

[REDACTED]

ANNA MARIE YORCK, an individual;
IRENE HADFIELD, an individual;
CHARLOTTE MILLER, an individual;
CYNTHIA MARTINEZ, an individual;
JOSEPH GOODRICH, an individual;
PAMELA MOORE, an individual;
LOIS LAWRENCE, an individual,
KEVIN SMEDLEY, an individual;
ROYCE KITCHENS, an individual;
VICTOR GARRETT, an individual;
FAYE MOORE, an individual;
PAULINE KING, an individual;
STANLEY LYLES, an individual;
SYLVIA BELLAMY, an individual;
PHYLLIS PIERCE, an individual;
DORIS EVERY, an individual;
ALLEN R. REEVES, an individual;
RONALD CRABTREE, an individual;
MARCIA GRIEVES, an individual;
JOHN CAPOBIANCO, an individual;
JO ETTA FOSTER, an individual;
KATHLEEN DREW, an individual; and

Plaintiffs,

v.

MERCK & CO., INC., a corporation,
MERCK SHARPE & DOHME CORP.,
a corporation; **McKESSON CORP.**, a
corporation,

Defendants.

**SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY**

DOCKET NO.: _____

CIVIL ACTION

COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their attorneys, [REDACTED], complain and allege against Defendants MERCK & CO., INC., (hereinafter, “Merck”), MERCK SHARPE & DOHME, CORP., and McKESSON CORP., 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 ANNA MARIE YORCK at all times relevant to this action was and is a citizen of the State of Pennsylvania, residing in Norristown. ANNA MARIE YORCK was inoculated with Defendants' ZOSTAVAX vaccine on or about October 11, 2006, at the SMS Bridgeport Family Practice, located in Bridgeport, 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 ANNA MARIE YORCK to contract a persistent strain of herpes zoster. On or about August 14, 2016, ANNA MARIE YORCK was treated Sonia M. Padgett, M.D. for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. On or about November 16, 2016, ANNA MARIE YORCK was treated again by Sonia M. Padgett, M.D. for ongoing and worsening symptoms of shingles outbreaks. On or about December 18, 2016, ANNA MARIE YORCK sought treatment at the Einstein Healthcare Network in Philadelphia, Pennsylvania for treatment of ongoing shingles and management of significant and uncontrolled pain. On or about December 28, 2016, ANNA MARIE YORCK was treated by Anthony Niescier, D.O. at SMA Bridgeport Family Practice for intense residual pain, which was diagnosed as post-herpetic neuralgia, a condition of chronic nerve pain and damage secondary to shingles infections. ANNA MARIE YORCK has been prescribed Valtrex, Domeboro soaks, Acyclovir, Gabapentin, and Lidocaine patches for management of her

persistent and painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff ANNA MARIE YORCK suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANNA MARIE YORCK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff IRENE HADFIELD at all times relevant to this action was and is a citizen of the State of Oregon, residing in Glide. IRENE HADFIELD was inoculated with Defendants' ZOSTAVAX vaccine on or about January 2, 2008 at the Douglass County Public Health Department, located in Roseburg, 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 IRENE HADFIELD to contract a persistent strain of herpes zoster. On or about August 11, 2015, IRENE HADFIELD was treated by Kerry Harrington, PA-C for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles accompanied by trigeminal neuralgia. On or about August 12, 2015, IRENE HADFIELD received subsequent treatment from Matthew Driver, M.D. at the Roseburg Urgent Care facility for continued and worsening symptoms of shingles and progressive trigeminal neuralgia. On or about August 13, 2015, IRENE HADFIELD was treated by Bonnie M. Gauer, O.D., M.S. for worsening outbreaks of shingles and complications. Shingles has spread to IRENE HADFIELD's back, neck, scalp and eyes, resulting in ocular adnexa, herpes zoster conjunctivitis, and keratitis. Because of the serious complications of zoster infections throughout the body and in the eye and trigeminal neuralgia, IRENE HADFIELD has been prescribed Acyclovir, Baclofen, Norco, Artificial

tears, lid care therapy, Valtrex, Emycin and other medications for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff IRENE HADFIELD suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff IRENE HADFIELD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff CHARLOTTE MILLER at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Cookeville. CHARLOTTE MILLER was inoculated with Defendants' ZOSTAVAX vaccine on or about July 17, 2013 at the CVS Pharmacy, located in Cookeville, 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 CHARLOTTE MILLER to contract a persistent strain of herpes zoster. On or about July 21, 2016, CHARLOTTE MILLER was treated by Valerie E. Waddel, LPN and Dr. Thomas Jenkins, M.D. at Cookeville Primary Care for the onset of a severe 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 CHARLOTTE MILLER suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CHARLOTTE MILLER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff CYNTHIA MARTINEZ at all times relevant to this action was and is a citizen of the State of Texas, residing in Angleton. CYNTHIA MARTINEZ was inoculated with Defendants' ZOSTAVAX vaccine on or about September 30, 2015 at the Kroger

Pharmacy, located in Angleton, Texas, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused CYNTHIA MARTINEZ to have extensive eye disorders and complications. The day after being administered the ZOSTAVAX vaccine, CYNTHIA MARTINEZ experienced pain and injection site redness and swelling, as well as pain in both of her eyes. On or about October 1, 2015, CYNTHIA MARTINEZ began to experience further eye issues, and sought treatment from Dr. Michael Koop and Dr. Charles Johnson at the Texas Eye Institute. CYNTHIA MARTINEZ was diagnosed with acute conjunctivitis in both eyes, multiple and a corneal ulcer attributable to the ZOSTAVAX vaccine. Between the dates of February 12, 2016 and October 27, 2016, CYNTHIA MARTINEZ underwent twelve additional medical encounters, and was treated at Teledoc Physicians, P.A. for multiple chalazions in both eyes, peripheral ulcers, severe eye pain and further complications with her vision resulting from her ZOSTAVAX vaccine. CYNTHIA MARTINEZ has been prescribed Osloxacin Ophthalmic Solution, Gentamicin Sulfate Ophthalmic, Ciprofloxacin, Penlac, Maxitrol drops and ointment, and Besibian for management of her painful ocular symptoms. As a direct and proximate result of these malfunctions, Plaintiff CYNTHIA MARTINEZ suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CYNTHIA MARTINEZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

12. Plaintiff JOSEPH GOODRICH at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Mount Sterling. JOSEPH GOODRICH was inoculated with Defendants' ZOSTAVAX vaccine on or about September 1, 2015 at the

Woodbright Medical Center – Kaiser Permanents, located in Woodbridge, Virginia, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused JOSEPH GOODRICH to contract a persistent strain of herpes zoster. On or about October 1, 2015, JOSEPH GOODRICH was treated at the Woodbridge Medical Center – Kaiser Permanente, located in Woodbridge, Virginia for the onset of a severe 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 JOSEPH GOODRICH suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOSEPH GOODRICH has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff PAMELA MOORE at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Richmond. PAMELA MOORE was inoculated with Defendants' ZOSTAVAX vaccine on or about May 22, 2016 at the Rite Aid Pharmacy, located in Richmond, 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 PAMELA MOORE to contract a persistent strain of herpes zoster. On or about June 10, 2016, PAMELA MOORE was treated by Rohan Alexander, ARNP, at the Berea Urgent Care of Kentucky, located in Berea, Kentucky, for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles. PAMELA MOORE has been prescribed Valtrex, Gabapentin, Triamcinolone for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff

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

14. Plaintiff LOIS LAWRENCE at all times relevant to this action was and is a citizen of the State of Louisiana, residing in New Orleans. LOIS LAWRENCE was inoculated with Defendants' ZOSTAVAX vaccine on or about January 1, 2014 at the Ochsner Center for Primary Care and Wellness, located in New Orleans, 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 LOIS LAWRENCE to contract a persistent strain of herpes zoster. On or about July 3, 2014, LOIS LAWRENCE was treated at the Ochsner Center Primary Care and Wellness Center, for the onset of a severe 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 LOIS LAWRENCE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LOIS LAWRENCE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff KEVIN SMEDLEY at all times relevant to this action was and is a citizen of the State of Utah, residing in West Jordan. KEVIN SMEDLEY was inoculated with Defendants' ZOSTAVAX vaccine on or about January 7, 2015 at the Davis County Health Services Department, located in Wood Cross, Utah, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as

intended, but rather caused KEVIN SMEDLEY to contract a persistent strain of herpes zoster. On or about August 10, 2015, KEVIN SMEDLEY was treated by Dr. Edward Shultz, M.D. at Granger Medical -Riverton, located in Riverton, Utah for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles. On or about August 17, 2015, KEVIN SMEDLEY received subsequent treatment by Jeremy Gerritsen, D.O. for continuing and worsening symptoms of herpes zoster that had spread to the eye, and was diagnosed as herpes zoster ophthalmicus. On or about August 19, 2015, KEVIN SMEDLEY was treated again by Jeremy P. Gerritsen, O.D. at Granger Medical Clinic for continued shingles in the eyes, with the added optical complications of iritis and ocular hypertension secondary to zoster. KEVIN SMEDLEY has been prescribed Famciclovir, Atopine Sulfate solution, and Prednisolone Acetate Ophthalmic for management of his symptoms and pain. As a direct and proximate result of these malfunctions, Plaintiff KEVIN SMEDLEY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff KEVIN SMEDLEY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff ROYCE KITCHENS at all times relevant to this action was and is a citizen of the State of Georgia, residing in Sugar Hill. ROYCE KITCHENS was inoculated with Defendants' ZOSTAVAX vaccine on or about April 22, 2015, at the Rite Aid Pharmacy located in Sugar Hill, Georgia, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused ROYCE KITCHENS to contract a persistent strain of herpes zoster. On or about October 1,

2015, ROYCE KITCHENS was treated by Dr. Richard Liotta, located in Suwanee, Georgia for the onset of a severe 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 ROYCE KITCHENS suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ROYCE KITCHENS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff VICTOR GARRETT at all times relevant to this action was and is a citizen of the State of Indiana, residing in Indianapolis. VICTOR GARRETT was inoculated with Defendants' ZOSTAVAX vaccine on or about June 9, 2009, administered by Greg Spurgin, M.D. at IU Health Physicians, located in Indianapolis, Indiana, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused VICTOR GARRETT to contract a persistent strain of herpes zoster. On or about November 5, 2012, VICTOR GARRETT was treated by Greg Spurgin, M.D. for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. On or about April 10, 2013, VICTOR GARRETT received subsequent treatment from Greg Spurgin, M.D. for ongoing and worsening symptoms of active problematic herpes zoster. VICTOR GARRETT has been prescribed Valtrex for management of his painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff VICTOR GARRETT suffered painful injuries and damages, and required extensive medical care and treatment. As a further

proximate result, Plaintiff VICTOR GARRETT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff FAYE MOORE at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Frankfurt. FAYE MOORE was inoculated with Defendants' ZOSTAVAX vaccine on or about November 12, 2008 at the Internal Medicine Group, located in Paducah, 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 FAYE MOORE to contract a persistent strain of herpes zoster. On or about December 16, 2011, FAYE MOORE was treated by Dr. Polly Labuhn, M.D. at Internal Medicine Group, located in Paducah, Kentucky for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as herpes zoster, or shingles. Beginning on or about April 9, 2012, FAYE MOORE was treated for a ongoing and worsening outbreak of shingles, which actively manifested continuously until April 27, 2015. FAYE MOORE has suffered exception complications of shingles, including persistent outbreaks for a period of more than three years. FAYE MOORE has been prescribed Valtrex, Voltaren, Tramadol, Lidocaine, and Lipoderm for management of her symptoms and pain. As a direct and proximate result of these malfunctions, Plaintiff FAYE MOORE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff FAYE MOORE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff PAULINE KING at all times relevant to this action was and is a citizen of the State of Kentucky, residing in Crittenden. PAULINE KING was inoculated with

Defendants' ZOSTAVAX vaccine on or about December 3, 2012 at the Total Care Pharmacy #4, located in Crittenden, 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 PAULINE KING to contract a persistent strain of herpes zoster. On or about September 3, 2012, PAULINE KING was treated by Joseph Hartig, M.D. at St. Elizabeth Health Care, located in Fort Mitchell, Kentucky for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. PAULINE KING has been prescribed Valtrex for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff FAYE MOORE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff PAULINE KING has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Plaintiff STANLEY LYLES at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Bolivar. STANLEY LYLES was inoculated with Defendants' ZOSTAVAX vaccine on or about February 1, 2013 at the VA Greater Los Angeles Healthcare System, located in Los Angeles, California, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused STANLEY LYLES to contract a persistent strain of herpes zoster. On or about August 19, 2016, STANLEY LYLES was treated at the Frix Jennings Clinic, located in Boliver, Tennessee for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff STANLEY

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

21. Plaintiff SYLVIA BELLAMY at all times relevant to this action was and is a citizen of the State of Kentucky, residing in the City of Iceland. SYLVIA BELLAMY was inoculated with Defendants' ZOSTAVAX vaccine on or about September 6, 2011 at the Rite Aid Pharmacy, located in Ashland, 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 SYLVIA BELLAMY to contract a persistent strain of herpes zoster. On or about December 29, 2015, SYLVIA BELLAMY was treated by Roland E. Benton, M.D. at Ironton Urgent Care, located in Ironton, Ohio for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. SYLVIA BELLAMY has been prescribed Famvir for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff SYLVIA BELLAMY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SYLVIA BELLAMY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

22. Plaintiff PHYLLIS PIERCE at all times relevant to this action was and is a citizen of State the Kentucky, residing in Hardinsburg. PHYLLIS PIERCE was inoculated with Defendants' ZOSTAVAX vaccine on or about November 20, 2013 at the Breckinridge County Health Department, located in Hardinsburg, 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 PHYLLIS PIERCE to contract a persistent strain of herpes zoster. On or about June 6, 2016, PHYLLIS PIERCE was treated by Dr. Marinette Vanlahr, M.D. for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff PHYLLIS PIERCE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff PHYLLIS PIERCE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

23. Plaintiff DORIS EVERY at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Knoxville. DORIS EVERY was inoculated with Defendants' ZOSTAVAX vaccine on or about September 12, 2012 at the Norwood Family Practice, located in Knoxville, 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 DORIS EVERY to contract a persistent strain of herpes zoster. On or about June 2, 2014, DORIS EVERY was treated by Michael H. West, M.D. at the Norwood Family Medicine practice, located in Knoxville, Tennessee for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff DORIS EVERY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DORIS EVERY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

24. Plaintiff ALLEN R. REEVES at all times relevant to this action was and is a citizen of the State of Louisiana, residing in West Monroe. ALLEN R. REEVES was inoculated with Defendants' ZOSTAVAX vaccine on or about November 20, 2015 at the Walgreens Pharmacy, located in West Monroe, 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 ALLEN R. REEVES to contract a persistent strain of herpes zoster. On or about December 7, 2015, ALLEN R. REEVES was treated by Dr. James Altick, Jr., M.D. for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. ALLEN R. REEVES was prescribed Valaciclovir, Triamcinolone Acetonide for management of his painful condition. As a direct and proximate result of these malfunctions, Plaintiff ALLEN R. REEVES suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ALLEN R. REEVES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

25. Plaintiff RONALD CRABTREE at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Jamestown. RONALD CRABTREE was inoculated with Defendants' ZOSTAVAX vaccine on or about April 25, 2014 at the VA Medical Center Murfreesboro, located in Murfreesboro, 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 RONALD CRABTREE to contract a persistent strain of herpes zoster. During May of 2016, RONALD CRABTREE was treated at the VA Medical Center Mufreesboro for the onset of a severe vesicular rash accompanied by

weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. As a direct and proximate result of these malfunctions, Plaintiff RONALD CRABTREE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RONALD CRABTREE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

26. Plaintiff MARCIA GRIEVES at all times relevant to this action was and is a citizen of the State of Tennessee, residing in Hendersonville. MARCIA GRIEVES was inoculated with Defendants' ZOSTAVAX vaccine on or about June 24, 2011 at the Walgreens Pharmacy, located in Hendersonville, 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 MARCIA GRIEVES to contract a persistent strain of herpes zoster. On or about February 8, 2013, MARCIA GRIEVES was treated at Care-Now Urgent Care clinic for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. MARCIA GREIEVES was referred by the urgent care facility to Dr. Chrystal G. Clamp, M.D. for subsequent treatment of her severe shingles. MARCIA GRIEVES has been prescribed Acyclovir for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff MARCIA GRIEVES suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARCIA GRIEVES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

27. Plaintiff JOHN CAPOBIANCO at all times relevant to this action was and is a citizen of the State of Massachusetts, residing in Haverhill. JOHN CAPOBIANCO was inoculated with Defendants' ZOSTAVAX vaccine on or about October 1, 2011, administered by Michael H. Bresnahan, M.D. at Reading Internal Medicine, located in Reading, Massachusetts, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused JOHN CAPOBIANCO to contract a persistent strain of herpes zoster. On or about November 23, 2013, JOHN CAPOBIANCO was treated by Charles J. Schmitt, M.D. at the Fletcher Allen Walk In Care Center, located in Colchester, Vermont for the onset of a severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as severe herpes zoster, or shingles. On or about October 1, 2015, JOHN CAPOBIANCO was treated by Shahrooz Hekmatpour, M.D. at the Winchester Hospital FMC Urgent Care for recurrent zoster outbreaks that were resistant to antiviral therapies. JOHN CAPOBIANCO has been prescribed Valtrex, Prednisone, Zostrix-HP, and Vicodin for management of his painful condition. As a direct and proximate result of these malfunctions, Plaintiff JOHN CAPOBIANCO suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOHN CAPOBIANCO has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

28. Plaintiff JO-ETTA FOSTER at all times relevant to this action was and is a citizen of the State of Mississippi, residing in Kosciusko. JO-ETTA FOSTER was inoculated with Defendants' ZOSTAVAX vaccine on or about October 5, 2015 at Fred's Pharmacy, located in Kosciusko, Mississippi, as recommended for routine adult health maintenance and

for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused JO-ETTA FOSTER to contract a persistent strain of herpes zoster. On or about July 26, 2016, JO-ETTA FOSTER was treated by John Gray Wallace, M.D. at Premier Medical Group of Koscuisko for a persistent and severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as chronic herpes zoster, or shingles. JO-ETTA FOSTER has been prescribed Acyclovir for management of her painful symptoms. As a direct and proximate result of these malfunctions, Plaintiff JO-ETTA FOSTER suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JO-ETTA FOSTER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

29. Plaintiff KATHLEEN DREW at all times relevant to this action was and is a citizen of the State of Michigan, residing in Comstock Park. KATHLEEN DREW was inoculated with Defendants' ZOSTAVAX vaccine on or about November 5, 2013 at Spectrum Health, located in Rockford, Michigan, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused KATHLEEN DREW to contract a persistent strain of herpes zoster. On or about October 1, 2014, KATHLEEN DREW was treated by Marty J. Mortimer, PA-C at the Spectrum Medical Group for a persistent and severe vesicular rash accompanied by weakened immune symptoms, which was diagnosed as chronic herpes zoster, or shingles and post-herpetic neuralgia. On or about October 15, 2014, KATHLEEN DREW was further treated by Marty J. Mortimer, PA-C for ongoing and worsening symptoms of shingles and post-herpetic neuralgia, a condition of chronic nerve pain and damage secondary to herpes zoster infections.

KATHLEEN DREW has been prescribed Valtrex, Gabapentin, Lidocaine, Lidoderm, Tramadol, and Hydrocodone-Acetaminophen for management of her painful symptoms and chronic pain. As a direct and proximate result of these malfunctions, Plaintiff KATHLEEN DREW suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff KATHLEEN DREW has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

30. At all relevant times to this action, as further detailed herein, Defendants MERCK & CO., MERCK SHARPE & DOHME, AND McKESSON CORP., 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.

31. Defendant Merck & Co. (“Merck”), 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.

32. 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.

33. Defendant McKesson Corporation (hereinafter “McKesson”) is a Delaware Corporation with its principal place of business at 2710 Gateway Oaks Drive, Sacramento, California, 95833. At all relevant times, 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 New Jersey, and regularly, continuously, and presently does business with this State, including manufacturing, marketing, selling and distributing the ZOSTAVAX vaccine. Defendant McKesson had and continues to have substantial contacts with New Jersey, purposefully availed itself of the

privilege of conducting activities and business within the State of New Jersey, derived substantial revenue from its contacts with the State of New Jersey, and its conduct in New Jersey directly relates to Plaintiffs' claim in this action. Plaintiffs' claim arises out of Defendant McKesson's contacts with the State of New Jersey.

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

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

36. 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.

37. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to N.J. R. 4:29-1(a) 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.

38. 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, and McKesson, 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

39. This action is brought by Plaintiffs, each of them resident citizens of the United States of America, pursuant to N.J. R. 4:4-3(a)(1).

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

41. This Court has personal jurisdiction over Defendant McKesson as registered agents of Merck, conducting business in the State of New Jersey, and pursuant to N.J. R. 4:4-4(b)(1)(A).

42. Venue is proper in this Court pursuant to N.J. 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 N.J. 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 throughout the State of New Jersey, including in Middlesex County.

43. 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.

44. Moreover, each Defendant 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, 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.

45. 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 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.

46. 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 and MERCK SHARPE & DOHME, McKESSON CORP.

47. Plaintiffs incorporate by reference all prior allegations.

48. At all times herein mentioned, Defendants Merck, Merck Sharp & Dohme, and McKesson 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.

49. There exists and, at all times herein mentioned, a unity of interest in ownership between Defendants Merck and Merck Sharp & Dohme 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.

50. At all times herein mentioned, Merck, Merck Sharp & Dohme, and McKesson, 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.

51. At all times herein mentioned, the officers and/or directors of Merck and Merck Sharp & Dohme 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.

52. Plaintiffs, would not have an adequate remedy if Defendants Merck Sharp & Dohme and McKesson were not a named parties in this action.

53. Defendant Merck Sharp & Dohme and McKesson 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.

54. 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.

55. 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.

56. 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, and Merck Sharp & Dohme, and each of them.

57. “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 McKesson and DOES 1 through 50, and each of them.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

58. Plaintiffs incorporate by reference all prior allegations.

59. 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.

60. Plaintiffs’ ignorance of the defective and unreasonably dangerous nature of the ZOSTAVAX vaccine and the causal connection between these defects and each Plaintiffs’

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.

61. 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.

62. 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.

63. 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

64. 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.

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

66. Varicella zoster is a virus that causes chickenpox.

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

68. 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.

69. 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.

70. 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.

71. 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.

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

73. 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.”
74. A risk of using a live virus vaccine is that it is not weakened enough or “under-attenuated”.
75. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.
76. 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.
77. Once injected, attenuated live virus has been shown to recombine into more virulent strains causing disease.

78. 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.

79. 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.

80. 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.

81. ZOSTAVAX is a stronger, more potent version of Merck’s chickenpox vaccine, Varivax.

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

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

84. 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.
85. 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.
86. 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.
87. 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 lesions, increased severity of pain and more diffuse involvement.
88. 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.

89. 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.

90. 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.

91. 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.

92. 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.

93. 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 keratitis resulting in vision loss; facial paralysis; pneumonia; brain inflammation (encephalitis); and death.

94. 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.

95. 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, Shingrix 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.

96. In early state testing, Shingrix 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 post-herpetic 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.

97. 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.

98. 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-vaccinate. 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.)

99. 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.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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

106. Plaintiffs incorporate by reference all prior allegations.

107. 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.

108. 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.

109. 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.

110. 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.

111. 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.

112. 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.

113. 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.)

114. Plaintiffs incorporate by reference all prior allegations.

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

116. 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.

117. 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.

118. 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.

119. 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.

120. 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.

121. 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.

122. 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 Plaintiffs and other consumers. Merck is therefore strictly liable for the Plaintiffs' injuries and damages sustained proximately caused by their use of the product.

123. 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.

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

125. 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 III:
PRODUCTS LIABILITY – FAILURE TO WARN
(N.J. Products Liability Act -N.J.S.A. 2A:58C-1)

126. Plaintiffs incorporate by reference all prior allegations.

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

128. 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.

129. 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.

130. 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

131. 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, post-herpetic neuralgia, or other diseases of the nervous system.

132. 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.

133. 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.

134. 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.

135. 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.

136. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert the Plaintiffs and/or their 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.

137. 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.

138. 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 causal relationship need not be proved when revisions to warning labels have been made. (*McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10)

139. 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.

140. 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.

141. 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.”)

142. 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)

143. Plaintiffs used Merck’s ZOSTAVAX vaccine as intended or in a reasonably foreseeable manner.

144. 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.)

145. 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. Moreover Plaintiffs, each of them, were not informed of the risk of contracting shingles, post-herpetic neuralgia, residual nerve pain and damage, or herpetic interference into the eyes, and vision loss. Given the knowledge of such risk, Plaintiffs would not have voluntarily become inoculated with ZOSTAVAX.

146. 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.

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

148. 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.

149. 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.

150. 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.

151. 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.

152. 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.

153. 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.

154. 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 IV:

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))

155. Plaintiffs incorporate by reference all prior allegations.

156. 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.”

157. 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.

158. 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.

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

160. 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.

161. 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.

162. 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 V:
BREACH OF IMPLIED WARRANTY

163. Plaintiffs incorporate by reference all prior allegations.

164. 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.

165. 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.

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

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

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

168. 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.

169. 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.

170. 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.

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

172. 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 Plaintiffs without substantial change in the condition in which it was manufactured and sold.

173. As a foreseeable, direct and proximate result of Merck's acts and omissions and Plaintiffs' 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 VI:
CONSCIOUS MISREPRESENTATION INVOLVING
RISK OF PHYSICAL HARM

174. Plaintiffs incorporate by reference all prior allegations.

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

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

177. 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.

178. 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. 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. Ann Redfield also worked as the "process owner" of Merck's Varicella Zoster Vaccine Identification Program. In this capacity, Ann Redfield drafted documents presented to the Merck employees who interacted directly with healthcare providers who recommend, prescribe, and dispense ZOSTAVAX. In addition, Ann 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, on behalf of Merck, Ann 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, 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.

179. Merck and Defendants 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.

180. Merck 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.

181. The intentional concealment and omissions of material fact concerning the safety of the ZOSTAVAX vaccine was undertaken purposefully, willfully, wantonly, fraudulently by Defendants Merck, 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.

182. 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.

183. 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.

184. 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.

185. 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.

186. 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.

187. 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.

188. 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.

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

190. 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.

191. 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 VII:
NEGLIGENT MISREPRESENTATION INVOLVING
RISK OF PHYSICAL HARM

192. Plaintiffs incorporate by reference all prior allegations.

193. 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.

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

195. 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.

196. 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.

197. 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.

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

199. 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.

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

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

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

203. 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.

204. 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 VIII:
UNJUST ENRICHMENT

205. Plaintiffs incorporate by reference all prior allegations.

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

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

208. Merck has accepted payment by Plaintiffs for the purchase of their product.

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

210. 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 IX:
STRICT LIABILITY

181. 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.

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 their 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.

222. 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 X:
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 Plaintiffs. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly, severally or in the alternative, for compensatory damages, punitive damages and costs of suit as provided by law.

[REDACTED]
[REDACTED]
By: [REDACTED]
[REDACTED]
[REDACTED]

Dated: August 17, 2017

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

[REDACTED]

By: _____

[REDACTED]

Dated: August 17, 2017

DESIGNATION OF TRIAL COUNSEL

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

[REDACTED]
[REDACTED]
By: [REDACTED]
[REDACTED]
[REDACTED]

Dated: August 17, 2017

CERTIFICATION PURSUANT TO RULE 4:5-1

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

[REDACTED]

By: [REDACTED]

Dated: August 17, 2017

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-004929-17

Case Caption: YORCK ANNAMARIE VS MERCK & CO., INC.

Case Type: PRODUCT LIABILITY

Case Initiation Date: 08/17/2017

Document Type: Complaint with Jury Demand

Attorney Name: [REDACTED]

Jury Demand: YES - 12 JURORS

Firm Name: [REDACTED]

Hurricane Sandy related? NO

Is this a professional malpractice case? NO

Related cases pending: YES

If yes, list docket numbers: MID-L-004075-17

Phone:

MID-L-004177-17

Name of Party: PLAINTIFF : YORCK, ANNAMARIE

MID-L-004353-17

Name of Defendant's Primary Insurance Company

MID-L-004457-17.

(if known): None

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)*

08/17/2017

Dated

[REDACTED]

Signed