

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

Mayor and City Council of Baltimore, on behalf  
of itself and all others similarly situated,

Plaintiffs,

vs.

Merck Sharp & Dohme Corp.,

Defendant.

Case No. Case No

**JURY TRIAL DEMANDED**

**COMPLAINT – CLASS ACTION**

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1. Plaintiff, the Mayor and City Council of Baltimore (“City of Baltimore” or “Plaintiff”), individually and on behalf of a class of all others similarly situated, bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure against Merck Sharp & Dohme Corporation (“defendant” or “Merck”). Plaintiff challenges Merck’s anticompetitive scheme to enhance and maintain its monopoly power in the market for rotavirus vaccines sold in the United States (“Rotavirus Vaccine Market”). Plaintiff brings this action on behalf of themselves individually and on behalf of a plaintiff class (the “Class”) consisting of all third-party payors in Repealer Jurisdictions who indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines during the period from March 3, 2019 until the anticompetitive effects of Merck’s challenged conduct cease (the “Class Period”). A Repealer Jurisdiction is a state or district that has repealed the bar on indirect purchaser plaintiffs recovering under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and includes: Arizona, California, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. Plaintiff brings this action against Defendant for injunctive relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, and for treble damages under the antitrust laws and consumer protection laws of the several states.

## I. INTRODUCTION

2. This action challenges Merck’s anticompetitive vaccine bundling scheme whereby Merck leverages its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market and, consequently, to charge supracompetitive prices to purchasers of its rotavirus vaccines.

3. Merck is one of the world's largest vaccines manufacturers and a leading manufacturer of vaccines in the United States. It is the sole United States manufacturer in the markets for multiple pediatric vaccines, including MMR (measles, mumps, and rubella), varicella, and human papilloma virus ("HPV"), holding 100% of United States sales for those vaccines. Merck is by far the dominant seller in the Rotavirus Vaccine Market, marketing its vaccine under the trade name RotaTeq; its only competitor in the Rotavirus Vaccine Market is GlaxoSmithKline plc ("GSK"), which markets its rotavirus vaccine under the trade name Rotarix.

4. Merck was the only seller of rotavirus vaccine in the United States from 2006 until 2008, when GSK received approval to market Rotarix. Even before the threat of competition from GSK, Merck had contracts that offered "bundled" price penalties that would condition non-penalty prices on buyer "loyalty" to an entire bundle of different Merck vaccines. In preparation for GSK's introduction of a competing rotavirus vaccine, Merck added a condition to its contracts that required customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial price penalties on not only RotaTeq but also on all other bundled Merck vaccines (the "RotaTeq Bundled Loyalty Condition" or the "Merck Bundle"). This new bundle meant that any Merck customer who also wanted to buy significant amounts of Rotarix from GSK (a "Merck Disloyal Buyer" or "Disloyal Buyer")<sup>1</sup> would be faced with paying substantial penalties on any RotaTeq the customer continued to buy from Merck, *plus* substantial price penalties on all other Merck vaccines in the Merck Bundle (including those for which there is no other supplier).

5. Discovery will show that the Merck Bundle forecloses competition in greater than 40% of the Rotavirus Vaccine Market. The Merck Bundle substantially forecloses competition by

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<sup>1</sup> As opposed to Disloyal Buyers, "Merck Loyal Buyers" or "Loyal Buyers" are those that were willing to abide by the terms of Merck's Bundle.

limiting GSK's ability to profitably win sales to foreclosed buyers with price cuts, thereby allowing Merck to maintain its monopoly share of the Rotavirus Vaccine Market despite continuing to charge foreclosed buyers monopoly prices. Because the Merck Bundle penalizes Merck Disloyal Buyers with high penalty prices, GSK can maximize its profits by selling to such Disloyal Buyers at high prices just below the penalty prices charged by Merck.

6. In other words, the Merck Bundle bifurcated the market between Merck Loyal and Disloyal Buyers, reducing the ability of GSK to compete on price for the Loyal Buyers, and the incentive to compete on price for the Disloyal Buyers. As a result, the Merck Bundle incentivizes GSK to maintain high prices instead of competing aggressively with Merck on the price of rotavirus vaccines. And as a result of the softened competition caused by the Merck Bundle, there is less competitive pressure on Merck to reduce pricing of RotaTeq.

7. Due to the Merck Bundle, instead of significantly decreasing the price of RotaTeq when GSK entered the market, as would normally be expected to result from competitive entry into a monopoly market, Merck has maintained the price of RotaTeq at supracompetitive levels, actually *increasing* its list price despite facing competition from GSK. Those supracompetitive prices are passed on by healthcare providers to patients and third-party payors such as Plaintiff and members of the class. As a result, Plaintiff and the class paid, and continue to pay, artificially inflated prices for rotavirus vaccines.

## **II. PARTIES**

### **A. Plaintiffs**

8. Plaintiff, the Mayor and City Council of Baltimore ("City of Baltimore" or "Plaintiff") is a municipality located in Baltimore, Maryland. During the Class Period, the City of Baltimore purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines, including Rotateq, for personal and/or household use on behalf of members

in the following states: Arizona, California, Connecticut, D.C., Iowa, Idaho, Massachusetts, Maryland, Missouri, North Carolina, and New York. The City of Baltimore paid more than it would have absent Merck's unlawful anticompetitive scheme and was injured as a result of the illegal and wrongful conduct alleged herein.

**B. Defendant**

9. Defendant Merck Sharp & Dohme Corporation ("Merck") is a company organized under the laws of New Jersey and headquartered in Whitehouse Station, New Jersey. Merck Sharp & Dohme Corporation is a wholly-owned subsidiary of the entity formerly known as Schering-Plough Corporation, which has in turn been renamed Merck & Co, Inc. Defendant Merck sells pediatric vaccines in the United States, including RotaTeq. Merck has facilities in numerous states, including research, development, and manufacturing facilities in this District. In particular, Merck tests and manufactures vaccines at its "West Point" facility in Lansdale, PA, and has a major research facility located in North Wales, PA.

**III. JURISDICTION AND VENUE**

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs; at least one member of the class is a citizen of a state different from that of the Defendant; and fewer than two-thirds of the proposed class are citizens of Pennsylvania.

11. Alternatively, this Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 4, 15(a) and 26, and 28 U.S.C. §§ 1331 and 1337, because this action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks declaratory and equitable relief for these violations.



12. This Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1367.

13. Venue is proper in this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b)(1)-(2) because Merck resides in and is an inhabitant of this District or is found or transacts business in this District and because a substantial part of the acts giving rise to the claims set forth herein occurred in this District.

14. This Court has personal jurisdiction over defendant because during the Class Period defendant had facilities involved in the research, development, and manufacturing of vaccines in this District; marketed and sold RotaTeq in this District; and has had substantial contacts within this District in furtherance of the anticompetitive activity alleged herein.

#### **IV. BACKGROUND ON THE MANUFACTURE, REGULATION, AND SALE OF PEDIATRIC VACCINES IN THE UNITED STATES**

##### **A. How Vaccines Work**

15. Vaccines help a patient develop immunity by, essentially, imitating an infection. A vaccine typically contains an agent that resembles a disease-causing micro-organism, and is often made from a weakened or killed form of the microbe, its toxins, or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as a threat, and in so doing, causes the body to create antibodies designed to fight the disease-causing organism. Thus, when exposed to a live version of the micro-organism in the future, the vaccinated body's immune system can more easily recognize and destroy these micro-organisms that it later encounters.

16. Because vaccines are meant to stimulate a particular immune response to a particular pathogen, vaccines for one disease (*e.g.*, rotavirus) are not interchangeable with vaccines for another (*e.g.*, polio).

17. Vaccines are manufactured in several different ways. These include live, attenuated vaccines, which contain a version of the living virus that has been weakened so that it does not cause disease, as well as inactivated vaccines, which are made by killing the virus during the process of making the vaccine.

18. For most vaccines—in particular, inactivated vaccines—the first dose does not provide as much immunity as possible. As a result, many vaccines require multiple doses to reach maximum immunity. In addition, because immunity can decrease over time, booster doses are often used to rebuild immunity. Booster doses are typically distinct from the initial vaccine given to a patient and can be configured in different ways.

19. Because of the large number of different diseases requiring vaccination, a child often needs multiple vaccine injections during a single visit to the doctor’s office. As a result, manufacturers have developed several combination vaccines, which inoculate against multiple diseases with a single dose injection.

**B. FDA Approval of Vaccines and CDC Immunization Schedules**

20. Vaccines are part of a category of pharmaceutical products known as biologics, or biopharmaceuticals. Biologics are drugs manufactured from biological sources as opposed to drugs that are produced through chemical synthesis. In the United States, both biologics and non-biologic pharmaceuticals are regulated by the Food and Drug Administration (“FDA”). However, biologics and non-biologic pharmaceuticals differ in that biologic products cannot receive FDA approval through the Abbreviated New Drug Application (“ANDA”) process, which allows drugs that are demonstrated to be “bioequivalent” to an approved drug to be marketed as generics. Instead, in 2009, Congress passed the Biologics Price Competition and Innovation Act (“BPCIA”) which provided an abbreviated approval pathway for licensure of biologic products that are “biosimilar” to an approved reference drug. However, even under this abbreviated approval pathway, in order

to get FDA approval for a biologic product, a potential biologics manufacturer (“sponsor”) must undertake expensive clinical trials to establish safety, purity, and effectiveness.

21. Vaccine licensure requires clinical trials and extensive lab testing that can take several years for completion. A sponsor who wishes to get approval for a new biologic product must first file an Investigational New Drug (“IND”) application. The IND describes the vaccine, its method of manufacture, and quality control tests for release. After receiving approval for the IND, the sponsor may begin pre-licensure clinical trials in human subjects. There are three phases of clinical trials, each of which expands the number of human subjects. If at any stage in the process the data raise significant concerns about safety or effectiveness, the FDA may request additional information or halt ongoing clinical studies. If all three phases of clinical trials are successful, the sponsor may submit a Biologics License Application (“BLA”), which is a request for permission to introduce a biologic product into interstate commerce. The FDA reviews the BLA and provides a final response letter to the sponsor, often requiring further clinical trials prior to final approval and licensure.

22. Each year, the Center for Disease Control’s (“CDC”) Advisory Committee on Immunization Practices (“ACIP”) publishes immunization schedules recommended for pediatric and adolescent persons living in the United States. The schedules have been approved by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists.

23. The current version of the schedule requires the following 16 vaccinations for all people under 18 years of age: (1) hepatitis B; (2) rotavirus; (3) diphtheria, tetanus, and acellular pertussis (“DTaP”); (4) tetanus, diphtheria, and acellular pertussis booster (“Tdap”); (5) *haemophilus influenzae* type b (“Hib”); (6) pneumococcal conjugate; (7) COVID-19; (8)

inactivated poliovirus (“IPV”); (9) influenza; (10) measles, mumps, and rubella (“MMR”); (11) varicella virus; (12) hepatitis A; (13) meningococcal disease; (14) human papillomavirus (“HPV”); (15) meningococcal B; and (16) pneumococcal polysaccharide.

**C. The Sale of Vaccines in the United States**

24. In the United States, pediatric vaccines are sold separately to the public sector and the private sector. In the public sector, federal government agencies such as the Veterans Administration and the Department of Defense purchase vaccines under the Federal Supply Schedule (“FSS”). In addition, the CDC purchases vaccines based on prices negotiated by the Department of Health and Human Services under the Vaccines for Children (“VFC”) program. The VFC program distributes these vaccines at no charge to state health departments and certain public health agencies for distribution to physicians’ offices and public health clinics registered as VFC providers where they are used to vaccinate eligible children based on inability to pay. The pricing obtained under the FSS and the VFC program is available only to specified government entities and is not offered to the private sector.

25. In the private sector, healthcare providers purchase vaccines directly from manufacturers such as Merck or from wholesalers. Most providers purchase their vaccines pursuant to contracts negotiated by Physician Buying Groups (“PBGs”) or other similar group purchasing organizations (“GPOs”). Those entities, and their roles in the marketplace, are explained further below.

26. When consumers participating in self-insured health plans then receive RotaTeq, self-insured parties, including Plaintiffs and other members of the class, purchase, pay for, and/or reimburse their members for some or all of the purchase price of RotaTeq.

## V. BACKGROUND ON ROTAVIRUS VACCINES

27. Rotavirus is the leading cause of severe acute gastroenteritis (vomiting and severe diarrhea) among infants and young children worldwide. The disease can be severe, leading to dehydration and death. Before rotavirus vaccines were prevalent, rotavirus disease was a common and serious health problem for children in the United States, with nearly all children in the United States experiencing at least one rotavirus infection before their fifth birthday. Every year before the vaccine was available, more than 200,000 children in the United States had to go to the emergency room, 55,000 to 70,000 had to be hospitalized, and up to 60 died.

28. The first vaccine for rotavirus, RotaShield, was licensed by Wyeth Pharmaceuticals and recommended by the CDC for routine childhood immunization in 1998. Wyeth Pharmaceuticals, however, withdrew the vaccine in 1999 due to safety concerns. Scientists associated the vaccine with a rare intestinal problem called intussusception, a potentially fatal telescoping of part of the bowel.

29. Merck was developing its RotaTeq vaccine while RotaShield was on the market. RotaTeq is a pentavalent vaccine; meaning that it protects patients against five rotavirus strains: G1, G2, G3, G4, and P1. It is created by combining human rotavirus genes with WC3 cow virus. It is administered in three oral doses that are provided as a ready-to-use liquid. The vaccine was created by Dr. H. Fred Clark of the Wistar Institute of the University of Pennsylvania and Dr. Paul Offit, Chief of Infectious Diseases at the Children's Hospital of Philadelphia ("CHOP"). From 1992 to 1993, Merck licensed the RotaTeq vaccine from CHOP and initiated an efficacy trial, with Drs. Clark and Offit as primary investigators. This trial led to a blinded, randomized, placebo-controlled proof-of-concept trial in 439 infants aged 2–6 months old, conducted between 1993 and 1994.

30. After Wyeth withdrew its RotaShield vaccine in 1999, Merck accelerated its testing. In March 2001, Merck began a double-blind, randomized, placebo-controlled “Rotavirus Efficacy and Safety Trial” (“REST trial”), which was believed to be large enough to demonstrate the efficacy of RotaTeq conclusively and to rule out increased intussusception risk. The REST trial tested RotaTeq on 68,000 infants administered at 2–3 months followed by two subsequent doses, each 1–2 months after the last. With the successful results, RotaTeq was licensed by the FDA in February 2006. At the time, Merck was the only manufacturer selling a rotavirus vaccine in the United States. Like many of Merck’s vaccines, RotaTeq is routinely administered to infants and young children as part of a regular vaccine schedule recommended by the CDC.

31. GSK’s Rotarix was developed by Dr. Richard Ward and Dr. David Bernstein at Cincinnati Children’s Hospital Medical Center in the early 1990s. Rotarix is an oral live attenuated human vaccine administered in two doses and is provided as a powder that is reconstituted before administration. Unlike RotaShield or Merck’s RotaTeq, Rotarix is a single strain or monovalent vaccine, which means it specifically protects against one strain of rotavirus, the G1 strain, which is the strain responsible for the majority of infections in the United States, and induces some cross-protection against other less-common strains (G3, G4, and G9). Rotarix is also unique among other rotavirus vaccine candidates in being a human rather than a rhesus or bovine reassortant virus.

32. In 1995, Cincinnati Children’s Hospital entered a licensing agreement with the Virus Research Institute, which merged with T Cell Sciences in August 1998 to form Avant Immunotherapeutics. Avant funded a Phase II clinical trial of Rotarix from August 1997 to June 1998 with Dr. Bernstein, now a consultant to Avant and Cincinnati Children’s Hospital researcher, as the trial’s principal investigator. This trial proved successful and there were few adverse events in the children tested. Avant completed a 2-year extension in May 2000 which showed that

effectiveness remained after two years from inoculation. GSK (then, SmithKline Beecham) negotiated worldwide marketing rights in 1997. GSK completed I/II bridging and Phase II trials in 2002. It then initiated a Phase III trial of 63,000 children aged 6 weeks to 6 months in the third quarter of 2003. The Phase III trial was billed by GlaxoSmithKline Biologicals as the largest infant vaccine trial ever conducted. Rotarix was approved by the FDA in April 2008 for sale in the United States.

33. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither ACIP nor the Academies of Pediatrics or Family Physicians state a preference for one vaccine over the other. In addition, ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. In other words, if a patient begins the series with RotaTeq, it should complete that series with RotaTeq and should not switch to Rotarix, and vice versa.

34. Merck and GSK are the only companies that market a rotavirus vaccine in the United States. But despite competition from Rotarix—a product that the CDC has stated is just as effective as RotaTeq in preventing rotavirus infection—Merck continues to dominate the Rotavirus Vaccine Market in the United States, currently enjoying over 80% market share.

## **VI. THE VACCINES INDUSTRY AND ITS RELEVANT MARKETS**

### **A. Vaccine Manufacturers**

35. The sales of vaccines are large and rapidly expanding. In 2005, global vaccine sales generated approximately \$10 billion in revenue, and that number more than quadrupled to approximately \$41 billion in 2015. Vaccines are commonly segmented into two target segments: adult and pediatric.

36. In recent decades, vaccine markets in the United States have become highly concentrated. In 1967, 26 different companies held vaccine licenses in the United States, but by

2002, that number had dropped to 12. In 2008, only four companies sold pediatric vaccines in the United States: Merck, GSK, Sanofi Pasteur Inc. (“Sanofi”), and Pfizer, Inc. (“Pfizer”). Novartis began selling one pediatric vaccine in the United States in February 2010 but sold its pediatric vaccine business to GSK in March of 2015. After Novartis sold its vaccine business to GSK, there were again only four manufacturers in the United States selling the pediatric vaccines recommended on the ACIP schedule. The pediatric vaccine marketplace is highly concentrated among Merck, Sanofi, GSK, and Pfizer.

37. In addition to this concentration, two of the largest vaccines manufacturers, Merck and Sanofi, have reached agreements to cooperate in various ways in their sales of vaccines. Since 1994, Merck and Sanofi have operated a joint venture, Sanofi Pasteur MSD, which markets both companies’ lines of vaccines in Europe. In the United States, because Merck and Sanofi have complementary vaccine lines and similar bundling programs, most PBGs provide access to, monitor, and enforce loyalty to both companies’ complementary bundles.

38. The following chart indicates the vaccine products manufactured by Merck and its rivals:<sup>2</sup>

	<b>Merck</b>	<b>Sanofi</b>	<b>GSK</b>	<b>Novartis</b>	<b>Pfizer</b>
<b>Hepatitis B</b>	Recombivax	Vaxelis* <sup>3</sup>	Engerix B Twinrix* <sup>4</sup> Pediarix*		

<sup>2</sup> Pfizer and Moderna additionally produce vaccines for COVID-19 that were approved by the FDA for emergency use during the COVID-19 pandemic, but they do not compete with Merck as Merck does not produce a COVID-19 vaccine.

<sup>3</sup> Vaxelis was approved by the FDA in December 2018.

<sup>4</sup> A “\*” indicates a combination vaccine. Additionally, Twinrix can only be used for adults and therefore is not functionally interchangeable with pediatric Hepatitis A vaccines.



	<b>Merck</b>	<b>Sanofi</b>	<b>GSK</b>	<b>Novartis</b>	<b>Pfizer</b>
<b>DTaP</b>		Daptacel Quadracel* Pentacel* Vaxelis*	Infanrix Kinrix* Pediarix*		
<b>Tdap</b>		Adacel	Boostrix		
<b>Polio (IPV)</b>		IPOL Pentacel* Vaxelis*	Kinrix* Pediarix*		
<b>Pneumococcal</b>	Pneumovax				Prevnar
<b>Hib</b>	PedvaxHIB <sup>5</sup>	ActHIB Pentacel* Vaxelis*	Hiberix		
<b>Rotavirus</b>	RotaTeq		Rotarix		
<b>MMR</b>	MMRII ProQuad*		PRIORIX <sup>6</sup>		
<b>Varicella</b>	Varivax ProQuad*				
<b>Hepatitis A</b>	Vaqta		Havrix Twinrix*		
<b>Meningitis (MCV4)</b>		Menactra Menomune	Bexsero	Menveo	Trumenba
<b>HPV</b>	Gardasil				

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<sup>5</sup> PedvaxHIB was the subject of a recall in late 2007. Merck had limited supplies for sale from 2007 through 2010.

<sup>6</sup> PRIORIX was approved by the FDA on June 3, 2022.

**B. Relevant Product Markets**

39. The Merck Bundle effectively leveraged Merck's market power in a number of pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market. To the extent that Plaintiffs must prove monopoly power circumstantially by first defining a relevant product market, the following eight product markets are potentially relevant to Plaintiffs' antitrust claims.

**1. Rotavirus Vaccine Market**

40. The sale of rotavirus vaccines in the United States is a relevant product market.

41. The Rotavirus Vaccine Market contains all FDA-approved vaccines that inoculate against rotavirus.

42. In February 2006, the FDA licensed RotaTeq, a rotavirus vaccine marketed by Merck, for sale in the United States. RotaTeq is administered in a three-dose series, with doses administered at ages two, four, and six months.

43. In April 2008, the FDA licensed Rotarix, a rotavirus vaccine marketed by GSK, for sale in the United States. Rotarix is administered in a two-dose series, with doses administered at ages two and four months. Since April 2008, Rotarix has been the only rival to RotaTeq in the Rotavirus Vaccine Market.

44. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither ACIP nor the Academies of Pediatrics or Family Physicians state a preference for either Rotarix or RotaTeq.

45. The ACIP pediatric immunization schedule recommends rotavirus vaccine as a two- or three-dose series, with the first dose at two months, the second at four months, and the third at six months (if RotaTeq is used).

46. There are no reasonably available substitutes for rotavirus vaccines.

47. Prior to 2008, Merck had 100% market share in the Rotavirus Vaccine Market. After GSK entered the market in 2008, Merck's market share dropped, but discovery will show that it remained above 68% through the present day. In 2016, Merck's market share was 73%. In 2022, Merck's market share had gone back up above 80%.

48. At all relevant times, Merck possessed monopoly power in the Rotavirus Vaccine Market.

49. A small but significant, non-transitory increase above competitive prices for rotavirus vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

50. Due to the conduct challenged herein, Merck has sold its rotavirus vaccine at supracompetitive prices well in excess of marginal costs and in excess of the competitive price, and has enjoyed high profit margins.

## **2. Measles, Mumps, and Rubella ("MMR") Vaccine Market**

51. The sale of MMR vaccines in the United States is a relevant product market.

52. The MMR Vaccine Market contains all FDA-approved vaccines that inoculate against the measles (rubeola), mumps, and rubella (German measles) viruses.

53. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of MMR vaccine at ages twelve through fifteen months and at ages four through six years.

54. Until June 2022, there were two MMR vaccines available in the United States, MMRII and ProQuad. ProQuad is a combination vaccine that also inoculates against Varicella. Merck sells both MMRII and ProQuad.

55. There are no reasonably available substitutes for MMR vaccines.

56. A small but significant, non-transitory increase above competitive prices for MMR vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

57. Merck was the sole provider of MMR vaccines in the United States and has been the sole provider for the relevant period until PRIORIX entered the United States market in June 2022.

### **3. Pediatric Varicella Vaccine Market**

58. The sale of pediatric varicella vaccines in the United States is a relevant product market.

59. The Pediatric Varicella Vaccine Market contains all vaccines that inoculate against the varicella virus, commonly known as chicken pox, that are FDA-approved for use in children from birth to 18 years of age.

60. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of varicella vaccine at ages twelve through fifteen months and at ages four through six years.

61. There are two pediatric varicella vaccines available in the United States: Varivax and ProQuad. ProQuad is a combination vaccine that also inoculates against MMR. Merck sells both Varivax and ProQuad.

62. Merck and GSK also sell adult varicella vaccines, brand name Zostavax and Shingrix, to prevent and treat Shingles, a disease which results from a recurrence of the varicella virus in adults. Merck received a license to sell Zostavax in 2006 for use in people 60 years of age and older and GSK received a license to sell Shingrix in 2017 for use in people 50 years of age and older. Neither is indicated for pediatric use and neither is substitutable for pediatric varicella vaccines.

63. There are no reasonably available substitutes for pediatric varicella vaccines.

64. A small but significant, non-transitory increase above competitive prices for pediatric varicella vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

65. Merck is the sole provider of pediatric varicella vaccines in the United States and has been the sole provider for the relevant period.

**4. HPV Vaccine Market**

66. The sale of HPV vaccines in the United States is a relevant product market.

67. The HPV vaccine inoculates against human papillomavirus infection.

68. The HPV Vaccine Market contains all FDA-approved vaccines that inoculate against human papillomavirus, which can cause a variety of cancers, such as cervical cancer in women, and genital warts in both men and women.

69. The ACIP pediatric vaccine schedule recommends that adolescents receive a three-dose series of HPV vaccine on a schedule of 0, 1 to 2, and 6 months, to all adolescents aged 11 through 12 years.

70. Merck sells the only HPV vaccines available in the United States, Gardasil (a quadrivalent vaccine) and Gardasil 9 (a 9-valent vaccine). Gardasil was licensed in June 2006, and is one of Merck's most profitable products, grossing \$5.7 billion in 2021.

71. GSK previously sold a competing HPV vaccine, Cervarix, which was licensed by the FDA in 2009. GSK voluntarily withdrew Cervarix from the United States market in 2016. That said, even when Cervarix was available in the United States, Merck maintained a dominant share of the HPV Vaccine Market. In 2015, Merck had a 99.7% share in the HPV Vaccine Market.

72. There are no reasonably available substitutes for HPV vaccines.

73. A small but significant, non-transitory increase to competitive prices for HPV vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

74. Merck was the sole provider of HPV vaccines in the United States until 2009, and has maintained a dominant share of the HPV Vaccine Market since then and throughout the

relevant period. In 2015, Merck had a 99.7% share in the HPV Vaccine Market, and in 2016, GSK exited the market, restoring Merck's 100% market share.

**5. Hepatitis A Pediatric Vaccine Market**

75. The sale of pediatric hepatitis A vaccines in the United States is a relevant product market.

76. The hepatitis A vaccine inoculates against the hepatitis A virus, which causes liver disease.

77. The Hepatitis A Pediatric Vaccine Market contains all FDA-approved vaccines for use in children from birth to 18 years of age that inoculate against the hepatitis A virus.

78. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of hepatitis A vaccine at ages twelve through twenty-three months and a second dose six to eighteen months after the first dose.

79. There are two pediatric hepatitis A vaccines available in the United States, Havrix and Vaqta. GSK sells Havrix and Merck sells Vaqta. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis A vaccines.

80. There are no reasonably available substitutes for pediatric hepatitis A vaccines.

81. A small but significant, non-transitory increase above competitive prices for hepatitis A pediatric vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

**6. Hepatitis B Pediatric Vaccine Market**

82. The sale of pediatric hepatitis B vaccines in the United States is a relevant product market.

83. Hepatitis B vaccines inoculate against the hepatitis B virus, which can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, and liver failure.

84. The Hepatitis B Pediatric Vaccine Market contains all FDA-approved vaccines that inoculate against the hepatitis B virus and are approved for use in children aged 0 to 18.

85. The ACIP pediatric vaccine schedule recommends that children get three doses of hepatitis B vaccine: at birth, between one and two months, and between six and eighteen months.

86. There are currently four different pediatric hepatitis B vaccines available in the United States. GSK sells Engerix B and Pediarix, a combination vaccine that includes pediatric hepatitis B vaccine. Merck sells Recombivax HB and sold Comvax until it was discontinued. Sanofi Pasteur sells Vaxelis, a combination vaccine that includes pediatric hepatitis B vaccine, which was approved by the FDA in December 2018.

87. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis B vaccines. Similarly, Dynavax sells Heplisav-B and VBI Vaccines sells PreHevbrio (FDA-approved in 2021) but they are only approved for adult use, and thus are not functionally interchangeable with pediatric hepatitis B vaccines.

88. There are no reasonably available substitutes for pediatric hepatitis B vaccines.

89. A small but significant, non-transitory increase above competitive prices for pediatric hepatitis B vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

**7. *Haemophilus Influenzae* Type B (“Hib”) Vaccine Market**

90. The sale of *haemophilus influenzae* type b (“Hib”) vaccines in the United States is a relevant product market.

91. Hib vaccines inoculate against a type of bacteria called *haemophilus influenzae* type b, which can cause meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), and epiglottitis (a severe throat infection).

92. The Hib Vaccine Market contains all FDA-approved vaccines that inoculate against *haemophilus influenzae* type b.

93. The ACIP pediatric vaccine schedule recommends that children get three or four doses of Hib vaccine at two, four, and six months (depending on the brand of vaccine used), and a booster dose between twelve and fifteen months.

94. There are currently five different Hib vaccines available in the United States: ActHIB, Hiberix, and PedvaxHIB, which are all monovalent vaccines, and Pentacel and Vaxelis which are combination vaccines that include a Hib vaccine. GSK sells Hiberix. Merck sells PedvaxHIB. Sanofi sells ActHIB, Pentacel, and Vaxelis. Merck also sold a sixth vaccine, Comvax, until March 31, 2014, at which point it was discontinued.

95. There are no reasonably available substitutes for Hib vaccines.

96. A small but significant, non-transitory increase above competitive prices for Hib vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

97. Sanofi has held a dominant share of the Hib Vaccine Market throughout the relevant period. Merck suspended production of both of its Hib vaccines from 2007 through 2009 because inspections of its facilities revealed contamination by foreign bacteria. Between 2010 and 2013, Merck's market share in the Hib Vaccine Market (including Pedvax HIB and Comvax) increased steadily from about 8% to 18%. However, Merck and Sanofi co-marketed their largely complementary line of vaccines, and their combined share in the Hib Vaccine market was greater than 98%, leaving GSK with less than 2%.



**8. Pneumococcal Vaccine Market**

98. The sale of pneumococcal vaccines in the United States is a relevant product market.

99. Pneumococcal vaccines inoculate against the bacteria *Streptococcus pneumoniae* which can cause pneumonia, meningitis, and sepsis.

100. The Pneumococcal Vaccine Market contains all FDA-approved vaccines that inoculate against *Streptococcus pneumoniae*. There are two types of Pneumococcal vaccines sold in the United States, pneumococcal conjugate vaccine (PCV 7 and PCV13) and pneumococcal polysaccharide vaccine (PPSV23).

101. PCV7 and PCV13 vaccines are sold by Pfizer under the brand names Prevnar and Prevnar13. Prevnar13 was approved by the FDA for sale in the United States on February 24, 2010 and replaced Pfizer's PCV7 vaccine.

102. PPSV23 vaccines are sold by Merck under the brand name Pneumovax. Pneumovax was licensed for sale in the United States in 2011.

103. The ACIP pediatric vaccine schedule recommends doctors administer three doses of Prevnar to infants at two, four, and six months, and a fourth dose between twelve and fifteen months.

104. The CDC recommends a dose of Pneumovax for adults over the age of 65, even if they have gotten one or more doses of pneumococcal vaccine before the age of 65, and also recommends the use of Pneumovax as a catch-up vaccine for children ages 2-18 years who have not completed the recommended infant schedule.

105. There are no reasonably available substitutes for pneumococcal vaccines.

106. A small but significant, non-transitory increase above competitive prices for pneumococcal vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

**C. The Relevant Geographic Market is the United States**

107. The relevant geographic market for the vaccine product markets described above is the United States. Vaccines are subject to a complex regulatory framework under which drug approval in the United States is governed by the FDA. In addition, prices vary widely as between inside and outside of the United States, respectively, due to different national regulatory regimes.

**D. Barriers to Entry**

108. United States vaccines markets, including pediatric vaccine markets, are characterized by high barriers to entry including substantial upfront fixed costs, intellectual property protection, and substantial regulatory hurdles. As one academic study notes, “threat of new entrants in this market is seemingly low as the barriers to entry when developing biological products like vaccines are quite high.”<sup>7</sup>

109. Vaccine manufacturing is characterized by high fixed costs and economies of scale. The processes used to manufacture vaccines often use proprietary cell lines and virus strains that are difficult to duplicate. In addition, a manufacturer cannot bring a vaccine to market in the United States without obtaining an FDA license through the regulatory process for biologics. The ANDA process is not available for biologics in the United States, and the approval process for biosimilar products requires new entrants to perform costly clinical studies in order to obtain FDA approval.

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<sup>7</sup> Kevin W. Caves & Hal J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* at 14 (2011) (quoting Frost & Sullivan, *Global Vaccines Market*, Dec. 7, 2009, at 4), available at <https://www.law.berkeley.edu/wp-content/uploads/2015/04/Caves-Singer-Bundles-in-the-Pharmaceutical-Industry-2011.pdf>.

Those time-consuming and costly clinical trials may or may not result in licensing for a new vaccine. As a result, fixed costs are high in United States vaccine markets and barriers to entry make it difficult for new companies to develop, license, and bring a new vaccine to market.

110. In addition to large upfront costs for R&D and capital expenditures necessary to manufacture a vaccine, there are substantial economies of scale in vaccine manufacturing. Thus, established firms with larger output can have lower per-unit costs than new entrants with lower volumes due to the ability to spread such costs as plant administration, quality control, laboratory operation, health and safety, and utilities over a higher volume of output.

111. Another barrier to entry is created by the long period of time required to gain FDA approval for a vaccine. Even if an entrant were willing to incur the costs of entry today, it would not be able to compete with incumbent manufacturers for several years until it received a license from the FDA to market its product in the United States. For example, as described above, GSK initiated Phase III trials for Rotarix in 2003, but was not licensed by the FDA to make sales in the United States until five years later in 2008. Altogether it can take more than 10 years to bring a new vaccine to market.

112. The existence of high entry barriers is also indicated by the rarity of market entry. For example, in the Rotavirus Vaccine Market, high entry barriers are confirmed by the lack of additional entry over the last 15 years.

## **VII. MERCK HAS WILLFULLY MAINTAINED ITS MONOPOLY POWER IN THE ROTAVIRUS VACCINE MARKET**

### **A. Merck Has Monopoly Power in the Rotavirus Vaccine Market and Others**

113. Merck has had monopoly power in the following markets throughout the relevant period and up to the present: the Rotavirus Vaccine Market, the MMR Vaccine Market, the Varicella Vaccine Market, and the HPV Vaccine Market. In addition, at certain times during the

relevant period, Merck has had market power in the Hepatitis B Pediatric Vaccine Market and the Hepatitis A Pediatric Vaccine Market. Merck has had the power to foreclose competition and price above competitive levels in each of these markets during the relevant period.

114. From the time it received FDA approval to sell RotaTeq in February 2006 until GSK entered the market in 2008, Merck had a 100% monopoly in the Rotavirus Vaccine Market in the United States. Until GSK's entry into the MMR vaccine market in 2022, Merck also had a 100% monopoly in the MMR, Varicella, and HPV Vaccine Markets, as well as a substantial share in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

115. In 2008, GSK planned to bring a competing rotavirus vaccine, Rotarix, to market. Rotarix was approved by the FDA in April 2008 for sale in the United States. At the time, GSK sold competing hepatitis A, hepatitis B, and Hib pediatric vaccines, but did not sell an MMR vaccine, a Varicella vaccine, or an HPV vaccine (until Cervarix was introduced later).

116. Merck responded to this competition from GSK not by lowering the price of RotaTeq as economics would predict, but instead by using the Merck Bundle to foreclose competition from GSK. Discovery will show that these contracts foreclose competition in more than 40% of the relevant market, and they have allowed Merck to leverage its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market. This scheme effectively divided the Rotavirus Vaccine Market in a way that softened competition by impairing competitive incentives, and thereby allowed both Merck and GSK to price at monopoly levels even after GSK entered the market with Rotarix.

**B. Merck Implemented the Merck Bundle Through a Series of Exclusionary Contracts**

117. Merck was the sole seller of pediatric rotavirus vaccine in the United States from 2006 until GSK received approval to sell Rotarix in 2008. In response to this competitive threat

from GSK in the Rotavirus Vaccine Market, Merck added an exclusionary RotaTeq Bundled Loyalty Condition to its contracts, thereby bundling RotaTeq with its other pediatric vaccines.

118. Under the RotaTeq Bundled Loyalty Condition, Merck customers must agree to purchase all or nearly all of their rotavirus vaccines from Merck, and thus forego purchasing Rotarix from GSK. Customers who do not abide by this loyalty requirement would face paying steep disloyalty penalties not only on their purchases of RotaTeq, but also on all of their purchases of hepatitis A, hepatitis B, Hib, Varicella, MMR, and HPV vaccines from Merck. Thus, customers who would purchase Rotarix from GSK are penalized by being forced to pay substantially higher prices for all of the vaccines in the Merck Bundle—including those vaccines for which Merck is the sole seller—from 2% to 58% higher, depending on the vaccine.

119. As part of the scheme challenged in this case, in May 2008, and in anticipation of competition from GSK in the rotavirus vaccine market, Merck sent a letter to Atlantic Health Partners (“AHP”), a PBG, to amend Merck’s contract with AHP so that it would now require 80% market share loyalty on Merck’s rotavirus vaccine in order to avoid bundled penalty prices on Merck’s MMR II, Pneumovax23, ProQuad, Varivax, Gardasil, and Zostavax vaccines. This new condition is the RotaTeq Bundled Loyalty Condition.

120. Although physicians, practices, and hospitals often purchase vaccines directly from manufacturers, most do so pursuant to contracts negotiated by PBGs or other similar GPOs (collectively referred to as “buying groups”).

121. PBGs are typically privately held, for-profit entities, with membership consisting of thousands of family practices, pediatricians, and other independent medical practices. PBGs coordinate member purchases of vaccines and other healthcare supplies through group purchasing contracts with major vaccine manufacturers and medical supply distributors. Because PBGs

seldom charge membership dues or participation fees, most or all of their compensation typically comes in the form of rebates and administrative fees paid by vendors (based on PBG members' aggregate expenditures). To qualify for non-penalty vaccine prices, PBGs typically require that participating practices agree to contractual terms that typically include manufacturer exclusivity. Manufacturers grant rebates to PBGs based on their success in enrolling practices and aggregating purchase volumes. The receipt of these administrative fees and rebates is usually dependent on the PBG's compliance with the loyalty terms contained in their contracts, and thus provides a strong incentive for the PBG to ensure its members maintain loyalty to the manufacturer.

122. Through the bundling scheme alleged herein, Merck has coopted the PBGs—who are paid by the vaccine manufacturers even though they ostensibly work on behalf of physicians—to impose and enforce its anticompetitive and exclusionary conduct. Continuing to the present, Merck has imposed the Merck Bundle through a series of exclusionary contracts with PBGs and other GPOs, and by extension, on the providers and institutions that are members of these groups. Before GSK entered the Rotavirus Vaccine Market, Merck already had agreements in place with buying groups that provided buyers certain contract prices for all vaccines in Merck's portfolio if (and only if) the buyers committed to buying all or nearly all of their hepatitis A and hepatitis B vaccines from Merck. Notably, before GSK received approval for Rotarix, Merck's contract prices were not contingent upon loyalty to RotaTeq, a vaccine for which Merck faced no competition, unlike with the vaccines for hepatitis A, hepatitis B, and Hib. In response to GSK's entry into the Rotavirus Vaccine Market, however, Merck added the RotaTeq Bundled Loyalty Condition to its contracts. This condition required the purchaser either to maintain a high RotaTeq share (such as 90% or 100%) of its total rotavirus vaccine purchases, or to be penalized by losing contract prices on all of Merck's pediatric vaccines and being forced to pay the higher "list" prices for the Merck

vaccines. Merck has continued to sign additional contracts and contract amendments through the present that include the RotaTeq Bundled Loyalty Condition.

123. After the addition of the RotaTeq Bundled Loyalty Condition, customers' receipt of bundled contract prices for Merck's portfolio of pediatric vaccines became contingent on maintaining loyalty to RotaTeq. Buying groups generate revenue primarily through the administrative fees and rebates paid by manufacturers as a percent of the buying group's total purchases of the manufacturer's products. When Merck added the RotaTeq Bundled Loyalty Condition to its contracts, however, it also made receipt of these rebates contingent upon the PBG or GPO maintaining member loyalty to RotaTeq, whereas before the RotaTeq Bundled Loyalty Condition was added, loyalty was only required on Merck's other vaccines. For example, under the new RotaTeq Bundled Loyalty Condition, if a buying group's members failed to meet their collective loyalty requirement on RotaTeq, that buying group would now face a catastrophic event, namely losing its administrative fee earned on *all* of its members' pediatric vaccine purchases from Merck, not just those earned on RotaTeq purchases.

124. Because Merck and Sanofi manufacture vaccines in complementary rather than competing markets (the only exceptions being the Hib Vaccine Market, which Merck withdrew from for much of the relevant period, and the Hepatitis B market, which Sanofi entered in 2018), many of Merck's bundled loyalty contracts allow customers to purchase Sanofi's complementary vaccines, but *forbid* the customer from purchasing competing vaccines from GSK. Thus, buying groups who sign contracts with Merck to offer bundled pricing to their members generally cannot enter into a simultaneous agreement with GSK to offer GSK's products to their members at bundled prices. In addition, in order not to jeopardize their administrative fees and rebates, Sanofi/Merck buying groups must actively discourage their members from purchasing GSK's

Rotarix by threatening to remove the member from the group, which would force the member to pay penalty prices for all of Merck's bundled vaccines.

125. The following summarizes some of the PBGs and GPOs that have exclusionary contracts with Merck that contain the RotaTeg Bundled Loyalty Condition, requiring *de facto* exclusivity or near exclusivity on Merck's rotavirus vaccines:

**1. CNHN Vaccine Group**

126. CNHN Vaccine Group offers a vaccine group purchase program with Merck. CNHN Vaccine Group's Purchase Information explained that:

**To receive our CNHN contract pricing, members agree to purchase Sanofi or Merck products where competing vaccines exist.** In return our members receive the region's best pricing on the full portfolio of Sanofi and Merck vaccines. Occasionally, a competing product may briefly be lower-priced; however, CNHN practices realize significant savings when you calculate the total vaccine purchases made annually by our practices. . . . **CNHN members cannot selectively participate in CNHN vaccine contract for some vaccine and simultaneously purchase competing products off contract.** CNHN pricing is tiered to contract performance. The closer we come to 100% ordering compliance, the better we all do. CNHN does not endorse practices ordering small amounts of competing products. Doing so violates our contract terms and jeopardizes group pricing for all our participating CNHN members.

127. This language indicates that, because of the incentives created by the Merck Bundle, CNHN does not offer GSK vaccines, and actively discourages its members from purchasing Rotarix or other GSK vaccines outside of its contract because that could lead to steep penalties from Merck under these contracts.

**2. Atlantic Health Partners**

128. Atlantic Health Partners is a leading PBG specializing in vaccines. AHP has negotiated exclusive vaccine purchasing contracts with both Merck and Sanofi. Participating physicians' practices agree to exclusivity on rotavirus vaccines (as well as others) in exchange for avoiding penalties on its prices for Merck's vaccine portfolio.



### 3. CCPA Purchasing Partners

129. CCPA Purchasing Partners offers a “Merck Contract Only” that requires physician practices to agree to “purchase Merck’s Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), MMR (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (Pe[d]Vax HIB) and Pneumococcal (Pneumovax23) vaccine products as needed. By selecting this option, [the] practice agrees **not** to purchase GlaxoSmithKline’s Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Rotarix, and Pediarix products, and/or any other vaccine product that competes with the Merck products noted above. It is understood that failure to comply with these compliance terms may result in price increases, loss of administrative awards, and termination of [the] practice from CCPAPP’s Merck contract.”<sup>8</sup>

130. The CCPA Purchasing Partners Vaccine Contracting Guide further explains that “[i]f your practice is participating *only* in the Merck agreement (and not the Sanofi Pasteur agreement with CCPAPP), your practice must agree to purchase as needed: Merck’s Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), Measles, Mumps and Rubella Virus (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (PedvaxHib) and Pneumococcal (Pneumovax 23) vaccine products. By selecting this option, your practice agrees not to purchase GlaxoSmithKline’s Hepatitis A (Havrix), Hepatitis B (Engerix-B), Hepatitis A-Hepatitis B combination (Twinrix), HPV (Cervarix), Rotavirus (Rotarix), HIB (Hiberix), and Polio-DTap-Hepatitis B combination (Pediarix) products, and/or any other vaccine product that competes with the Merck products noted above.”<sup>9</sup>

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<sup>8</sup> *CCPA Purchasing Partners Vaccine Contracting & Compliance Form, available at [https://www.ccpapp.org/assets/1/7/7.\\_2016\\_Vaccine\\_Contracting\\_and\\_Compliance\\_Form\\_Fillable1.pdf](https://www.ccpapp.org/assets/1/7/7._2016_Vaccine_Contracting_and_Compliance_Form_Fillable1.pdf).*

<sup>9</sup> *CCPA Purchasing Partners Vaccine Contracting Guide, available at [https://www.ccpapp.org/assets/1/7/CCPAPP\\_Vaccine\\_Contracting\\_Guide\\_2016.pdf](https://www.ccpapp.org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016.pdf).*

#### **4. CASA Physicians Alliance**

131. CASA Physicians Alliance offered its members a Merck contract that included “Core Products,” which “should be purchased through Merck or one of the Prime Distributors approved by Merck in lieu of equivalent vaccines from any other vendors.” The Core Products included RotaTeq. If CASA members met the performance requirements on the core products, it provided penalty-free prices on the full-line of Merck vaccines, including Gardasil, MMRII, ProQuad, Varivax, and RotaTeq.<sup>10</sup>

#### **5. Main Street Vaccines**

132. Merck’s agreement with the Main Street Vaccines PBG “requires the preferential use of: RECOMBIVAX, VAQTA, RotaTeq, Gardasil/Gardasil 9, [and] ZOSTAVAX.” Main Street Vaccines also has agreements with its individual members that require exclusivity to Merck’s vaccines, and do not allow the customer to purchase any competing vaccines from GSK, such as Rotarix. According to the Main Street Vaccines’ web page describing the agreements, “Members can use any combination of Merck vaccine *but may not use competing vaccines from other manufacturers.*”

#### **6. Medical Practice Purchasing Group**

133. Medical Practice Purchasing Group (“MPPG”) offers special pricing and additional rebates to physician members. Under the MPPG contract, members agree “to use the full portfolio of vaccine-related pharmaceutical products covered under the MPPG contracts in the volume and ratios contemplated by the recommended immunization schedules.”<sup>11</sup> MPPG pays rebates, which

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<sup>10</sup> Discount vaccines available to CASA Physician GPO members, available at <http://www.casaalliance.net/merck>.

<sup>11</sup> *MPPG Member Agreement*, available at [http://www.mppg.net/wp-content/uploads/2016/04/April-2016-participation\\_agreement\\_.pdf](http://www.mppg.net/wp-content/uploads/2016/04/April-2016-participation_agreement_.pdf).

it calls “loyalty payments,” to members “since our group pricing is based on brand loyalty. Members purchasing our contracted partners’ products and not their competitors’ can earn eligibility for these awards.”<sup>12</sup> MPPG’s FAQs also remind members that “[i]f you are interested in receiving the vaccine discounts, keep in mind our group pricing is based on our members purchasing Merck and/or Sanofi Pasteur vaccines and not their competitors.”<sup>13</sup> This indicates that the contract between MPPG and Merck disincentivized the PBG from offering any vaccines to its members that compete with Merck’s vaccines, such as Rotarix, or from making GSK vaccines available to its members. The FAQs also note that “Our compliance rates are exceptionally high and we appreciate our members’ dedication to the group’s benefit.”<sup>14</sup>

## **7. National Discount Vaccine Alliance**

134. National Discount Vaccine Alliance’s (“NDVA”) 2009 Membership Agreement for Merck vaccines required that NDVA and its members maintain a minimum level of 90% market share on RotaTeq and other Merck pediatric vaccines, or “be considered non-compliant and subject to immediate removal from the contract. This will be monitored no less than quarterly.” If a medical practice is non-compliant, it risks having penalties imposed as follows: 34% on purchases of Recombivax, 29% on purchases of Vaqta, 6% on purchases of RotaTeq, 3% on purchases of ProQuad, MMR, and Varivax, and 2% on purchases of Pneumovax 23, Zostavax and Gardasil.

## **8. Unified Physicians Society**

135. Unified Physicians Society (“UPS”) is a for-profit PBG that has thousands of pediatrician members. UPS has negotiated market share agreements with Merck and Sanofi.

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<sup>12</sup> *FAQs*, available at <http://www.mppg.net/membership/faqs/>.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

According to UPS' FAQs, "[i]n order to receive the highest discounts, our members have chosen to utilize these product lines exclusively. The only vaccine our members do not purchase on contract is Pneumococcal Conjugate Vaccine for Pediatric Use, which is not available through Sanofi Pasteur or Merck."<sup>15</sup>

**9. PedsPal**

136. PedsPal, a GPO, has an agreement with Merck that is similar to CASA Physicians Alliance's agreement with Merck.<sup>16</sup>

**10. River Valley Pediatricians, Inc.**

137. River Valley Pediatricians, Inc. ("RVPI") is a group purchasing organization that serves 44 pediatric practices in greater Cincinnati, northern Kentucky, and southeast Indiana. It allows members to avoid penalties on their pricing on RotaTeq and other Merck vaccines in exchange for loyalty. RVPI's membership application "requires total purchasing support of those contracts that include 'loyalty/compliance' discount clauses that have been approved by the RVPI Board. These require achievement by all members collectively of market share purchases equal to or greater than 90% of total product purchases."<sup>17</sup> The agreement also states that "[f]ailure to comply with these purchasing agreements will result in termination from the agreements."<sup>18</sup>

**C. Merck Works with PBGs to Enforce the Merck Bundle**

138. Since 2008 and continuing to the present, Merck has worked together with PBGs to enforce the exclusionary terms of the Merck Bundle and to make sure that customers do not buy GSK's Rotarix. Merck enforces the contracts through the threat of higher prices for RotaTeq and

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<sup>15</sup> *FAQs*, available at <http://www.unifiedphysiciansociety.com/index.php/faqs>.

<sup>16</sup> *PedsPal Group Purchasing Program*, available at <http://www.pedspal.org/SiteCollectionDocuments/Join/PEDSPAL-JoinNow.pdf>.

<sup>17</sup> RVPI Membership Application (as of June 16, 2016).

<sup>18</sup> *Id.*

other vaccines in the bundle as well as through the threat of withholding administrative fees and rebates from PBGs whose members purchase Rotarix from GSK. As a result, Merck incentivizes the PBG's to be coopted into helping Merck ensure that the PBG members do not buy Rotarix.

139. For example, CCPA Purchasing Partners' Vaccine Contracting Guide explains that “[b]ecause failure to meet contract compliance by practices may result in price increases and loss of administrative fees for ALL CCPAPP practices, we do not tolerate non-compliance within our contract terms. CCPAPP will notify your practice of any purchase activity that is not in compliance with our Merck agreement. If the non-compliance continues, we will promptly send written notice via certified mail to your practice informing you of your termination from our contract.”<sup>19</sup>

140. Similarly, CASA Physicians Alliance's website explains that it “reviews individual member purchases on a continuous basis to insure individual clinic performance meets the participation requirements.”<sup>20</sup> CNHN Vaccine Group explains that “[t]he closer our group comes to 100% contract purchase compliance, the better the pricing for all. CNHN will remove practices from CNHN contracts for failure to comply with contract terms.” A “Frequently Asked Questions” page on the Main Street Vaccines website explains that “[w]e get rock bottom prices on Sanofi Pasteur and Merck Vaccines by agreeing to their exclusive use. Main Street Vaccines and its member practices may not use competing vaccines except for explicit reasons of medical necessity or product unavailability.”<sup>21</sup>

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<sup>19</sup> *CCPA Purchasing Partners Vaccine Contracting Guide*, available at [https://www.ccpapp.org/assets/1/7/CCPAPP\\_Vaccine\\_Contracting\\_Guide\\_2016.pdf](https://www.ccpapp.org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016.pdf).

<sup>20</sup> Discount vaccines available to CASA Physician GPO members, available at <http://www.casaalliance.net/merck>.

<sup>21</sup> Kevin W. Caves & Hal J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* at 25 n.56 (2011) (quoting *Frequently Asked Questions*, <http://www.mainstreetvac.com/faq.html>).

141. PBGs also help Merck monitor their members' compliance with the Merck Bundle. For example, a question on the Main Street Vaccines "Frequently Asked Questions" page asks "Can you really tell if I am buying vaccines outside the contract?" The answer is "Yes, we can. When that happens you may receive a warning or a notice terminating your membership with the loss of all accrued benefits. Periodically, competing manufacturers 'advise' members of ways to skirt our agreements and use their products. This is almost always detected and results in removal from our contract(s)."<sup>22</sup> Similarly, Unified Physicians Society's "Frequently Asked Questions" page explains that "[o]ur contract member purchases are monitored by the manufacturers and our discounts/terms are based on members adhering to these guidelines."<sup>23</sup>

**D. The Merck Bundle Has Substantially Foreclosed Competition in the Rotavirus Vaccine Market**

142. By requiring their customers to purchase all or nearly all of their rotavirus vaccines from Merck, Merck's RotaTeq Bundled Loyalty Condition substantially foreclosed competition in the Rotavirus Vaccine Market. Discovery will show that Merck's contracts containing the RotaTeq Bundled Loyalty Condition have foreclosed competition in greater than 40% of the relevant market.

143. GSK is the only competitor to Merck in the Rotavirus Vaccine Market, having received a license for Rotarix in April 2008 and entered the market shortly thereafter.

144. Because failure to comply with the RotaTeq Bundled Loyalty Condition can lead to substantial penalties on a portfolio of other vaccines that physicians purchase from Merck (including those that they cannot get from anyone else), the contracts effectively raised the cost of purchasing Rotarix by a substantial degree. Even if GSK decided to counter the RotaTeq Bundled

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<sup>22</sup> *Id.*

<sup>23</sup> *FAQs*, available at <http://unifiedphysiciansociety.com/index.php/faqs>.

Loyalty Condition by offering Rotarix at a lower price than RotaTeq, physicians and hospital purchasers would have to weigh that difference against the penalty they would be forced to pay on *all* of their other vaccine purchases from Merck.

145. For example, assuming a physician practice purchased the ACIP recommended portfolio of pediatric vaccines for each of its patients, Merck's RotaTeq Bundled Loyalty Condition imposed penalties of \$25.91 per rotavirus dose, which represents approximately 40% of Merck's nominal loyal RotaTeq price (\$64.71). This means that GSK would have to price its competing rotavirus vaccine more than forty percent below Merck's Loyal price for RotaTeq in order to counterbalance the penalties the customer would have to pay on Merck's portfolio of vaccines. And GSK had no incentive to cut price in this way because the Merck Bundle was designed to, and did, ensure that even if Merck continued to price at monopoly levels, GSK could not gain sufficient sales from price cuts to foreclosed (Loyal) buyers to make such price cuts profitable.

146. GSK's ability to counter the RotaTeq Bundled Loyalty Condition with aggressive competition was made even more difficult because Merck offered multiple vaccines that GSK did not, including HPV, MMR, and Varicella vaccines. Given that these vaccines are required under the ACIP recommendations, physician buyers needed to purchase these products from Merck. GSK had no alternative to several of Merck's monopoly vaccines. Moreover, because ACIP recommends that patients complete their vaccination schedule using the same brand of vaccine for each dose, at any given point in time a substantial portion of the demand for Merck's vaccines by physician practices and hospitals is incontestable, meaning that the customer cannot, consistent with good medical practice, switch *all* of its purchases to another supplier no matter what price is

offered. Thus, the customer would still be forced to pay penalty prices on the remaining Merck vaccines that it could not switch to GSK.

147. As a result, the Merck Bundle reduced GSK's ability to compete for buyers foreclosed by the RotaTeq Bundled Loyalty Condition. This in turn reduced GSK's incentive to compete for market share in the Rotavirus Vaccine Market by reducing the price of Rotarix. The Merck Bundle prevented the erosion of Merck's market share and monopoly power, allowing Merck to foreclose a substantial share of the Rotavirus Vaccine Market and maintain high prices. Had Merck not used the Merck Bundle to foreclose competition in the Rotavirus Vaccine Market, GSK would have achieved greater sales at lower prices than it actually did and would have forced Merck to respond with lower prices to avoid losing substantial market share.

148. In addition, the Merck Bundle has prevented physician practices and hospital purchasers from making a free choice between RotaTeq and Rotarix based on price, quality, service, and clinical preference.

149. Discovery will show that Merck has executed contracts containing the RotaTeq Bundled Loyalty Condition requiring *de facto* exclusivity or near exclusivity on RotaTeq, with PBGs and other GPOs and hospital networks covering the vast majority of private physician and hospital purchasers of rotavirus vaccines in the United States. Under the terms of these contracts, physicians and hospital purchasers must purchase all or nearly all of their rotavirus vaccines from Merck to avoid substantial pricing penalties on all of Merck's vaccines. Discovery will show that these contracts collectively foreclosed more than 40% of the Rotavirus Vaccine Market, which is a substantial part of the available opportunities for the distribution of rotavirus vaccines in the United States.



### VIII. ANTICOMPETITIVE HARM AND ANTITRUST IMPACT

150. The purpose and effect of the RotaTeq Bundled Loyalty Condition was to insulate Merck's RotaTeq from competition from GSK's Rotarix. By artificially dividing the Rotavirus market, the Merck Bundle prevented the price declines and market share erosion that would normally occur upon competitive entry into a market dominated by a monopolist. As a result, healthcare providers paid substantially more for both RotaTeq and Rotarix than they otherwise would have. They then passed those increased prices on to patients and third-party payors who cover all or part of the cost of vaccines for their members.

151. As a result of the Merck Bundle, Plaintiff and members of the proposed class have repeatedly paid artificially inflated prices for rotavirus vaccines from the time Rotarix entered the market through the present.

#### A. Economic Theory Demonstrates How The Merck Bundle Leads to Higher Prices

152. A number of economists have explained how bundled loyalty contracts can increase profits and anticompetitively raise prices, resulting in harm to purchasers. Bundled loyalty contracts effectively function as market allocation agreements because they can result in the same outcome as would occur from horizontal agreements to divide customers, for example through a geographic market allocation agreement.<sup>24</sup>

153. In a competitive marketplace without any bundled loyalty contracts, the entrance of a second product such as Rotarix to compete with a former monopolist would cause prices to drop. This is because, absent collusion, competing firms acting in their own rational self-interest

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<sup>24</sup> See Einer Elhauge, *How Loyalty Discounts Can Perversely Discourage Discounting*, 5 J. COMP. L. & ECON. 189 (2009); Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397, 459-61 (2009); Einer Elhauge & Abraham L. Wickelgren, *Robust Exclusion and Market Division Through Loyalty Discounts*, 43 INT'L J. INDUS. ORG. 111 (2015).

will reduce their prices if by doing so they can gain or retain sufficient market share to offset the reduced profits on their existing sales due to the lower price. However, by imposing the RotaTeq Bundled Loyalty Condition in its contracts, Merck prevented this normal price competition from occurring by effectively bifurcating the Rotavirus Vaccine Market into two groups: (1) restrained (foreclosed) buyers who are subject to the RotaTeq Bundled Loyalty Condition who purchased many other Merck pediatric vaccines, and thus would face high penalties on those vaccines if they bought Rotarix (Merck Loyal Buyers), and (2) unrestrained buyers who were not subject to the bundled loyalty condition or did not buy other Merck vaccines, and thus faced little to no penalty for switching to Rotarix. As described above, the first group of restrained buyers was foreclosed from purchasing Rotarix due to Merck's bundled loyalty contracts, while the second group of unrestrained buyers was not foreclosed.

154. Because the RotaTeq Bundled Loyalty Condition effectively divided the market in this way, it changed GSK's profit-maximizing strategy from that which it would have employed under normal competitive circumstances. Because of the Merck Bundle, in order to convince a foreclosed (Merck Loyal) customer to purchase Rotarix, GSK would have to compensate the customer for the increased penalties that customer would be forced to pay on the other vaccines in the Merck Bundle. That limited the ability of GSK to compete for foreclosed customers and thus allowed Merck to retain a dominant share even as it continued to price at monopoly levels. Because GSK could not gain sufficient share from price cuts to such foreclosed (Loyal) buyers to make such price cuts profitable, the Merck Bundle decreased GSK's incentive to engage in price competition for such foreclosed buyers.

155. For unforeclosed buyers, the RotaTeq price was even higher than the monopoly price charged to Loyal Buyers, because Merck penalized customers with higher prices for not committing to the Merck Bundle.

156. Given the size of the disloyalty penalties, and the fact that a significant portion of the demand for Merck's bundled vaccines is not subject to competition at least in the short run, the Merck Bundle was designed to, and did, foreclose a large enough share of the Rotavirus Vaccine Market to ensure that the profit-maximizing choice for GSK was to refrain from competing vigorously on price for both foreclosed and unforeclosed customers. As a result, purchasers of RotaTeq were robbed of the benefits of competition due to the Merck Bundle and forced to pay higher prices.

157. Because the Merck Bundle reduced GSK's ability to compete for foreclosed buyers, and thus reduced GSK's incentive to compete on price, it also led to increased Rotarix prices as well. That is, since the Merck Bundle effectively divided the market in a way that lessened the ability and incentive of GSK to compete with Merck, prices of both RotaTeq and Rotarix were higher than they would have been absent Merck's imposition of the Merck Bundle. Due to the conduct challenged herein, rotavirus vaccine prices were increased market-wide for foreclosed and un-foreclosed customers. Those customers then passed on that artificial price inflation to Plaintiff and members of the class.

158. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the

next level.” Well-accepted economic models can be used to measure both the extent and the amount of the supra-competitive overcharge passed through from healthcare providers to class members. Thus the economic harm to Plaintiff and members of the class can be quantified.

159. Further, the institutional structure of pricing and regulation in the healthcare industry assures that overcharges at the higher level of distribution are passed on to end payors. Merck sold rotavirus vaccines either directly to healthcare providers or to distributors. Distributors passed on the inflated prices of rotavirus vaccines to healthcare providers, who then passed on those increased prices to patients and their insurers. Merck’s scheme enabled it to indirectly charge end-payors prices in excess of what it otherwise would have been able to charge absent its unlawful conduct. The prices were inflated as a direct and foreseeable result of Merck’s anticompetitive conduct.

**B. Instead of Decreasing RotaTeq Prices After Rotarix Entered the Rotavirus Vaccine Market, Merck Increased Prices or Kept Them Constant**

160. Consistent with the economic theory discussed above, instead of significantly decreasing the price of RotaTeq when GSK entered the market, as would normally be expected to result from competitive entry into a monopoly market, Merck has maintained the price of RotaTeq at supracompetitive levels, actually *increasing* its list price over time.

161. The following table illustrates the private sector list price per dose for RotaTeq in each year since it was introduced in 2006. Merck’s anticompetitive conduct insulated it from competition, preventing prices from falling in response to the introduction of Rotarix in 2008 and instead allowing Merck to *increase* list prices:

Date	Price per dose
Apr. 2006	\$63.25
May 2007	\$66.94

<b>Date</b>	<b>Price per dose</b>
Sept. 2008	\$69.59
Dec. 2009	\$69.59
Dec. 2010	\$69.59
Dec. 2011	\$69.59
Nov. 2012	\$72.34
Nov. 2013	\$75.20
Dec. 2014	\$75.20
Nov. 2015	\$78.18
Dec. 2016	\$81.28
Dec. 2017	\$82.89
Dec. 2018	\$82.89
Dec. 2019	\$84.53
Sep. 2020	\$84.53
Oct. 2021	\$87.88
Nov. 2022	\$93.19

### **IX. CONTINUING VIOLATION**

162. From 2008 and continuing to the present day, Merck has entered into new contracts containing the exclusionary RotaTeq Bundled Loyalty Condition.

163. From 2008 and continuing to the present day, Merck has enforced and threatened to enforce the terms of the RotaTeq Bundled Loyalty Condition.

164. From 2008 and continuing to the present day, Merck's anticompetitive scheme has allowed it to repeatedly overcharge customers throughout the United States for RotaTeq, with each sale causing additional anticompetitive harm.

165. From 2008 and continuing to the present day, class members have overpaid each time they indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines.

**X. EFFECT ON INTRASTATE AND INTERSTATE COMMERCE**

166. The pharmaceutical vaccine products at issue in this case, including RotaTeq, are sold in interstate commerce, and Merck's conduct set forth herein substantially affected interstate commerce throughout the United States and caused antitrust injury throughout the United States. Since Merck began marketing and selling RotaTeq, Merck has promoted, distributed, sold, and/or shipped in a continuous and uninterrupted flow of commerce across state lines and sold to customers located outside its state of manufacture.

167. Merck's anticompetitive conduct occurred in part in trade and commerce within the Repealer Jurisdictions set forth herein. During the class period, Merck has shipped RotaTeq into each Repealer Jurisdiction and sold RotaTeq to customers in each of those jurisdictions. Merck's scheme has resulted in healthcare providers and members of the class in each Repealer Jurisdiction paying artificially inflated prices for RotaTeq.

168. In addition, Merck's conduct had and continues to have substantial interstate and intrastate effects because health care providers within each state have been coerced by Merck's contracts with purchasing organizations to refrain from purchasing rotavirus vaccines that compete with RotaTeq or administering competing vaccines to patients. As a result, patients and health plans within each state have been forced to continue paying supra-competitive prices for RotaTeq, which, in the absence of Merck's anticompetitive scheme, would have been reduced as a result of competition from GSK's Rotarix.

## XI. CLASS ACTION ALLEGATIONS

169. Plaintiffs bring this action on behalf of themselves and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure as representative of a class defined as follows:

All third-party payors in Repealer Jurisdictions that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of RotaTeq, other than for resale, at any time during the period from March 3, 2019 through such time as the effects of Merck's illegal conduct have ceased.

170. Excluded from the Class are:

- a. Merck and its counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- b. all federal governmental entities;
- c. fully insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
- d. all judges assigned to this case and any members of their immediate families.

171. A Repealer Jurisdiction is a state, district, or territory that has repealed the bar on indirect purchaser plaintiffs recovering under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and includes the following: Arizona, California, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin.

172. Hundreds or thousands of entities in the United States have indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of RotaTeq during the Class Period. Thus, the class is so numerous and geographically dispersed that joinder is impracticable.

173. Plaintiff's claims are typical of those of the class.

174. Plaintiff and all members of the class were injured in the form of overcharges by the same conduct of the defendant.

175. Plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the plaintiff are not antagonistic to the class.

176. Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

177. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members because Merck has acted and refused to act on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Merck's exclusionary and anticompetitive conduct in monopolizing and attempting to monopolize the Rotavirus Vaccine Market, as more fully alleged herein.

178. Questions of law and fact common to the class include:

- a. whether Merck intentionally and unlawfully impaired or impeded competition in the Rotavirus Vaccine Market;
- b. whether Merck maintained or enhanced monopoly power in the Rotavirus Vaccine Market;



- c. whether Merck engaged in anticompetitive conduct in order to unlawfully disadvantage its competitors and maintain monopoly power in the Rotavirus Vaccine Market;
- d. whether Merck had and has monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets;
- e. whether Merck had procompetitive reasons for its conduct;
- f. the effects of Merck's anticompetitive conduct on rotavirus vaccine prices;
- g. whether Plaintiff and other members of the class have been overcharged and thus damaged by paying artificially inflated prices for rotavirus vaccines as a result of Merck's unlawful behavior; and
- h. the proper measure of damages.

179. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable for them to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

180. Plaintiff knows of no difficulty to be encountered in the maintenance of this action as a class action.

## **XII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS**

181. In accordance with the requirements of Arizona Rev. Stat. § 44-1415; Connecticut Gen. Stat. § 35-37; Hawaii Rev. Stat. § 480-13.3(a); Minnesota Stat. § 325D.63; Nevada Rev.

Statute § 598A.210(3); New York Gen. Bus. Law § 340(5); Oregon Rev. Stat. § 646.780(5)(b); Rhode Island Gen. Laws § 6-36-21; and Utah Code § 76-10-3109, on or about March 3, 2023, Plaintiff's counsel sent letters regarding this class-action complaint to the Attorneys General of Arizona, Connecticut, Hawaii, Minnesota, Nevada, New York, Oregon, Rhode Island, and Utah. The letters informed the Attorneys General of the existence of this complaint, identified the relevant state antitrust provisions at issue, and enclosed a copy of this complaint.

182. On or about March 3, 2023, counsel sent a demand letter to Merck regarding this class-action complaint, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., Massachusetts). The demand letters identified the claimant as Plaintiff, in its individual and representative capacity; described the allegedly unfair or deceptive acts or practices committed by Merck (i.e. its efforts to foreclose competition in the Rotavirus vaccine market); described Plaintiff's and the class's injury (inflated prices for rotavirus vaccines); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

### **XIII. VIOLATIONS OF ANTITRUST LAWS**

#### **FIRST CLAIM FOR RELIEF**

#### **Monopolization of the Rotavirus Vaccine Market (15 U.S.C. §§ 2, 3(b)) (On behalf of residents in Repealer Jurisdictions for declaratory and equitable relief)**

183. Plaintiff incorporates by reference the above allegations.

184. At all relevant times, Merck has had and continues to have monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

185. Merck has willfully maintained its monopoly power in the Rotavirus Vaccine Market through exclusionary and anticompetitive means. Merck leveraged its monopoly power in

the MMR, Varicella, HPV, and Rotavirus Vaccine Markets by imposing contractual terms on purchasers of its vaccines that penalized customers for buying rotavirus vaccines from rivals such as GSK. Since at least 2008, Merck's RotaTeq Bundled Loyalty Condition unfairly impaired, and continues to impair, the incentive of rivals such as GSK to compete for market share, and has thus preserved Merck's monopoly power in the Rotavirus Vaccine Market.

186. By engaging in this exclusionary conduct as alleged herein, Merck has gained an artificial and unlawful advantage in the Rotavirus Vaccine Market from its monopoly power in a variety of vaccine markets, as opposed to offering products with lower prices or higher quality. As a result, Merck has unfairly impeded, and continues to unfairly impede, competition in the Rotavirus Vaccine Market. The purpose and effect of Merck's conduct has been, and continues to be, to suppress competition rather than to promote it.

187. By suppressing competition and maintaining its monopoly power, Merck has been able to artificially inflate the price of RotaTeq above levels that would have prevailed in a world without Merck's anticompetitive conduct alleged herein. In addition, because Merck's conduct removed price cutting as an effective competitive response for GSK, Rotarix's price was, and continues to be, higher than it otherwise would have. Accordingly, the challenged conduct caused, and continues to cause, Plaintiff and members of the proposed class to indirectly pay artificially inflated prices for rotavirus vaccines sold into the private market.

188. There are no procompetitive justifications for Merck's conduct.

189. Plaintiff and members of the Class have been, and continue to be, injured in their business and property by reason of Merck's unlawful monopolization. Plaintiffs' injuries consist of paying higher prices to indirectly purchase rotavirus vaccines than they would have paid absent

Merck's unlawful conduct as alleged herein. Plaintiffs' injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

190. The goal, purpose, and effect of Merck's anticompetitive scheme was to suppress competition in the Rotavirus Vaccine Market, maintain its dominance in that market, and maintain RotaTeq's prices at supracompetitive levels.

191. Merck's scheme substantially harmed competition in the relevant market. But for Merck's illegal conduct, its competitors would have been able to fairly compete in the Rotavirus Vaccine Market in a full and timely manner, and Plaintiff and Class members, who are third-party payors, would have purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines at lower prices.

192. Plaintiff and all others similarly situated are threatened with future injury to their business and property by reason of Merck's continuing violation of Section 2 of the Sherman Act within the meaning of Section 16 of the Clayton Antitrust Act, 15 U.S.C. § 26.

193. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a), Plaintiffs and the Class seek a declaratory judgment that Defendant's conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

194. Plaintiff and members of the Class seek and are entitled to an injunction against Defendant, preventing and restraining the violations alleged herein.

**SECOND CLAIM FOR RELIEF**

**Anticompetitive Agreements in Unreasonable Restraint of Trade (15 U.S.C. §§ 1, 3(a))  
(On behalf of residents in repealer jurisdictions for declaratory and equitable relief)**

195. Plaintiff incorporates by reference the above allegations.

196. At all relevant times, Merck has had and continues to have monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

197. Merck entered into, and continues to enter into, a series of unlawful exclusionary agreements with PBGs, hospital groups, and other GPOs whose purpose and effect is to unreasonably restrain competition in the Rotavirus Vaccine Market by penalizing customers with high prices on a portfolio of vaccines if the customer does not agree to refrain from purchasing rotavirus vaccines from Merck's rivals.

198. Merck entered into, and continues to enter into agreements with PBGs to enforce the RotaTeq Bundled Loyalty Condition. These agreements include written exclusionary agreements in unreasonable restraint of trade.

199. There is no legitimate business justification for these agreements and these agreements: (a) substantially foreclose and exclude competition from rotavirus vaccine manufacturers; and (b) result in Merck's willful maintenance and unlawful exercise of monopoly power in the Rotavirus Vaccine Market.

200. At all relevant times, Merck's exclusionary agreements assisted Merck, and continue to assist Merck, in: (a) effectively excluding less expensive competitive products from the Rotavirus Vaccine Market; (b) maintaining Merck's dominant market share and monopoly power in the Rotavirus Vaccine Market; (c) maintaining prices at artificially high levels for RotaTeq; and (d) otherwise reaping the benefits of its illegal monopoly power.

201. None of the claims of Plaintiff or class members in this matter flows from provisions in any PBG or GPO contract with Merck standing alone. Rather, Plaintiff alleges here that all of the contracts at issue that contain or pertain to enforcing the RotaTeq Bundled Loyalty Condition *taken together* form part of the anticompetitive bundling scheme at issue.

202. There is no procompetitive justification for Merck's conduct.

203. Plaintiff and members of the Class have been, and continue to be, injured in their businesses and property by reason of the alleged collusion and conspiracy, which facilitated, enabled, assisted, and furthered Merck's substantial foreclosure and exclusion of competition and monopolization of the Rotavirus Vaccine Market. Plaintiff's injuries consist of paying higher prices to indirectly purchase, pay, and/or provide reimbursement for some or all of the purchase price of RotaTeq and Rotarix than they would have absent Merck's unlawful conduct. Plaintiff and Class members' injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

204. Plaintiff and all others similarly situated are threatened with future injury to their business and property by reason of Merck's continuing violation of Section 1 of the Sherman Act within the meaning of Section 16 of the Clayton Antitrust Act, 15 U.S.C. § 26.

205. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a), Plaintiff and the Class seek a declaratory judgment that Defendant's conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 1 of the Sherman Act.

206. Plaintiff and members of the Class seek and are entitled to an injunction against Defendant, preventing and restraining the violations alleged herein.

**THIRD CLAIM FOR RELIEF**  
**Monopolization and Anticompetitive Agreements in Unreasonable Restraint of Trade**  
**Under State Antitrust Laws**

207. Plaintiff incorporates by reference the above allegations.

208. At all relevant times, Merck has had and continues to have monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

209. Merck has willfully maintained its monopoly power in the Rotavirus Vaccine Market through exclusionary and anticompetitive conduct. Merck leveraged its monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets by imposing contractual terms on purchasers of its vaccines that penalized customers for buying rotavirus vaccines from rivals such as GSK. Since at least 2008, Merck's RotaTeq Bundled Loyalty Condition unfairly impaired, and continues to impair, the incentive of rivals such as GSK to compete for market share, and has thus preserved Merck's monopoly power in the Rotavirus Vaccine Market.

210. Merck entered into, and continues to enter into, a series of unlawful exclusionary agreements with PBGs, hospital groups, and other GPOs whose purpose and effect is to unreasonably restrain competition in the Rotavirus Vaccine Market by penalizing customers with high prices on a portfolio of vaccines if the customer does not agree to refrain from purchasing rotavirus vaccines from Merck's rivals. These agreements include written exclusionary agreements in unreasonable restraint of trade.

211. There is no legitimate business justification for these agreements and these agreements: (a) substantially foreclose and exclude competition from rotavirus vaccine manufacturers; and (b) result in Merck's willful maintenance and unlawful exercise of monopoly power in the Rotavirus Vaccine Market.

212. The goal, purpose, and effect of Merck's anticompetitive schemes were to suppress competition in the Rotavirus Vaccine Market, maintain its dominance in that market, and maintain RotaTeq's prices at supracompetitive levels.

213. By suppressing competition and maintaining its monopoly power, Merck has been able to artificially inflate the price of RotaTeq above levels that would have prevailed in a world without Merck's anticompetitive conduct alleged herein. In addition, because Merck's conduct removed price cutting as an effective competitive response for GSK, Rotarix's price was, and continues to be, higher than it otherwise would have.

214. Merck sold rotavirus vaccines to healthcare providers (or sold rotavirus vaccines to distributors that sold them to healthcare providers) within each State under whose laws Plaintiff brings a claim, from whom members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines during the Class Period.

215. As a direct and proximate cause of Merck's conduct, Plaintiff and members of the Class have been, and continue to be, injured in their businesses and property by reason of the alleged collusion, which facilitated, enabled, assisted, and furthered Merck's substantial foreclosure and exclusion of competition and monopolization of the Rotavirus Vaccine Market. But for Defendant's conduct set forth herein, the price of rotavirus vaccines would have been lower, in an amount to be determined at trial. Those lower prices would have been passed on to patients as well as Plaintiff and members of the Class. Plaintiff and members of the Class's injuries consist of paying higher prices to indirectly purchase, pay, and/or provide reimbursement for some or all of the purchase price of RotaTeq and Rotarix than they would have absent Merck's unlawful conduct. Given that Merck's conduct continues to this day, Plaintiff and members of the Class are threatened with future injury.



216. Plaintiff and Class members' injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

217. Merck's scheme substantially harmed competition in the relevant market. But for Merck's illegal conduct, its competitors would have been able to fairly compete in the Rotavirus Vaccine Market in a full and timely manner, and Plaintiff and Class members, who are third-party payors, would have purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines at lower prices. Merck's unlawful conduct substantially affected the trade and commerce of each State under whose laws Plaintiff brings a claim by increasing the prices of rotavirus vaccines sold to healthcare providers in those States and then resold to patients and third-party payors in those States. These effects occurred both before and after rotavirus vaccines were imported into the States under whose laws Plaintiff brings a claim, as doctors in those States were continuously restrained in their ability to freely sell Rotarix to their patients.

218. A substantial part of Merck's unlawful conduct in the Rotavirus Vaccine Market occurred in each State under whose laws Plaintiff brings a claim.

219. Merck established or maintained a monopoly within the intrastate commerce of each State under whose laws Plaintiff brings a claim and restrained competition in the free exercise of the conduct of the business of rotavirus vaccines within the intrastate commerce of each State under whose laws Plaintiff brings a claim.

220. Merck's conduct was inimical to public welfare, with the effect of restraining trade, increasing the price of rotavirus vaccines and hindering competition in the sale of rotavirus vaccines.

221. At least thousands of sales of rotavirus vaccines took place in each State under whose laws Plaintiff brings a claim during the Class Period.

222. Plaintiff or members of the Class are residents or citizens of, or have their principal place of business in, each State under whose laws Plaintiff brings a claim, and Plaintiff or members of the class purchased, paid, and/or provided reimbursement for rotavirus vaccines on behalf of residents or citizens of those States.

223. By engaging in the foregoing conduct, Merck intentionally, flagrantly, willfully, and wrongfully monopolized the relevant market and entered into, and continues to enter into, a series of unlawful exclusionary agreements in violation of the following state antitrust laws:

- a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of rotavirus vaccines in Arizona by class members and/or by Arizona residents.
- b. Cal. Bus. & Prof. Code § 16700, *et seq.*, with respect to purchase of rotavirus vaccines in Arizona by class members and/or by California residents.
- c. Conn. Gen. Stat. § 35-24, *et seq.*, with respect to purchase of rotavirus vaccines in Connecticut by class members and/or by Connecticut residents.
- d. D.C. Code § 28-4501, *et seq.*, with respect to purchase of rotavirus vaccines in the District of Columbia by class members and/or by District of Columbia residents.
- e. 740 Ill. Comp. Stat. Ann. 10/3(1), *et seq.*, with respect to purchase of rotavirus vaccines in Illinois by class members and/or by Illinois residents.
- f. Iowa Code § 553.1, *et seq.*, with respect to purchase of rotavirus vaccines in Iowa by class members and/or by Iowa residents.
- g. Kan. Stat. Ann. § 50-101, *et seq.*, with respect to purchase of rotavirus vaccines in Kansas by class members and/or by Kansas residents.
- h. Me. Rev. Stat. Ann. Tit. 10 § 1101, *et seq.*, with respect to purchase of rotavirus vaccines in Maine by class members and/or by Maine residents.
- i. Md. Code Ann. § 11-204(A), *et seq.*, with respect to purchase of rotavirus vaccines in Maryland by class members and/or by Maryland residents.

- j. Mich. Comp. Laws § 445.771, *et seq.*, with respect to purchase of rotavirus vaccines in Michigan by class members and/or by Michigan residents.
- k. Minn. Stat. § 325D.49, *et seq.* & § 325D.57, *et seq.* with respect to purchase of rotavirus vaccines in Minnesota by class members and/or by Minnesota residents.
- l. Miss. Code Ann. § 72-21-1, *et seq.*, with respect to purchase of rotavirus vaccines in Mississippi by class members and/or by Mississippi residents.
- m. Neb. Rev. Stat. § 59-801, *et seq.*, with respect to purchase of rotavirus vaccines in Nebraska by class members and/or by Nebraska residents.
- n. Nev. Rev. Stat. § 598A.010, *et seq.*, with respect to purchase of rotavirus vaccines in Nevada by class members and/or by Nevada residents.
- o. N.H. Rev. Stat. Ann. tit. XXXI, § 356, *et seq.*, with respect to purchase of rotavirus vaccines in New Hampshire by class members and/or by New Hampshire residents.
- p. N.M. Stat. Ann. § 57-1-1, *et seq.*, with respect to purchase of rotavirus vaccines in New Mexico by class members and/or by New Mexico residents.
- q. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchase of rotavirus vaccines in New York by class members and/or by New York residents.
- r. N.C. Gen. Stat. § 75-1, *et seq.*, with respect to purchase of rotavirus vaccines in North Carolina by class members and/or by North Carolina residents.
- s. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchase of rotavirus vaccines in North Dakota by class members and/or by North Dakota residents.
- t. Or. Rev. Stat. § 646.705 *et seq.*, with respect to purchase of rotavirus vaccines in Oregon by class members and/or by Oregon residents.
- u. P.R. Laws Tit. 10, § 260, *et seq.*, with respect to purchase of rotavirus vaccines in Puerto Rico by class members and/or by Puerto Rico residents.
- v. 6 R.I. Gen. Laws § 6-36-1, *et seq.*, with respect to purchase of rotavirus vaccines in Rhode Island by class members and/or by Rhode Island residents.
- w. S.D. Codified Laws § 37-1-3.1, *et seq.*, with respect to purchase of rotavirus vaccines in South Dakota by class members and/or by South Dakota residents.

- x. Tenn. Code § 47-25-101, *et seq.*, with respect to purchase of rotavirus vaccines in Tennessee by class members and/or by Tennessee residents.
- y. Utah Code § 76-10-3101, *et seq.*, with respect to purchase of rotavirus vaccines in Utah by class members and/or by Utah residents.
- z. W. Va. Code § 47-18-1, *et seq.*, with respect to purchase of rotavirus vaccines in West Virginia by class members and/or by West Virginia residents.
- aa. Wis. Stat. § 133.01, *et seq.*, with respect to purchase of rotavirus vaccines in Wisconsin by class members and/or by Wisconsin residents.

224. Plaintiff and members of the Class are entitled to all forms of relief available under the above laws, including recovery of treble damages, interest, and injunctive relief, plus reasonable attorneys' fees and costs.

#### **XIV. VIOLATIONS OF STATE CONSUMER PROTECTION LAWS**

225. Plaintiff incorporates by reference the above allegations.

226. Merck engaged in unfair competition, unconscionable conduct, and deceptive acts and practices in order to wrongfully restrain trade in the Rotavirus Vaccines Market, in violation of the state consumer protection statutes set forth below.

227. As a direct and proximate result of Merck's anticompetitive, deceptive, unfair, and/or unconscionable acts or practices, Plaintiff and the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines at a higher prices than they should have.

228. The gravity of harm from Merck's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Merck's wrongful conduct.

229. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of their members for personal, family, or household purposes.

230. As a result of Merck's unfair and unconscionable conduct, Plaintiff and the Class were: (1) denied the opportunity to purchase lower-priced rotavirus vaccines that should have resulted from competition with Rotarix, and (2) purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines at a higher price than they otherwise would have but for Merck's unlawful conduct. In other words, there was and is a gross disparity between the price that Plaintiff and the Class paid for rotavirus vaccines and the value they received. This injury is of the type the state consumer-protection statutes were designed to prevent and it directly results from Merck's unlawful conduct.

231. The following Fourth through Twentieth claims for relief are pleaded under the consumer protection or similar laws of each State or jurisdiction identified below, on behalf of Plaintiff and members of the Class.

**FOURTH CLAIM FOR RELIEF  
VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW,  
CAL. BUS. & PROF. CODE § 17200, *et seq.* (THE "UCL")**

232. Plaintiff incorporates by reference the above allegations.

233. Section 17200 *et seq.* of the California Business and Professional Code (the "UCL") prohibits any "unlawful, unfair, or fraudulent act or practice[]."

234. Merck violated the UCL by (among other things) engaging in its scheme to enhance and maintain its monopoly power in the market for rotavirus vaccines sold in the United States, which is described above, and which included, among other things, requiring customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial price penalties on not only RotaTeq but also on all other bundled Merck vaccines.

235. Merck violated the UCL's unlawful prong insofar as its conduct also violated federal antitrust law, as well as California's antitrust law (CA BUS & PROF § 16720).

236. Merck's conduct also constitutes unfair or unconscionable acts or practices in violation of the UCL, regardless of whether or not that conduct violates state or federal antitrust laws.

237. Merck's conduct was intentional, i.e., it entered into exclusionary agreements in order to suppress competition in the Rotavirus Vaccines Market.

238. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines in California during the Class Period.

239. Merck's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for rotavirus vaccines. The unlawful and unfair business practices of Merck, and each of them, as described above, have caused and continue to cause members of the Class to purchase, pay, and/or provide reimbursement for some or all of the purchase price of rotavirus vaccines sold in the State of California at supra-competitive and artificially-inflated prices. Plaintiff and members of the Class suffered injury in fact and lost money or property as a result of such unfair competition.

240. This claim is instituted pursuant to section 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Merck for acts that violated the UCL, as described above.

241. Plaintiff and members of the Class are entitled to, *inter alia*, full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Merck as a result of such business acts or practices. Plaintiff and the Class are also entitled to all other appropriate relief under the UCL.

242. The illegal conduct alleged herein is continuing and there is no indication that Merck will not continue such activity into the future.

243. As alleged in this Complaint, Merck has been unjustly enriched as a result of their wrongful conduct and by Merck's unfair competition. Plaintiff and members of the Class are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Merck as a result of such business practices, pursuant to California Business and Professions Code Sections 17203 and 17204.

**FIFTH CLAIM FOR RELIEF  
VIOLATION OF THE DISTRICT OF COLUMBIA CONSUMER PROTECTION  
PROCEDURES ACT, D.C. CODE § 28-3901, *et seq.***

244. Plaintiff incorporates by reference the above allegations.

245. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines, on behalf of members for personal, family, or household purposes. Plaintiff and members of the Class do not re-sell rotavirus vaccines after they purchase, pay, or reimburse for them.

246. By reason of the conduct alleged herein, Merck has violated D.C. CODE § 28-3901, *et seq.*

247. Merck is a "merchant" within the meaning of D.C. CODE § 28-3901(a)(3).

248. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market a substantial part of which occurred within the District of Columbia, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

249. Merck's conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the District of Columbia.

250. Merck’s unlawful conduct substantially affected the District of Columbia’s trade and commerce by artificially inflating the prices of rotavirus vaccines sold to patients who are residents of the District of Columbia and inflating the reimbursements paid by third-party payors in the District of Columbia.

251. As a direct and proximate cause of Defendant’s unlawful conduct, Plaintiff and members of the Class have been injured in their business or property and are threatened with further injury.

252. By reason of the foregoing, Plaintiff and members of the Class are entitled to seek all forms of relief, including treble damages or \$1500 per violation (whichever is greater) plus punitive damages, reasonable attorney’s fees and costs under D.C. CODE § 28-3901, *et seq.*

**SIXTH CLAIM FOR RELIEF  
VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES  
ACT, FLA. STAT. § 501.201(2), *et seq.***

253. Plaintiff incorporates by reference the above allegations.

254. The Florida Deceptive & Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* (the “FDUTPA”), prohibits “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.” FLA. STAT. § 501.204(1).

255. The primary policy of the FDUTPA is “[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce.” FLA. STAT. § 501.202(2).

256. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this complaint. *See* FLA. STAT. § 501.211(1) (“anyone aggrieved by a violation of this [statute] may bring an action . . .”).



257. Members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within the State of Florida during the Class Period. But for Merck's conduct set forth herein, the price of rotavirus vaccines would have been lower, in an amount to be determined at trial.

258. Merck entered into a contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Florida.

259. Merck established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market for the purpose of excluding competition or controlling, fixing or maintaining prices in Florida at a level higher than the competitive market level, beginning at least as early as March 3, 2019 and continuing through the date of this filing.

260. Merck's conduct was intentional, i.e., it entered into exclusionary agreements in order to suppress competition in the Rotavirus Vaccines Market.

261. Accordingly, Merck's conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Florida.

262. Merck's unlawful conduct substantially affected Florida's trade and commerce.

263. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and the members of the Class have been injured in their business or property by virtue of overcharges for rotavirus vaccines. Because Merck continues to enter into exclusionary agreements with PBGs and GPOs, and because Plaintiffs and members of the class continue to reimburse patients for rotavirus vaccines at inflated prices on an ongoing basis, there is a high probability that Plaintiff and members of the Class will suffer injury in the future as a result of Merck's conduct.

264. By reason of the foregoing, members of the Class are entitled to seek all forms of relief, including injunctive relief pursuant to Fla. Stat. § 501.208 and declaratory judgment, actual damages, reasonable attorneys' fees and costs pursuant to Fla. Stat. § 501.211.

**SEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE HAWAII REVISED STATUTES ANNOTATED,  
§§ 480-1, *ET SEQ.***

265. Plaintiff incorporates by reference the above allegations.

266. Hawaii's unfair competition statute prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." HAW. REV. STAT. ANN. § 480-2.

267. Merck's anticompetitive scheme, which is described above, constitutes an unfair method of competition, or unfair, unconscionable, or deceptive acts or practices, in violation of the HAW. REV. STAT. ANN. §§ 480-1, *et seq.*

268. Merck's conduct was intentional, i.e., it entered into exclusionary agreements in order to suppress competition in the Rotavirus Vaccines Market.

269. During the Class Period, Merck's illegal conduct substantially affected Hawaii commerce and consumers.

270. Merck's unlawful conduct had the following effects: (1) rotavirus vaccine price competition was restrained, suppressed, and eliminated throughout Hawaii; (2) rotavirus vaccine prices were fixed, maintained, and stabilized at artificially high levels throughout Hawaii; (3) members of the Class were deprived of free and open competition; (4) members of the Class paid, purchased, and/or provided reimbursement at supracompetitive, artificially inflated prices for rotavirus vaccines; and (5) healthcare providers in Hawaii were prevented from freely purchasing Rotarix and administering it to their patients.

271. During the Class Period, members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within Hawaii.

272. As a direct and proximate result of Merck's unlawful conduct, Plaintiff and members of the class have been injured and there is a high probability that they will suffer injury in the future as a result of Merck's conduct.

273. In light of the above, members of the Class are entitled to seek all available relief under Hawaii's consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys' fees, costs, etc.

**EIGHTH CLAIM FOR RELIEF  
VIOLATION OF THE IDAHO CONSUMER PROTECTION ACT,  
IDAHO CODE § 48-601, et seq.**

274. Plaintiff incorporates by reference the above allegations.

275. The Idaho Consumer Protection Act (the "ICPA") prohibits "unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce," IDAHO CODE §§ 48-601, which includes, among other things, "any unconscionable method, act or practice in the conduct of any trade or commerce." *Id.* § 48-603C.

276. Merck's anticompetitive efforts, which are described above, constituted an unfair method of competition, or an unconscionable practice, under the ICPA.

277. Merck intentionally engaged in the above conduct in order to maintain its monopoly power.

278. Merck's alleged conduct would outrage or offend the public conscious.

279. During the Class Period, Plaintiff and members of the class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines in Idaho.

280. Merck's conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for rotavirus vaccines.

281. Because Rotavirus Vaccines are purchased on an ongoing basis, there is a high probability that Plaintiff and members of the Class will suffer injury in the future, as a result of Merck's conduct.

282. In light of the above, Plaintiff and the Class are entitled to seek actual damages, along with any other form of relief that the Court deems proper under the ICPA, including actual damages, statutory damages, punitive damages, attorneys' fees, costs, injunctive relief, etc. *See* IDAHO CODE § 48-608.

**NINTH CLAIM FOR RELIEF  
VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT,  
MASS. GEN. LAWS. CH. 93A § 1, *et seq.***

283. Plaintiff incorporates by reference the above allegations.

284. The Massachusetts Consumer Protection Act prohibits "unfair or deceptive act[s] or practice[s]." MASS. GEN. LAWS ch. 93A § 9(2).

285. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within the Commonwealth of Massachusetts during the Class Period. But for Merck's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

286. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market a substantial part of which occurred within Massachusetts, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

287. Merck's conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the Commonwealth of Massachusetts.

288. Merck's unlawful conduct substantially affected Massachusetts' trade and commerce.

289. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of members for personal, family, or household purposes. Plaintiff and members of the Class do not re-sell rotavirus vaccines after they purchase, pay, or reimburse for them.

290. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and the members of the Class have been injured in their business or property and are threatened with further injury.

291. By reason of the foregoing, Plaintiff and the Class are entitled to seek all forms of relief, including actual damages, treble damages, reasonable attorney's fees, costs, and injunctive relief under Massachusetts General Laws ch. 93A § 9.

**TENTH CLAIM FOR RELIEF**  
**VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT**  
**MO. ANN. STAT. § 407.010, et seq.**

292. Plaintiff incorporates by reference the above allegations.

293. Chapter 407 of the Missouri Merchandising Practices Act (the "MMPA") generally governs unlawful business practices, including antitrust violations such as restraints of trade and monopolization.

294. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within the State of Missouri during the Class Period. But for Merck's conduct set forth herein, the price of rotavirus vaccines would have been lower, in an amount to be determined at trial.

295. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of members for personal, family, or household purposes.

296. Under Missouri law, indirect purchasers have standing to maintain an action under the MMPA based on the facts alleged in this Complaint. *Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669 (Mo. 2007).

297. Merck contracted, combined or conspired in restraint of trade or commerce of rotavirus vaccines within the intrastate commerce of Missouri, and monopolized or attempted to monopolize the Rotavirus Vaccine Market within the intrastate commerce of Missouri by possessing monopoly power in the market and willfully maintaining that power through agreements to fix prices, allocate markets and otherwise control trade, in violation of Mo. Stat. § 407.010, *et seq.*

298. Plaintiff and members of the Class were injured with respect to purchases, payments, and/or reimbursements for some or all of the purchase price of rotavirus vaccines in Missouri and are entitled to all forms of relief, including actual damages or liquidated damages in an amount which bears a reasonable relation to the actual damages which have been sustained, as well as reasonable attorneys' fees, costs, and injunctive relief.

**ELEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE MONTANA UNFAIR TRADE PRACTICES AND CONSUMER  
PROTECTION ACT OF 1970,  
MONT. CODE, §§ 30-14-103, *et seq.*, AND §§ 30-14-201, *et seq.***

299. Plaintiff incorporates by reference the above allegations.

300. Merck has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, MONT. CODE, §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*

301. Merck's unlawful conduct had the following effects: (1) rotavirus vaccine price competition was restrained, suppressed, and eliminated throughout Montana; (2) rotavirus vaccine prices were raised, fixed, maintained, and stabilized at artificially high levels throughout Montana; (3) Plaintiff and members of the Class were deprived of free and open competition; and (4) Plaintiff and members of the Class paid supra-competitive, artificially inflated prices for rotavirus vaccines; and (5) healthcare providers in Montana were prevented from freely purchasing Rotarix and administering it to their patients.

302. Members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within Montana during the Class Period. But for Merck's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

303. Members of the Class purchased paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of members for personal, family, or household purposes. Members of the Class do not re-sell rotavirus vaccines after they purchase, pay, or reimburse for them.

304. During the Class Period, Merck's illegal conduct substantially affected Montana commerce and consumers.

305. As a direct and proximate result of Merck's unlawful conduct, Plaintiff and members of the Class have been injured and are threatened with further injury. Merck has engaged in unfair competition or unfair or deceptive acts or practices in violation of MONT. CODE, §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*, and, accordingly, Plaintiffs and members of the Class seek all relief available under that statute.

**TWELFTH CLAIM FOR RELIEF**  
**VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT,**  
**NEB. REV. STAT. § 59-1602, *et seq.***

306. Plaintiff incorporates by reference the above allegations.

307. By reason of the conduct alleged herein, Merck has violated NEB. REV. STAT. § 59-1602, *et seq.*

308. Members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within Nebraska during the Class Period. But for Merck's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

309. Under Nebraska law, indirect purchasers have standing to maintain an action under the Nebraska Consumer Protection Act based on the facts alleged in this Complaint. *See* NEB. REV. STAT. § 59-1609.

310. Merck has entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Nebraska.

311. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Nebraska.

312. Merck's conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nebraska.

313. Merck's conduct had a direct or indirect impact upon Plaintiff's and members-of-the-Class's ability to protect themselves.

314. Merck's unlawful conduct substantially affected Nebraska's trade and commerce.



315. As a direct and proximate cause of Merck's unlawful conduct, members of the Class have been injured in their business or property and are threatened with further injury.

316. By reason of the foregoing, members of the Class are entitled to seek all forms of relief available under NEB. REV. STAT. § 59-1614.

**THIRTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEVADA DECEPTIVE TRADE PRACTICES ACT,  
NEV. REV. STAT. § 598.0903, *et seq.***

317. Plaintiff incorporates by reference the above allegations.

318. By reason of the conduct alleged herein, Merck has violated NEV. REV. STAT. § 598.0903, *et seq.*

319. Merck engaged in a deceptive trade practice, as defined within the Nevada Deceptive Trade Practices Act, with the intent to injure competitors and to substantially lessen competition.

320. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Nevada.

321. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Nevada, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

322. Merck's conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nevada.

323. Merck's conduct amounted to a fraudulent act or practice committed by a supplier in connection with a consumer transaction.

324. Merck's unlawful conduct substantially affected Nevada's trade and commerce.

325. Merck's conduct was willful.

326. As a direct and proximate cause of Merck's unlawful conduct, members of the Class have been injured in their business or property and are threatened with further injury.

327. By reason of the foregoing, the Class is entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs, and a civil penalty of up to \$5,000 per violation under NEV. REV. STAT. § 598.0993.

**FOURTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEW HAMPSHIRE CONSUMER PROTECTION ACT,  
N.H. REV. STAT. ANN. tit. XXXI, § 358-A:1, *et seq.***

328. Plaintiff incorporates by reference the above allegations.

329. By reason of the conduct alleged herein, Merck has violated N.H. REV. STAT. tit. XXXI, § 358-A:1, *et seq.*

330. Under New Hampshire law, indirect purchasers have standing to maintain an action under the New Hampshire Consumer Protection Act based on the facts alleged in this Complaint. *See LaChance v. U.S. Smokeless Tobacco Co.*, 156 N.H. 88, 92-100 (2007).

331. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within New Hampshire. Health care providers within New Hampshire have been coerced by Merck's contracts with purchasing organizations to refrain from purchasing rotavirus vaccines that compete with RotaTeq or administering competing vaccines to patients.

332. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within New Hampshire.

333. Merck's conduct was unfair or deceptive within the conduct of commerce within the State of New Hampshire.

334. Merck's conduct was willful and knowing.

335. Merck's conduct had a direct or indirect impact upon Plaintiff's and members-of-the-Class's ability to protect themselves.

336. Merck's unlawful conduct substantially affected New Hampshire's trade and commerce.

337. As a direct and proximate cause of Merck's unlawful conduct, members of the Class have been injured in their business or property and are threatened with further injury.

338. By reason of the foregoing, members of the Class are entitled to seek all forms of relief available under New Hampshire Revised Statutes §§ 358-A:10 and 358-A:10-a.

**FIFTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEW MEXICO UNFAIR PRACTICES ACT,  
N.M. STAT. ANN. § 57-12-1, *et seq.***

339. Plaintiff incorporates by reference the above allegations.

340. By reason of the conduct alleged herein, Merck has violated N.M. STAT. § 57-12-3, *et seq.*

341. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within New Mexico.

342. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Relevant Market and Submarkets, a substantial part of which occurred within New Mexico, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

343. Merck's conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of New Mexico.

344. Merck's unlawful conduct substantially affected New Mexico's trade and commerce.

345. Merck's conduct constituted "unconscionable trade practices" in that such conduct, *inter alia*, resulted in a gross disparity between the value received by Class members and the price paid by them for rotavirus vaccines as set forth in N.M. STAT. § 57- 12-2E.

346. Merck's conduct was willful.

347. As a direct and proximate cause of Merck's unlawful conduct, members of the Class have been injured in their business or property and are threatened with further injury.

348. By reason of the foregoing, members of the Class are entitled to seek all forms of relief, including actual damages or up to \$300 per violation, whichever is greater, plus reasonable attorney's fees under N.M. STAT. § 57-12-10.

**SIXTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE  
PRACTICES ACT, N.C. GEN. STAT. § 75-1.1, *et seq.***

349. Plaintiff incorporates by reference the above allegations.

350. By reason of the conduct alleged herein, Merck has violated N.C. GEN. STAT. § 75-1.1, *et seq.*

351. Under North Carolina law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. *See Hyde v. Abbott Labs., Inc.*, 123 N.C. App. 572, 584 (1996).

352. Merck entered into a contract, combination, or conspiracy in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within North Carolina.

353. Merck's conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of North Carolina.

354. Merck's trade practices are and have been immoral, unethical, unscrupulous, and substantially injurious to consumers.

355. Merck's unlawful conduct substantially affected North Carolina's trade and commerce.

356. Merck's conduct constitutes consumer-oriented deceptive acts or practices within the meaning of North Carolina law, which resulted in consumer injury and broad adverse impact on the public at large and harmed the public interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

357. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and members of the Class have been injured in their business or property and are threatened with further injury.

358. By reason of the foregoing, Plaintiff and members of the Class are entitled to seek all forms of relief, including treble damages under N.C. Gen. Stat. § 75-16.

**SEVENTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE RHODE ISLAND DECEPTIVE TRADE PRACTICES ACT,  
R.I. GEN. LAWS § 6-13.1-1, *et seq.***

359. Plaintiff incorporates by reference the above allegations.

360. By reason of the conduct alleged herein, Merck has violated R.I. Gen. Laws § 6-13.1-1, *et seq.*

361. Merck engaged in an unfair or deceptive act or practice with the intent to injure competitors and consumers through supra-competitive profits.

362. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Rhode Island.

363. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Rhode Island, for the purpose of controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

364. Merck's conduct was unfair or deceptive within the conduct of commerce within the State of Rhode Island.

365. Merck's conduct amounted to an unfair or deceptive act or practice committed by a supplier in connection with a consumer transaction.

366. Merck's unlawful conduct substantially affected Rhode Island's trade and commerce.

367. Merck's conduct was willful.

368. Plaintiff and members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of members for personal, family, or household purposes. Plaintiff and members of the Class do not re-sell rotavirus vaccines after they purchase, pay, or reimburse for them.

369. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and members of the Class have been injured in their business or property and are threatened with further injury.

370. By reason of the foregoing, Plaintiff and members of the Class are entitled to seek all forms of relief, including actual damages or \$200 per violation, whichever is greater, and injunctive relief and punitive damages under R.I. Gen. Laws § 6-13.1-5.2.

**EIGHTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE SOUTH CAROLINA'S UNFAIR TRADE PRACTICES ACT,  
S.C. CODE ANN. §§ 39-5-10, *et seq.***

371. Plaintiff incorporates by reference the above allegations.

372. By reason of the conduct alleged herein, Merck has violated S.C. Code Ann. § 39-5-10, *et seq.*

373. Merck has entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within South Carolina.

374. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within South Carolina.

375. Merck's conduct was unfair or deceptive within the conduct of commerce within the State of South Carolina.

376. Merck's conduct had a direct or indirect impact upon Plaintiff's and members-of-the-Class's ability to protect themselves.

377. Merck's unlawful conduct substantially affected South Carolina trade and commerce.

378. Merck's unlawful conduct substantially harmed the public interest of the State of South Carolina, as Class members in South Carolina purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines on behalf of at least thousands of patients.

**NINETEENTH CLAIM FOR RELIEF  
VIOLATION OF THE UTAH CONSUMER SALES PRACTICES ACT,  
UTAH CODE ANN. §§ 13-11-1, *et seq.***

379. Plaintiff incorporates by reference the above allegations.

380. By reason of the conduct alleged herein, Merck has violated Utah Code Ann. §§ 13-11-1, *et seq.*

381. Merck is a supplier within the meaning of UTAH CODE ANN. §§ 13-11-3.

382. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Utah.

383. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Utah, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

384. Merck's conduct was unfair and unconscionable within the conduct of commerce within the State of Utah.

385. Merck's conduct and/or practices were unconscionable and were undertaken in connection with consumer transactions within the meaning of UTAH CODE ANN. §§ 13-11-3.

386. Merck knew or had reason to know that its conduct was unconscionable.

387. Merck's unlawful conduct substantially affected Utah's trade and commerce.

388. Members of the Utah Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of goods, namely rotavirus vaccines, on behalf of members for personal, family, or household purposes. Members of the Class do not re-sell rotavirus vaccines after they purchase, pay, or reimburse for them.



389. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and the members of the Class have been injured in their business or property and are threatened with further injury.

390. By reason of the foregoing, members of the Class are entitled to seek all forms of relief, including declaratory judgment, injunctive relief, and ancillary relief, pursuant to Utah Code Ann. §§ 13-11-19(5) and 13-11-20.

**TWENTIETH CLAIM FOR RELIEF  
VIOLATION OF THE VERMONT CONSUMER FRAUD ACT,  
VT. STAT. ANN. TIT. 9, CH. 63 §2451, *et seq.***

391. Plaintiff incorporates by reference the above allegations.

392. By reason of the conduct alleged herein, Merck has violated Vt. Stat. Ann. tit. 9, § 2451, *et seq.*

393. Title 9 of the Vermont Statutes generally governs commerce and trade in Vermont. Chapter 63 thereof governs consumer protection and prohibits, *inter alia*, “unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce.” *See* VT. STAT ANN. tit. 9, § 2453(a).

394. Members of the Class purchased, paid, and/or provided reimbursement for some or all of the purchase price of rotavirus vaccines within the State of Vermont during the Class Period. But for Merck's conduct set forth herein, the price of rotavirus vaccines would have been lower, in an amount to be determined at trial.

395. Under Vermont law, indirect purchasers have standing under the antitrust provisions of the Vermont Statutes to maintain an action based on the facts alleged in this complaint. VT. STAT. ANN. TIT. 9, § 2465(b); *see also Elkins v. Microsoft Corp.*, 174 Vt. 328, 341 (2002).

396. Merck competed unfairly by restraining trade as set forth herein, in violation of Vt. Stat. tit. 9, § 2453, *et seq.*

397. Merck entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Vermont.

398. Merck established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Rotavirus Vaccine Market, a substantial part of which occurred within Vermont, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the Rotavirus Vaccine Market.

399. Merck's violations of Vermont law were flagrant.

400. Merck's conduct caused or was intended to cause unfair methods of competition within the State of Vermont.

401. Merck's unlawful conduct substantially affected Vermont's trade and commerce.

402. As a direct and proximate cause of Merck's unlawful conduct, Plaintiff and the members of the Class have been injured in their business or property and are threatened with further injury.

403. Members of the Class were injured with respect to purchases, payments, and/or reimbursements for some or all of the purchase price of rotavirus vaccines in Vermont and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' fees.

## XV. PETITION FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully ask the Court for a judgment that:

1. Certifies the Class pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) and directs that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declares Plaintiff as representative of the Class;
2. Appoints Plaintiff and its attorneys as class representatives and class counsel, respectively;
3. Enters judgment against Defendant, and in favor of Plaintiff and the Class, holding Defendant liable for the antitrust violations alleged;
4. Awards a declaratory judgment that Merck's practice of bundling RotaTeq with other Merck vaccines was done for illegal, anticompetitive purposes, was an unreasonable restraint of trade, and had anticompetitive effects on the U.S. market for rotavirus vaccines in violation of the Sherman Act, §§ 1-2 and the state laws of the Repealer Jurisdictions.
5. Grants permanent injunctive relief:
  - a. enjoining Merck from engaging in future anticompetitive conduct with the purpose or effect of preventing actual or potential rivals from gaining a foothold in the Rotavirus Vaccine Market and eliminating or impairing the price discipline that would come from free and fair competition; and
  - b. requiring Merck to take affirmative steps to dissipate the continuing effects of its prior unlawful conduct;
6. Awards Plaintiff and the Class actual, double, treble, and exemplary damages as permitted and as sustained by reason of the antitrust violations alleged herein, plus interest in accordance with law;

7. Awards such equitable relief as is necessary to correct for the anticompetitive market effects caused by Merck's unlawful conduct, including disgorgement, restitution, and the creation of a constructive trust;
8. Awards Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law;
9. Directs such further relief as it may deem just and proper.

**XVI. JURY TRIAL DEMANDED**

Plaintiffs demand a trial by jury of all of the claims asserted in this complaint so triable.

Respectfully submitted,

Dated: March 3, 2023

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