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

$400

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	MDL NO. 2848 Master Docket No.: 18-md-2848
SHERRI FORRESTALL and TERRI BLACKMAN, as surviving children of DARLENE HOWARD, deceased, Plaintiffs, vs. MERCK & CO., INC. and MERCK SHARP & DOHME CORP.	JUDGE HARVEY BARTLE, III DIRECT FILED COMPLAINT PURSUANT TO PRETRIAL ORDER NO. 22 Civil Action No.: 19 2902

FILED
JUL 02 2019
KATE BARKMAN, Clerk
By: Dep. Clerk

COMPLAINT

Plaintiffs SHERRI FORRESTALL and TERRI BLACKMAN, AS SURVIVING CHILDREN OF DARLENE HOWARD, DECEASED ("Plaintiffs") file this Complaint pursuant to PTO No. 22, and are to be bound by the rights, protections and privileges and obligations of that PTO. Plaintiffs state that but for the Order permitting direct filing in the Eastern District of Pennsylvania pursuant to PTO No. 22, Plaintiffs would have filed this Complaint in the United States District Court for the Eastern District of Louisiana ("District"). Further, in accordance with PTO No. 22, Plaintiffs, hereby designate the United States District Court for the Eastern District of Louisiana as the place of remand as this case may have originally been filed there.

Plaintiffs, by and through their attorneys, Pendley, Baudin & Coffin, L.L.P, complain, allege and, pursuant to La. C.C. articles 2315.1 and 2315.2, bring survival and wrongful death

actions against Defendants MERCK & CO., INC. and MERCK SHARP & DOHME, CORP. (collectively, "Defendants" and/or "Merck") for their mother Darlene Howard's death, on information and belief, as follows:

PARTIES

1. Plaintiffs SHERRI FORRESTALL and TERRI BLACKMAN ("Plaintiffs") and Darlene Howard, at all times relevant to this action, were and are residents and citizens of the State of Louisiana. As surviving children of the deceased, Darlene Howard, Plaintiffs are the proper parties to bring survival and wrongful death actions pursuant to La. C.C. articles 2315.1 and 2315.2.

2. At the time of Darlene Howard's use of Zostavax, she was a resident and was domiciled in Metairie, Louisiana. Sherri Forrestall is a resident of and is domiciled in Baton, Louisiana, and Terri Blackman is a resident of and is domiciled in Madisonville, Louisiana.

3. 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 the 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.

4. 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, including the District. 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.

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

a. duly authorized to conduct business in the 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

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

7. 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 and to promote judicial efficiency.

NO FEDERAL PREEMPTION

8. 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

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

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

11. Varicella zoster is a virus that causes chickenpox.

12. Once the VZV causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

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

14. When reactivated, VZV 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.

15. 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.

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

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

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

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

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

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

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

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

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

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

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

21. 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.

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

23. Shingles is a reactivation of the latent VZV.

24. 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.

25. 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.

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

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

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

29. 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.

30. As of June 2016, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of viral infections, such as shingles.

31. 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.

32. 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 infections. 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.

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

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

34. 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, shingles, vision loss, 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.

35. 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 and acute transverse myelitis.

36. 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.

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

38. 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.

39. 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 contain various mutated live strains of actual VZV virus which can directly infect the vaccinated human host and/or activate dormant VZV virus.

40. 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.

41. 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.

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

CASE-SPECIFIC FACTS

43. Darlene Howard at all times relevant to this action was a citizen of the state of Louisiana, residing and domiciled in Metairie, Louisiana.

44. During a trip to Walgreens Pharmacy to fill a prescription, a Walgreens pharmacist suggested that she should get the Zostavax shingles vaccination. On April 28, 2015, Plaintiff was inoculated with Defendants' Zostavax vaccine at Walgreens Pharmacy Store No. 15067 in Metairie, Louisiana for routine health maintenance and for its intended purpose: the prevention of shingles (herpes zoster).

45. Shortly after receiving Defendants' Zostavax vaccine, on or before June 1, 2015, Darlene Howard suffered a severe outbreak of disseminated shingles that eventually covered her body which forced her to be admitted to East Jefferson General Hospital in Metairie, Louisiana.

46. Due to the debilitating and severe shingles outbreak, which affected other organs and other bodily systems, Darlene Howard died on July 3, 2015.

47. As a direct and proximate result of Merck's defective Zostavax vaccine, Darlene Howard's injuries and death and Plaintiffs' injuries were caused by Merck's product and caused by the Zostavax vaccine. Due to the shingles and resulting injuries, Darlene Howard suffered excruciating physical pain and suffering, mental anguish and emotional distress, and loss of enjoyment of life prior to her death.

48. Due to their mother's death, Plaintiffs experienced severe mental anguish and emotional distress as well as other economic and non-economic damages.

49. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, Darlene Howard sustained severe and disfiguring personal injuries and death. Further, as a tragic consequence of Merck's wrongful conduct, Plaintiffs suffered severe emotional anguish and distress and specifically assert wrongful death claims under La. C.C. art. 2315.2 and survival actions pursuant to La. C.C. art. 2315.1 arising from the death of their mother, Darlene Claire Howard.

FRAUDULENT CONCEALMENT- EQUITABLE TOLLING

50. Merck committed acts of concealment (including acts and omissions) in order to prevent consumers, such as Darlene Howard, and Plaintiffs from learning about the risks of injury associated with Zostavax as discussed in this Complaint.

51. The acts and omissions concealed the true risks of injury from Plaintiffs and prevented them from asserting such rights. Plaintiffs, while exercising reasonable diligence, could not have known of the operative facts giving rise to a cause of action until they saw a legal advertisement on television discussing legal claims against Merck in September of 2018.

52. Due to the acts and omissions of concealment, Plaintiffs were not cognizant of the facts supporting these claims and causes of action against Merck until years after their mother's death. As such, Plaintiffs' statutes of limitations were tolled in light of Merck's fraudulent concealment.

53. Merck's misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs of vital information essential to the pursuit of the claims in this complaint, without any fault or lack of diligence on his part. Plaintiffs relied on Merck's omissions and therefore could

not reasonably have known or become aware of facts that would lead a reasonable, prudent person to inquire further and to discover Merck's tortious conduct.

EQUITABLE ESTOPPEL

54. In the alternative, Merck is estopped and may not invoke the statute of limitations as through the fraud or concealment noted above, specifically the acts and omissions, Merck caused the Plaintiffs to relax their vigilance and/or deviate from their right of inquiry into the facts as alleged in this complaint.

55. Merck induced Plaintiffs to delay bringing this complaint by Merck's acts and omissions in failing to address the risk of harm discussed in this Complaint and provide this information to patients and the medical providers prescribing the vaccine, including Darlene Howard, her prescriber and to the Plaintiffs.

56. Merck is and was under a continuing duty to monitor and disclose the true character, quality, and nature of Zostavax. Because of Merck's misconduct and fraudulent concealment of the true character, quality, and nature of its Zostavax, Merck is estopped from relying on any statute of limitations defense.

COUNT I:
STRICT LIABILITY - DESIGN AND MANUFACTURING DEFECT UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

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

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

59. 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.

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

61. 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.

62. 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.

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

64. Darlene Howard's Zostavax prescriber 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.

65. At the time Zostavax left the Merck's control there existed an alternative design for the product that was capable of preventing Darlene Howard's injury, and the likelihood that Zostavax's design would cause her injury and the gravity of that injury resulting in her death, outweighed the burden on the manufacturer of adopting an alternative design.

66. 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 Darlene Howard and other consumers. Merck is therefore strictly liable for Darlene Howard's injuries, death and the Plaintiffs' damages sustained proximately caused by Darlene Howard's use of the product.

67. Darlene Howard could not, by the exercise of reasonable care, discover the defective condition of Merck's product and/or perceive its defective dangers prior to its administration by her healthcare provider.

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

69. Merck's defective Zostavax vaccine was a substantial, proximate, and contributing factor in causing Darlene Howard's death and Plaintiffs' injuries and damages.

70. As a proximate result of Merck's acts and omissions and Darlene Howard's use of Merck's defective product, Plaintiffs suffered severe injury and damages alleged herein.

COUNT II:

PRODUCTS LIABILITY - FAILURE TO WARN UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

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

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

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

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

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

76. 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, serious viral infections resulting in shingles.

77. 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 serious viral infection that could cause shingles. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer, and therefore, contained an inadequate warning.

78. 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 Darlene Howard and her prescriber, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

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

80. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert Darlene Howard and/or her prescriber and healthcare providers to the dangerous risks and reactions associated with it, including possible severe shingles and viral infections.

81. 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.

82. Darlene Howard used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

83. 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.

84. Darlene Howard did not have the same knowledge as Merck and no adequate warning was communicated to her prescriber and/or healthcare providers.

85. Merck had a continuing duty to warn consumers of its Zostavax vaccine, including Darlene Howard, 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.

86. 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.

87. As a direct and proximate result of Merck's failure to adequately warn or other acts and omissions of Merck described herein, Darlene Howard suffered severe and permanent injuries, pain, and mental anguish resulting in death which caused Plaintiffs' injuries.

88. 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.

89. 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 the administration of its Zostavax vaccine, including, but not limited to, possible viral infection, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, including Darlene Howard and her prescriber of Zostavax, knowing the product could cause serious injury.

90. 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.

91. As a proximate result of Merck's acts and omissions and Darlene Howard's use of Merck's defective product, Plaintiffs suffered serious injuries and damages.

COUNT III:

BREACH OF EXPRESS WARRANTY UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

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

93. 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."

94. 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 and shingles, of which Merck had full knowledge and did not accurately or adequately warn.

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

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

97. Darlene Howard, through her prescriber and/or other healthcare providers, did rely on Merck's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

98. 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.

99. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiffs suffered severe and permanent mental anguish, emotional distress and economic and non-economic damages as a result of the death of their mother.

COUNT IV:
BREACH OF IMPLIED WARRANTY IN REDHIBITION

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

101. 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.

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

103. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Darlene Howard, her prescriber, 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.

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

105. 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.

106. Darlene Howard, her prescriber of Zostavax 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.

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

108. If Darlene Howard had been aware of the substantial risks associated with Zostavax, she would not have purchased or used it.

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

110. 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 Darlene Howard without substantial change in the condition in which it was manufactured and sold.

111. As a foreseeable, direct and proximate result of Merck's acts and omissions Darlene Howard's use of Merck's defective product, Darlene Howard suffered serious injuries resulting in her death and causing life-long damages and injuries to the Plaintiffs as described herein.

COUNT V
NEGLIGENT MISREPRESENTATION

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

113. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Darlene Howard, 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.

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

115. After Merck became aware of the risks of Zostavax, Merck failed to communicate to Darlene Howard, her prescriber, and other members of the general public, that the administration of this vaccine increased the risk of infection.

116. 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.

117. Merck breached its duty in representing to Darlene Howard, her prescriber 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 Darlene Howard and other similarly situated patients.

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

119. 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.

120. The above misrepresentations were made to Darlene Howard, as well as the general public.

121. Darlene Howard, and her prescriber and physicians, justifiably relied on Merck's misrepresentations.

122. Consequently, Darlene Howard's use of Zostavax was to her detriment as Merck's negligent misrepresentations proximately caused Darlene Howard's injuries and death and Plaintiffs' damages.

123. 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.

124. As a direct and proximate consequence of Merck's negligent misrepresentations, Plaintiffs sustained injuries and damages as alleged herein including damages for the loss of love and affection, loss of support, medical expenses and funeral expenses sustained by Plaintiffs as a result of their mother's death, in addition to all pre-death mental and physical pain and suffering of Darlene Howard.

WHEREFORE, for all claims alleged herein, Plaintiffs demands judgment against Defendants, and requests compensatory damages for the pain and suffering, medical costs and expenses suffered by their mother Darlene Howard prior to her death; as well as their own mental anguish, emotional distress, and loss of enjoyment of life and all other economic and non-economic damages caused by her death; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as alleged herein including:

a. Compensatory damages for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries, health and medical care costs, lost wages, sustained by their mother, Darlene

Howard, prior to her death; as well as the mental anguish and emotional distress each Plaintiff suffered as a result of the death of their mother, Darlene Howard, 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; and

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby request a trial by jury of all issues triable by jury.

Dated: June 27, 2019

Respectfully Submitted,

FILED
JUL 02 2019
KATE BARKMAN, Clerk
By Dep. Clerk

Nicholas R. Rockforte, La. Bar Roll 31305
PENDLEY, BAUDIN & COFFIN, L.L.P.
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Attorneys for Plaintiffs

JS 44 (Rev 06/17)

HB

CIVIL COVER SHEET

19-cv- 2902

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

Sherri Forrestall and Terri Blackman, as surviving children of Darlene Howard, deceased

(b) County of Residence of First Listed Plaintiff East Baton Rouge Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nicholas R. Rockforte; Pendley, Baudin & Coffin, L.L.P.
24110 Eden St., Plaquemine, LA 70765
(225) 687-6396

DEFENDANTS

19 2902

Merck & Co., Inc., et al

County of Residence of First Listed Defendant Union County
(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
- ☐ 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
New Member Case In Re: Zostavax (Zoster Vaccine Live) Product Liability Litigation

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 18-md-2848

DATE 06/27/2019

SIGNATURE OF ATTORNEY OF RECORD

JUL - 2 2019

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JUL - 2 2019

HB

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

19 2902

DESIGNATION FORM

(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: 5023 Williamsburg Drive, Baton Rouge, Louisiana & 241 Grand Oaks Drive, Madisonville, Louisiana 70447

Address of Defendant: 2000 Galloping Hill Road, Kenilworth, New Jersey 07033

Place of Accident, Incident or Transaction: Metairie, Louisiana

RELATED CASE, IF ANY:

Case Number: 18-md-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 06/27/2019 *Attorney-at-Law / Pro Se Plaintiff* LA Bar Roll# 31305 *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, Nicholas R. Rockforte, 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.

JUL - 2 2019

DATE 06/27/2019 *Attorney-at-Law / Pro Se Plaintiff* LA Bar Roll# 31305 *Attorney I D # (if applicable)*

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

Sherri Forrestall and Terri Blackman, as surviving children of Darlene Howard, deceased v. Merck & Co., Inc., et al	MDL NO 2848 Master Docket No 18-md-2848 JUDGE HARVEY BARTLE, III DIRECT FILED COMPLAINT PURSUANT TO PRETRIAL ORDER NO 22	CIVIL ACTION 19 2902 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. ( )

6/27/2019	Nicholas R. Rockforte	Sherri Forrestall and Terri Blackman, as surviving children of Darlene Howard, deceased
Date	**Attorney-at-law**	**Attorney for**
(225) 687-6396	(225) 687-6398	nrockforte@pbclawfirm.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JUL - 2 2019