects a live attenuated virus into the patient, Shingrex uses a non-live, adjuvanted, subunit (HZ/su) which is comprised of glycoprotein E, a protein found on the VZV that causes shingles, to enhance the immune response to the antigen.

74. In early state testing, Shingrex has demonstrated clinical efficacy that far surpasses ZOSTAVAX, and does not pose any risks of reactivation that a live attenuated vaccine carries. In the phase III trials of the GSK Shingrix, the vaccine was 97% effective against shingles in those 50 years and older, and was 89.8% effective for those 70 years and older. Shingrex was 91% effective in preventing postherpetic neuralgia for patients 50 years and older. In similar sized clinical studies (37,000 tested), the success rates of ZOSTAVAX were recorded at 51%, whereas Shingrex has efficacy of 91%, with no significant side effects.

75. The Center for Disease Control and Prevention ("CDC") published that the ZOSTAVAX vaccine wanes in efficacy within five years, having almost no remaining preventative effects after seven years. This allegation is not included on any labeling or packaging literature to alert users of decreased efficacy of the vaccine with time.

76. The instructions and information published by Merck regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccine. Patients who received the ZOSTAVAX vaccine do so with the intention to have long-term protection from herpes zoster, although even upon perfect use, the efficacy of the vaccine will decrease significantly after four years (according to the CDC.)

77. Additionally, unlike the live-attenuated vaccine, ZOSTAVAX, protein-based vaccine alternatives, such as Shingrex, are safe and effective even in immunocompromised patients. Non-live vaccines, like Shingrex, carry no risk of reactivation inducing shingles after inoculation. Unlike ZOSTAVAX, non-live vaccines, like Shingrex, also maintain efficacy, with 88% lower risk to develop shingles after four years than ZOSTAVAX, which diminishes in efficacy steadily with time.

78. Merck knew, or should have known, that the pharmaceutical efficacy and overall safety and benefit of a protein based vaccine, such as Shingrex, is a safer alternative to the ZOSTAVAX vaccine. The existence of safer alternatives to shingles-preventative care which is widely known to the scientific community has been tested in clinical trials alongside ZOSTAVAX comparing efficacy and shows that such dangers of ZOSTAVAX were known or discoverable, as was a safer and more effective alternative. Merck cannot claim that risks or alternatives were "scientifically undiscoverable" in the context of the state-of-the-art defense.

79. It follows that given the increased risk of viral infection due to vaccination, such complications are also possible complications of ZOSTAVAX. It also follows that post-vaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

80. Despite this information and the potential correlation between being administered the ZOSTAVAX vaccine and developing an infection within a relatively short period of time, leading to the development of shingles or varicella-zoster virus pneumonia, Merck failed to properly address and provide this information both to patients and the medical providers prescribing the vaccine.

81. As a direct result of the vaccine, Plaintiffs suffered, are suffering and/or will continue to suffer from mental and emotional distress due to resulting physical limitations and seriousness of their condition.

82. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of ZOSTAVAX, Plaintiffs sustained severe and permanent personal injuries. Further, as a tragic consequence of Merck's wrongful conduct, Plaintiffs suffered serious, progressive, permanent, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

83. Plaintiffs have incurred and will continue to incur medical expenses and other economic harm as a direct result of use of ZOSTAVAX.

COUNT I:

NEGLIGENCE

84. Plaintiffs s incorporate by reference all prior allegations.

85. At all relevant times, as set forth, *supra*, Defendants, and each of them, engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, packaging, processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce the ZOSTAVAX vaccine, and, through that conduct, have knowingly and intentionally placed the ZOSTAVAX vaccine into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become administered the vaccine.

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

87. Merck failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions,

and distribution of ZOSTAVAX because Merck knew, or should have known, that its product caused viral infection, and was therefore not safe for administration to consumers.

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

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

89. Merck continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that ZOSTAVAX posed a serious risk of bodily harm to consumers. This is especially true given its tenuous efficacy.

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

91. As a direct and proximate consequence of Merck's negligence, Plaintiffs sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT II:

PRODUCTS LIABILITY - DEFECTIVE DESIGN

(N.J. Products Liability Act-N.J.S.A. 2A:58C-1 et seq.)

92. Plaintiffs incorporate by reference all prior allegations.

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

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

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

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

97. Merck's ZOSTAVAX vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation, because when it left the hands of Merck, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

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

99. Plaintiffs' physicians and/or healthcare providers used and administered the ZOSTAVAX vaccine for the purpose intended by Merck, and in a manner normally intended

to be used and administered, namely for vaccination against shingles (herpes zoster). Merck had a duty to design, create, and manufacture products that were reasonably safe and not unreasonably dangerous for their normal, common, and intended use. Merck's product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

100. Merck designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of the Plaintiff sand other consumers. Merck is therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by their use of the product.

101. Plaintiffs could not, by the exercise of reasonable care, discover the defective condition of Merck's product and/or perceive its defective dangers prior to its administration by her physicians and/or healthcare providers.

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

103. As a proximate result of Merck's acts and omissions, the Plaintiffs' serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described in this Complaint, including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

WHEREFORE, Plaintiffs demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other

relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IV:

PRODUCTS LIABILITY – FAILURE TO WARN

(N.J. Products Liability Act -N.J.S.A. 2A:58C-1)

104. Plaintiffs incorporate by reference all prior allegations.

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

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

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

108. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its ZOSTAVAX vaccine and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product

109. Merck's ZOSTAVAX vaccine, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Merck, was defective due to the product's inadequate warnings and instructions. Merck knew, or should have known, and adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, viral infection, resulting in shingles, postherpetic neuralgia, or other diseases of the nervous system.

110. The product was under the exclusive control of Merck and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the risk of developing a disease in the nervous system due to viral infection. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

111. Notwithstanding Merck's knowledge of the defective condition of its product, Merck failed to adequately warn the medical community and consumers of the product, including the Plaintiffs and their healthcare providers, of the dangers and risk of harm associated with the use and administration of its ZOSTAVAX vaccine.

112. If the Plaintiffs were equipped with the knowledge of the defective condition and potential harms of the ZOSTAVAX vaccine, they would not have purchased it and agreed to have it injected into their body.

113. Merck downplayed the serious and dangerous side effects of its product to encourage sales of the product; consequently, Merck placed its profits above its customers' safety.

114. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert the Plaintiffs and/or her healthcare providers to the dangerous risks and reactions associated with it, including possible viral infection of the nervous system or another disease of the nervous system.

115. Even though Merck knew or should have known of the risks and reactions associated with their product, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

116. Regulation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.S. 301 to 399 ("FDCA") requires labels to be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug; thus a casual relationship need not be proved

when revisions to warning labels have been made. (*McDarby v. Merck & Co., Inc., 401 N.J. Super. 10)*

117. The Court in *McDarby* held that a pharmaceutical manufacturer's request or petition to the FDA to amend or supplement warning labels or literature of pharmaceutical products is effectual acknowledgement of the known and previously undiscovered or undisclosed risks and is sufficient alone to overcome the rebuttable presumption of adequacy of warning established by N.J.S.A. 2A-58C-4.

118. On or about March 17, 2017, Merck requested FDA approval and regulatory action to issue a clinical efficacy supplement regarding a change in method of production of ZOSTAVAX.

119. Since May 25, 2006, Merck has requested and received approval on thirteen separate occasions to amend, supplement, revise and otherwise change the warning labels, package insert, efficacy data, intended use, and method of production of ZOSTAVAX. Each regulatory action required by or petitioned to the FDA is sufficient to overcome the rebuttable presumption that the warning labels of ZOSTAVAX are and were adequate by the standards of New Jersey Product Liability Act ("PLA.")

120. New Jersey Superior Court has held that the FDCA does not pre-empt state-law tort remedies for similarly situated instances of failure to warn. (*McDarby v. Merck & Co., Inc., 401 N.J. Super. 10)*

121. Plaintiff used Merck's ZOSTAVAX vaccine as intended or in a reasonably foreseeable manner.

122. New Jersey has held the standard for similarly situated Plaintiffs injured by pharmaceutical drugs to determine "if a reasonable person would conclude that 'the magnitude of the scientifically perceivable danger…outweighed the benefits of the way the product was so designed and marketed." (*Crispin v. Volkswagenwerk AG*, 248 N.J. Super. 540, 558 (App. Div.)

123. Plaintiffs, each of them, were not informed of the risk of contracting persistent and chronic shingles, the very condition the vaccine was intended to prevent. Given the knowledge of such risk, Plaintiffs would not have voluntarily become inoculated with ZOSTAVAX.

124. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Merck had knowledge of the dangerous risks and side effects of its product.

125. Plaintiffs did not have the same knowledge as Merck and no adequate warning was communicated to her physicians and/or healthcare providers.

126. Merck had a continuing duty to warn consumers of its ZOSTAVAX vaccine, including the Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, Merck breached its duty.

127. Although Merck knew, or should have known, of the defective nature of its ZOSTAVAX vaccine, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of its product so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by its ZOSTAVAX vaccine.

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

129. Merck's failure to warn extended beyond the product's label and into other media available to Merck, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

130. Upon information and belief, the ZOSTAVAX vaccine as manufactured and supplied by Merck, was further defective due to inadequate post-market warnings or instructions because after Merck knew, or should have known, of the risk of serious bodily harm from the administration of its ZOSTAVAX vaccine, including, but not limited to, possible viral infection, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

131. The ZOSTAVAX vaccine, upon information and belief, as manufactured and supplied by Merck, was defective due to inadequate post-market warnings or instructions when it left Merck's control.

132. As a proximate result of Merck's acts and omissions and the Plaintiffs' use of Merck's defective product, Plaintiffs suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint, including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical bills and other expenses, and other losses and damages.

WHEREFORE, Plaintiffs demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT V:

BREACH OF EXPRESS WARRANTY

(N.J. Products Liability Act -N.J.S.A. 12A: 2-313, N.J.S.A 2A: 58C-1.b(3))

133. Plaintiffs incorporate by reference all prior allegations.

134. Merck, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that its ZOSTAVAX vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

a. Specifically, Merck stated that "ZOSTAVAX is a vaccine that is used for adults 60 years of age or older to prevent shingles (also known as zoster)."

b. Merck also stated that "ZOSTAVAX works by helping your immune system protect you from getting shingles."

c. Merck, in the SPS paper, stated that "…the vaccine did not cause or induce herpes zoster."

135. At the time of making such express warranties, Merck knew and/or should have known that its ZOSTAVAX vaccine did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which Merck had full knowledge and did not accurately or adequately warn.

136. The ZOSTAVAX vaccine manufactured and sold by Merck did not conform to these representations because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as the Plaintiff, when used in routinely administered dosages.

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

138. Plaintiffs, through their physicians and/or other healthcare providers, did rely on Merck's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

139. Members of the medical community, including physicians and other healthcare professionals, relied upon Merck's representations and express warranties in connection with the use recommendation, description, and dispensing of Merck's ZOSTAVAX vaccine.

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

WHEREFORE, Plaintiffs demand judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VI:

BREACH OF IMPLIED WARRANTY

141. Plaintiffs incorporate by reference all prior allegations.

142. At all times relevant to this action, Merck manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its ZOSTAVAX vaccine for use in preventing shingles.

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

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

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healthcare providers, that ZOSTAVAX vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

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

146. At the time Merck's product was promoted, marketed, distributed, and/or sold by Merck, Merck knew of the use for which it was intended and impliedly warranted its product to be of merchantable quality and safe and fit for such use.

147. Plaintiffs, their physicians and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of Merck, as manufacturer, developer, distributor, and seller of the ZOSTAVAX vaccine, as to whether it was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was manufactured and sold.

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

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

150. Merck placed its product into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the product was expected to and did reach the Plaintiff without substantial change in the condition in which it was manufactured and sold.

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

WHEREFORE, Plaintiffs demand judgement against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable

COUNT VII:

CONSCIOUS MISREPRESENTATION INVOLVING

RISK OF PHYSICAL HARM

152. Plaintiffs incorporate by reference all prior allegations.

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

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

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

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

a. Merck represented through its labeling, advertising, marketing material, advertisements, and packaging that ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles;

b. Merck represented that ZOSTAVAX did not cause or induce shingles;

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

d. Merck represented that ZOSTAVAX was safe, when, indeed, it was not.

e. Defendant Ann Redfield, MSN, RN, working with part of the "vaccine team" as part of Merck's Clinical Safety and Risk Management Department, wrote the comment section for Merck's WAES adverse experience reports.

f. Defendant Redfield also worked as the "process owner" of Merck's Varicella Zoster Vaccine Identification Program. In this capacity, Defendant Redfield drafted documents presented to the Merck employees who interacted directly with healthcare providers who recommend, prescribe, and dispense ZOSTAVAX. In addition, Defendant Redfield gave presentations to Merck's field personnel, which was the sales force of Merck employees who interacted directly with healthcare providers.

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

157. Merck and Defendant Redfield were under a duty to disclose to the Plaintiffs and their physicians and healthcare providers, the defective design and

formulation of its product, which design and formulation heightened the risk of suffering the injuries, diseases, and maladies more specifically described in this Complaint.

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

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

160. At the time Defendants made these misrepresentations, including Merck through its various officers, directors, agents, representatives, and employees, and at the times the Plaintiffs were administered Merck's product, Plaintiffs were unaware of Defendants' falsehoods, and reasonably believed them to be true.

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

162. In reliance upon Defendants' false and fraudulent misrepresentations, through her physicians and healthcare providers, the Plaintiffs were induced to, and did, reasonably rely upon Defendants' misrepresentations regarding the safety and efficacy of Merck's product, thereby sustaining severe and permanent personal injuries and damages. Defendants knew and had reason to know that Plaintiffs, their physicians and healthcare providers, in using Merck's product, did not have the ability to determine the true facts

intentionally concealed by Defendants, and would not have used the product if the true facts regarding the product had been known by Plaintiffs, their physicians, and their healthcare providers.

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

164. Merck had a duty when disseminating information to the public to provide truthful information, and a parallel duty not to deceive the public, the Plaintiffs, their healthcare providers and physicians, and the FDA.

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

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

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

168. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, Plaintiffs were caused to suffer the serious and dangerous side effects as are more specifically described in this Complaint.

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

WHEREFORE, Plaintiffs demand judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VIII:

NEGLIGENT MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM

170. Plaintiffs incorporate by reference all prior allegations.

171. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiffs, the truth regarding Merck's claims that Merck's product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Merck, in fact, were false and Merck was careless or negligent in ascertaining the truth of the representations at the time Merck made the misrepresentations.

172. Merck represented and marketed ZOSTAVAX as being safe and effective.

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

174. Merck failed to exercise ordinary care in making representations concerning its product and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce. Merck negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the product's unreasonable, dangerous and adverse side effects associated with the administration, use, and injection of the product.

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

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

177. Merck negligently misrepresented material facts about ZOSTAVAX in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Merck made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

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

179. Plaintiffs and their healthcare providers, pharmacists and physicians, justifiably relied on Merck's misrepresentations.

180. Consequently, Plaintiffs' use of ZOSTAVAX was to their own detriment as Merck's negligent misrepresentations proximately caused plaintiff's injuries and monetary losses.

181. As a foreseeable, direct, and proximate result of Merck's negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Merck knew, or had

reason to know, that Merck's product had not been sufficiently tested, that the product lacked adequate, accurate, and prominent warnings, and that injection with the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

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

WHEREFORE, Plaintiffs demands judgment against Merck, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IX:

UNJUST ENRICHMENT

183. Plaintiffs incorporate by reference all prior allegations.

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

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

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

187. Plaintiffs have not received the safe and effective vaccine for which they paid.

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

WHEREFORE, Plaintiffs demands judgment against Merck, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable

COUNT X

STRICT LIABILITY

181. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

182. Defendants manufactured, sold, distributed, marketed, and/or supplied ZOSTAVAX in a defective and unreasonably dangerous condition to consumers, including Plaintiffs, each of them.

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

184. Plaintiffs used ZOSTAVAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendants.

185. ZOSTAVAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

186. ZOSTAVAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

187. ZOSTAVAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

188. ZOSTAVAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiffs, of the risks described herein, including, but not limited to, the propensity to induce herpes zoster or shingles, post herpetic neuralgia, herpes zoster keratis, vision loss, residual chronic pain, and scarring.

189. Although Defendants knew or should have known of the defective nature of ZOSTAVAX, it continued to design, manufacture, market, and sell ZOSTAVAX vaccines so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by ZOSTAVAX.

190. Neither Plaintiffs nor their prescribing physicians could have, through the exercise of reasonable care, discovered ZOSTAVAX defects or perceived the extent of the dangers posed by the vaccine.

191. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered severe shingles outbreaks, post herpetic neuralgia, herpes zoster keratis, vision loss and other painful impediments. In addition, Plaintiffs

required and will continue to require healthcare and services and Plaintiffs have incurred and will continue to incur medical and related expenses as a result of thier injuries. Plaintiffs also have suffered and will continue to suffer 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. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

200. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages under common law and in accordance with N.J.S.A 2A: 58C-1, so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

COUNT XI:

PUNITIVE DAMAGES

193. Plaintiffs repeat, reiterate, and re-allege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

194. Defendant has been repeatedly admonished by the FDA about the manner in which it has marketed ZOSTAVAX to consumers and physicians.

195. Defendants have repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to which warnings relating to public hazards should be included in materials. Defendants have engaged in other similar incidents with other drugs it sells and this evidence tends to show that overstating the benefits of a drug while minimizing the risk of the drug is a pattern and practice of Defendants, which continues even to the present time.

196. Defendants' acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

196. Punitive damages are appropriate under New Jersey law.

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

a For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For statutory damages as set forth above, in an amount to be proven at the time of trial;

d. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant 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

Demand is hereby made for a trial by jury.

DESIGNATION OF TRIAL COUNSEL

Pursuant to N.J. R. 4:25-4, Alexandra Colella, is hereby designated as trial counsel in this matter.

MARC J. BERN & PARTNERS, LLP

By: Alexandra Colella

Dated: July 18, 2017

CERTIFICATION PURSUANT TO RULE 4:5-1

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

MARC J. BERN & PARTNERS, LLP

By: Alexandra Colella

Dated: July 18, 2017

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-004353-17

Case Caption: SENF CARMEN VS MERCK & CO. INC.
Case Initiation Date: 07/20/2017
Attorney Name: MARGARET ELIZABETH CORDNER
Firm Name: MARC J. BERN & PARTNERS LLC
Address: 60 EAST 42ND ST STE 950
NEW YORK NY 10165
Phone:
Name of Party: PLAINTIFF : senf, CARMEN
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: Yes - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: 004177-17
004075-17
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

07/20/2017
Dated

/s/ MARGARET ELIZABETH CORDNER
Signed