JS 44 (Rev. 02/19)

CIVIL COVER SHEET

19-CV-5201

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

I. (a) PLAINTIFFS

Martha Conrad

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Andrea Sapone, Annesley DeGaris and Harold McCall- The Wright Law Firm- 2 N. 20th Street, Ste. 1030, Birmingham, AL 35203
205-558-9000

DEFENDANTS

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

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability- Personal Injury

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Harvey Bartle, III DOCKET NUMBER 1:18-md-2848

DATE 11/4/2019

SIGNATURE OF ATTORNEY OF RECORD Andrea R Sapone

NOV - 5 2019

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM 19 5201
(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: P.O. Box 142, West Hamlin, West Virginia 25571

Address of Defendant: 2000 Galloping Hill Road, Kenilworth, New Jersey

Place of Accident, Incident or Transaction: West Hamlin, West Virginia

RELATED CASE, IF ANY:

Case Number: MDL 2848 Judge: Harvey Bartle, III Date Terminated: _____

Civil cases are deemed related when ***Yes*** is answered to any of the following questions:

		Yes	No
1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	☐	☑
2.	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	☑	☐
3.	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	☐	☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	☐	☑

I certify that, to my knowledge, the within case ☑ **is** / ☐ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 11/04/2019 Andrea L. Sapone ASB-4438-E68S
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☐ 11. All other Federal Question Cases
  (Please specify): _____

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☑ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

ARBITRATION CERTIFICATION
(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Andrea L. Sapone, counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

DATE: 11/04/2019 Andrea L. Sapone ASB-4438-E68S
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOV – 5 2019

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

Civ. 609 (5/2018)

HB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Martha Conrad

v.

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

MDL NO. 2848
Master Docket No.- 1:18-md-2848
Judge Harvey Bartle, III
Direct Filed Complaint Pursuant to Pretrial Order No. 22

CIVIL ACTION

19 5201

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (x)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

11/4/19		Martha Conrad
Date	**Attorney-at-law**	**Attorney for**
205-558-9000	205-588-5231	asapone@degarislaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

NOV -5 2019

IN THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION MARTHA CONRAD, Plaintiff, vs. MERCK & CO., INC. and MERCK SHARP & DOHME CORP., Defendants.	19 5201 MDL NO. 2848 Master Docket No.: 18-md-2848 JUDGE HARVEY BARTLE, III DIRECT FILED COMPLAINT PURSUANT TO PRETRIAL ORDER NO. 22 Civil Action No.:_____

COMPLAINT

Plaintiff MARTHA CONRAD ("Plaintiff") files this Complaint pursuant to PTO No. 22, and is to be bound by the rights, protections and privileges and obligations of PTO No. 22. Plaintiff states that but for the Order permitting direct filing in the Eastern District of Pennsylvania pursuant to PTO No. 22, Plaintiff would have filed this Complaint in the United States District Court for the Southern District of West Virginia. Further, in accordance with PTO No. 22, Plaintiff, hereby designates the United States District Court for the Southern District of West Virginia as the place of remand as this case may have originally been filed there.

Plaintiff, by and through her counsel, THE WRIGHT LAW FIRM, complains and alleges against Defendants MERCK & CO., INC. and MERCK SHARP & DOHME CORP. (collectively, "Defendants" and/or "Merck"), on information and belief, as follows:

PARTIES

1. Plaintiff MARTHA CONRAD ("Plaintiff") at all times relevant to this action was and is a resident and citizen of the state of West Virginia.

2. Defendant MERCK & CO., INC. is incorporated in New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK & CO., INC. developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Zostavax vaccine to be administered to patients throughout the United States, including this district. Merck has conducted business and derived substantial revenue within the District, including, but not limited to, its business activities related to the Zostavax vaccine.

3. Defendant MERCK SHARP & DOHME CORP. is a wholly owned subsidiary of Defendant MERCK & CO., INC. and part of the MERCK & CO., INC. family of companies. Defendant MERCK SHARP & DOHME CORP. is incorporated in New Jersey with its headquarters located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK SHARP & DOHME CORP., developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Zostavax vaccine to be administered to patients throughout the United States. Defendant MERCK SHARP & DOHME CORP. has conducted business and derived substantial revenue within the District, including but not limited to, its business activities related to the Zostavax vaccine.

4. Furthermore, based upon information and belief, Merck is, and was at all times relevant hereto,

a. duly authorized to conduct business in this District;

b. regularly conducted and solicited business within the District and continues to do so;

c. does business in the District, and at all times relevant hereto, has sold and distributed the Zostavax vaccine in the District;

d. derives substantial revenue from goods used or consumed in the District;

e. advertised its Zostavax vaccine to patients, doctors and hospitals in the District and/or other medical facilities located in the District;

f. advertises or otherwise promotes its business in the District; and

g. reasonably expects to be subject to the District's product liability law.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy, as to the Plaintiff, exceeds $75,000.00, exclusive of interest and costs, and because complete diversity of citizenship exists between the Plaintiff and the Defendants.

6. Furthermore, this Court has jurisdiction and venue is appropriate over this action pursuant to Pretrial Order No. 22 (Direct Filing-Stipulated) which authorizes direct filing of cases into MDL No. 2848 in order to eliminate delays associated with transfer of cases to promote judicial efficiency.

NO FEDERAL PREEMPTION

7. 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. Pursuant to § 11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table. The Zostavax vaccine is not a vaccine listed in the Vaccine Injury Table.

FACTS

8. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the Zostavax vaccine.

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

10. Varicella zoster is a virus that causes chickenpox.

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

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

13. 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.

14. 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.

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

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

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

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

b. As further described in this paper, "[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient's quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression." N. Eng. J. Med. 2005; 252(22) at 2272.

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

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

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

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

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

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

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

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

22. Shingles is a reactivation of the latent VZV.

23. The approval granted by the FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that Merck agreed to complete to, *inter alia*, ensure the safety of this vaccine. These commitments 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.

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

25. Zostavax is a stronger, more potent version of Merck's chickenpox vaccine, Varivax.

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

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

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

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

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

c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

29. As of February 2014, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of viral infection.

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

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

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

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

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

34. Since Zostavax's introduction in 2006, vaccine adverse event reports (VAERs) appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis.

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

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

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

38. In October 2017, the FDA approved Shingrix – an alternative shingles vaccine manufactured by GlaxoSmithKline. Shingrix was created by extracting a glycoprotein located on the surface of the varicella zoster virus. This glycoprotein triggers the body's immune system to activate and fight against the varicella zoster virus. The glycoprotein itself, however, cannot infect the body as it is not a virus. GlaxoSmithKline added the extracted glycoprotein with an adjuvant, a substance that enhances the body's immune response to an antigen, to create Shingrix. When Shingrix enters the body, the vaccine induces an immune response that cannot directly infect the vaccinated human host nor activate dormant VZV virus. In direct contrast, Zostavax contains various mutated live strains of actual VZV virus which can directly infect the vaccinated human host and/or activate dormant VZV virus.

39. Shingrix was proven to be safe and effective to prevent shingles in over 90% of users in contrast to Zostavax's effectiveness rates that were as low as 18% in certain age groups. Shingrix was proven to stay effective in preventing shingles at least four years in contrast to Zostavax's effectiveness that waned over a five-year period.

40. The safety, effectiveness, and the simple superiority of the design of Shingrix over Zostavax allowed the Center for Disease Control ("CDC") to make an unprecedented decision to recommend Shingrix over Zostavax to the general public after only a few days of Shingrix being approved by the FDA.

41. Upon information and belief, Merck possessed, or should have possessed, the knowledge to create a Shingles vaccine similarly designed as Shingrix.

CASE-SPECIFIC FACTS

42. Plaintiff at all times relevant to this action was and is a citizen of the state of West Virginia, residing in West Hamlin, West Virginia.

43. In or around September of 2017, Plaintiff was inoculated with Defendants' Zostavax vaccine for routine health maintenance and for its intended purpose: the prevention of shingles.

44. In or around October of 2018, Plaintiff presented to Lincoln Primary Care in Hamlin, West Virginia with complaints of a rash on her right lower leg. Plaintiff was diagnosed with Shingles by her primary care physician. The Shingles outbreak lasted several weeks and resulted in skin discoloration.

45. As a direct and proximate result of Merck's defective Zostavax vaccine, Plaintiff's symptoms have resulted in physical limitations not present prior to using Merck's product. Plaintiff also experiences mental and emotional distress due to resulting physical limitations and seriousness of the Plaintiff's condition.

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

47. As a direct and proximate result of Defendants' conduct, Plaintiff has incurred and will continue to incur medical expenses and other economic harm as a direct result of Zostavax.

COUNT I:
STRICT LIABILITY- DESIGN AND MANUFACTURING DEFECT

48. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

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

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

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

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

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

55. Plaintiff's physicians and/or healthcare providers used and administered the Zostavax vaccine for the purpose intended by Merck, and in a manner normally intended to be used and administered, namely for vaccination against shingles (herpes zoster). Merck had a duty

to design, create, and manufacture products that were reasonably safe and not unreasonably dangerous for their normal, common and intended use. Merck's product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

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

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

58. Furthermore, Merck defectively manufactured the subject Zostavax vaccine such that it unreasonably increased the risk of contracting an infection from the vaccine.

59. Merck's defective Zostavax vaccine was a substantial, proximate, and contributing factor in causing Plaintiff's injuries.

60. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described in this Complaint, including, but not limited to the following:

a. Plaintiff required and will continue to require healthcare and services;

b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

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

COUNT II: NEGLIGENCE

61. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

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

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

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

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

67. As a direct and proximate consequence of Merck's negligence, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

a. Plaintiff required and will continue to require healthcare and services;

b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

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

COUNT III:
FAILURE TO WARN

68. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

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

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

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

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

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

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

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

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

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

79. Plaintiff used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

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

81. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to her physician(s) and/or healthcare providers.

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

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

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

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

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

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

88. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint, including, but not limited to, the following:

a. Plaintiff required and will continue to require healthcare and services;

b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

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

COUNT IV:
BREACH OF EXPRESS WARRANTY

89. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

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

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

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

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

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

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

94. Plaintiff, through Plaintiff's healthcare providers, did rely on Merck's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

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

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

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys'

fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT V:
BREACH OF IMPLIED WARRANTY

97. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

99. Merck knew of the intended use of its Zostavax vaccine at the time Merck marketed, sold, and distributed its product for use by Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

100. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Plaintiff, her physicians, and her healthcare providers, that Zostavax vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

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

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

103. Plaintiff, her 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.

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

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

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

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

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

COUNT VI:
NEGLIGENT MISREPRESENTATION

108. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

110. Merck represented and marketed Zostavax as being safe and effective.

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

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

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

114. Merck failed to warn the Plaintiff, and other consumers, of the defective condition of Zostavax, as manufactured and/or supplied by Merck.

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

116. The above misrepresentations were made to Plaintiff, as well as the general public.

117. Plaintiff, and Plaintiff's healthcare providers and physicians, justifiably relied on Merck's misrepresentations.

118. Consequently, Plaintiff's use of Zostavax was to Plaintiff's detriment as Merck's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

119. As a foreseeable, direct, and proximate result of Merck's negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Merck, knew, or had reason to know, that Merck's product had not been sufficiently tested, that the product lacked adequate, accurate, and prominent warnings, and that injection with the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

120. As a direct and proximate consequence of Merck's negligent misrepresentations, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

a. Plaintiff required and will continue to require healthcare and services;

b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys'

fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VII:
UNJUST ENRICHMENT

121. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

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

123. Plaintiff paid for Merck's product for the purpose of preventing shingles.

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

125. Plaintiff has not received the safe and effective vaccine for which Plaintiff paid.

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

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

COUNT VIII:
PUNITIVE DAMAGES

127. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

128. Defendants conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of

the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Merck, and each of them, individually, jointly, severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

b. Restitution and disgorgement of profits;

c. Reasonable attorneys' fees;

d. The costs of these proceedings;

e. All ascertainable economic damages;

f. Punitive damages; and

g. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury.

Dated: November 4, 2019

Respectfully submitted,

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