IN THE CIRCUIT COURT OF THE NINTH JUDICIAL CIRCUIT FOR ORANGE COUNTY, FLORIDA

CIVIL CIRCUIT DIVISION

CASE NO.:

ALICE PEALE, JANETTE HOLMES, JAMES MELTON, DAVID FONTAINE, SHARON MADDOX, JUDY GLADNEY, ANTHONY VESPA, RICHARD ORTIZ, CELESTE JONES, LEONARD REISS, GARRY SCHUEMANN, RICHARD MCDONALD, ROBERT MASUCCI, MARTHA WATSON, RUTH MUZZEY, ANDREA PRESTON, NICHOLAS SPEIDEL, JOYCE STEDMAN. WILLIAM KELSHAW JR., JAMES SANTO, FRANCES LANE, NATALIE ROBINSON, SANDRA SIUDVINSKI, RUTH LINTEAU, JOSI ZENDZIAN, VERNON LEE, JOSEPH YEPEZ, SYLVIA LAGUERRA, CAROL SNYDER, EDNA MIDDLETON, and HELEN OPORTO,

Plaintiffs,

vs.

MERCK & CO., INC., a foreign corporation, MERCK SHARP & DOHME CORP., a foreign corporation; and McKESSON CORP., a foreign corporation,

Defendants.

### **COMPLAINT FOR DAMAGES**

Plaintiffs, ALICE PEALE, JANETTE HOLMES, JAMES MELTON, DAVID FONTAINE, SHARON MADDOX, JUDY GLADNEY, ANTHONY VESPA, RICHARD ORTIZ, CELESTE JONES, LEONARD REISS, GARRY SCHUEMANN, RICHARD

MCDONALD, ROBERT MASUCCI, MARTHA WATSON, RUTH MUZZEY, ANDREA PRESTON, NICHOLAS SPEIDEL, JOYCE STEDMAN, WILLIAM KELSHAW JR., JAMES SANTO, FRANCES LANE, NATALIE ROBINSON, SANDRA SIUDVINSKI, RUTH LINTEAU, JOSI ZENDZIAN, VERNON LEE, JOSEPH YEPEZ, SYLVIA LAGUERRA, CAROL SNYDER, EDNA MIDDLETON, and HELEN OPORTO, by and through their attorneys, MARC J. BERN & PARTNERS LLP, complain and allege against Defendants MERCK & CO., INC., (hereinafter, "Merck"), MERCK SHARP & DOHME, CORP., and McKESSON CORP., and each of them (collectively, "Defendants"), on information and belief, allege as follows:

### **INTRODUCTION**

- 1. Plaintiffs brings this action for personal injuries and damages suffered as a result of being inoculated with the ZOSTAVAX® vaccine.
- 2. The ZOSTAVAX® vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and other zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 3. Plaintiffs were inoculated with the ZOSTAVAX® vaccine for the long-term prevention of shingles and zoster-related injuries. Plaintiffs were diagnosed with shingles and/or other zoster-related injuries after and despite being inoculated with the ZOSTAVAX® vaccine, and suffered serious physical, emotional, and economic damages as a result of their shingles and other zoster-related injuries.

#### **PARTIES**

4. Plaintiff ALICE PEALE at all times relevant to this action was and is a resident of the State of Florida, residing at 7010 Balboa Drive, Apartment 108, Orlando, Florida 32818. On

or about November 22, 2013, ALICE PEALE was inoculated with the ZOSTAVAX vaccine at the Tavares Pharmacy, located in Tavares, Florida, as recommended for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. Upon information and belief, on or about November 22, 2013, Dr. Gretchen San Miguel, M.D., Taveres, Florida recommended, prescribed, and/or administered the ZOSTAVAX vaccine to ALICE PEALE for the intended purpose of the long-term prevention of shingles and zosterrelated injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2013, ALICE PEALE was treated by Dr. Gertrude at 1000 Waterman Way, Suite 331, Taveres, Florida for shingles. In or about 2013 through 2014, ALICE PEALE was treated by various physicians and/or nurses at Mederi Caretenders in Eustis, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff ALICE PEALE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ALICE PEALE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

5. Plaintiff JANETTE HOLMES at all times relevant to this action was and is a resident of the State of Florida, residing at 9745 W. Laurel Oak Lane, Crystal River, Florida 34428. In or about October 2016, JANETTE HOLMES was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located at 310 US-19 in Crystal River, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In or about February 2017, JANETTE HOLMES was treated at Seven Rivers Regional Medical Center in Crystal Rivers, Florida for zoster-related pneumonia. As a direct and proximate result of the

ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JANETTE HOLMES suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JANETTE HOLMES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 6. Plaintiff JAMES MELTON at all times relevant to this action was and is a resident of the State of Florida, residing at 10762 Standing Stone Drive, Wimauma, Florida 33598. In approximately 2015, JAMES MELTON was inoculated with the ZOSTAVAX vaccine at the MacDill Air Force, located in MacDill AFB, Florida, for routine adult health maintenance and the intended purpose for the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended as intended. Later in 2015, JAMES MELTON was treated at Late Hours Urgent Care Center, located in Riverview, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JAMES MELTON suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JAMES MELTON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 7. Plaintiff DAVID FONTAINE at all times relevant to this action was and is a resident of the State of Florida, residing at 2700 Courtland Boulevard, Deltona, Florida 32738. On or about August 18, 2016, DAVID FONTAINE was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Deltona, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. Upon information and belief, on or about August 18, 2016, Dr. Shah, Vaccine MD, located at 7550 West

University Avenue, Gainesville, Florida, recommended and/or administered the ZOSTAVAX vaccine to DAVID FONTAINE for its intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about August 31, 2016, DAVID FONTAINE was treated by Bhanu Visvalingham, M.D., at Mid-Florida Hematology and Oncology in Orange City, Florida, for herpes zoster, or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff DAVID FONTAINE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DAVID FONTAINE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

8. Plaintiff SHARON MADDOX at all times relevant to this action was and is a resident of the State of Florida, residing at 405 E. Damon Street, Apartment 404, Plant City, Florida 33563. In 2012, SHARON MADDOX was inoculated with the ZOSTAVAX vaccine at Watson Clinic, Bella Vista Building, 1755 North Florida Avenue in Lakeland, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about October 19, 2016, SHARON MADDOX was treated at Family Medical Specialists of Florida PLC in Plant City, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff SHARON MADDOX suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SHARON MADDOX has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 9. Plaintiff JUDY GLADNEY at all times relevant to this action was and is a resident of the State of Florida, residing at 20829 Gleneagles Links Drive, Estero, Florida 33928. On or about October 14, 2010, JUDY GLADNEY was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Lawrenceville, Georgia, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. Upon information and belief, on or about October 14, 2010, Dr. Cooper from Take Care Clinic, Hwy 5, in Douglasville, Georgia, recommended and/or administered the ZOSTAVAX vaccine to JUDY GLADNEY for its intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In or about 2013, JUDY GLADNEY was treated at Estero Urgent Care located in Estero, Florida, for a shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JUDY GLADNEY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JUDY GLADNEY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 10. Plaintiff ANTHONY VESPA at all times relevant to this action was and is a resident of the State of Florida, residing at 1305 Tradition Circle, Apartment 101A, Melbourne, Florida 32901. In 2011, ANTHONY VESPA was inoculated with the ZOSTAVAX vaccine at Omni Healthcare, located in Indian Harbour Beach, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about October 25, 2016, ANTHONY VESPA was treated by Joseph J. Chanda, M.D., located in Melbourne, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or

despite receiving ZOSTAVAX for the long-term prevention of shingles and zoster-related injuries, Plaintiff ANTHONY VESPA suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANTHONY VESPA has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 11. Plaintiff RICHARD ORTIZ at all times relevant to this action was and is a resident of the State of Florida, residing at 9446 Bearwalk Path, Weeki Wachee, Florida 34613. On or about February 7, 2015, RICHARD ORTIZ was inoculated with the ZOSTAVAX vaccine at the Publix Super Market, located in Weeki Wachee, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. Upon information and belief, on or about February 7, 2015, Dr. Alvie Craig in Florida recommended, prescribed, and/or administered the ZOSTAVAX vaccine to RICHARD ORTIZ for its intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about October 28, 2016, RICHARD ORTIZ was treated by Walter J. Szydlowski Jr., M.D., located in Brooksville, Florida, for zosterrelated rash. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff RICHARD ORTIZ suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RICHARD ORTIZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 12. Plaintiff CELESTE JONES at all times relevant to this action was and is a resident of the State of Florida, residing at 5499 Bounty Circle, Tavares, Florida 32778. On or about October 17, 2014, CELESTE JONES was inoculated with the ZOSTAVAX vaccine at the CVS

Pharmacy, located inside Target® at 17450 US Highway 441, Mount Dora, Florida, for routine adult health maintenance and the intended purpose for the prevention of shingles. Upon information and belief, on or about October 17, 2014, Dr. Gretchen San Miguel, M.D., Taveres, Florida recommended, prescribed, and/or administered the ZOSTAVAX vaccine to CELESTE JONES for the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about December 18, 2014, through June 2016, CELESTE JONES was treated by Dr. Sampathkumar Shanmugham, M.D., in Eustis, Florida; Central Florida Oral & Maxillofacial Surgery located in Orlando, Florida; and Dr. Gretchen San Miguel and various physicians at Vista Del Sol Adult & Geriatric Medical Associates in Taveres, Florida for zoster-related injuries. CELESTE JONES was treated for zosterrelated blurred vision, shingles, and trigeminal neuralgia syndrome. On or about June 20, 2016, CELESTE JONES underwent surgery for her zoster-related injuries. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff CELESTE JONES suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CELESTE JONES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff LEONARD REISS at all times relevant to this action was and is a resident of the State of Florida, residing at 15304 Walleye Pass, Spring Hill, Florida 34609. On or about September 16, 2014, LEONARD REISS was inoculated with the ZOSTAVAX vaccine at the Publix Pharmacy, located in Spring Hill, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. Upon information and belief, on or about September 16, 2014, Ralph Abi-Nader at the Barclay Crossing Publix

Pharmacy in Spring Hill, Florida prescribed, recommended, and/or administered the ZOSTAVAX vaccine to LEONARD REISS for the intended purpose of long-term prevention of shingles or zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2014, LEONARD REISS was treated by Dr. Leonard Orban at the VA Brooksville Clinic located at 14540 Cortez Blvd, Brooksville, Florida, for shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff LEONARD REISS suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LEONARD REISS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff GARRY SCHUEMANN at all times relevant to this action was and is a resident of the State of Florida, residing at 315 Melrose Place, Naples, Florida 34104. In 2013, GARRY SCHUEMANN was inoculated with the ZOSTAVAX vaccine at the Physicians Regional Hospital, located in Naples, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2015, GARRY SCHUEMANN was treated by the NCH Healthcare System, located in Naples, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff GARRY SCHUEMANN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff GARRY SCHUEMANN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 15. Plaintiff RICHARD MCDONALD at all times relevant to this action was and is a resident of the State of Florida, residing at 2007 Patriot Ridge Road, Jacksonville, Florida 32221. In 2013, RICHARD MCDONALD was inoculated with the ZOSTAVAX vaccine at the Naval Hospital Jacksonville, located in Jacksonville, Florida, as recommended for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2013, RICHARD MCDONALD was treated by the Naval Hospital Jacksonville, located in Jacksonville, Florida, for herpes zoster, or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff RICHARD MCDONALD suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RICHARD MCDONALD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 16. Plaintiff ROBERT MASUCCI at all times relevant to this action was and is a resident of the State of Florida, residing at 15538 Royal Oak Court, Clermont, Florida 34711. On or about February 11, 2016, ROBERT MASUCCI was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy located in Clermont, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. Upon information and belief, in or around February 2016, Dr. C. Davis, M.D., at the Walgreens Pharmacy located at 2590 E. Highway 50, Clermont, Florida 34711 prescribed, recommended, and/or administered the ZOSTAVAX vaccine to ROBERT MASUCCI for the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2016, ROBERT MASUCCI was treated

by the Buswell- Charkow and Wentzell M.D., located in Ocoee, Florida, for shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff ROBERT MASUCCI suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ROBERT MASUCCI has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 17. Plaintiff MARTHA WATSON at all times relevant to this action was and is a resident of the State of Florida, residing at 6710 Heidi Road, Jacksonville, Florida 32277. In 2015, MARTHA WATSON was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Jacksonville, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injurie. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about May 20, 2015, MARTHA WATSON was treated by Brian Granger, D.O., in Jacksonville, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff MARTHA WATSON suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARTHA WATSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 18. Plaintiff RUTH MUZZEY at all times relevant to this action was and is a resident of the State of Florida, residing at 1556 Carmen Avenue, Holly Hill, Florida 32117. On or about October 27, 2011, RUTH MUZZEY was inoculated with the ZOSTAVAX vaccine at the K-Mart Pharmacy, located in Somerville, South Carolina, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine

did not prevent shingles or zoster-related injuries as intended. On or about February 18, 2015, RUTH MUZZEY was treated by Therese Ibrahim, M.D., at MetCare, located in Ormond Beach, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff RUTH MUZZEY suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUTH MUZZEY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 19. Plaintiff ANDREA PRESTON at all times relevant to this action was and is a resident of the State of Florida, residing at 4110 El Camino Real E., Lakeland, Florida 33813. In 2013, ANDREA PRESTON was inoculated with the ZOSTAVAX vaccine at the Rite Aid Pharmacy, located in Charlevoix, Michigan, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2013, ANDREA PRESTON was treated by Roxann C. Cook, D.O., located in Lakeland, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff ANDREA PRESTON suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANDREA PRESTON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 20. Plaintiff NICHOLAS SPEIDEL at all times relevant to this action was and is a resident of the State of Florida, residing at 8516 103<sup>rd</sup> Court, Vero Beach, Florida 32967. In 2014, NICHOLAS SPEIDEL was inoculated with the ZOSTAVAX vaccine at the Treasure Coast

Community Health Facility, located in Fellsmere, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2014, NICHOLAS SPEIDEL was treated by the Sebastian River Medical Center, located in Sebastian, Florida, for symptoms of a blistering vesicular outbreak, which was diagnosed as herpes zoster, or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff NICHOLAS SPEIDEL suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff NICHOLAS SPEIDEL has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

21. Plaintiff JOYCE STEDMAN at all times relevant to this action was and is a resident of the State of Florida, residing at 301 West Platt Street, Tampa, Florida 33609.On or about May 17, 2015, JOYCE A. STEDMAN was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Tampa, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2015, JOYCE STEDMAN was treated by Jorge A. Gaddea, M.D., located in Tampa, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JOYCE STEDMAN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOYCE STEDMAN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 22. Plaintiff WILLIAM KELSHAW JR., at all times relevant to this action was and is a resident of the State of Florida, residing at 6181 Sundown Drive North, Saint Petersburg, Florida 33709. On or about August 22, 2009, WILLIAM KELSHAW JR. was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Saint Petersburg, Florida, as recommended for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about September 24, 2015, WILLIAM KELSHAW JR. was treated by Stephen J. Shields, M.D., located in Clearwater, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff WILLIAM KELSHAW JR. suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM KELSHAW JR. has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 23. Plaintiff JAMES SANTO at all times relevant to this action was and is a resident of the State of Florida, residing at 2583 Spring Meadows Drive, Middleburg, Florida 32068. In 2013, JAMES SANTO was inoculated with the ZOSTAVAX vaccine at the CVS Pharmacy, located in Orange Park, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2014, JAMES SANTO was treated by Jayalakshmi Padmanabhan, M.D., located in Orange Park, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JAMES SANTO suffered painful injuries and damages, and required extensive medical care and treatment.

As a further proximate result, Plaintiff JAMES SANTO has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 24. Plaintiff FRANCES LANE at all times relevant to this action was and is a resident of the State of Florida, residing at 6126 Townsend Road, Lot 39, Jacksonville, Florida 32244. In 2013, FRANCES LANE was inoculated with the ZOSTAVAX vaccine by James Fetchero, D.O., at the Family Medicine Center Argyle in Jacksonville, Florida, for routine adult health maintenance and the intended purpose of the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about August 10, 2015, FRANCES LANE was treated by James Fetchero, D.O., at the Family Medicine Center Argyle located in Jacksonville, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff FRANCES LANE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff FRANCES LANE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 25. Plaintiff NATALIE ROBINSON at all times relevant to this action was and is a resident of the State of Florida, residing at 3611 W. Derry Drive, Sebastian, Florida 32958. In 2015, NATALIE ROBINSON was inoculated with the ZOSTAVAX vaccine at the Publix Pharmacy in the Riverwalk Shopping Center, located in Sebastian, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2015, NATALIE ROBINSON was treated by Edgar R. Blecker, M.D., located in Sebastian, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or

despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff NATALIE ROBINSON suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff NATALIE ROBINSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 26. Plaintiff SANDRA SIUDVINSKI at all times relevant to this action was and is a resident of the State of Florida, residing at 512 Fox Run Trail, Apollo Beach, Florida 33572. In 2015, SANDRA SIUDVINSKI was inoculated with the ZOSTAVAX vaccine at the Winn-Dixie Pharmacy, located in Apollo Beach, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. Later in 2015, SANDRA SIUDVINSKI was treated by Christopher Blazejowski, M.D., located in Tampa, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff SANDRA SIUDVINSKI suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SANDRA SIUDVINSKI has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 27. Plaintiff RUTH LINTEAU at all times relevant to this action was and is a resident of the State of Florida, residing at 510 Estero Boulevard, Fort Myers Beach, Florida 339311. On or about September 15, 2014, RUTH LINTEAU was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Naples, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2015, RUTH LINTEAU was treated

by Robert Pritt, D.O, located in Fort Myers, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff RUTH LINTEAU suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUTH LINTEAU has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 28. Plaintiff JOSI ZENDZIAN at all times relevant to this action was and is a resident of the State of Florida, residing at 1005 South Bay Shore Boulevard, Unit 107, Safety Harbor, Florida 34695. In 2012, JOSI ZENDZIAN was inoculated with the ZOSTAVAX vaccine at the University of Connecticut Hospital, located in Farmington, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2014, JOSI ZENDZIAN was treated by El-Alami Othman, M.D., located in Kensington, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JOSI ZENDZIAN suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOSI ZENDZIAN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 29. Plaintiff VERNON LEE at all times relevant to this action was and is a resident of the State of Florida, residing at 4018 Via Mirada, Sarasota, Florida 34238. On or about August 28, 2012, VERNON LEE was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Sarasota, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or

zoster-related injuries as intended. In 2014, VERNON LEE was treated by George E. Mansour, M.D., located in Sarasota, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff VERNON LEE suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VERNON LEE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 30. Plaintiff JOSEPH YEPEZ at all times relevant to this action was and is a resident of the State of Florida, residing at 11718 South West 72<sup>nd</sup> Circle, Ocala, Florida 34476. On or about October 21, 2015, JOSEPH YEPEZ was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Ocala, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2016, JOSEPH YEPEZ was treated at Baptist Hospital, located in Miami, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff JOSEPH YEPEZ suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOSEPH YEPEZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 31. Plaintiff SYLVIA LAGUERRA at all times relevant to this action was and is a resident of the State of Florida, residing at 1302 Lake Lucerne Way, Number 104, Brandon, Florida 33511. In 2015, SYLVIA LAGUERRA was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Brandon, Florida, for routine adult health maintenance and the

intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2015, SYLVIA LAGUERRA was treated by Victor Zampano, M.D., in Brandon, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff SYLVIA LAGUERRA suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SYLVIA LAGUERRA has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 32. Plaintiff CAROL SNYDER at all times relevant to this action was and is a resident of the State of Florida, residing at 8300 Seminole Boulevard, Lot 346, Seminole, Florida 33772. On or about September 16, 2012, CAROL SNYDER was inoculated with the ZOSTAVAX vaccine at the Walgreens Pharmacy, located in Seminole, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. On or about June 30, 2014, CAROL SNYDER was treated by Bruce Smith, M.D., located in Seminole, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff CAROL SNYDER suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CAROL SNYDER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.
- 33. Plaintiff EDNA MIDDLETON at all times relevant to this action was and is a resident of the State of Florida, residing at 944 Reynolds Road, Lot 53, Lakeland, Florida 33801. On or about October 18, 2013, EDNA MIDDLETON was inoculated with the ZOSTAVAX

vaccine at the North County Dermatology Clinic, located in Lakeland, Florida, for routine adult health maintenance and the intended purpose of long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2016, EDNA MIDDLETON was treated at the North County Dermatology Clinic, located in Lakeland, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff EDNA MIDDLETON suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff EDNA MIDDLETON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

34. Plaintiff HELEN OPORTO at all times relevant to this action was and is a resident of the State of Florida, residing at 4375 South East 107th Lane, Belleview, Florida 34420. In 2015, HELEN OPORTO was inoculated with the ZOSTAVAX vaccine by Glen Morgan, M.D., at The Villages Health Mulberry Grove Care Center located in The Villages, Florida, for routine adult health maintenance and the intended purpose for the long-term prevention of shingles and zoster-related injuries. The vaccine did not prevent shingles or zoster-related injuries as intended. In 2016, HELEN OPORTO was treated by Glen Morgan, M.D., at The Villages Health Mulberry Grove Care Center located in The Villages, Florida, for herpes zoster or shingles. As a direct and proximate result of the ZOSTAVAX vaccine, and/or despite receiving ZOSTAVAX for long-term prevention of shingles and zoster-related injuries, Plaintiff HELEN OPORTO suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff HELEN OPORTO has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

- 35. At all relevant times to this action, as further detailed herein, Defendants 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 Florida, 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 Florida.
- 36. Defendant Merck & Co., Inc. ("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 07033.
- 37. Defendant Merck Sharp & Dohme Corp. ("MSD"), is a New Jersey company that is a wholly-owned subsidiary of Merck and part of the Merck family of companies. MSD is a corporation organized and existing under the laws of the State of New Jersey with its headquarters located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. MSD is foreign corporation registered to conduct business in Florida and can be served via its registered agent CT Corporation System, 1200 S. Pine Island Road, Plantation, Florida 33324
- 38. Defendant McKesson Corp. ("McKesson") is a Delaware Corporation with its principal place of business at 2710 Gateway Oaks Boulevard, Sacramento, California, 95833. McKesson is foreign corporation registered to conduct business in Florida and can be served via its registered agent The Prentice Hall Corporation System, Inc., 1201 Hays Street, Suite 105, Tallahassee, Florida 32301.

### **JURISDICTION AND VENUE**

- 39. This is an action for damages in excess of \$15,000.00, excluding interest, costs, and attorneys' fees.
- 40. This Court has personal jurisdiction over Plaintiffs, each as parties to this action and residents of the State of Florida.
- 41. This Court has personal jurisdiction over Defendants pursuant to Fla. Stat. § 48.193. Defendants caused injury to Plaintiffs within the State of Florida arising out of an act or omission by the Defendants inside this state and outside this state.
  - 42. Each Defendant was engaged in solicitation or service activities within this state.
- 43. At all relevant times, products, materials, or things processed, distributed, marketed, serviced, or manufactured by each named Defendant anywhere were used or consumed within this State in the ordinary course of commerce, trade, or use.
- 44. Venue is proper in this Court because venue is deemed proper in the Circuit Court in the county in which cause of action arose, or where any party to the action resides. The actions alleged herein took part in Florida. Further, a substantial amount of the Defendants' conduct, as alleged herein by Plaintiffs, took place throughout the State of Florida, including within Orange County.
- 45. Requiring Defendants to litigate these claims in Florida does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.
- 46. Moreover, each Defendant systematically availed themselves of the State of Florida by conducting regular and sustained business and engaging in substantial commerce and business activity in Florida, 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 Florida, either directly or indirectly, its products, including ZOSTAVAX vaccine.

- 47. 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 Florida; 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.
- 48. Each of the above-named Plaintiffs' claims arise from and relate to Defendants' purposeful avail of the State of Florida 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 Florida. Therefore, the claims of Plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of Florida. Further and independently, McKesson Corporation consented to jurisdiction in the State of Florida by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.
- 49. 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.

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

# ALTER-EGO LIABILITY, VICARIOUS AND SUCCESSOR LIABILITY, AND PIERCING THE CORPORATE VEIL AS A RESULT OF THE RELATIONSHIPS BETWEEN MERCK, MSD, AND McKESSON

- 51. At all relevant times, Merck, MSD, 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 would foreseeably cause harm to the Plaintiffs.
- 52. At all relevant times, Merck, MSD, and McKesson 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 Defendants is individually, as well as jointly and severally, liable to Plaintiffs for their damages.
- 53. Plaintiffs would not have an adequate remedy if Merck, MSD, and McKesson were not named parties in this action.
- 54. A unity of interest in ownership between Merck and MSD exists or existed at all relevant times, such that any individuality and separateness between Merck and MSD has ceased

and Merck and MSD are alter-egos of the other. Adherence to the fiction of the separate existence of Merck and MSD as entities distinct from each other will permit an abuse of corporate privilege and would sanction a fraud and/or promote injustice. Sufficient grounds exist to disregard the corporate form and extend liability to MSD and Merck for the other's acts through piercing the corporate veil.

- 55. MSD and Merck exercised, and continues to exercise, complete and domination of the finances, policy, and business practices regarding the ZOSTAVAX vaccine of McKesson to such an extent that McKesson has no separate minds, wills or existences of its own.
- 56. The aforesaid control was used by Merck and/or MSD 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, and Plaintiffs' health care providers and pharmacists.
- 57. McKesson exercised, and continues to exercise, complete control, and/or equal participation in the policy and business practices of Merck and/or MSD regarding the production, promotion, packaging, advertising, distribution, and selling of the ZOSTAVAX vaccine to such an extent that Merck, MSD, and McKesson have no separate mind, will or own existence in this regard.
- 58. McKesson used its aforesaid control over Merck and MSD, acting as an agent of Merck, to research, process, assemble, inspect, distribute, market, label, promote, package, advertise, and/or sell the ZOSTAVAX vaccine for use by consumers like Plaintiffs, their health care providers, and their pharmacists.

- 59. McKesson, individually and as Merck's agent, developed and implemented the marketing strategy to promote and sell and distribute the ZOSTAVAX vaccine nationwide, including in Florida.
- 60. McKesson developed the "Vaccine Information Statement" for the ZOSTAVAX vaccine with Merck, and published and disseminated the ZOSTAVAX "Vaccine Information Statement" nationwide, including in Florida.
- 61. Merck and/or MSD impliedly and explicitly consented to have McKesson act on Merck and/or MSD's behalf with regard to the creation, implementation, marketing, distribution, and wide dissemination of the marketing materials for the ZOSTAVAX vaccine and the product itself nationwide, including in Florida.
- 62. Merck and MSD manifested McKesson's authority to act on their behalf by allowing McKesson to create, develop, and implement the marketing strategy and campaign for the ZOSTAVAX vaccine.
- 63. Merck and MSD manifested McKesson's authority to act on their behalf by allowing McKesson to develop, publish, and disseminate the "Vaccine Information Statement" for the ZOSTAVAX vaccine, and/or to develop, publish, and disseminate marketing and promotional materials for the ZOSTAVAX vaccine.
- 64. McKesson, Merck, and MSD are liable for all acts and omissions made by each other because of their alter-ego, business partner, or agency relationship.
- 65. "Merck" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors-in-interest including but not limited to Schering-Plough Corporation, successors, assigns, officers, directors, employees, agents and representatives of Merck, MSD, and each of them.

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

### ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

- 68. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs, and their healthcare professionals, did not discover, and could not reasonably discover, the defects and unreasonably dangerous propensities of the ZOSTAVAX vaccine.
- 69. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the ZOSTAVAX vaccine and the causal connection between these defects and Plaintiffs' injuries and damages, is due 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.
- 70. Defendants' acts and omissions include intentional concealment from Plaintiffs, prescribing healthcare professionals, pharmacists, and the general consuming public and the FDA of material information that the ZOSTAVAX vaccine had not been demonstrated to be safe or effective for its intended purpose.
- 71. Defendants are estopped from relying on any statutes of limitation or repose by unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

### **COUNT I: NEGLIGENCE**

- 72. Herpes zoster, or shingles, is caused by the varicella zoster virus (VZV). The incidence and severity of shingles increases as people age.
- 73. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox.
- 74. The ZOSTAVAX vaccine was designed, developed, marketed, and sold with the intended purpose of long-term prevention of shingles.
- 75. At all relevant times, Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the ZOSTAVAX vaccine.
- 76. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 77. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 78. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 79. Merck had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiffs, to manufacture to design, manufacture, process, package, label, market, promote, distribute, and sell a product that was safe and effective for its normal, common, and intended purpose.
- 80. MSD had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiffs, to manufacture to design, manufacture, process, package, label,

market, promote, distribute, and sell a product that was safe and effective for its normal, common, and intended purpose.

- 81. McKesson had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiffs, to package, label, market, promote, distribute, and sell a product that was safe and effective for its normal, common, and intended purpose.
- 82. Merck, MSD, and McKesson each directly advertised or marketed the ZOSTAVAX vaccine to consumers or persons responsible for consumers, and therefore each Defendant had a duty to warn of the risks associated with the use of the product.
- 83. Merck, MSD, and McKesson each had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiffs, and the prescribers and/or administrators of the ZOSTAVAX vaccine, including Plaintiffs' physicians and healthcare providers, to disclose or warn about unreasonable dangers in the contemplated use of the product.
- 84. Merck, MSD, and McKesson each had a duty of reasonable care to consumers of the ZOSTAVAX vaccine, which includes the Plaintiffs, and the prescribers and/or administrators of the ZOSTAVAX vaccine, including Plaintiffs' physicians and healthcare providers, to disclose or warn about any of the product's inherently dangerous propensities that are not obvious.
  - 85. Varicella zoster is a virus that causes chickenpox.
- 86. Once the varicella zoster virus causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.
- 87. 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.

- 88. 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.
- 89. The ZOSTAVAX vaccine is a stronger, more potent version of the Varivax® vaccine, which is a varicella live-attenuated virus vaccine intended to prevent chicken pox in individuals 12 months of age or older.
- 90. The ZOSTAVAX vaccine 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.
- 91. The ZOSTAVAX vaccine is developed from a live-attenuated version of the Oka/Merck VZV vaccine strain.
- 92. A risk of using a live-attenuated virus vaccine is that it is not weakened enough or "under- attenuated".
- 93. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.
  - 94. Under-attenuated live VZV has been shown to reactivate.<sup>1</sup>
- 95. Once injected, attenuated live virus vaccines have been shown to recombine into more virulent strains causing disease.
- 96. 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.

<sup>&</sup>lt;sup>1</sup> 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.

- 97. 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.
- 98. 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."<sup>2</sup>
- 99. FDA approval of the ZOSTAVAX vaccine was based in large part on the results of the Shingles Prevention Study ("SPS") supported by Merck and/or MSD.
- 100. 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 Post-herpetic Neuralgia in Older Adults". *N. Engl. J. Med.* 2005; 352(22):2271-84.
- 101. The approval granted by the FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that Merck and/or MSD agreed to complete, among other things, to insure the safety of the ZOSTAVAX 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.
- 102. Since ZOSTAVAX's introduction in 2006, a significant number of various adverse effects, including but not limited to shingles, viral infection resulting in disease of the central nervous system, and death were reported to Merck and MSD during the post-marketing commitments made by Merck and MSD for the FDA approval of ZOSTAVAX in 2006.

31

<sup>&</sup>lt;sup>2</sup> FDA Approval Letter, May 25, 2006.

- 103. 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").
- 104. Since ZOSTAVAX's introduction in 2006, VAERS regarding the ZOSTAVAX vaccine appeared in significant numbers addressing various adverse effects, including, but not limited to, shingles, viral infection resulting in disease of the central nervous system including but not limited to acute disseminated encephalomyelitis and post-herpetic neuralgia, and death.
- 105. As of September 2015, VAERS received 1,111 submissions of serious adverse event reports regarding the ZOSTAVAX vaccine, which included reports 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.
- 106. Other than post-herpetic 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.
- 107. Despite having knowledge of this information, and that correlation exists between being administered the ZOSTAVAX vaccine and developing a viral infection leading to the development of shingles or varicella-zoster related injuries within a relatively short period of time, Defendants failed to provide this information both to patients and the medical providers prescribing the vaccine.
- 108. At all relevant times, the ZOSTAVAX vaccine's patient information sheet, its label, and its prescribing information did not adequately address the risk of viral infection or possible diseases of the nervous system associated with the use of the product.

- 109. The ZOSTAVAX vaccine's patient information sheet only addressed the concern that a rash and itching might develop at the injection site.
- 110. The ZOSTAVAX vaccine's patient information sheet failed to notify its readers that shingles was a noted occurrence during the product's clinical trials.
- 111. When Plaintiffs were inoculated with ZOSTAVAX, the patient information sheet, label, and prescribing information distributed with the ZOSTAVAX vaccine lacked an adequate and conspicuous reference to the potential risk of viral infection.
- 112. 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.
- 113. The ZOSTAVAX vaccine's patient information sheet, label, and prescribing information does not adequately notify its readers or users of the known risk of interactions between ZOSTAVAX and other common vaccinations, such as the Flumist influenza vaccination.
- 114. Reasonably prudent manufacturers, distributors, suppliers, and/or sellers would not have placed the ZOSTAVAX vaccine in the stream of commerce with knowledge of its inherent, hidden, and unreasonably dangerous risks.
- 115. Reasonably prudent manufacturers, distributors, suppliers, and/or sellers would not have placed the ZOSTAVAX vaccine in the stream of commerce without adequate warnings or disclosures of its inherent, hidden, and unreasonably dangerous risks.

- 116. Merck, MSD, and McKesson 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 and MSD knew, or should have known, that the ZOSTAVAX vaccine carried the serious risk of causing viral infection and was therefore not unreasonably dangerous to its consumers.
- 117. Merck, MSD, and McKesson 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, MSD, and McKesson knew, or should have known, that the ZOSTAVAX vaccine was not effective for long-term prevention of shingles in adults over 60 years of age.
- 118. Merck, MSD, and McKesson failed to issue to consumers and/or their healthcare providers adequate warnings or disclosures, through labels or other means, regarding the risks of serious bodily injury, including viral infection, resulting from use of the ZOSTAVAX vaccine. Merck, MSD, and McKesson's failure was a breach of their duty of reasonable care.
- 119. Merck, MSD, and McKesson failed to issue to consumers and/or their healthcare providers adequate warnings or disclosures, through labels or other means, regarding the actual efficacy of the ZOSTAVAX vaccine and the actual risks and benefits of the product. Merck, MSD, and McKesson's failure were a breach of each of their duty of reasonable care.
- 120. The ZOSTAVAX vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck, MSD, and McKesson was unreasonably and inherently dangerous due the risks associated with its use, was more dangerous than expected by the ordinary consumer, and those dangers were not known or obvious to any

other party except Defendants (each of them). Merck, MSD, and McKesson breached their duty of reasonable care by selling the unreasonably dangerous ZOSTAVAX vaccine.

- 121. Merck and MSD continued to manufacture, market, and sell the ZOSTAVAX vaccine despite the knowledge, whether direct or ascertained with reasonable care, that ZOSTAVAX posed a serious risk of bodily harm to consumers.
- 122. Merck and MSD continued to manufacture, market, and sell the ZOSTAVAX vaccine despite the knowledge that its efficacy waned significantly over time, and was effectively worthless after seven years post-inoculation.
- 123. McKesson continued to label, package, market, promote, distribute, and sell the ZOSTAVAX vaccine without adequate instructions or warnings despite the knowledge, whether direct or ascertained with reasonable care, that ZOSTAVAX posed a serious risk of bodily harm to consumers.
- 124. Merck, MSD, and McKesson breached their duty of reasonable care by continuing to sell the unreasonably dangerous ZOSTAVAX vaccine without adequate disclosures despite having actual or constructive knowledge of its associated risks and lack of efficacy.
- 125. Merck, MSD, and McKesson had a continuing duty to warn consumers of the ZOSTAVAX vaccine, including the Plaintiffs, of the dangers associated with the product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of the product, each Defendant breached its duty.
- 126. Plaintiffs each suffered from shingles, with painful and persistent physical injuries and damages, and other serious injuries despite being inoculated with the ZOSTAVAX vaccine.

- 127. Plaintiffs each suffered from shingles, with painful and persistent physical injuries and damages, and other serious injuries as a direct and proximate result of being inoculated with the ZOSTAVAX vaccine.
- 128. As a direct and proximate result of the breach of care by Merck, MSD, and McKesson, Plaintiffs suffered severe and permanent personal injuries, including significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.
- 129. As a direct and proximate result of the breach of care by Merck, MSD, and McKesson, Plaintiffs suffered, are suffering, and/or will continue to suffer from mental and emotional distress due to resulting physical limitations and seriousness of their physical conditions.
- 130. As a direct and proximate result of the breach of care by Merck, MSD, and McKesson, Plaintiffs incurred and will incur medical expenses and other economic harm.

## COUNT II: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

- 131. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 132. At all relevant times, as set forth, 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.

- 133. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 134. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 135. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 136. At all relevant times, Defendants, each of them, placed the ZOSTAVAX vaccine into the stream of commerce with full knowledge that it would reach consumers such as Plaintiff who would become inoculated with the vaccine.
- 137. The ZOSTAVAX vaccine was expected to, and did, reach the intended consumers, handlers, and persons administering the product with no substantial change in the condition in which the product was designed, produced, and manufactured by Merck and MSD and sold, distributed, labeled, and marketed by Merck, MSD, and McKesson.
- 138. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson was defective in design and formulation because when it left the hands of Merck, MSD, and McKesson, the product was unreasonably dangerous.
- 139. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson, was defective in design and formulation, because when it left the hands of Merck, MSD, and McKesson, the product was more dangerous than expected by the ordinary consumer.
- 140. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson, was

defective in design and formulation, because when it left the hands of Merck, MSD, and McKesson, the product's inherent dangers were not known or obvious to any other party except Defendants (each of them).

- 141. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson, was defective in design and formulation because when it left the hands of Merck, MSD, and McKesson, the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.
- 142. At all relevant times, Merck, MSD, and McKesson knew and had reason to know that the ZOSTAVAX vaccine was inherently defective and unreasonably dangerous as designed and formulated by Merck and MSD, and when used and administered in the form sold, distributed, and supplied by Merck, MSD, and McKesson, and in the manner instructed by Merck, MSD, and McKesson to be used and administered to the Plaintiffs and other consumers.
- 143. Merck, as a leading designer, manufacturer, marketer, and distributor of pharmaceutical products, knew or should have known of a safer alternative vaccine for shingles prevention, in the form of a non-live or inactivated vaccine strain that carries no change of inducing the condition it was intended to prevent.
- 144. MSD, as a leading designer and manufacturer of pharmaceutical products, knew or should have known of a safer alternative vaccine for shingles prevention, in the form of a non-live or inactivated vaccine strain that carries no change of inducing the condition it was intended to prevent.
- 145. McKesson as a leading manufacturer, marketer, distributor, and seller of pharmaceutical products, and specifically a leading marketer, distributor of the ZOSTAVAX vaccine, knew or should have known of a safer alternative vaccine for shingles prevention, in the

form of a non-live or inactivated vaccine strain that carries no change of inducing the condition it was intended to prevent.

- 146. Merck and MSD had knowledge of a non-live vaccine during the time that each Plaintiff learned of and purchased ZOSTAVAX, at the time when each Plaintiff was administered the ZOSTAVAX vaccine. Merck was owner of the patent of a non-live alternative, but let the non-live vaccine patent lapse, and chose rather to continue utilizing the recycled Oka vaccine strain (as already used in Merck's pre-existing "Varivax" vaccine, amplified by fourteen-times in strength for zoster prevention).
- 147. Unlike the live-attenuated vaccine, ZOSTAVAX, protein-based vaccine alternatives are safe and effective even in immunocompromised patients. Non-live vaccines carry no risk of reactivation inducing shingles after inoculation.
- 148. Unlike ZOSTAVAX, non-live vaccines maintain efficacy, with 88% lower risk to develop shingles after four years than ZOSTAVAX, which diminishes in efficacy steadily with time (to zero after four years).
- 149. Merck, MSD, and McKesson knew, or should have known, that the pharmaceutical efficacy and overall safety and benefit of a protein-based vaccine is a safer alternative to the ZOSTAVAX vaccine.
- 150. 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. The risks or alternatives were scientifically discoverable in the context of the state-of-the-art defense.

- 151. An alternative design of the ZOSTAVAX vaccine, such as an inactivated, non-live, or protein-based vaccine, would have eliminated the possibility of inducing shingles, and would have prevented the injury suffered by Plaintiffs.
- 152. Merck knew or should have known that there were widely-publicized and economically feasible methods to "de-activate" the ZOSTAVAX vaccine strain, for example using heat or gamma-radiation, to eliminate the possibility of re-activating the virus upon being inoculated, as occurred in Plaintiffs.
- 153. MSD knew or should have known that there were widely-publicized and economically feasible methods to "de-activate" the ZOSTAVAX vaccine strain, for example using heat or gamma-radiation, to eliminate the possibility of re-activating the virus upon being inoculated, as occurred in Plaintiffs.
- 154. McKesson knew or should have known that there were widely-publicized and economically feasible methods to "de-activate" the ZOSTAVAX vaccine strain, for example using heat or gamma-radiation, to eliminate the possibility of re-activating the virus upon being inoculated, as occurred in Plaintiffs.
- 155. 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).
- 156. The ZOSTAVAX vaccine's instructions, labeling, and packaging did not alert potential ZOSTAVAX vaccine consumers or administrators or prescribers of the product of its decreased efficacy over time.

- 157. The instructions and information published by Merck, MSD, and McKesson regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccine.
- 158. It was reasonably foreseeable that consumers of the ZOSTAVAX vaccine, including Plaintiffs, would contract the vaccine-strain of herpes zoster, after being inoculated with the ZOSTAVAX vaccine that was intended to prevent this condition.
- 159. Merck knew, or should have known, that consumers, such as the Plaintiffs, would foreseeably suffer injury because of the design and/or manufacture of the ZOSTAVAX vaccine.
- 160. MSD knew, or should have known, that consumers, such as the Plaintiffs, would foreseeably suffer injury because of the design and/or manufacture of the ZOSTAVAX vaccine.
- 161. McKesson knew, or should have known, that consumers, such as Plaintiffs, to whom it marketed and distributed the ZOSTAVAX vaccine, would suffer serious injury because of the design and/or manufacture of the ZOSTAVAX vaccine.
- 162. Plaintiffs' physicians and/or healthcare providers used and administered the ZOSTAVAX vaccine for the purpose intended by Merck, MSD, and McKesson, and in a manner normally intended to be used and administered, namely for long-term prevention against shingles.
- 163. Plaintiffs could not, by the exercise of reasonable care, discover the defective condition of the ZOSTAVAX vaccine and/or perceive its defective dangers prior to its administration by their physicians and/or healthcare providers.
  - 164. Plaintiffs were each inoculated with the ZOSTAVAX® vaccine for its purpose.
- 165. Plaintiffs, their physicians, and their pharmacists used the ZOSTAVAX vaccine in the manner in which it was intended.
  - 166. The ZOSTAVAX® vaccine did not serve its intended purpose.

167. As a direct and proximate result of the ZOSTAVAX vaccine's defective design, 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 III: STRICT PRODUCTS LIABILITY: FAILURE TO WARN**

- 168. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 169. At all relevant times, as set forth, 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.
- 170. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 171. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 172. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 173. Merck, as a manufacturer, marketer, and distributor of pharmaceutical products, is held to the level of knowledge of an expert in the field. At all relevant times, Merck had knowledge

of the dangerous risks and side effects of the ZOSTAVAX vaccine. At all relevant times, Merck had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.

- 174. MSD, as a designer and manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field. At all relevant times, MSD had knowledge of the dangerous risks and side effects of the ZOSTAVAX vaccine. At all relevant times, MSD had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.
- 175. McKesson, as a leading manufacturer, marketer, and distributer of pharmaceutical products, and specifically a leading marketer and distributor of the ZOSTAVAX vaccine at all relevant times is held to the level of knowledge of an expert in the field. At all relevant times, McKesson had knowledge of the dangerous risks and side effects, and of the waning efficacy, of the product.
- 176. Plaintiffs did not have the same knowledge as Defendants and no adequate warning was communicated to their respective physicians and/or healthcare providers.
- 177. At all relevant times, Defendants, each of them, placed the ZOSTAVAX vaccine into the stream of commerce with full knowledge that it would reach consumers such as Plaintiffs who would become inoculated with the vaccine.
- 178. The ZOSTAVAX vaccine was under the exclusive control of Merck, MSD, and McKesson.
- 179. The ZOSTAVAX vaccine was defective when it left the possession of Merck, MSD, and McKesson, in that it contained inadequate warnings and instructions to alert the Plaintiffs and/or Plaintiffs' healthcare providers that the ZOSTAVAX vaccine created a risk of serious and dangerous side effects, including but not limited to viral infection resulting in shingles.

- 180. The ZOSTAVAX vaccine was defective when it left the possession of Merck, MSD, and McKesson, in that it contained insufficient warnings or disclosure to alert the Plaintiffs and/or Plaintiffs' healthcare providers to the actual efficacy of the product over time.
- 181. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson was defective because when it left the hands of Merck, MSD, and McKesson, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer, and those dangers were not known or obvious to any other party except Defendants (each of them).
- 182. The ZOSTAVAX vaccine, as designed, produced, and manufactured by Merck and MSD and as sold, distributed, labeled, and marketed by Merck, MSD, and McKesson, was defective due to inadequate warnings or instructions regarding the inherent, hidden, and unreasonable dangers of the product.
- 183. 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 sold by Merck, MSD, and McKesson.
- 184. The risk of inducing shingles was a side-effect that was reasonably foreseeable to Defendants, each of them.
- 185. The risk of inducing shingles, the very condition ZOSTAVAX was intended to prevent, was a risk that was not obvious to a consumer of the vaccine, such as Plaintiffs, or a prescriber or administrator of the vaccine following the indications of the label, prescribing instructions, or instructions for use.

- 186. When Plaintiffs were each vaccinated with ZOSTAVAX at the doctors' offices and pharmacies, listed *infra*, the ZOSTAVAX vaccine lacked adequate and conspicuous warning that that the live vaccine could re-activate a serious strain of the herpes zoster virus.
- 187. The waning efficacy of the ZOSTAVAX vaccine over after inoculation, to effectively zero after four years, is not obvious to a consumer of the vaccine, such as Plaintiffs, or a prescriber or administrator of the vaccine following the indications of the label, prescribing instructions, or instructions for use.
- 188. Patients who received the ZOSTAVAX vaccine do so with the intention to have long-term protection from herpes zoster.
- 189. Even upon perfect use, the efficacy of the vaccine will decrease significantly after four years. Merck, MSD, and McKesson each knew the rate at which the ZOSTAVAX vaccine's efficacy declined.
- 190. The CDC published that the ZOSTAVAX vaccine wanes significantly in efficacy within five years, having almost no remaining preventative effects after seven years. This information is not included on any labeling or packaging literature to alert potential ZOSTAVAX vaccine consumers or administers or prescribers of its decreased efficacy over time.
- 191. The instructions and information published and provided by Merck, MSD, and McKesson regarding the ZOSTAVAX vaccine indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccine.
- 192. When Plaintiffs were each vaccinated with ZOSTAVAX on the respective dates and at the facilities, named *infra*, the ZOSTAVAX vaccine lacked adequate and conspicuous warning or disclosures that the efficacy rate of the ZOSTAVAX vaccine would be effectively zero after four years.

- 193. If the Plaintiffs were equipped with the knowledge of the unreasonably dangerous risks associated with the ZOSTAVAX vaccine, Plaintiffs would not have purchased it and agreed to have it injected into their bodies.
- 194. If the Plaintiffs' physicians, pharmacists, or healthcare providers were equipped with the unreasonably dangerous risks associated with the ZOSTAVAX vaccine, they would not have recommended, prescribed, purchased, or administered it to the Plaintiffs.
- 195. If the Plaintiffs were equipped with the knowledge of the efficacy of the ZOSTAVAX vaccine over time, including the rate at which its efficacy wanes, Plaintiffs would not have purchased it and agreed to have it injected into their body.
- 196. If the Plaintiffs' physicians, pharmacists, or healthcare providers were equipped with the knowledge of the efficacy of the ZOSTAVAX vaccine over time, including the rate at which its efficacy wanes, they would not have recommended, prescribed, purchased, or administered it to the Plaintiffs.
- 197. When Plaintiffs were vaccinated with ZOSTAVAX, the ZOSTAVAX vaccine was administered and used as intended.
- 198. Upon information and belief, the ZOSTAVAX vaccine as manufactured by Merck and/or MSD, and marketed, distributed, and sold by Merck, MSD, and McKesson, was further defective due to inadequate post-market warnings or instructions.
- 199. As a proximate result of the ZOSTAVAX vaccine's defectiveness through inadequate warnings, and the Plaintiffs' use of the defective product, Plaintiffs suffered serious physical injuries including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, diminished quality of life, and incurred medical bills and other expenses, and other losses and damages.

## **COUNT IV: BREACH OF EXPRESS WARRANTY**

- 200. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 201. At all relevant times, as set forth, 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.
- 202. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 203. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 204. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 205. Merck, through its officers, directors, agents (including distributer McKesson), representatives, and written literature and packaging, and written and media advertisements, expressly warranted that the 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.

- 206. Merck, MSD, and McKesson, through their officers, directors, agents, representatives, and through 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.
  - 207. Merck warrantied that "...the vaccine did not cause or induce herpes zoster."
  - 208. MSD warrantied that "...the vaccine did not cause or induce herpes zoster."
- 209. Additionally, Merck, MSD, and McKesson, each of them, through their officers, directors, agents, representatives, and through written literature and packaging, and written and media advertisements, represented that:
  - a. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it.
  - b. That serious adverse effects were experienced by less than 1% of individuals in the ZOSTAVAX vaccine's clinical trials and studies.
  - c. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults.
  - d. That ZOSTAVAX was a "well-studied vaccine."
  - e. That ZOSTAVAX "significantly reduced" the risk of developing shingles compared with placebo."
  - f. That ZOSTAVAX would benefit its users "in the prevention of long-term nerve pain from shingles (post-herpetic neuralgia) can be primarily attributed to the vaccine's effect on the prevention of shingles." (emphasis added).
  - g. That the efficacy of ZOSTAVAX is 51% for everyone.

- h. That the efficacy of ZOSTAVAX did not diminish over time after vaccination.
- i. That the immunity provided by ZOSTAVAX was unlimited.
- j. That the immunity provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated.
- k. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles.
- 1. That ZOSTAVAX was safe.
- m. That ZOSTAVAX was effective.
- 210. The ZOSTAVAX vaccine did not conform to the representations made by Merck and MSD because it could and did induce shingles.
- 211. The ZOSTAVAX vaccine did not conform to the representations made by Merck, MSD, and McKesson because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as the Plaintiffs, when used in routinely administered dosages.
- 212. The ZOSTAVAX vaccine did not conform to the representations made by Merck, MSD, and McKesson because it was not effective for the long-term prevention of shingles it was not effective at all after four years.
- 213. The ZOSTAVAX vaccine did not conform to the representations made by Merck, MSD, and McKesson because its efficacy was not the same for all of its users its peak efficacy rate of 51% was only in users that are 60 years of age.
- 214. At the time of making such express warranties, Merck and MSD knew that the ZOSTAVAX vaccine could induce herpes zoster.
- 215. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew and/or should have known that the ZOSTAVAX vaccine did not conform to the express warranties and representations:

- 216. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine was associated with numerous serious side effects, including the possibility of viral infection.
- 217. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine waned in efficacy to effectively zero after four years post-inoculation.
- 218. At the time of making such express warranties, Merck, MSD, and McKesson, each of them, knew that the ZOSTAVAX vaccine was only 51% effective at its peak, if the user was inoculated at age 60.
  - 219. Merck, MSD, and McKesson breached each of their express warranties.
- 220. Plaintiffs, through Plaintiffs' physicians and/or other healthcare providers, did rely on the express warranties made by Merck, MSD, and McKesson regarding the safety and efficacy of the ZOSTAVAX vaccine in purchasing, administering, and using the product.
- 221. Members of the medical community, including physicians and other healthcare professionals, relied upon each Defendants' representations and express warranties in connection with the use recommendation, description, and dispensing of the ZOSTAVAX vaccine.
- 222. As a foreseeable, direct, and proximate result of the breach of the express warranties by Merck, MSD, and McKesson, the Plaintiffs contracted herpes zoster, shingles, and/or other zoster-related injuries and disease, resulting in the Plaintiffs suffering serious physical injuries including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, diminished quality of life, and incurred medical bills and other expenses, and other losses and damages.

### **COUNT V: BREACH OF IMPLIED WARRANTY**

- 223. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 224. At all relevant times, as set forth, 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
- 225. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 226. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 227. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

### **Merck**

- 228. At all times relevant to this action, Merck manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold the ZOSTAVAX vaccine for its intended use for the long-term prevention of shingles and zoster-related injuries.
- 229. Merck knew of the intended use of the 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.

- 230. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiffs, their physicians, and their 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.
- 231. Merck's representations and implied warranties were false, misleading, and inaccurate because the ZOSTAVAX vaccine was not safe or effective for its intended purpose and was not of merchantable quality.
- 232. At the time the ZOSTAVAX vaccine 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.
- 233. 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.
- 234. Contrary to Merck's implied warranties, the ZOSTAVAX vaccine 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 and was not effective for the long-term prevention of shingles.

- 235. Merck breached its implied warranty because the ZOSTAVAX vaccine was not fit for its intended use and purpose.
- 236. Merck placed the ZOSTAVAX vaccine into the stream of commerce in its 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.
- 237. As a foreseeable, direct and proximate result of Merck's breach of its implied warranties, and Plaintiffs' use of the ZOSTAVAX vaccine, Plaintiffs suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for the injuries described herein.

#### **MSD**

- 238. At all times relevant to this action, MSD manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold the ZOSTAVAX vaccine for the long-term prevention of shingles and zoster-related injuries.
- 239. MSD knew of the intended use of the ZOSTAVAX vaccine at the time MSD designed, manufactured, marketed, sold, and distributed the ZOSTAVAX vaccine for use by the Plaintiffs, their physicians, and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.
- 240. MSD impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiffs, their physicians, and their 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.

- 241. MSD's representations and implied warranties were false, misleading, and inaccurate because its product was not safe or effective for its intended purpose and was not of merchantable quality.
- 242. At the time the ZOSTAVAX vaccine was promoted, marketed, distributed, and/or sold by MSD, MSD 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.
- 243. Plaintiffs, their physicians, and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of MSD, 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.
- 244. Contrary to MSD's implied warranties, the ZOSTAVAX vaccine 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 and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein and was not effective for the long-term prevention of shingles and zoster-related injuries.
- 245. MSD breached its implied warranty because the ZOSTAVAX vaccine was not fit for its intended use and purpose.
- 246. MSD placed the ZOSTAVAX vaccine 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.

247. As a foreseeable, direct and proximate result of MSD's breach of its implied warranties and Plaintiffs' use of the ZOSTAVAX vaccine, Plaintiffs suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described herein.

#### McKesson

- 248. At all times relevant to this action, McKesson, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its ZOSTAVAX vaccine for its intended use for the long-term prevention of shingles and zoster-related injuries.
- 249. McKesson knew of the intended use of the ZOSTAVAX vaccine at the time McKesson marketed, sold, and distributed the ZOSTAVAX vaccine 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.
- 250. McKesson impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiffs, their physicians, and 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.
- 251. McKesson's representations and implied warranties were false, misleading, and inaccurate because the ZOSTAVAX vaccine was not safe or fit for its intended use and was not of merchantable quality.
- 252. At the time the ZOSTAVAX vaccine was promoted, marketed, distributed, and/or sold by McKesson, McKesson 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.

- 253. Plaintiffs, their physicians, and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of McKesson, as marketer, 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.
- 254. Contrary to McKesson's implied warranties, the ZOSTAVAX vaccine as used by the Plaintiffs was not safe or fit for its intended use because the product was unreasonably dangerous as described herein and was not effective for the long-term prevention of shingles.
- 255. McKesson breached its implied warranty because the ZOSTAVAX vaccine was not fit for its intended use and purpose.
- 256. McKesson placed the ZOSTAVAX vaccine 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.
- 257. As a foreseeable, direct and proximate result of McKesson's breach of its implied warranties, and Plaintiffs' use of the ZOSTAVAX vaccine, Plaintiffs suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described herein.

#### **COUNT VI: FRAUDULENT MISREPRESENTATION**

258. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.

- 259. At all relevant times, as set forth, 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
- 260. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 261. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 262. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.

## **Merck and MSD**

- 263. Merck and MSD represented to the medical community, the FDA, and consumers, including the Plaintiffs and their health care providers, that the ZOSTAVAX vaccine had been adequately tested in clinical trials and was found to be safe and effective for its intended use for the long-term prevention of shingles.
- 264. Merck and MSD knew or believed at the time it made its representations that its misrepresentations were false regarding the efficacy of ZOSTAVAX and the dangers and risks associated with use of the ZOSTAVAX vaccine as intended.
- 265. Merck and MSD made its misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of the ZOSTAVAX vaccine, such as Plaintiffs.

- 266. Merck's and MSD's misrepresentations include the following: that ZOSTAVAX is effective in preventing shingles and post-herpetic neuralgia to consumers over the age of 59; that ZOSTAVAX has a lasting preventative effect of the ZOSTAVAX vaccine against the herpes zoster virus, even after an extended time period; and that ZOSTAVAX did *not* induce serious side effects such as shingles and post-herpetic neuralgia.
- 267. Merck's employee Melissa Lore disseminated information available on the labeling of ZOSTAVAX vaccine as it was administered to each Plaintiff. The labeling contained misleading information, such as the efficacy and safety of ZOSTAVAX as a preventative measure for shingles, particularly that it was not known to cause or induce post-herpetic neuralgia, shingles, or other complications suffered by Plaintiffs. McKesson also disseminated this misleading information in its patient information materials, brochures, and marketing materials.
- 268. Merck's website includes information about ZOSTAVAX and states that the ZOSTAVAX vaccine prevents the reactivation of the zoster virus and effectively prevent shingles.
- 269. David Gutsch, M.D., is currently the Executive Director, Vaccines Regulatory, for Merck and MSD.
- 270. Upon information and belief, from 2005 through 2016, Gutsch gave presentations to Merck's, MSD's, and McKesson's field personnel, and the ZOSTAVAX sales force, who interacted directly with healthcare providers including Plaintiffs' healthcare providers.
- 271. During his presentations between 2006 and 2017, Gutsch in his presentations, instructed the ZOSTAVAX field personnel and sales force who interacted directly with healthcare providers to represent to physician: that ZOSTAVAX was effective <u>indefinitely</u> after a single administration; that ZOSTAVAX did <u>not</u> cause shingles; that ZOSTAVAX was safe and <u>effective</u>

for the <u>long-term prevention of shingles</u>; that ZOSTAVAX was <u>effective to treat pain</u> associated with shingles.

- 272. The ZOSTAVAX sales force relayed Gutsch's misinformation directly to Plaintiffs' physicians and pharmacists though in-person office visits, over the telephone, and during lunches and dinners.
- 273. Ann Redfield, M.S.N., R.N., formally known as Ann R. Sweet, M.S.N., R.N., upon information and belief, worked in a key capacity on Merck's Clinical Safety and Risk Management Department as part of the "vaccine team" at Merck West Point, located in West Point, Pennsylvania. Redfield acted at all times pertinent hereto within the scope of her employment as proprietor of key safety and prescribing information for the ZOSTAVAX vaccine, at issue.
- 274. Redfield, 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. Redfield also worked as the "process owner" of Merck's Varicella Zoster Vaccine Identification Program. In this capacity, Redfield drafted documents presented to the Merck employees who interacted directly with healthcare providers, who recommend, prescribe, and dispense the ZOSTAVAX vaccine.
- 275. Upon information and belief, Redfield gave presentations to the ZOSTAVAX sales force who interacted directly with healthcare providers and instructed the ZOSTAVAX field personnel and sales force who interacted directly with healthcare providers to represent to physician: that ZOSTAVAX was effective indefinitely after a single administration; that ZOSTAVAX did <u>not</u> cause shingles; that ZOSTAVAX was effective to treat pain associated with shingles.

- 276. Upon information and belief, the ZOSTAVAX sales force relayed Redfield's misinformation directly to Plaintiffs' physicians and pharmacists though in-person office visits, over the telephone, and during lunches and dinners.
- 277. In May 2006, Mark Feinberg, M.D., Ph.D., was the vice president of policy, public health and medical affairs of Merck Vaccines.
- 278. In May 2006, Mark Feinberg, M.D., Ph.D., stated that shingles is an "often painful disease in older adults."
- 279. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, Merck and MSD represented the following material information to the public:
  - a. That adult shingles causes pain in almost every instance;
  - b. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it;
  - c. That the ZOSTAVAX vaccine was approved to treat the pain associated with shingles;
  - d. That serious adverse effects were experienced by less than 1% of individuals in the ZOSTAVAX vaccine's clinical trials and studies;
  - e. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults;
  - f. That "[t]here is no way to predict when the varicella-zoster virus (VZV) will reactivate or who will develop zoster."
  - g. That ZOSTAVAX was a "well-studied vaccine."
  - h. That ZOSTAVAX "significantly reduced" the risk of developing shingles compared with placebo."
  - i. That ZOSTAVAX would benefit its users "in the prevention of longterm nerve pain from shingles (post-herpetic neuralgia) can be primarily attributed to the vaccine's effect on the prevention of shingles." (emphasis added).
  - j. That the efficacy of ZOSTAVAX is 51% for everyone.

- k. That the efficacy of ZOSTAVAX did not diminish over time after vaccination.
- 1. That the immunity provided by ZOSTAVAX was unlimited.
- m. That the immunity provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated.
- n. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles.
- o. That ZOSTAVAX was safe.
- p. That ZOSTAVAX was effective.
- 280. Merck and MSD made the aforesaid statements through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 281. Merck and MSD made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in medical journals that physicians throughout the United States, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where each Plaintiff's physicians work, subscribed, received, and read in 2006.
- 282. Merck and MSD made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the American Journal of Health-System Pharmacy in 2006. Physicians throughout the United States, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work, subscribed, received, and read these ZOSTAVAX journal ads.
- 283. Merck and MSD made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the Journal of the American Geriatrics Association in 2007. Physicians throughout the United States, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work, subscribed, received, and read these ZOSTAVAX journal ads.

- 284. Merck and MSD made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in the medical journal American Family Physician in 2007. Physicians throughout the United States, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work, subscribed, received, and read these ZOSTAVAX journal ads.
- 285. Merck and MSD made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in medical journals that physicians throughout the United States, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiff's physicians work, subscribed, received, and read.
- 286. Merck and MSD made the aforesaid statements to the public, including directly to consumers, including Plaintiffs, and the medical community, through the May 26, 2006 video news release for the ZOSTAVAX vaccine.
- 287. The May 26, 2006 video news release for the ZOSTAVAX vaccine was disseminated through broadcast television, cable television, national newspapers such as the New York Times, Washington Post, USA Today, and other national media outlets.
- 288. Merck and MSD provided the May 26, 2006 video news release for the ZOSTAVAX vaccine electronically via email and fax to broadcast television; cable television; national newspapers including the New York Times; Washington Post; USA Today; to BusinessWire, a press release distributor, which distributed these representations to national media outlets; and other national media outlets.
- 289. In May 2006, Merck and MSD made the ZOSTAVAX video news release available to broadcast media (including broadcast television, cable television, and other national media

outlines) via satellite feed, electronic feed, and videocassette. The broadcast media then disseminated Merck's and MSD's ZOSTAVAX video news release to the public, including directly to consumers, and to the medical community, including Plaintiffs and their healthcare providers.

- 290. In June 2006, Merck and MSD made the ZOSTAVAX video news release available to broadcast media (including broadcast television, cable television, and other national media outlines) via satellite feed, electronic feed, and videocassette. The broadcast media then disseminated Merck's and MSD's ZOSTAVAX video news release to the public, including directly to consumers, and to the medical community including Plaintiffs and their healthcare providers.
- 291. Merck's and MSD's representations intentionally concealed the following material information:
  - a. From 2006 until present date, Merck and MSD intentionally concealed the effect of time since vaccination on ZOSTAVAX's efficacy.
  - b. From 2006 until present date, Merck and MSD intentionally concealed that the effect of time since vaccination significantly decreases the efficacy rate of ZOSTAVAX.
  - c. From 2006 until present date, Merck and MSD intentionally concealed the fact that four years after vaccination, the efficacy rate of ZOSTAVAX is zero.
  - d. From 2006, when the ZOSTAVAX vaccine was first marketed, until 2014, Merck and MSD knowingly omitted in the packaging for ZOSTAVAX that the ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases including post herpetic neuralgia.
- 292. On June 13, 2006, Jill Bradley was Merck's Director of Marketing Communications.
- 293. On June 13, 2006, Nancy Chamberlin, Pharm. D., Regulatory Review Officer, APLB, submitted a memorandum to Jill Bradley, Merck's Director of Marketing Communications,

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

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

- 294. On June 13, 2006, Jill Bradley decided, on behalf of Merck and MSD and in the scope of her employment with Merck, to intentionally omit the aforesaid warnings associated with the vaccination of a live attenuated virus for the 2006 ZOSTAVAX label.
- 295. On June 13, 2006, when Merck and MSD decided to omit information on the 2006 ZOSTAVAX vaccine's label, Jill Bradley knew and/or had reason to know the risks associated with the vaccination of a live attenuated virus was material information that would be relied upon by the medical community, including each Plaintiff's healthcare providers, and by Plaintiffs.
- 296. On or about June 13, 2006, Merck and MSD knew or had reason to know that the ZOSTAVAX vaccine's label omitted statements about the warnings and precautions of using a live virus vaccine.
- 297. On or about June 13, 2006, Merck and MSD knew or had reason to know that the ZOSTAVAX vaccine's label omitted a warning regarding vaccination with a live attenuated virus.
- 298. From June 13, 2006, Merck and MSD intentionally omitted material facts from the ZOSTAVAX label and while marketing and selling the ZOSTAVAX vaccine.
- 299. Merck and MSD knowingly omitted in the packaging for the ZOSTAVAX vaccine that the ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases.

- 300. From 2006 until 2014, Merck and MSD represented to the public, including directly to consumers, including Plaintiffs and their healthcare providers, that ZOSTAVAX did <u>not</u> cause or induce shingles through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 301. Since 2006, Merck and MSD represented to the medical community, to the public, and directly to consumers, including Plaintiffs and healthcare providers, that known adverse effects associated with ZOSTAVAX use were no more serious that a "rash" through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 302. On November 3, 2009, Dr. Rose Tiernan from the OVRR DVRPA called Dr. Gutsch to notify Merck that the term "rash" was too general to be useful. Merck and MSD failed to remedy this inadequate warning.
- 303. From 2006 until 2017, Merck's and MSD's professional representatives met physicians throughout the United States in person, including Plaintiffs' healthcare providers and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work. Merck's and MSD's professional representatives represented to said physicians that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 304. From 2006 through at least 2017, Merck and MSD represented to the medical community, including to Plaintiffs' physicians, through seminars that the effect of time since vaccination on ZOSTAVAX's vaccine efficacy is not statistically significant.

- 305. On October 2008, Dr. M. Levin, acting on behalf of Merck and MSD, presented at the Annual ICAAC/IDSA Annual Meeting in Washington, DC, and represented that "protection [from shingles] persists for up to 7 years." Medical professionals in academia, government, and private practice attended this meeting. This information reached Plaintiffs' healthcare providers directly or through word of mouth from their peers.
- 306. On October 23, 2010, Dr. M. Levin, acting on behalf of Merck and MSD, presented at the 48th Annual ICAAC/IDSA 46th Annual Meeting in Washington, DC, and represented that "protection [from shingles] persists for up to 7 years." Medical professionals in academia, government, and private practice attended this meeting. This information reached Plaintiffs' healthcare providers directly or through word of mouth from their peers.
- 307. Plaintiffs' healthcare providers, physicians, and received these representations made by Dr. M. Levin on October 23, 2010 regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and relied upon these representations.
- 308. On May 18, 2011, Merck and MSD represented that "The effect of time since vaccination on VE [vaccine efficacy] (waning effect) is not statistically significant" in a presentation regarding the "Persistence of Zoster Vaccine Efficacy" at the Society of Clinical Trials ("SCT") Annual Meeting in Vancouver, BC Canada. Medical professionals in academia, government, and private practice attended this SCT Annual Meetings, including medical care providers in the United States. This information reached Plaintiffs' healthcare providers directly or through word of mouth from their peers.
- 309. Plaintiffs' healthcare providers, physicians, and received these representations made by Merck and MSD in the May 18, 2011 SCT Annual Meeting regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and relied upon these representations.

- 310. Merck's and MSD's representations that "the effect of time since vaccination on [ZOSTAVAX's] vaccine efficacy is not statistically significant" are false.
- 311. Merck's and MSD representations that ZOSTAVAX's protection from shingles persist are false.
  - 312. ZOSTAVAX's efficacy four years after vaccination is zero.
  - 313. ZOSTAVAX's efficacy four years after vaccination is statistically the same as zero.
  - 314. ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.
- 315. Merck and MSD knew that ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.
- 316. The ZOSTAVAX vaccine can cause the chickenpox virus to reactivate and cause shingles upon its administration.
- 317. From 2006 until 2017, Merck's and MSD's professional representatives met physicians throughout the United States in person, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs physicians work.
- 318. Merck's and MSD's professional representatives represented to said physicians that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 319. Between 2006 and 2017, Merck and MSD, through sales representatives and agents' word-of-mouth recommendations, specifically made oral representations to Plaintiffs' healthcare providers, physicians, and pharmacists that ZOSTAVAX's efficacy rate was "between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered."

- 320. Between 2006 and 2017, Plaintiffs' healthcare providers, physicians, and pharmacists relied upon Merck's and MSD's representations that ZOSTAVAX's efficacy rate was between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result regardless of each Plaintiffs' age at the time of administration of ZOSTAVAX.
- 321. Merck's and MSD's representations were false: the maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration. ZOSTAVAX's efficacy rate continually declines after age 60.
- 322. Between 2006 and 2017, Merck and MSD, through sales representatives and agents' word-of-mouth recommendations, specifically made oral representations to Plaintiffs' healthcare providers, physicians, and pharmacists that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation."
- 323. Between 2006 and 2017, Plaintiffs' healthcare providers, physicians, and pharmacists relied upon Merck's and MSD's representations that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation" and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result regardless of each Plaintiffs' age at the time of administration of ZOSTAVAX.
- 324. Merck's and MSD's representations were false: ZOSTAVAX's efficacy rate does not remain constant, and above 50%, post-inoculation; its efficacy rate declines to almost zero four years post-vaccination.
- 325. From 2006 until 2017, Merck and MSD held convention panels that were attended by physicians throughout the United States in person, including Plaintiffs' healthcare providers,

and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work.

- 326. During these convention panels, Merck and MSD represented that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 327. Plaintiffs' healthcare providers, physicians, and pharmacists attended Merck's and MSD's convention panels regarding ZOSTAVAX and heard and received Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and relied upon these representations.
- 328. Plaintiffs' healthcare providers, physicians, and pharmacists heard and received Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof through word-of-mouth from their peers and relied upon these representations.
- 329. Plaintiffs' healthcare providers, physicians, and pharmacists relied upon Merck's and MSD's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result.
- 330. Since May 2006 and during all relevant times, ZOSTAVAX vaccine's television commercials, radio commercials, and print advertisements were published and run in magazines targeting 50-year-old-and-older adults, and in broadcast television, cable television, mainstream radio, and other broadcast media outlets.

- 331. From 2006 until 2017, Merck and MSD broadcasted numerous television commercials on public television and cable television promoting ZOSTAVAX, wherein actors and/or celebrities spoke in detail about how painful shingles is.
- 332. In 2014, Merck and MSD ran numerous television commercials broadcasted on public television promoting ZOSTAVAX featuring former football quarterback Terry Bradshaw ("Bradshaw Ad"), wherein Bradshaw spoke in detail about how painful shingles is.
- 333. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.
- 334. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs, that ZOSTAVAX was intended for long-term prevention of pain caused by shingles.
- 335. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs and Plaintiffs' healthcare providers, physicians, and pharmacists, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.
- 336. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs and Plaintiffs' healthcare providers, physicians, and pharmacists, that ZOSTAVAX was intended for long-term prevention of pain caused by shingles.
  - 337. Plaintiffs saw the Bradshaw Ad.
- 338. Plaintiffs were influenced by and relied upon the Bradshaw Ad and were induced to use ZOSTAVAX for long-term prevention of shingles as a result.
  - 339. Plaintiffs' healthcare providers, physicians, and pharmacists saw the Bradshaw Ad.

- 340. Plaintiffs' healthcare providers, physicians, and pharmacists were influenced by and relied upon the Bradshaw Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs for long-term prevention of shingles as a result.
- 341. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs, that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.
- 342. The Bradshaw Ad represented to the viewing public and consumers, including Plaintiffs, that ZOSTAVAX was intended for long-term prevention of pain caused by shingles.
- 343. Merck's and MSD's representations that ZOSTAVAX was highly effective in preventing shingles and shingles pain was false and misleading.
- 344. From 2015 through 2017, Merck and MSD ran television commercials broadcasted on public television and cable television promoting ZOSTAVAX that depicted a person struggling through a day at an office job because of shingles pain ("Day #7 with Shingles Ad").
- 345. The Day #7 with Shingles Ad showed graphic depictions of blistering skin and described the pain associated with shingles, representing to their viewers that shingles always causes pain in every patient.
- 346. The Day #7 with Shingles Ad represented to the viewing public and consumers that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.
  - 347. Plaintiffs saw the Day #7 with Shingles Ad.
- 348. Plaintiffs were influenced by and relied upon the Day #7 with Shingles Ad and were induced to use ZOSTAVAX for long-term prevention of shingles as a result.

- 349. Plaintiffs' healthcare providers, physicians, and pharmacists saw the Day #7 with Shingles Ad.
- 350. Plaintiffs' healthcare providers, physicians, and pharmacists were influenced by and relied upon the Day #7 with Shingles Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs for long-term prevention of shingles as a result.
  - 351. Shingles is not always accompanied by pain.
  - 352. ZOSTAVAX was not approved to treat pain.
- 353. The Day #7 with Shingles Ad's representations regarding pain occurrence with shingles were false and misleading.
- 354. Viewers and consumers who saw the Day #7 with Shingles Ad do not equate a vaccine with the *highest* efficacy rate of 51% if vaccinated at age 60 with "highly effective."
- 355. Viewers and consumers who saw the Day #7 with Shingles Ad relied upon the ad's representation that ZOSTAVAX was effective to prevent shingles and understood that representation to indicate that ZOSTAVAX would prevent shingles indefinitely.
- 356. The Day #7 with Shingles Ad concealed from its viewers that ZOSTAVAX vaccine can cause the reactivation of the chicken pox virus and cause shingles.
- 357. Merck and MSD knew that the Day #7 with Shingles Ad's representations were false and misleading.
- 358. From 2015 through 2017, Merck and MSD ran television commercials broadcasted on public television promoting ZOSTAVAX that showing a person who gives up on a game of golf because of shingles pain. ("Day #18 with Shingles Ad").
- 359. The Day #18 with Shingles Ad showed graphic depictions of blistering skin and depicted the person suffering from shingles failing to bend down without experiencing strong pain.

- 360. The Day #18 with Shingles Ad showed graphic depictions of blistering skin and described the pain associated with shingles, representing to their viewers that shingles always causes pain in every patient.
- 361. The Day #18 with Shingles Ad depicted the actor posing as a shingles sufferer, who states: "After almost three weeks, I just really wanted to give it a shot."
- 362. The Day #18 with Shingles Ad represented to their viewers that the blisters caused by shingles lasts at least three weeks.
- 363. The Day #18 with Shingles Ad represented to their viewers that the pain caused by shingles lasts at least three weeks.
- 364. The Day #18 with Shingles Ad informed its viewers: "If you had chicken pox, the shingles virus is already inside you."
  - 365. Plaintiffs saw the Day #18 with Shingles Ad.
- 366. Plaintiffs were influenced by and relied upon the Day #18 with Shingles Ad and were induced to use ZOSTAVAX for long-term prevention of shingles as a result.
- 367. Plaintiffs' healthcare providers, physicians, and pharmacists saw the Day #18 with Shingles Ad.
- 368. Plaintiffs' healthcare providers, physicians, and pharmacists were influenced by and relied upon the Day #18 with Shingles Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs for long-term prevention of shingles as a result.
  - 369. Shingles is not always accompanied by pain.
  - 370. ZOSTAVAX was not approved to treat pain.
  - 371. Shingles is not always accompanied by painful blisters or blistering rash.

- 372. The painful, fluid-filled blisters depicted in the Day #18 Shingles Ad that sometimes accompany shingles do not typically last three weeks.
- 373. The Day #18 with Shingles Ad's representations regarding pain occurrence with shingles were false and misleading.
- 374. Viewers and consumers who saw the Day #18 with Shingles Ad do not equate a vaccine with the *highest* efficacy rate of 51% if vaccinated at age 60 with "highly effective."
- 375. Viewers and consumers who saw the Day #18 with Shingles Ad relied upon the ad's representation that ZOSTAVAX was effective to prevent shingles and understood that representation to indicate that ZOSTAVAX would prevent shingles indefinitely.
- 376. The Day #18 with Shingles Ad concealed from its viewers that ZOSTAVAX vaccine can cause the reactivation of the chickenpox virus and cause shingles.
- 377. Merck and MSD knew that the Day #18 with Shingles Ad's representations were false and misleading.
- 378. Beginning in September 2016 through 2017, Merck and MSD ran television commercials broadcasted on public television promoting ZOSTAVAX, featuring a woman swimming alone in a pool while a voice-over represents to its viewers that "shingles virus [has] been lurking inside you since you had the chicken pox . . . [and] can surface anytime as a painful, blistering rash. One in three people will get me in their lifetime . . .will it be you?" ("Linda Ad").
- 379. The Linda Ad represented to the viewing public and consumers that ZOSTAVAX was highly effective in preventing shingles and shingles pain, and that ZOSTAVAX was effective after a single shot.
  - 380. Plaintiffs saw the Linda Ad.

- 381. Plaintiffs were influenced by and relied upon the Linda Ad and were induced to use ZOSTAVAX for long-term prevention of shingles as a result.
- 382. Plaintiffs' healthcare providers, physicians, and pharmacists saw the Linda Ad with Shingles Ad.
- 383. Plaintiffs' healthcare providers, physicians, and pharmacists were influenced by and relied upon the Linda Ad and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs for long-term prevention of shingles as a result.
- 384. Merck's and MSD's representations that ZOSTAVAX was highly effective in preventing shingles and shingles pain was false and misleading.
- 385. Viewers and consumers who saw the Linda Ad do not equate a vaccine with the *highest* efficacy rate of 51% if vaccinated at age 60 with "highly effective."
- 386. Viewers and consumers who saw the Linda Ad relied upon the representation that ZOSTAVAX was effective to prevent shingles after a single shot and understood that representation to indicate that a single shot would prevent shingles indefinitely.
- 387. The Linda Ad concealed from its viewers that ZOSTAVAX vaccine can cause the reactivation of the chicken pox virus and cause shingles.
- 388. Beginning in September 2016 to present date, Merck and MSD published the ZOSTAVAX vaccine's print advertisements, which ran in magazines targeting 50-year-olds, showing graphic photos of a rash associated with shingles.
- 389. ZOSTAVAX vaccine's print advertisements showing graphic photos of a rash associated with shingles represented to their viewers and/or readers that shingles always causes pain in every patient.
  - 390. Plaintiffs saw the ZOSTAVAX vaccine's print advertisements in magazines.

- 391. Plaintiffs were influenced by and relied upon the ZOSTAVAX vaccine's print advertisements in magazines and were induced to use ZOSTAVAX for long-term prevention of shingles as a result.
- 392. Plaintiffs' healthcare providers, physicians, and pharmacists saw the ZOSTAVAX vaccine's print advertisements in magazines with Shingles Ad.
- 393. Plaintiffs' healthcare providers, physicians, and pharmacists were influenced by and relied upon the ZOSTAVAX vaccine's print advertisements in magazines and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs for long-term prevention of shingles as a result.
  - 394. Shingles is not always accompanied by pain.
  - 395. ZOSTAVAX was not approved to treat pain.
  - 396. Shingles is not always accompanied by painful blisters or blistering rash.
- 397. ZOSTAVAX vaccine's print advertisements' representations regarding pain occurrence with shingles were false and misleading.
- 398. Viewers and consumers who saw, heard, or read the ZOSTAVAX vaccine's television commercials, radio commercials, and/or print advertisements, including Plaintiff and her healthcare providers, do not believe that the highest efficacy rate of 51% if vaccinated at age 60 is highly effective.
- 399. Viewers and consumers who saw, heard, or read the ZOSTAVAX vaccine's television commercials, radio commercials, and/or print advertisements, including Plaintiffs and their healthcare providers, relied upon the advertisements' representation that ZOSTAVAX was effective to prevent shingles and understood that representation to indicate that ZOSTAVAX would prevent shingles indefinitely.

- 400. The ZOSTAVAX vaccine's television commercials, radio commercials, and/or print advertisements concealed from their viewers, listeners, and readers, including Plaintiffs and their healthcare providers, that ZOSTAVAX vaccine can cause the reactivation of the chickenpox virus and cause shingles.
- 401. Merck and MSD knew that the ZOSTAVAX vaccine's television commercials, radio commercials, and/or print advertisements' representations were false and misleading.
- 402. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 403. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine and its true efficacy.
- 404. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine created great risk of causing serious personal injury to the users of the ZOSTAVAX vaccine.
- 405. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.
- 406. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine.
- 407. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine.
- 408. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of it causing shingles and other injuries and conditions associated with the herpes zoster virus.

- 409. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true efficacy of the ZOSTAVAX vaccine.
- 410. Merck and MSD intentionally misrepresented facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs to rely upon Merck's and MSD's misrepresentations and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles.
- 411. Merck and MSD intentionally misrepresented facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs' physicians and healthcare providers to rely upon Merck's and MSD's representations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles so that Plaintiffs' physicians and healthcare providers would purchase, prescribe, administer and/or dispense the ZOSTAVAX vaccine.
- 412. Merck and MSD intentionally omitted and/or concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs to rely upon Merck's and MSD's misrepresentations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles, and to purchase and use the ZOSTAVAX vaccine as a result.
- 413. Merck and MSD intentionally omitted and/or concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs' physicians and healthcare providers to rely upon Merck's and MSD's representations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles so that Plaintiffs' physicians and healthcare providers would purchase, prescribe, administer and/or dispense the ZOSTAVAX vaccine.
- 414. At the time Merck and MSD made these misrepresentations, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs, Plaintiffs' physicians and/or

pharmacists, and the medical community were unaware of the representations' falsehoods, and reasonably believed them to be true.

- 415. At the time Merck and MSD concealed and intentionally omitted these material facts, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs' physicians and/or pharmacists, and the medical community were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 416. Merck and MSD knew or believed at the time they made representations about the ZOSTAVAX vaccine that the representations were false.
- 417. Merck and MSD knew or believed at the time they made false representations about the ZOSTAVAX vaccine that the false representations were material.
- 418. Merck and MSD knew or believed at the time they intentionally omitted material facts about the ZOSTAVAX vaccine that the facts omitted were material.
- 419. Merck and MSD knew or believed at the time they concealed material facts about the ZOSTAVAX vaccine that the facts concealed were material.
- 420. Merck and MSD knew and had reason to know that Plaintiffs, Plaintiffs' physicians and healthcare providers, in recommending, prescribing, purchasing, administering, and/or using the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.
- 421. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if Plaintiffs knew the true facts regarding its safety and efficacy.
- 422. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.

- 423. Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.
- 424. Because Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 425. Plaintiff's physicians reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 426. Because Plaintiffs' physicians, reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 427. Merck's and MSD's false representations and intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.
- 428. Merck's and MSD's false representations and intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard for the health and safety of the public, its consumers, and the Plaintiffs.

- 429. As a foreseeable, direct, and proximate result of Merck's and MSD's intentional false representations, omissions, and concealment of material facts, Plaintiffs suffered the serious injuries alleged herein.
- 430. As a direct and proximate consequence of Merck's and MSD's fraudulent misrepresentations, omissions, and concealment of material fact, Plaintiffs sustained serious personal injuries including physical pain and suffering, mental anguish, diminished capacity for the enjoyment of life, diminished quality of life, medical and related expenses, and other losses and damages.
- 431. As a direct and proximate consequence of MSD's fraudulent misrepresentations, omissions, and concealment of material fact, Plaintiffs sustained serious personal injuries including physical pain and suffering, mental anguish, diminished capacity for the enjoyment of life, diminished quality of life, medical and related expenses, and other losses and damages.

## **McKesson**

- 432. McKesson represented to the medical community, the FDA, and consumers, including the Plaintiffs and Plaintiffs' health care providers, that the ZOSTAVAX vaccine had been adequately tested in clinical trials and was found to be safe and effective.
- 433. McKesson knew or believed at the time it made its misrepresentations, that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of the ZOSTAVAX vaccine as intended.
- 434. McKesson made its misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of the ZOSTAVAX vaccine, including Plaintiffs.

- 435. McKesson's fraudulent misrepresentations include the following: the efficacy of ZOSTAVAX, particularly that it was effective in preventing shingles and post-herpetic neuralgia to consumers over the age of 59; longevity of efficacy of the ZOSTAVAX vaccine, specifically the lasting preventative effect of the ZOSTAVAX vaccine against the herpes virus, even after an extended time period; and the safety of ZOSTAVAX, particularly that the ZOSTAVAX vaccine did *not* induce serious side effects (such as shingles and post-herpetic neuralgia).
- 436. McKesson designed, created, and disseminated information available on the labeling of ZOSTAVAX vaccine as it was administered to Plaintiffs.
- 437. The ZOSTAVAX labeling contained misleading information, such as the efficacy and safety of ZOSTAVAX as a preventative measure for shingles, particularly that it was not known to cause or induce post-herpetic neuralgia, shingles, or other complications suffered by Plaintiffs.
- 438. McKesson also disseminated this misleading information in its patient information materials, brochures, and marketing materials.
- 439. McKesson's website includes information that the ZOSTAVAX vaccine prevents the reactivation of the zoster virus, to effectively prevent shingles.
- 440. McKesson created, developed, designed, and implemented the marketing and sales strategy for ZOSTAVAX.
- 441. From 2006 until 2017, McKesson through its sales personnel and agents gave presentations to the ZOSTAVAX field personnel and sales force who were directly involved with in-person marketing and sales of ZOSTAVAX to physicians and/or hospitals, including Plaintiffs' healthcare providers.

- 442. During these presentations from 2006 until 2017, McKesson through its sales personnel and agents instructed Merck's, MSD's, and McKesson's field personnel, and the ZOSTAVAX sales force, who interacted directly with healthcare providers, including Plaintiffs' healthcare providers, to represent to physicians during these presentations: that ZOSTAVAX was effective <u>indefinitely</u> after a single administration during these presentations; that ZOSTAVAX did <u>not</u> cause shingles during these presentations; that ZOSTAVAX was safe and <u>effective</u> for the <u>long-term prevention of shingles</u>; that ZOSTAVAX was <u>effective to treat pain</u> associated with shingles.
- 443. The ZOSTAVAX sales force relayed McKesson's misinformation directly to Plaintiffs' physicians and pharmacists though in-person office visits, over the telephone, and during lunches and dinners.
- 444. Since May 2006, when ZOSTAVAX was approved by the FDA for commercial marketing in the United States, McKesson represented the following material information to the public:
  - a. That adult shingles causes pain in almost every instance;
  - b. That the ZOSTAVAX vaccine would effectively prevent shingles and specifically the pain that accompanied it;
  - c. That the ZOSTAVAX vaccine was approved to treat the pain associated with shingles;
  - d. That serious adverse effects were experienced by less than 1% of individuals in the ZOSTAVAX vaccine's clinical trials and studies;
  - e. That the ZOSTAVAX vaccine was evaluated for safety in more than 20,000 adults and found to be safe, effective for the long-term prevention of shingles, and without any adverse effects in more than 20,000 adults;
  - f. That "[t]here is no way to predict when the varicella-zoster virus (VZV) will reactivate or who will develop zoster."
  - g. That ZOSTAVAX was a "well-studied vaccine."

- h. That ZOSTAVAX "significantly reduced" the risk of developing shingles compared with placebo."
- i. That ZOSTAVAX would benefit its users "in the prevention of longterm nerve pain from shingles (post-herpetic neuralgia) can be primarily attributed to the vaccine's effect on the prevention of shingles." (emphasis added).
- j. That the efficacy of ZOSTAVAX is 51% for everyone.
- k. That the efficacy of ZOSTAVAX did not diminish over time after vaccination.
- 1. That the immunity provided by ZOSTAVAX was unlimited.
- m. That the immunity provided by ZOSTAVAX was the same regardless of the age of the patient vaccinated.
- n. That ZOSTAVAX had been tested and was found to be safe and effective for preventing shingles.
- o. That ZOSTAVAX was safe.
- p. That ZOSTAVAX was effective.
- 445. McKesson made the aforesaid statements through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 446. McKesson made the aforesaid statements to physicians and the medical community in ZOSTAVAX "Physician Journal Ad[s]" published in medical journals that physicians throughout the United States in person, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work, subscribed, received, and read from 2006 until 2017.
- 447. McKesson made the aforesaid statements in Community Health Care brochures that it designed, created, published, and disseminated to the public and specifically targeted for the care of adults over the age of 60.
- 448. McKesson made the aforesaid statements in each State's Department of Health's Immunization Policies and Procedures that it designed, created, published, and disseminated to the public including Plaintiffs and their healthcare providers, by and through each state government's health department, including upon information and belief Florida.

- 449. McKesson's representations intentionally concealed the following material information:
  - a. From 2006 until present date, McKesson intentionally concealed the effect of time since vaccination on ZOSTAVAX's efficacy.
  - b. From 2006 until present date, McKesson intentionally concealed that the effect of time since vaccination significantly decreases the efficacy rate of ZOSTAVAX.
  - c. From 2006 until present date, McKesson intentionally concealed the fact that four years after vaccination, the efficacy rate of ZOSTAVAX is zero.
  - d. From 2006, when the ZOSTAVAX vaccine was first marketed, until 2014, McKesson knowingly omitted in the packaging for ZOSTAVAX that the ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases including post herpetic neuralgia.
- 450. On June 13, 2006, when McKesson decided to omit information on the 2006 ZOSTAVAX vaccine's label, McKesson knew and/or had reason to know the risks associated with the vaccination of a live attenuated virus was material information that would be relied upon by the medical community, including Plaintiffs' healthcare providers, and by Plaintiffs.
- 451. On or about June 13, 2006, McKesson knew or had reason to know that the ZOSTAVAX vaccine's label omitted statements about the warnings and precautions of using a live virus vaccine.
- 452. On or about June 13, 2006, McKesson knew or had reason to know that the ZOSTAVAX vaccine's label omitted a warning regarding vaccination with a live attenuated virus.
- 453. From June 13, 2006, McKesson intentionally omitted material facts from the ZOSTAVAX label and while marketing and selling the ZOSTAVAX vaccine.
- 454. McKesson knowingly omitted in the packaging for the ZOSTAVAX vaccine that the ZOSTAVAX vaccine can actually cause a viral infection, leading to an array of other infections and/or diseases.

- 455. From 2006 until 2014, McKesson represented to the public, including directly to consumers, including Plaintiffs and their healthcare providers, that ZOSTAVAX did <u>not</u> cause or induce shingles through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 456. Since 2006, McKesson represented to the medical community, to the public, and directly to consumers including Plaintiffs and their healthcare providers, that known adverse effects associated with ZOSTAVAX use were no more serious that a "rash" through the ZOSTAVAX vaccine's labeling, advertising, marketing material, advertisements, and/or packaging.
- 457. McKesson represented that the effect of time since vaccination on ZOSTAVAX's vaccine efficacy is not statistically significant.
- 458. McKesson represented that ZOSTAVAX protected its users for shingles indefinitely.
- 459. McKesson's representation that the effect of time since vaccination on ZOSTAVAX's vaccine efficacy is not statistically significant is false.
- 460. McKesson's representations that ZOSTAVAX protected its users for shingles indefinitely were false.
  - 461. ZOSTAVAX's efficacy four years after vaccination is zero.
  - 462. ZOSTAVAX's efficacy four years after vaccination is statistically the same as zero.
  - 463. ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.
- 464. McKesson knew that ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.

- 465. The ZOSTAVAX vaccine can cause the chickenpox virus to reactivate and cause shingles upon its administration.
- 466. From 2006 until 2017, McKesson's professional representatives met physicians throughout the United States in person, including Plaintiffs' healthcare providers, and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work.
- 467. During these in-person meetings from 2006 through 2017, McKesson's professional representatives represented to said physicians, including to Plaintiffs' physicians and pharmacists, that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 468. From 2006 through at least 2011, McKesson represented to the medical community, including to Plaintiffs' physicians, through seminars that the effect of time since vaccination on ZOSTAVAX's vaccine efficacy is not statistically significant.
- 469. Between 2006 and 2017, McKesson, through its sales representatives and through its agents' word-of-mouth recommendations, specifically made oral representations to Plaintiffs' healthcare providers, physicians, and pharmacists that ZOSTAVAX's efficacy rate was "between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered."
- 470. Between 2006 and 2017, Plaintiffs' healthcare providers, physicians, and pharmacists relied upon McKesson's representations that ZOSTAVAX's efficacy rate was between 50% and 60% regardless of the age of the patient at the time that ZOSTAVAX was administered and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result regardless of each Plaintiffs' age at the time of administration of ZOSTAVAX.

- 471. McKesson's representations were false: the maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration. ZOSTAVAX's efficacy rate continually declines after age 60.
- 472. Between 2006 and 2017, McKesson, through its sales representatives and through its agents' word-of-mouth recommendations, specifically made oral representations to Plaintiffs' healthcare providers, physicians, and pharmacists that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation."
- 473. Between 2006 and 2017, Plaintiffs' healthcare providers, physicians, and pharmacists relied upon McKesson's representations that "ZOSTAVAX's efficacy rate remained constant, and above 50%, post-inoculation" and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result regardless of each Plaintiffs' age at the time of administration of ZOSTAVAX.
- 474. McKesson's representations were false: ZOSTAVAX efficacy rate declines to almost zero four years post-inoculation.
- 475. From 2006 until 2017, McKesson held convention panels that were attended by physicians throughout the United States in person, including Plaintiffs' healthcare providers and the administrators and senior level physicians at the medical facilities where Plaintiffs' physicians work.
- 476. During these convention panels, McKesson represented that ZOSTAVAX was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.

- 477. Upon information and belief, Plaintiffs' healthcare providers, physicians, and pharmacists attended McKesson's convention panels regarding ZOSTAVAX and heard and received McKesson's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and relied upon these representations.
- 478. Plaintiffs' healthcare providers, physicians, and pharmacists heard and received McKesson's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof through word-of-mouth from their peers and relied upon these representations.
- 479. Plaintiffs' healthcare providers, physicians, and pharmacists relied upon McKesson's representations made during these convention panels regarding the ZOSTAVAX vaccine's efficacy and the effect of time on it and ZOSTAVAX's risks or lack thereof and were induced to prescribe, administer, and/or recommend ZOSTAVAX to Plaintiffs as a result.
- 480. McKesson had the duty to disclose to the Plaintiffs and Plaintiffs' physicians and healthcare providers of the defective design and formulation of the ZOSTAVAX vaccine, which heightened the risk of suffering the injuries, diseases, and maladies that Plaintiffs suffered as a result as alleged.
- 481. McKesson was also under a duty to disclose to Plaintiffs and Plaintiffs' healthcare providers of the defective or ineffective nature of the ZOSTAVAX vaccine that it marketed, distributed, and sold to them.
- 482. Upon information and belief, McKesson 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.

- 483. McKesson, with Merck and MSD, had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 484. McKesson knew and had reason to know that the ZOSTAVAX vaccine created great risk of causing serious personal injury to the users of the ZOSTAVAX vaccine.
- 485. McKesson knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.
- 486. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine. McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true safety of the ZOSTAVAX vaccine.
- 487. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine. Upon information and belief, McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true risks of the ZOSTAVAX vaccine.
- 488. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of it causing shingles and other injuries and conditions associated with the herpes zoster virus. Upon information and belief, McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing that it carried a real and serious risk of causing shingles and other injuries and conditions associated with the herpes zoster virus.
- 489. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true efficacy of the ZOSTAVAX vaccine. Upon information and belief, McKesson knew of

the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true efficacy of the ZOSTAVAX vaccine.

- 490. McKesson intentionally misrepresented material facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to mislead Plaintiffs, Plaintiffs' physicians, consumers, and the public.
- 491. McKesson omitted material facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to mislead Plaintiffs, Plaintiffs' physicians, consumers, and the public.
- 492. McKesson concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine with the intent to mislead Plaintiffs, Plaintiffs' physicians, consumers, and the public.
- 493. McKesson intentionally misrepresented material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs to rely upon McKesson's misrepresentations and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles.
- 494. McKesson intentionally misrepresented material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs' physicians and healthcare providers to rely upon McKesson's representations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles so that Plaintiffs' physicians and healthcare providers would purchase, prescribe, administer and/or dispense the ZOSTAVAX vaccine.
- 495. McKesson intentionally omitted and/or concealed facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs to rely upon McKesson's

misrepresentations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles, and to purchase and use the ZOSTAVAX vaccine as a result.

- 496. McKesson intentionally omitted and/or concealed facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers, including Plaintiffs and her healthcare providers to rely upon McKesson's misrepresentations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles, and to purchase and use the ZOSTAVAX vaccine as a result.
- 497. McKesson intentionally omitted and/or concealed facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce Plaintiffs' physicians and healthcare providers to rely upon McKesson's representations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles so that Plaintiffs' physicians and healthcare providers would purchase, prescribe, administer and/or dispense the ZOSTAVAX vaccine.
- 498. McKesson intentionally omitted and/or concealed facts concerning the safety of the ZOSTAVAX vaccine to induce the medical community including Plaintiffs' healthcare providers, to rely upon McKesson's representations that the ZOSTAVAX vaccine was a safe vaccine for the long-term prevention of shingles so that the medical community, including Plaintiffs healthcare providers, would purchase, prescribe, administer and/or dispense the ZOSTAVAX vaccine.
- 499. At the time McKesson made these misrepresentations, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the representations' falsehoods, and reasonably believed them to be true.
- 500. At the time McKesson intentionally omitted material facts, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the material

facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.

- 501. At the time McKesson made these misrepresentations, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs' physicians and/or pharmacists were unaware of the representations' falsehoods, and reasonably believed them to be true.
- 502. At the time McKesson intentionally omitted and concealed material facts, and at the times that the Plaintiffs was administered the ZOSTAVAX vaccine, Plaintiffs' physicians and/or pharmacists were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 503. McKesson knew or believed at the time it made representations about the ZOSTAVAX vaccine that the representations were false.
- 504. McKesson knew or believed at the time it made false representations about the ZOSTAVAX vaccine that the false representations were material.
- 505. McKesson knew or believed at the time it intentionally omitted material facts about the ZOSTAVAX vaccine that the facts omitted were material.
- 506. McKesson knew or believed at the time it concealed material facts about the ZOSTAVAX vaccine that the facts concealed were material.
- 507. McKesson's fraudulent misrepresentations were made with the intent of defrauding and deceiving the public, consumers, the medical community, including Plaintiffs' healthcare providers, the Plaintiffs, and also inducing the medical community, including Plaintiffs' healthcare providers, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the ZOSTAVAX vaccine.

- 508. McKesson knew and had reason to know that Plaintiffs, Plaintiffs' physicians and healthcare providers, in recommending, prescribing, purchasing, administering, and/or using the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.
- 509. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 510. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 511. Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and was induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.
- 512. Because Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 513. Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 514. Because Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.

- 515. McKesson's false representations regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.
- 516. McKesson's false representations regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard for the health and safety of the public, its consumers, and the Plaintiffs.
- 517. McKesson's intentional omissions of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.
- 518. McKesson's intentional omissions of material facts regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard and depraved indifference for the health and safety of the public, its consumers, and the Plaintiffs.
- 519. McKesson's intentional concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, fraud, and deceit.
- 520. McKesson's intentional concealment of material facts regarding the safety and efficacy of ZOSTAVAX were made and perpetrated willfully, wantonly, purposefully, and with reckless disregard and depraved indifference for the health and safety of the public, its consumers, and the Plaintiffs.
- 521. McKesson's intentional misrepresentations concerning the safety of the ZOSTAVAX vaccine were purposeful, willful, wanton, and fraudulent.
- 522. McKesson's intentional misrepresentations concerning the efficacy of the ZOSTAVAX vaccine were purposeful, willful, wanton, and fraudulent.
- 523. McKesson's intentional concealment and omissions of material facts concerning the safety of the ZOSTAVAX vaccine were purposeful, willful, wanton, and fraudulent.

- 524. McKesson's intentional concealment and omissions of material facts concerning the efficacy of the ZOSTAVAX vaccine were purposeful, willful, wanton, and fraudulent.
- 525. As a direct and proximate consequence of McKesson's fraudulent misrepresentations and concealment, Plaintiffs were caused to suffer the serious and dangerous side effects, including painful and persistent outbreaks of the herpes zoster virus, the very condition the vaccine was intended to prevent, and other zoster-related injuries. 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, medical and related expenses, and other losses and damages.

## **COUNT VII: NEGLIGENT MISREPRESENTATION**

- 526. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 527. At all relevant times, as set forth, 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
- 528. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 529. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine

- 530. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 531. Merck, MSD, and McKesson had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiffs, the truth regarding Defendants' claims that the ZOSTAVAX vaccine had been tested, and found to be safe and effective for its stated purpose: the long-term prevention of shingles and zoster-related injuries.

## Merck and MSD

- 532. Merck and MSD had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiffs, the truth regarding its claims that Merck's and MSD's product the ZOSTAVAX vaccine had been tested, and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.
- 533. Merck and MSD represented and marketed ZOSTAVAX as being safe and effective.
- 534. Merck and MSD failed to exercise ordinary care in making representations concerning the ZOSTAVAX vaccine and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.
- 535. Merck and MSD negligently and/or carelessly misrepresented and concealed the truth regarding the high risk of the ZOSTAVAX vaccine's unreasonable, dangerous and adverse side effects associated with the administration, use, and injection of the product.
- 536. Merck and MSD negligently and/or carelessly misrepresented and concealed the truth regarding the actual low efficacy rate of the ZOSTAVAX vaccine, which wanted to near-zero after four years post-inoculation.

- 537. Merck and MSD breached each of their duties by representing to the Plaintiffs, Plaintiffs' physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine did not carry the risk of serious side effects such as those suffered by Plaintiffs and other similarly situated patients.
- 538. Merck and MSD breached each of their duties by representing to the Plaintiffs, Plaintiffs' physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 539. Merck and MSD breached each of their duties by failing to warn the Plaintiffs and other consumers, of the defective condition of ZOSTAVAX, as manufactured and/or supplied by Merck and MSD.
- 540. Merck and MSD made the misrepresentations as previously alleged in ¶¶263-409, and Plaintiffs re-allege and re-incorporate their allegations in ¶¶263-409.
  - 541. The representations made by Merck and MSD, in fact, were false.
- 542. The maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration.
  - 543. ZOSTAVAX's efficacy rate continually declines after age 60.
- 544. ZOSTAVAX's efficacy rate does not remain constant post-vaccination, at the same rate at which it was effective when it was administered, indefinitely.
- 545. ZOSTAVAX's efficacy rate does not remain at a rate above 50% post-vaccination indefinitely.
  - 546. ZOSTAVAX's efficacy rate four years after vaccination is zero.

- 547. ZOSTAVAX's efficacy rate four years after vaccination is statistically the same as zero.
  - 548. ZOSTAVAX's efficacy rate wanes to near zero after four years post-vaccination.
- 549. The ZOSTAVAX vaccine can cause the chickenpox virus to reactivate and cause shingles upon its administration.
- 550. Merck and MSD knew, or should have known, that the maximum efficacy rate of ZOSTAVAX is 51% at the time of administration only if the patient is 60 years of age on the date of its administration.
- 551. Merck and MSD knew, or should have known, that ZOSTAVAX's efficacy rate continually declines after age 60.
- 552. Merck and MSD knew, or should have known, that ZOSTAVAX's efficacy rate wanes to near zero after four years after vaccination.
- 553. Merck and MSD knew, or should have known, that ZOSTAVAX can cause the chickenpox virus to reactivate and cause shingles upon its administration.
- 554. Merck and MSD were careless or negligent by failing to ascertain the truth of these representations at the time it made them.
- 555. Merck and MSD negligently misrepresented material facts about ZOSTAVAX: Merck and MSD made such misrepresentations when Merck and MSD knew or reasonably should have known of the falsity of such misrepresentations.
- 556. Alternatively, Merck and MSD made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.
- 557. The above misrepresentations were made to Plaintiffs, Plaintiffs' physicians and/or pharmacists, the medical community, as well as the general public.

- 558. Plaintiffs and Plaintiffs' healthcare providers, pharmacists and physicians, justifiably relied on Merck's and MSD's misrepresentations.
- 559. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 560. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine and its true efficacy.
- 561. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine created great risk of causing serious personal injury to the users of the ZOSTAVAX vaccine.
- 562. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings that accompanied it.
- 563. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine.
- 564. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine.
- 565. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of it causing shingles and other injuries and conditions associated with the herpes zoster virus.
- 566. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true efficacy of the ZOSTAVAX vaccine.
- 567. Merck and MSD made these representations to induce consumers such as Plaintiffs and Plaintiffs' physicians and pharmacists to rely upon Merck's and MSD's misrepresentations

and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles and purchase the product to Merck's and MSD's gain and financial profit.

- 568. Merck and MSD knew, or had reason to know, that the ZOSTAVAX vaccine had not been sufficiently tested; that the product lacked adequate, accurate, and prominent warnings; 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; and that the ZOSTAVAX vaccine was not as effective at the time of vaccination and after inoculation as represented.
- 569. At the time Merck and MSD made its misrepresentations, and at each time that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 570. Consumers, including the Plaintiffs and Plaintiffs' physicians and healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.
- 571. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if Plaintiffs knew the true facts regarding its safety and efficacy.
- 572. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 573. Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and was induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.

- 574. Because Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 575. Plaintiffs' physicians reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 576. Because Plaintiffs' physicians reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 577. Consequently, Plaintiffs' use of ZOSTAVAX was to Plaintiffs' own detriment as Merck's and MSD's negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.
- 578. Merck and MSD's negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.
- 579. As a direct and proximate consequence of Merck's and MSD's negligent misrepresentations, Plaintiffs contracted a serious strain of herpes zoster virus and other zoster-related injuries and 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, medical and related expenses, and other losses and damages.

## **McKesson**

- 580. McKesson had a duty to accurately and truthfully represent to the medical community, state governments, and U.S. consumers, including Plaintiffs, the truth regarding its claims that the ZOSTAVAX vaccine had been tested and found to be safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.
- 581. McKesson represented and marketed ZOSTAVAX as being safe and effective for the long-term prevention of shingles and injuries and conditions associated with the herpes zoster virus.
- 582. McKesson failed to exercise ordinary care in making representations concerning the ZOSTAVAX vaccine and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.
- 583. McKesson negligently and/or carelessly misrepresented and concealed the truth regarding the high risk of the ZOSTAVAX vaccine's unreasonable, dangerous and adverse side effects associated with the administration, use, and injection of the product.
- 584. McKesson negligently and/or carelessly misrepresented and concealed the truth regarding the actual low efficacy rate of the ZOSTAVAX vaccine, which wanted to near-zero after four years post-inoculation.
- 585. McKesson breached its duty by representing to the Plaintiffs, Plaintiffs' physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine did not carry the risk of serious side effects such as those suffered by Plaintiffs and other similarly situated patients.

- 586. McKesson breached its duty by representing to the Plaintiffs, Plaintiffs' physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine was effective for the long-term prevention of shingles; that ZOSTAVAX's efficacy rate did not decrease over time after vaccination; and that ZOSTAVAX created no risk of causing shingles or other injuries or complications associated with herpes zoster.
- 587. McKesson breached its duty by failing to warn the Plaintiffs and other consumers, of the defective condition of ZOSTAVAX, as marketed and/or supplied by McKesson.
  - 588. McKesson was aware of the risks of ZOSTAVAX.
- 589. McKesson failed to communicate to the Plaintiffs, Plaintiffs' healthcare providers, and other members of the general public, that the administration of this vaccine increased the risk of viral infection.
- 590. McKesson failed to communicate to the Plaintiffs, Plaintiffs' healthcare providers and other members of the general public, that the administration of the ZOSTAVAX vaccine would not remain effective past four years.
- 591. McKesson failed to exercise ordinary care in making representations concerning its product and its design, marketing, promotion, distribution, and sale in interstate commerce.
- 592. McKesson negligently and/or carelessly misrepresented and 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.
- 593. McKesson breached its duty in representing to the Plaintiffs, Plaintiffs' physicians and healthcare providers, and the medical community that the ZOSTAVAX vaccine did not carry the risk of serious side effects such as those suffered by Plaintiffs and other similarly situated patients.

- 594. McKesson failed to warn the Plaintiffs and other consumers, of the defective condition of ZOSTAVAX, as packaged, labeled, promoted, marketed, distributed, and sold by McKesson.
- 595. McKesson made the misrepresentations as previously alleged in ¶¶432-488 and Plaintiffs re-allege and re-incorporate their allegations in ¶¶432-488.
  - 596. The misrepresentations made by McKesson, in fact, were false.
- 597. McKesson was careless or negligent by failing to ascertain the truth of its representations at the time it made them.
- 598. McKesson negligently misrepresented material facts about ZOSTAVAX: it in that it made such misrepresentations when it knew or reasonably should have known of the falsity of such misrepresentations.
- 599. Alternatively, McKesson made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.
- 600. The above misrepresentations were made to Plaintiffs, Plaintiffs' physicians and/or pharmacists, the medical community at the time Plaintiffs were prescribed ZOSTAVAX.
- 601. Plaintiffs and Plaintiffs' healthcare providers, pharmacists and physicians, justifiably relied on McKesson's misrepresentations.
- 602. The above misrepresentations were made to Plaintiffs, Plaintiffs' physicians and/or pharmacists, the medical community, as well as the general public.
- 603. Plaintiffs and Plaintiffs' healthcare providers, pharmacists and physicians, justifiably relied on McKesson's misrepresentations.

- 604. McKesson, with Merck and MSD, had sole access to material facts concerning the ZOSTAVAX vaccine and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 605. McKesson, with Merck and MSD, had sole access to material facts concerning the ZOSTAVAX vaccine and its true efficacy.
- 606. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine. McKesson knew the results of Merck's and MSD's research and testing which revealed the true safety of the ZOSTAVAX vaccine.
- 607. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine. McKesson knew the results of Merck's and MSD's research and testing which revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine.
- 608. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of it causing shingles and other injuries and conditions associated with the herpes zoster virus. McKesson knew the results of Merck's and MSD's research and testing which revealed the true risks of the ZOSTAVAX vaccine, including that it could cause shingles and other injuries and conditions associated with the herpes zoster virus.
- 609. Merck's and MSD's research and testing of the ZOSTAVAX vaccine revealed the true efficacy of the ZOSTAVAX vaccine. McKesson knew the results of Merck's and MSD's research and testing which revealed the true efficacy of the ZOSTAVAX vaccine.
- 610. McKesson made these representations to induce consumers such as Plaintiffs and Plaintiffs' physicians and pharmacists to rely upon McKesson's misrepresentations and use the

ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles and purchase the product to McKesson's gain and financial profit.

- 611. McKesson knew, or had reason to know, that the ZOSTAVX vaccine 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; and that ZOSTAVAX was not as effective at the time of vaccination or any time post-inoculation as represented.
- 612. At the time McKesson made its misrepresentations, and at each time that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 613. Consumers, including the Plaintiffs and Plaintiffs' physicians and healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.
- 614. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if Plaintiffs knew the true facts regarding its safety and efficacy.
- 615. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 616. Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and was induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.

- 617. Because Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 618. Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 619. Because Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 620. Consequently, Plaintiffs' use of ZOSTAVAX was to Plaintiffs' own detriment because McKesson's negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.
- 621. McKesson's negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.
- 622. As a direct and proximate consequence of McKesson's negligent misrepresentations, Plaintiffs contracted a serious strain of herpes zoster virus and other zoster-related injuries and 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, medical and related expenses, and other losses and damages.

## **COUNT VIII: UNJUST ENRICHMENT**

### Merck and MSD

- 623. Merck and MSD are and at all times were the manufacturer(s), seller(s), marketer(s), and/or supplier(s) of the shingles vaccine, ZOSTAVAX.
- 624. Plaintiffs paid for the ZOSTAVAX vaccine to obtain a safe and effective form the long-term prevention of shingles and zoster-related injuries.
- 625. Merck and MSD have accepted payment by Plaintiffs for the purchase of the ZOSTAVAX vaccine.
- 626. Plaintiffs have not received the safe and effective form of long-term prevention of shingles and zoster-related injuries for which Plaintiffs paid.
  - 627. Instead, Plaintiffs suffered from shingles and/or other zoster-related injuries.
- 628. It would be inequitable for Merck and MSD to keep this money if Plaintiffs did not in fact receive a safe and effective form of long-term prevention for shingles and zoster-related injuries.

### **McKesson**

- 629. McKesson is and at all times was the marketer, promoter, packager, labeler, distributor, and seller of the ZOSTAVAX vaccine.
- 630. Plaintiffs paid for the ZOSTAVAX vaccine to obtain a safe and effective form the long-term prevention of shingles and zoster-related injuries.
- 631. McKesson have accepted payment by Plaintiffs for the purchase of the ZOSTAVAX vaccine.
- 632. Plaintiffs have not received the safe and effective form of long-term prevention of shingles and zoster-related injuries for which Plaintiffs paid.

- 633. Instead, Plaintiffs suffered from shingles and/or other zoster-related injuries.
- 634. It would be inequitable for McKesson to keep this money if Plaintiffs did not in fact receive a safe and effective form of long-term prevention for shingles and zoster-related injuries.

#### **COUNT IX: CONSUMER FRAUD**

- 635. The ZOSTAVAX vaccine was and is intended for the long-term prevention of herpes zoster (or shingles) and zoster-related injuries as manufactured, designed, licensed, processed, assembled, marketed, promoted, packaged, labeled, distributed, supplied, and/or sold by Defendants.
- 636. At all relevant times, as set forth, 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.
- 637. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 638. MSD designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine
- 639. McKesson labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the ZOSTAVAX vaccine.
- 640. Protection of Florida consumers is codified in the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

- 641. Commercial behavior that constitutes "unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce" is unlawful pursuant to the FDUTPA, and a consumer who suffered a loss as a result of this conduct may bring an action for damages.
- 642. At all relevant times, Merck, MSD, and McKesson engaged in continuous and pointed commercial marketing activity and introduced the ZOSTAVAX vaccine heavily into the stream of commerce within Florida and to Florida consumers.
- 643. At all relevant times, Merck, MSD, and McKesson engaged in a distribution and sales strategy within the state of Florida intending to reach Florida consumers, including Plaintiffs.
- 644. At all relevant times, the ZOSTAVAX vaccine's aggressive marketing campaign, containing advertising techniques that evaded divulging the known serious risks and warnings to consumers, including Plaintiffs, was unconscionable commercial behavior and is impermissible under FDUTPA.

### Merck and MSD

- 645. Merck's and MSD's intentional misrepresentations, omissions, and concealment of material facts regarding the ZOSTAVAX vaccine constitutes unfair and deceptive conduct.
- 646. Merck and MSD made the misrepresentations as previously alleged in ¶¶263-409, and Plaintiffs re-allege and re-incorporate their allegations in ¶¶263-409.
- 647. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, Merck and MSD widely disseminated these material representations of material fact regarding the safety and efficacy of the ZOSTAVAX vaccine as previously alleged directly to consumers, including Plaintiffs, in its advertising and promotional campaign using television and radio commercials on broadcast television, cable television and

other national media outlets; print advertisements run in magazines targeted, journals, and newspapers towards consumers and prescribers including national newspapers such as the New York Times, Washington Post, USA Today; posters and other signage in pharmacies where consumers bought their prescription drugs, including Plaintiffs' pharmacy; product handouts and brochures; its own website; and other ZOSTAVAX marketing materials.

- 648. Each of these representations is false.
- 649. Merck and MSD knew or believed at the time it made the aforesaid representations that its representations regarding the efficacy of ZOSTAVAX, safety of ZOSTAVAX, the dangers and risks associated with use of the ZOSTAVAX vaccine, and the portrayal of the shingles condition and pain and ZOSTAVAX's role in treating or preventing same, were false, misleading, and deceiving.
- 650. Merck and MSD knew or believed at the time it made the aforesaid false representations about the ZOSTAVAX vaccine that the false representations were material.
- 651. Consumers, such as Plaintiffs, who saw or read the ZOSTAVAX vaccine's marketing materials do not believe that the highest efficacy rate of 51% if vaccinated at age 60 is highly effective.
- 652. Consumers, such as Plaintiffs, who saw or read the ZOSTAVAX vaccine's commercial marketing materials relied upon the advertisements' representation that ZOSTAVAX was effective to prevent shingles and understood that representation to indicate that ZOSTAVAX would prevent shingles indefinitely.
- 653. Merck and MSD knew that the ZOSTAVAX vaccine's commercial marketing materials were false and misleading and would likely deceive any viewer into believing that ZOSTAVAX was safe and effective for its intended use.

- 654. Merck and MSD had sole access to material facts concerning the ZOSTAVAX vaccine, its efficacy, and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 655. Merck's and MSD's own research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine; the true risks of serious harm including viral infection, shingles and shingles-related conditions, and other injuries associated with the use of the ZOSTAVAX vaccine; and the true efficacy of the ZOSTAVAX vaccine.
- 656. Merck and MSD knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and would not effective at all after four years post-inoculation.
- 657. Merck and MSD intentionally misrepresented, omitted, and/or concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers such as Plaintiffs to rely upon Merck's and MSD's misrepresentations and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles and purchase the product to Merck's and MSD's gain and to the consumers' detriment.
- 658. At the time Merck and MSD concealed and intentionally omitted these material facts, and at the times that the Plaintiffs were administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 659. Merck and MSD knew and had reason to know that consumers, including the Plaintiffs and Plaintiffs' physicians and healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, did not have the ability

to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.

- 660. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if Plaintiffs knew the true facts regarding its safety and efficacy.
- 661. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 662. Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.
- 663. Because Plaintiffs reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 664. Plaintiffs' physicians reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 665. Because Plaintiffs' physicians reasonably relied on Merck's and MSD's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 666. Merck's and MSD's false representations and intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute

wrongful conduct, unfair conduct, deceptive conduct, and fraudulent conduct aimed towards consumers.

- 667. As a direct and proximate consequence of Merck's and MSD's unfair and deceptive acts and omissions, Plaintiffs sustained serious personal injuries including physical pain and suffering, mental anguish, diminished capacity for the enjoyment of life, diminished quality of life, medical and related expenses, and other losses and damages.
- 668. Plaintiffs' injuries and damages were directly and proximately caused by the unfair and deceptive commercial acts of Merck and MSD.

#### McKesson

- 669. McKesson's intentional misrepresentations of material facts regarding the ZOSTAVAX vaccine constitutes unfair and deceptive conduct.
- 670. McKesson made the misrepresentations as previously alleged in ¶¶432-488, and Plaintiffs re-allege and re-incorporate their allegations in ¶¶432-488.
- 671. Since May 2006, on the date that ZOSTAVAX was approved by the FDA for commercial marketing in the United States, McKesson widely disseminated material representations of material fact regarding the safety and efficacy of the ZOSTAVAX vaccine directly to consumers, including Plaintiffs, in its advertising and promotional campaign using television and radio commercials on broadcast television, cable television and other national media outlets; print advertisements run in magazines targeted, journals, and newspapers towards consumers and prescribers including national newspapers such as the New York Times, Washington Post, USA Today; posters and other signage in pharmacies where consumers bought their prescription drugs, including Plaintiff's pharmacy; product handouts and brochures; its own website; materials provided to Florida's State Department of Health; materials provided to

insurance companies for dissemination to policyholders and consumers, including Plaintiffs; and other ZOSTAVAX marketing materials.

- 672. Each of these representations is false.
- 673. McKesson knew or believed at the time it made the aforesaid representations that its representations regarding the efficacy of ZOSTAVAX, safety of ZOSTAVAX, the dangers and risks associated with use of the ZOSTAVAX vaccine, and the portrayal of the shingles condition and pain and ZOSTAVAX's role in treating or preventing same, were false, misleading, and deceiving.
- 674. McKesson knew or believed at the time it made the aforesaid false representations about the ZOSTAVAX vaccine that the false representations were material.
- 675. Consumers, such as Plaintiffs, who saw or read the ZOSTAVAX vaccine's marketing materials do not believe that the highest efficacy rate of 51% if vaccinated at age 60 is highly effective.
- 676. Consumers, such as Plaintiffs, who saw or read the ZOSTAVAX vaccine's commercial marketing materials relied upon the advertisements' representation that ZOSTAVAX was effective to prevent shingles and understood that representation to indicate that ZOSTAVAX would prevent shingles indefinitely.
- 677. McKesson knew that the ZOSTAVAX vaccine's commercial marketing materials were false and misleading and would likely deceive any viewer into believing that ZOSTAVAX was safe and effective for its intended use.
- 678. McKesson's representations intentionally concealed the following material information:
  - a. From 2006 until present date, McKesson intentionally concealed the effect of time since vaccination on ZOSTAVAX's efficacy.

- b. From 2006 until present date, McKesson intentionally concealed that the effect of time since vaccination significantly decreases the efficacy rate of ZOSTAVAX.
- c. From 2006 until present date, McKesson intentionally concealed the fact that four years after vaccination, the efficacy rate of ZOSTAVAX is zero.
- 679. Upon information and belief, McKesson had sole access to material facts concerning the nature of ZOSTAVAX, its efficacy, and its propensity to cause serious and dangerous injuries and damages to consumers who used the product.
- 680. Upon information and belief, McKesson, with Merck and MSD, had sole access to material facts concerning the nature of ZOSTAVAX, its efficacy, and its propensity to cause serious and dangerous injuries and damages to consumers who used the product.
- 681. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true safety of the ZOSTAVAX vaccine. McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true safety of the ZOSTAVAX vaccine.
- 682. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of serious harm associated with the use of the ZOSTAVAX vaccine. McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true risks of the ZOSTAVAX vaccine.
- 683. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true risks of it causing shingles and other injuries and conditions associated with the herpes zoster virus. McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing that it carried a real and serious risk of causing shingles and other injuries and conditions associated with the herpes zoster virus.

- 684. Merck's and/or MSD's research and testing of the ZOSTAVAX vaccine revealed the true efficacy of the ZOSTAVAX vaccine. McKesson knew of the results of Merck's research and testing of the ZOSTAVAX vaccine showing the true efficacy of the ZOSTAVAX vaccine.
- 685. McKesson knew and had reason to know that the ZOSTAVAX vaccine was not effective for the long-term prevention of shingles and would not effective at all after four years post-inoculation.
- 686. McKesson intentionally misrepresented, omitted, and/or concealed material facts concerning the safety and efficacy of the ZOSTAVAX vaccine to induce consumers such as Plaintiffs to rely upon Merck's misrepresentations and use the ZOSTAVAX vaccine as a safe vaccine for the long-term prevention of shingles and purchase the product to Merck's gain and to the consumers' detriment.
- 687. At the time McKesson concealed and intentionally omitted these material facts, and when the Plaintiffs were each administered the ZOSTAVAX vaccine, Plaintiffs were unaware of the material facts regarding the true safety and efficacy of ZOSTAVAX, and reasonably believed that ZOSTAVAX was safe and effective for the long-term prevention of shingles.
- 688. McKesson knew and had reason to know that consumers, including the Plaintiffs and Plaintiffs' physicians and healthcare providers that recommended, prescribed, purchased, administered, and/or otherwise used the ZOSTAVAX vaccine, did not have the ability to determine the true facts regarding the ZOSTAVAX vaccine's safety and efficacy that it intentionally concealed.
- 689. Plaintiffs would not have purchased and used the ZOSTAVAX vaccine if Plaintiffs knew the true facts regarding its safety and efficacy.

- 690. Plaintiffs' physicians would not have recommended, prescribed, purchased, and/or administered the ZOSTAVAX vaccine if they knew the true facts regarding its safety and efficacy.
- 691. Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and was induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain.
- 692. Because Plaintiffs reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 693. Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to recommend, prescribe, purchase, and/or administer the ZOSTAVAX vaccine to Plaintiffs for the long-term prevention of shingles and pain.
- 694. Because Plaintiffs' physicians reasonably relied on McKesson's misrepresentations regarding the safety and efficacy of the ZOSTAVAX vaccine and were induced to purchase and use the ZOSTAVAX vaccine for the long-term prevention of shingles and pain, Plaintiffs sustained severe and permanent personal injuries and damages.
- 695. McKesson's false representations and intentional omissions and concealment of material facts regarding the safety and efficacy of ZOSTAVAX constitute wrongful conduct, unfair conduct, deceptive conduct, and fraudulent conduct aimed towards consumers.
- 696. As a direct and proximate consequence of McKesson's unfair and deceptive acts and omissions, Plaintiffs sustained serious personal injuries including physical pain and suffering,

mental anguish, diminished capacity for the enjoyment of life, diminished quality of life, medical and related expenses, and other losses and damages.

697. Plaintiffs' injuries and damages were directly and proximately caused by the unfair and deceptive commercial acts of McKesson.

#### **COUNT X: PUNITIVE DAMAGES**

- 698. Merck and MSD have been repeatedly admonished by the FDA about the way they have marketed ZOSTAVAX to consumers and physicians.
- 699. Merck and MSD at all relevant times continued to market ZOSTAVAX to consumers and physicians in the same manner for which the FDA admonished them.
- 700. McKesson has been aware of the FDA's repeated admonishments of Merck's and MSD's marketing of ZOSTAVAX.
- 701. McKesson continued to market ZOSTAVAX in the same manner despite this knowledge.
- 702. Merck, MSD, and McKesson, each of them, 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.
- 703. Merck, MSD, and McKesson each has 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 conduct 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.

- 704. Merck, MSD, and McKesson, each of them, has engaged in other similar incidents with other drugs it designs, markets, and sells; 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 Merck, MSD, and McKesson, each of them, which continues even to the present time.
- 705. Merck's, MSD's, and McKesson's acts were willful and malicious in that each Defendant's conduct was carried on with a conscious disregard for the safety and rights of the public, consumers, and Plaintiffs.
- 706. Merck's, MSD's, and McKesson's unconscionable conduct thereby warrant an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants and deter similar conduct in the future.
  - 773. Punitive damages are appropriate under Florida 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 Merck, MSD, and McKesson, jointly, severally or in the alternative, for compensatory damages, punitive damages and costs of suit as provided by law.

# Respectfully submitted, MARC J. BERN & PARTNERS LLP

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