UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

LORI DECOSTANZO, on behalf of herself and all others similarly situated, Plaintiff, -against- GLAXOSMITHKLINE PLC, Defendant.	Case No. 1:20-cv-2284 **ORIGINAL CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Lori DeCostanzo ("**Ms. DeCostanzo**" or "**Plaintiff**"), on behalf of herself and all similarly situated individuals, through her attorneys Siri & Glimstad LLP, alleges on personal knowledge, investigation of her counsel, and on information and belief, the following claims against GlaxoSmithKline plc ("**GSK**"):

INTRODUCTION

1. Plaintiff Lori DeCostanzo brings this action against GSK for unjust enrichment, negligent misrepresentation, fraud, and violations of the consumer protection, false advertising, implied warranty, and express warranty laws with regard to its product trade named Boostrix.

2. Ms. DeCostanzo is one of the millions of consumers who received Boostrix. Boostrix is a tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis biological product. GSK vigorously markets this product to consumers in the United States. GSK claims that those receiving Boostrix are less likely to infect babies with pertussis. Pertussis, which is also known as whopping cough, can lead to serious complications and death in babies.

3. GSK's claim that Boostrix will make those receiving this product less likely to become infected and transmit pertussis is false. Boostrix actually increases the likelihood that

those receiving this product will become infected with and transmit pertussis. This is because while Boostrix may reduce the symptoms of pertussis, it does not prevent those receiving this product from becoming infected with and transmitting pertussis.

4. Researchers at the U.S. Food and Drug Administration ("**FDA**") and at premier universities have established that even though Boostrix decreases the odds of a person experiencing the symptoms of pertussis, it creates a defective form of immunity to pertussis in the person receiving this product. This defective immunity actually renders them susceptible to becoming repeatedly infected with pertussis, potentially every month, without knowing they are infected. Boostrix therefore creates a state in which individuals receiving this product can repeatedly become infected, have little or no symptoms to indicate they have been infected (e.g., paucisymptomatic or asymptomatic carriers, respectively), and hence silently spread pertussis.

5. GSK's advertisement uses fear to increase sales of Boostrix by making it appear that if people do not receive Boostrix, they will be endangering babies. For example, GSK maintains a consumer-facing website aboutwhoopingcough.com with imagery and text of grandparent figures who, without receiving Boostrix, are like wolves ready to kill an infant. The following is a copy of the homepage of this website:

The following is the top portion of the "Understand the Risk" webpage of that website:

6. The following are three still images from a GSK commercial advertising Boostrix:

7. These advertisements were designed to spread the false premise that by receiving Boostrix, the recipient could not be infected with and transmit pertussis. Even though GSK knew or should have known that this was false, it believed that the fear of spreading the infection generated by this advertising campaign would increase the sales of Boostrix.

8. Plaintiff Lori DeCostanzo is one of the millions of consumers who saw these advertisements, including commercials on television. Based on these commercials, GSK wrongfully influenced Ms. DeCostanzo to be injected with Boostrix believing that it would prevent transmission of pertussis. Unbeknown to Ms. DeCostanzo, and the millions of similarly situated consumers, receiving Boostrix increased their likelihood of silently transmitting pertussis.

9. Ms. DeCostanzo now brings this action, on behalf of herself and others similarly situated, seeking to recover compensatory and punitive damages, and to secure injunctive relief to require GSK to cease its illegal conduct.

SUBJECT MATTER JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act ("CAFA") 28 U.S.C. §§ 1332(d)(2) and (d)(6), because there is diversity of citizenship and the claims of individual Class members, in the aggregate, exceed the jurisdictional minimum of $5,000,000, exclusive of interest and costs.

11. Venue is proper in this Court under 28 U.S.C. § 1391(b) because GSK victimized Plaintiff through its advertising at her residence located in Plainview, New York. Venue is also proper in this Court under 28 U.S.C. § 1391(b) because GSK regularly does business in the district and division, and they are subject to this Court's personal jurisdiction with respect to this civil action in the district and, as such, they "reside" in the district.

PARTIES AND PERSONAL JURISDICTION

12. Plaintiff is, and at all times mentioned herein was, an individual citizen of the State of New York who resides in Plainview, New York.

13. GSK is a public limited company organized under the laws of England and Wales with its principal place of business at 980 Great West Road, Brentford, Middlesex TW89GS,

England. GSK, either directly or through wholly-owned subsidiaries, has its principal place of business in the United States in Philadelphia, Pennsylvania. GSK is engaged in manufacturing, marketing, promoting, selling and/or distributing Boostrix and conducts these activities throughout the United States, including in New York.

14. GSK has derived substantial revenue from goods and products, including Boostrix, sold in the State of New York. GSK expected or should have expected their acts to have consequences within the State of New York, and derived substantial revenue from interstate commerce.

FACTUAL ALLEGATIONS

15. Pertussis, commonly known as whooping cough, is caused by the bacterium *Bordetella pertussis*. Pertussis in adults is generally mild and can, if necessary, be treated with antibiotics. However, pertussis can cause serious illness in newborns and infants infected with this bacterium.

16. Boostrix is a biological product sold by GSK. GSK may only market this product in the United States to individuals aged 10 years of age and older. Sales of this product in the United States were approximately $365,000,000 in 2019.

Big Bad Cough Campaign

17. Mick Stanley, GSK's Director of Commercial Strategy, has explained that GSK set out to create an advertising campaign to increase the use of Boostrix. https://www.youtube.com/watch?v=3Oh2keKb_zM

18. For example, he stated that GSK did "a lot of research with grandparents" and the "problem" was that they had a "very low awareness…that whooping cough was a danger." GSK decided to create an advertising campaign designed to target adults directly regarding the dangers

of pertussis. GSK's intent was to make them concerned enough about the risk that they would want to approach their doctors to request Boostrix and demand that others in their social circle also receive this product. https://www.youtube.com/watch?v=3Oh2keKb_zM

19. In or about April 2015, GSK launched a multimedia advertising campaign entitled "The Big Bad Cough." https://www.ispot.tv/ad/dkbG/big-bad-cough-grandma

20. The campaign began with print and online ads in April 2015 and advertisements for this campaign began to be aired on television in June 2015. https://www.youtube.com/watch?v=7JTq2m7EUPs

21. The Big Bad Cough campaign specifically targeted adults who might come into contact with infants, and GSK sought to increase uptake of Boostrix among adults by educating them to be aware of the danger whooping cough (pertussis) posed to infants. https://www.youtube.com/watch?v=3Oh2keKb_zM

22. GSK advertised that "whooping cough is a highly contagious disease" and that "it can be especially serious, even fatal, for infants." They then directed consumers to visit BigBadCough.com for more information. https://www.youtube.com/watch?v=7JTq2m7EUPs

23. On the Big Bad Cough website, the homepage shows a picture of a loving mother figure admiring an infant but, in the mirror, her reflection depicts a wolf. https://www.aboutwhoopingcough.com/index.html

24. GSK explained that this campaign was based on the tale of Little Red Riding Hood where a wolf ate a young child when she came to visit her grandmother's house.

25. GSK admitted that "…a wolf can be scary. So whooping cough as the wolf is a symbol of that danger." https://www.youtube.com/watch?v=3Oh2keKb_zM

26. When a consumer visits the Big Bad Cough website and clicks on the link to "Get the Facts About Whooping Cough," the consumer is directed to a page titled "Understand the Risk." This page has several statistics, describes the symptoms and risks of whooping cough, and includes an audio file of an infant with pertussis coughing. https://www.aboutwhoopingcough.com/understand-the-risk.html.

27. Even though Boostrix is not licensed for infants, the "FAQ" page for the Big Bad Cough website answers the question: "Who is most at risk for severe pertussis illness?" by saying: "Infants too young to be vaccinated are most at risk for severe illness. Complications can include hospitalization, pneumonia, seizures, brain disorders, and, on very rare occasions, death." https://www.aboutwhoopingcough.com/faq.html

28. Likewise, the "Fight Back" page on the website tells consumers that babies "are most at risk for severe illness" and that "you should receive a booster at least 2 weeks before having close contact with an infant." https://www.aboutwhoopingcough.com/fight-back.html

29. Next, there is a webpage where a consumer can enter a zip code to find a medical provider or pharmacy where the consumer can go to receive Boostrix. https://www.aboutwhoopingcough.com/vaccination.html

Plaintiff Watched GSK's Big Bad Cough Advertisement and Received Boostrix

30. In or about May 2017, Ms. DeCostanzo was awaiting the arrival of her new granddaughter. Ms. DeCostanzo had seen GSK's Big Bad Cough advertisement on television many times. She believed from the advertisement that receiving Boostrix would help her do her part to protect her new grandchild.

31. On May 22, 2017, based on the information from GSK's advertisement that receiving this product could help Ms. DeCostanzo protect her newborn granddaughter, Ms.

DeCostanzo expended time and resources to travel to her local pharmacy where she requested and was injected with this product.

32. Plaintiff later found out that the information she received from GSK's advertising campaign is false and misleading because while this product may provide some protection in the recipient from manifesting symptoms of pertussis, it does not prevent asymptomatic infection and silent transmission of pertussis.

Boostrix Causes the Very Issue it Claims to Prevent

33. The FDA and university researchers have confirmed that the form of immunity created by Boostrix, and all other inoculation products against pertussis currently used in the United States, renders those receiving this product susceptible to repeatedly being infected with pertussis and capable of transmitting the pertussis bacteria while not presenting symptoms. See, e.g., PNAS (2014) https://www.ncbi.nlm.nih.gov/pubmed/24277828 ("[W]e have confirmed that, as in humans, aP [pertussis] vaccines provide excellent protection against severe disease in baboons. However, aP [pertussis] vaccines do not prevent colonization following direct challenge or infection by transmission."); Vaccine (2018) https://www.ncbi.nlm.nih.gov/pubmed/29180031 ("neither DTP, nor DTaP or Tdap [which is synonymous with Boostrix] prevent asymptomatic infection and silent transmission of the [pertussis] pathogen").

34. This means that people receiving Boostrix can repeatedly become infected with and are capable of transmitting pertussis while remaining asymptomatic (presenting no symptoms) or paucisymptomatic (presenting few symptoms).

35. On the other hand, individuals who have *not* received this product may become infected with the pertussis bacteria, have symptoms, and as a result, know they are sick and hence should stay away from others, and will thereafter have immunity that prevents them from

becoming re-infected with pertussis for many years. *Id.* ("in contrast to prior infection [with pertussis], current pertussis vaccines do not prevent asymptomatic infection").

36. The medical literature provides an explanation for the defective immunity created by Boostrix. Inoculations against pertussis are designed to generate antibodies to antigens secreted by or found on the surface of the pertussis bacteria. The genome of the pertussis bacteria (its total number of genes) is estimated to have approximately 3,000 genes, many of which encode surface or secreted proteins. All pertussis inoculation products currently used in the United States, including Boostrix, contain only 5 of these antigens, and hence can only generate antibodies to 5 of the thousands of antigens on the surface of or secreted by the pertussis bacteria.

37. By generating antibodies to only 5 of the surface antigens and secreted toxins of the pertussis bacteria, the result is that individuals may have few or no symptoms if infected with pertussis *but* will still become colonized with and silently transmit pertussis.

38. This defective immunity remains even after an individual receiving Boostrix becomes infected with pertussis. The body of such a person will continue to generate a vigorous immune response only to the 5 antigens included in Boostrix, but not to other pertussis antigens. This defective immune response appears to remain irrespective of how many times a person that received this product is infected with pertussis.

39. This defective immunity is caused by what is known as "linked epitope suppression" which locks in the initial immune response created by the 5 select antigens in Boostrix. An epitope is the portion of the antigen to which an antibody will bind. Since Boostrix generates antibodies to only 5 epitopes (antigens) of the pertussis bacteria, when the body later encounters the pertussis bacteria, it generates antibodies to these five antigens but does not generate antibodies to the other surface antigens of the pertussis bacteria that might be crucial for

preventing further re-infection. Due to "linked epitope suppression," the generation of antibodies to the five epitopes from Boostrix suppresses the creation of antibodies to a broader range of other epitopes that comprise the pertussis bacteria.

40. In contrast, an individual who has not received Boostrix or a similar product but who has had pertussis will have generated antibodies to the broad array of pertussis antigens; and when re-exposed to pertussis, their antibodies immediately coat the pertussis bacteria and prevent them from colonizing their respiratory tract. Because the defective immunity to pertussis created by Boostrix is apparently permanent, individuals receiving this product are susceptible to repeated infection and colonization by the pertussis bacteria, potentially every few weeks, for the rest of their life.

41. GSK's Big Bad Cough campaign provided that those receiving Boostrix will be less likely to transmit pertussis. In reality, those receiving this product become more likely to asymptomatically transmit pertussis.

GSK Targets Millions with Its Advertising Campaign

42. GSK's advertising campaign was national in scope and intended to reach all individuals in the United States. One of the clips posted on GSK's Facebook page advertisement states that "almost 4 million US babies were born in 2014. That makes a lot of grandparents!" The ad further encourages viewers to "Tag a grandparent to help raise awareness." https://www.facebook.com/GSK/videos/888276841241270/

43. Individuals like Ms. DeCostanzo, who viewed the advertisement were led to believe that, like wolves that are a danger to children, or the big bad wolf that ate a child, if they do not follow GSK's advice in its advertisements and receive Boostrix, they too are a danger to their grandchildren.

44. GSK admits that the bottom line is to improve uptake of Boostrix and in the end they will know if the campaign was successful if individuals receive this product. https://www.youtube.com/watch?v=3Oh2keKb_zM

45. GSK's Big Bad Cough campaign was a successful marketing campaign that not only brought home Best Film Award from the Medical Marketing and Media Awards in 2016, but also yielded "big bad results" according to one of the judges. https://www.mmm-online.com/mmm-awards/best-film-or-video-of-2016/

46. Upon information and belief, the Big Bad Cough campaign had a 78% aided awareness and 31% unaided awareness within 6 months of launch, and a survey showed that 72% of the target audience had either consulted their doctors about receiving a biologic for pertussis or planned to do so. A physician survey confirmed this and revealed a high rate of grandparents asking about this product, with more than 75% asking to receive this product. https://www.mmm-online.com/mmm-awards/best-film-or-video-of-2016/

47. GSK targeted individuals in the United States with false and misleading information that receiving Boostrix would help protect them from spreading pertussis, when in reality, it rendered them more likely to silently spread pertussis. In the end, the only thing this campaign benefited was GSK's bottom line.

Boostrix is Not Without Risk

48. Boostrix can cause serious adverse reactions.

49. GSK discloses that in its clinical trial of Boostrix, "Serious adverse events were reported to occur by 4.2% … of subjects who received Boostrix." A "serious adverse event" is defined as a reaction that resulted in: death, hospitalization (emergency room visit not sufficient), disability or permanent damage resulting in substantial disruption of a person's ability to conduct

normal life functions, congenital anomaly/birth defect, or required medical or surgical intervention to prevent permanent impairment or damage.

50. Among the harms identified, GSK discloses that Boostrix can cause encephalopathy (brain damage), coma, decreased level of consciousness or prolonged seizure. The CDC therefore cautions that before receiving this product, consumers should tell their doctor if they "had a coma, decreased level of consciousness or prolonged seizure within 7 days after a previous dose of … Tdap [i.e., Adacel or Boostrix]."

51. In addition to the pre-licensure clinical trial for a drug, federal law requires that its package insert list the serious adverse events identified after licensure. 21 C.F.R. § 201.57. This federal regulation requires that its manufacturer list "*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id.* The list of adverse reactions that GSK has disclosed it has a basis to believe are caused by Boostrix include: lymphadenitis and lymphadenopathy (enlargement and/or swelling in one or more lymph nodes), allergic reactions, myocardistis (inflammation of the middle layer of the heart wall), extensive swelling of the injected limb, arthralgia (joint pain), backpain, myalgia (muscle pain), convulsions, encephalitis (brain swelling), facial palsy, and loss of consciousness.

CLASS ACTION ALLEGATIONS

52. Plaintiff brings this action on behalf of herself and those similarly situated. As detailed at length in this Complaint, GSK orchestrated deceptive marketing practices. GSK's customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution, including injunctive relief.

The Class

53. The Class is defined as follows:

> All consumers who received Boostrix anywhere in the United States during the Class Period. Excluded from this class definition are any employees, officers, or directors of GSK, the attorneys appearing in this case, and any judge assigned to hear this action.

54. The Class Period is defined as any individual who received Boostrix at any time during the applicable statute of limitations period up to and including the present. Plaintiff reserves the right to modify this class definition as she obtains relevant information through discovery.

55. Each of the persons identified in this Class has been harmed by the acts of GSK because they were falsely induced to receive Boostrix based on GSK's claim that doing so would help to reduce their chances of transmitting pertussis to others, and given the mild or treatable nature of pertussis for adults and the defective immune response created by Boostrix, absent this false advertising these people would not have received Boostrix.

The New York Subclass

56. The New York Subclass (collectively with the Class, the "Putative Classes"), to the extent necessary and appropriate, is defined as follows:

> All consumers who received Boostrix anywhere in New York during the Class Period. Excluded from this class definition are any employees, officers, or directors of GSK, the attorneys appearing in this case, and any judge assigned to hear this action.

57. Plaintiff reserves the right to modify this class definition as she obtains relevant information through discovery.

58. Each of the persons identified in this New York Subclass has been harmed by the acts of GSK because they were falsely induced to receive Boostrix based on GSK's claim that doing so would help to reduce their chances of transmitting pertussis to others, and given the mild

or treatable nature of pertussis for adults and the defective immune response created by Boostrix, absent this false advertising these people would not have received Boostrix.

The Action Meets the Requirements to be Certified as a Class

59. Plaintiff is a member of both proposed classes.

60. The proposed classes can be identified through sales records for Boostrix.

61. Numerosity. The number of Putative Class members is believed to be in the thousands or potentially millions, rendering the classes so numerous that individual joinder of all Class members is impracticable.

62. Commonality. There are questions of law and fact common to Plaintiff and to the proposed classes, including but not limited to the following:

a. Whether GSK is responsible for the conduct alleged herein, which was all the same course of conduct directed at all consumers who received Boostrix;

b. Whether GSK's misconduct set forth in this Complaint demonstrates that it engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of Boostrix;

c. Whether GSK's false and misleading statements concerning Boostrix and/or its concealment of material facts regarding Boostrix were likely to deceive reasonable consumers;

d. Whether Plaintiff and the Classes are entitled to injunctive relief; and

e. Whether Plaintiff and the Classes are entitled to money damages under the same causes of action as the other Class members.

63. Typicality. Fed. R. Civ. P. 23(a)(3). Plaintiff's claims are typical of the claims of the two (2) proposed Putative Classes' members. Plaintiff would only seek individual or actual

damages if class certification is denied. In addition, Plaintiff is entitled to relief under the same causes of action and upon the same facts as the other members of the proposed classes.

64. Adequacy. Fed. R. Civ. P. 23(a)(4). Plaintiff is an adequate representative of the two (2) proposed Putative Classes because her interests coincide with, and are not antagonistic to, the interests of the members of each proposed Putative Class she seeks to represent; she has retained counsel competent and experienced in such litigation; and she intends to prosecute this action vigorously. Plaintiff and her counsel will fairly and adequately protect the interests of members of the two (2) proposed Putative Classes.

65. Superiority. Fed. R. Civ. P. 23(b)(3). Questions of law and fact common to the two (2) proposed Putative Classes' members predominate over questions affecting only individual members, and a class action is superior to other available methods for fair and efficient adjudication of the controversy. Liability will be determined based on a common set of facts and legal theories. Willfulness will be determined based on GSK's conduct and knowledge, not upon the effect of GSK's conduct on the two (2) Putative Classes' members.

a. The joinder of thousands or millions of individual Putative Class members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Putative Class members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly burdensome, and expensive, if not totally impossible, to justify individual actions;

c. When GSK's liability has been adjudicated, all Putative Class members' claims can be determined by the Court and administered efficiently in a manner far less

burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of class claims;

e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;

f. This class action will assure uniformity of decisions among Putative Class members; and

g. The Putative Classes are readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation, which could produce inconsistent results.

66. Class certification is appropriate because GSK has acted on grounds generally applicable to the two proposed Putative Classes, making appropriate equitable injunctive relief with respect to Plaintiff and the two proposed Putative Classes' members. Fed. R. Civ. P. 23(b)(2).

67. Injunctive and Declaratory Relief Appropriate. GSK has acted on grounds generally applicable to the Putative Classes, thereby making final injunctive relief and corresponding declaratory relief with respect to the Putative Classes appropriate on a class-wide basis. Moreover, on information and belief, and based on her experience, Plaintiff alleges that the illegal marketing campaign by GSK and/or their affiliates, agents, and/or other persons or entities acting on GSK's behalf that are complained of herein are substantially likely to continue in the future if an injunction is not entered.

INJUNCTIVE CLASS RELIEF

68. Rules 23(b) (1), (2), and (3) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, GSK has engaged in a course of conduct that misled consumers about Boostrix's ability to prevent others from becoming infected with pertussis. Since GSK has subjected all consumers nationwide to the same course of conduct, and the conduct continues presently, injunctive relief on a class-wide basis is a viable and suitable solution to remedy GSK's continuing misconduct.

69. The injunctive class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the injunctive Class members would be wholly impracticable. GSK's Boostrix product has been received by at least thousands of people nationwide.

b. Commonality: Questions of law and fact are common to members of the class. GSK subjected consumers to the same course of conduct. Thus, all members of the class have a common cause against GSK to cease their misleading conduct through an injunction. Since the issues presented by this injunctive class deal exclusively with GSK's misconduct, resolution of these questions would necessarily be common to the entire class. Moreover, there are common questions of law and fact inherent in the resolution of an injunctive class, including, *inter alia*:

   i. Resolution of the issues presented in the 23(b)(3) class;

   ii. Whether members of the class will continue to suffer harm by virtue of GSK's deceptive marketing for Boostrix; and

iii. Whether, on equitable grounds, GSK should be prevented from continuing to omit material information from their marketing.

c. Typicality: Plaintiff's claims are typical of the claims of the injunctive class because her claims arise from the same course of conduct (i.e. GSK's deceptive and misleading product marketing and practices). Plaintiff is a typical class representative, because, like all members of the injunctive class, she received GSK's Boostrix product, which was sold unfairly and deceptively to consumers nationwide.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the injunctive class. Her consumer protection claims are common to all members of the injunctive class and she has a strong interest in vindicating her rights. In addition, Plaintiff and the class are represented by counsel who is competent in both consumer protection and class action litigation.

70. The injunctive class is properly brought and should be maintained as a class action under Rule 23(b)(2) because Plaintiff seeks injunctive relief on behalf of the Class members on grounds generally applicable to the entire injunctive class. Certification under Rule 23(b)(2) is appropriate because GSK has acted or refused to act in a manner that applies generally to the injunctive class (i.e., GSK has marketed Boostrix using the same misleading and deceptive marketing to all of the Class members). Any final injunctive relief or declaratory relief would benefit the entire injunctive class because GSK would be prevented from continuing their misleading and deceptive marketing practices for Boostrix.

CAUSES OF ACTION

COUNT I

VIOLATION OF NEW YORK GBL § 349
ON BEHALF OF PLAINTIFF AND THE CLASS AND/OR NEW YORK SUBCLASS

71. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

72. New York General Business Law §349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . .."

73. The conduct of GSK alleged herein constitutes recurring "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and the Class members seek monetary damages and permanent injunctive relief against GSK, enjoining it from inaccurately describing, marketing, and promoting the product.

74. There is no adequate remedy at law.

75. GSK misleadingly, inaccurately and deceptively presented Boostrix to consumers.

76. GSK's improper consumer-oriented conduct—including advertising of Boostrix—is misleading in a material way in that it, *inter alia*, induced Plaintiff and Class members to seek out and become a consumer of Boostrix when they otherwise would not have.

77. GSK engaged in unfair, deceptive, fraudulent and/or unconscionable acts or practices in the conduct of trade or commerce by making false or misleading statements regarding the efficacy of Boostrix and by not advising consumers that this product would render them more likely, not less likely, to silently transmit pertussis.

78. Studies conducted by the FDA in 2013, well before GSK's Big Bad Cough campaign began, demonstrated that pertussis products such as Boostrix render those receiving this product susceptible to becoming infected with and transmitting pertussis. The finding was so concerning that the FDA put out a press release that year stating that their research "suggests that although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants who are susceptible to pertussis disease."

79. GSK nonetheless proceeded with the conduct alleged herein even though it knew or reasonably should have known that Boostrix did not confer protection against spreading pertussis.

80. Information regarding the true efficacy of Boostrix was known or should have been known to GSK before it commenced the Big Bad Cough advertising campaign but was not reasonably known to Plaintiff and members of the Class.

81. GSK made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

82. GSK's misrepresentations and omissions were material to Plaintiff and members of the Putative Classes who relied or should be presumed to have relied upon those misrepresentations and omissions in purchasing and using Boostrix. The reasonable consumer would have expected Boostrix to meet its advertised specifications and would have expected the product to, among other things, prevent them from transmitting pertussis. Plaintiff and the Class would not have purchased or used Boostrix had they known the truth about this product.

83. Receiving Boostrix is not without risk. In clinical trials of Boostrix, "[s]erious adverse events were reported to occur by 4.2% … of subjects who received Boostrix … during the

6-month period after vaccination." For example, GSK has disclosed that Boostrix can, among other serious potential harms, cause encephalopathy (brain damage), coma, decreased level of consciousness and prolonged seizures.

84. Plaintiff and the Class members have been injured by, *inter alia*, expending time and resources to seek out and obtain Boostrix, paying, directly or indirectly, in whole or in part, for Boostrix, and after GSK led them to fear that without Boostrix they were in danger of spreading pertussis, receiving the product has actually rendered them more likely to spread pertussis and hence only increased the fear created by GSK. Accordingly, Plaintiff and the Class members did not receive what they bargained for.

85. As a direct and proximate result of GSK's misrepresentations and omissions, the Plaintiff and members of the Class were damaged in an amount to be proven at trial.

86. GSK's deceptive and misleading practices constitute deceptive acts and practices in the conduct of business in violation of New York General Business Law § 349(a) and Plaintiff and the Class have been damaged thereby.

87. As a result of GSK's recurring, "unlawful" deceptive acts and practices, Plaintiff and Class members are entitled to monetary and compensatory damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of GSK's unlawful conduct, interest, and attorneys' fees and costs.

88. Plaintiff and Class members seek damages, including treble damages, under GBL § 349.

89. By reason of the foregoing, GSK's conduct, as alleged herein, constitutes deceptive acts and practices in violation of New York General Business Law § 349, and GSK is liable to Plaintiff and the New York Class members for the damages they have suffered as a result of GSK's

actions. The amount of such damages is to be determined at trial, but not be less than $1,628,000,000.00. N.Y. GEN. BUS. LAW § 349(h), which is GSK's sales of Boostrix in the United States during the last six years.

COUNT II

VIOLATION OF NEW YORK GBL § 350

ON BEHALF OF PLAINTIFF AND THE CLASS AND/OR NEW YORK SUBCLASS

90. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

91. N.Y. Gen. Bus. Law § 350 provides, in part, as follows:

> False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful.

92. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

> The term "false advertising" means advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual.

93. GSK misleadingly, inaccurately, and deceptively marketed and advertised Boostrix to consumers. GSK's marketing and advertisements contain untrue and materially misleading statements concerning GSK's product because, *inter alia*, they mislead and misrepresent that an individual receiving Boostrix will be protected from being able to become infected with and transmit pertussis to others.

94. GSK's improper consumer-oriented conduct—including advertising of Boostrix—is misleading in a material way in that it, *inter alia*, induced Plaintiff and Class members to seek out and become a consumer of Boostrix when they otherwise would not have.

95. GSK engaged in unfair, deceptive, fraudulent and/or unconscionable acts or practices in the conduct of trade or commerce by making false or misleading statements regarding the efficacy of Boostrix and not advising consumers that this product would render them more likely, not less likely, to silently transmit pertussis.

96. Studies conducted by the FDA in 2013, well before GSK's Big Bad Cough campaign began, demonstrated that pertussis products such as Boostrix render those receiving this product susceptible to becoming infected with and transmitting pertussis. The finding was so concerning that the FDA put out a press release that year stating that their research "suggests that although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants who are susceptible to pertussis disease."

97. GSK nonetheless proceeded with the conduct alleged herein even though it knew or reasonably should have known that Boostrix did not confer the protection against preventing recipients from spreading pertussis.

98. Information regarding the true efficacy of Boostrix was known to GSK, but was not reasonably known to Plaintiff and members of the Class.

99. GSK made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

100. Plaintiff and members of the Putative Classes relied or should be presumed to have relied upon GSK's misrepresentations and omissions in purchasing and using Boostrix. The

Plaintiff and the Putative Classes would not have purchased or used Boostrix had they known the truth about this product.

101. Receiving Boostrix is not without risk. In clinical trials of Boostrix, "[s]erious adverse events were reported to occur by 4.2% … of subjects who received Boostrix … during the 6-month period after vaccination." For example, GSK has disclosed that Boostrix can, among other serious potential harms, cause encephalopathy (brain damage), coma, decreased level of consciousness and prolonged seizures.

102. Plaintiff and the Class members have been injured by, *inter alia*, expending time and resources to seek out and obtain Boostrix, paying, directly or indirectly, in whole or in part, for Boostrix, and after GSK lead them to fear that without Boostrix they were in danger of spreading pertussis, receiving the product has actually rendered them more likely to spread pertussis and hence only increased the fear created by GSK. Accordingly, Plaintiff and the Class members did not receive what they bargained for.

103. As a direct and proximate result of GSK's misrepresentations and omissions, the Plaintiff and members of the Class were damaged in an amount to be proven at trial.

104. GSK's conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

105. GSK made the material misrepresentations described in this Complaint in GSK's advertising and marketing willfully, wantonly, and with reckless disregard for the truth.

106. GSK's material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. All consumers receiving Boostrix were and continue to be exposed to GSK's material misrepresentations.

107. As a result of GSK's recurring, "unlawful" deceptive acts and practices, Plaintiff and Class members are entitled to monetary and compensatory damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of GSK's unlawful conduct, interest, and attorneys' fees and costs.

108. Plaintiff and Class members seek damages, including treble damages, under N.Y. Gen. Bus. Law § 350.

COUNT III

VIOLATION OF NEW YORK GBL § 350-a(1)
ON BEHALF OF PLAINTIFF AND THE CLASS AND/OR NEW YORK SUBCLASS

109. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

110. N.Y. Gen. Bus. Law § 350-a(1) expressly covers material omissions:

> In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual…

111. GSK's marketing and advertising contains misleading and/or unfair material omissions concerning Boostrix. The marketing and advertising for Boostrix omits that receiving this product will modify the immune response to pertussis such that the recipient of the product may have fewer symptoms but will continue to be able to become serially infected with and transmit pertussis.

112. By its omissions of the facts regarding Boostrix, GSK's marketing and advertising of Boostrix was misleading, inaccurate, and deceptive because, *inter alia*, they mislead consumers

into believing that an individual receiving Boostrix will be protected from being able to become infected with and transmit pertussis to others.

113. GSK's improper consumer-oriented conduct was misleading by omission in a material way in that it, *inter alia*, induced Plaintiff and Class members to seek out and become a consumer of Boostrix when they otherwise would not have.

114. GSK engaged in unfair, deceptive, fraudulent and/or unconscionable acts or practices in the conduct of trade or commerce by acts that rendered its marketing and advertising false and misleading, including because GSK failed to advise consumers that Boostrix would render consumers more likely, not less likely, to silently transmit pertussis.

115. Studies conducted by the FDA in 2013, well before GSK's Big Bad Cough campaign began, demonstrated that pertussis products such as Boostrix render those receiving this product susceptible to becoming infected with and transmitting pertussis. The finding was so concerning that the FDA put out a press release that year stating that their research "suggests that although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants who are susceptible to pertussis disease."

116. GSK nonetheless proceeded with the conduct alleged herein even though it knew or reasonably should have known that Boostrix did not confer the protection against preventing recipients from spreading pertussis.

117. Information regarding the true efficacy of Boostrix was known to GSK but was not reasonably known to Plaintiff and members of the Class.

118. GSK made its omissions regarding Boostrix's actual efficacy willfully, wantonly, and with reckless disregard for the truth.

119. GSK's marketing and advertising of Boostrix induced the Plaintiff and Class members to seek out and be injected with Boostrix. Plaintiff and members of the Class relied or should be presumed to have relied upon GSK's misrepresentations and omissions regarding Boostrix. The Plaintiff and the Class would not have purchased or used Boostrix had they known the truth about this product.

120. Receiving Boostrix is not without risk. In clinical trials of Boostrix, "[s]erious adverse events were reported to occur by 4.2% … of subjects who received Boostrix … during the 6-month period after vaccination." For example, GSK has disclosed that Boostrix can, among other serious potential harms, cause encephalopathy (brain damage), coma, decreased level of consciousness and prolonged seizures.

121. Plaintiff and the Class members have been injured by, *inter alia*, expending time and resources to seek out and obtain Boostrix, paying, directly or indirectly, in whole or in part, for Boostrix, and after GSK lead them to fear that without Boostrix they were in danger of spreading pertussis, receiving the product has actually rendered them more likely to spread pertussis and hence only increased the fear created by GSK. Accordingly, Plaintiff and the Class members did not receive what they bargained for.

122. As a direct and proximate result of GSK's misrepresentations and omissions, the Plaintiff and members of the Class were damaged in an amount to be proven at trial.

123. GSK's dissemination of advertising containing material omissions of fact constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

124. GSK's material misrepresentations by way of omission, as described in this Complaint, were substantially uniform in content, presentation, and impact upon consumers at

large. Moreover, all consumers of Boostrix were and continue to be exposed to GSK's material misrepresentations by way of omission.

125. Plaintiff and Class members relied on GSK's advertising, which was deceptive, false, and contained material omissions.

126. Plaintiff and Class members seek damages, including treble damages, under GBL § 350-a(1).

127. As a result of GSK's false and misleading advertising, the Plaintiff and Class members are entitled to monetary and compensatory damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of GSK's unlawful conduct, interest, and attorneys' fees and costs.

COUNT IV

VIOLATION OF STATE CONSUMER PROTECTION STATUTES
ON BEHALF OF PLAINTIFF AND THE CLASS

128. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

129. Plaintiff and Class members have been injured as a result of GSK's violations of the following state consumer protection statutes, which also provide a basis for redress to Plaintiff and Class members based on GSK's fraudulent, deceptive, unfair and unconscionable acts, practices, and conduct.

130. GSK's conduct as alleged herein violates the consumer protection, unfair trade practices and deceptive acts laws of each of the following jurisdictions:

a. **Alaska:** GSK's practices were and are in violation of Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, *et seq.*

b. **Arizona:** GSK's practices were and are in violation of Arizona's Consumer Fraud Act, Ariz. Rev. Stat. Ann. § 44-1521, *et seq.*

c. **Arkansas:** GSK's practices were and are in violation of Arkansas Code Ann. § 4-88-101, *et seq.*

d. **California:** GSK's practices were and are in violation of California Consumer Legal Remedies Act, Civil Code § 1750, *et seq.*, California's Unfair Competition Law, California Business and Professions Code § 17200, *et seq.*, and California's False Advertising Law, California Business and Professions Code § 17500, *et seq.*

e. **Colorado**: GSK's practices were and are in violation of Colorado's Consumer Protection Act, Colo. Rev. Stat. § 61-1-101, *et seq.*

f. **Connecticut:** GSK's practices were and are in violation of Connecticut's Gen. Stat. § 42-110a, *et seq.*

g. **Delaware:** GSK's practices were and are in violation of Delaware's Consumer Fraud Act, Del. Code Ann. tit. 6, § 2511, *et seq.* and the Deceptive Trade Practices Act, Del. Code Ann. tit. 6, § 2531, *et seq.*

h. **District of Columbia:** GSK's practices were and are in violation of the District of Columbia's Consumer Protection Act, D.C. Code § 28-3901, *et seq.*

i. **Florida:** GSK's practices were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq.*

j. **Hawaii:** GSK's practices were and are in violation of the Hawaii's Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. § 481A-1, *et seq.* and Haw. Rev.

Stat. § 480-2.

k. **Idaho:** GSK's practices were and are in violation of Idaho's Consumer Protection Act, Idaho Code Ann. § 48-601, *et seq.*

l. **Illinois:** GSK's acts and practices were and are in violation of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2; and Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/2.

m. **Indiana:** GSK's practices were and are in violation of Indiana's Deceptive Consumer Sales Act, Ind. Code Ann. § 24-5-0.5-1, *et seq.*

n. **Kansas:** GSK's practices were and are in violation of Kansas's Consumer Protection Act, Kan. Stat. Ann. § 50-623, *et seq.*

o. **Kentucky:** GSK's practices were and are in violation of Kentucky's Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, *et seq.*

p. **Maine:** GSK's practices were and are in violation of the Maine Unfair Trade Practices Act, 5 Me. Rev. Stat. Ann. Tit. 5, § 205-A, *et seq.* and 10 Me. Rev. Stat. Ann. § 1101, *et seq.*

q. **Maryland:** GSK's practices were and are in violation of Maryland's Consumer Protection Act, Md. Code Ann. Com. Law § 13-101, *et seq.*

r. **Massachusetts:** GSK's practices were unfair and deceptive acts and practices in violation of Massachusetts' Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 2.

s. **Michigan:** GSK's practices were and are in violation of Michigan's Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, *et seq.*

t. **Minnesota:** GSK's practices were and are in violation of Minnesota's Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, *et seq.* and the Unlawful Trade Practices law, Minn. Stat. § 325D.09, *et seq.*

u. **Missouri:** GSK's practices were and are in violation of Missouri's Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*

v. **Nebraska:** GSK's practices were and are in violation of Nebraska's Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.* and the Uniform Deceptive Trade Practices Act, § 87-302, *et seq.*

w. **Nevada:** GSK's practices were and are in violation of Nevada's Deceptive Trade Practices Act, Nev. Rev. Stat. Ann. §§ 598.0903 and 41.600.

x. **New Hampshire:** GSK's practices were and are in violation of New Hampshire's Regulation of Business Practices for Consumer Protection, N.H. Rev. Stat. Ann. § 358-A:1, *et seq.*

y. **New Jersey:** GSK's practices were and are in violation of New Jersey's Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, *et seq.*

z. **New Mexico:** GSK's practices were and are in violation of New Mexico's Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq.*

aa. **New York:** GSK's practices were in and are in violation of New York's Gen. Bus. Law § 349, *et seq.*

bb. **North Carolina:** GSK's practices were and are in violation of North Carolina's Unfair Deceptive Trade Practices Act, N.C. Gen. Stat. Ann. § 75-1, *et seq.*

cc. **North Dakota:** GSK's practices were and are in violation of North Dakota's Unlawful Sales or Advertising Practices law, N.D. Cent. Code § 51-15- 01, *et seq.*

dd. **Ohio:** GSK's practices were and are in violation of Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, *et seq.* and Ohio's Deceptive Trade Practices Act, Ohio Rev. Code Ann. § 4165.01, *et seq.*

ee. **Oklahoma:** GSK's practices were and are in violation of Oklahoma's Consumer Protection Act, Okla. Stat. Ann. tit. 15 § 751, *et seq.*, and Oklahoma's Deceptive Trade Practices Act, Okla. Stat. Ann. tit. 78 § 51, *et seq.*

ff. **Oregon:** GSK's practices were and are in violation of Oregon's Unlawful Trade Practices law, Or. Rev. Stat. § 646.605, *et seq.*

gg. **Pennsylvania:** GSK's practices were and are in violation of Pennsylvania's Unfair Trade Practice and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et seq.*

hh. **Rhode Island:** GSK's practices were and are in violation of Rhode Island's Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*

ii. **South Dakota:** GSK's practices were and are in violation of South Dakota's Deceptive Trade Practices and Consumer Protection Act, S.D. Codified Laws § 37-24-1, *et seq.*

jj. **Texas:** GSK's practices were and are in violation of Texas' Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.*

kk. **Utah:** GSK's practices were and are in violation of Utah's Consumer Sales Practices Act, Utah Code Ann. § 13-11-1, *et seq.*, and Utah's Truth in Advertising Law, Utah Code Ann. § 13-11a-1, *et seq.*

ll. **Vermont:** GSK's practices were and are in violation of Vermont's Consumer Fraud Act, Vt. Stat. Ann. tit. 9 § 2451, *et seq.*

mm. **Washington:** GSK's practices were and are in violation of Washington Consumer Protection Act, Wash. Rev. Code Ann. § 19.86, *et seq*.

nn. **West Virginia:** GSK's practices were and are in violation of West Virginia's Consumer Credit and Protection Act, W. Va. Code § 46A-6-101, *et seq.*

oo. **Wisconsin:** GSK's practices were and are in violation of Wisconsin's Consumer Act, Wis. Stat. §421.101, *et seq*.

pp. **Wyoming:** GSK's practices were and are in violation of Wyoming's Consumer Protection Act, Wyo. Stat. Ann. §40-12-101, *et seq*.

131. The allegations in Counts I, II and III are hereby incorporated by reference as if fully set forth herein.

132. The acts, practices, misrepresentations and omissions by GSK described above, and GSK's dissemination of deceptive and misleading advertising and marketing materials in connection therewith, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

133. GSK's acts and practices created a likelihood of confusion or of misunderstanding and misled, deceived or damaged Plaintiff and members of the Class in connection with the sale or advertisement of Boostrix. GSK's conduct also constituted the use or employment of deception,

fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression or omission in connection with the sale or advertisement of goods or services whether or not a person has in fact been misled, deceived or damaged in violation of each of the above-enumerated statutes.

134. Plaintiff, on behalf of herself and the Class members, seeks monetary damages, treble damages and such other and further relief as set forth in each of the above enumerated statutes.

COUNT V

VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301 *et seq.*
ON BEHALF OF PLAINTIFF AND THE CLASS

135. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

136. Plaintiff brings this claim individually and on behalf of all members of the Class. Upon certification, the Class will consist of more than 100 named plaintiffs.

137. The Magnuson-Moss Warranty Act provides a federal remedy for consumers who have been damaged by the failure of a supplier or warrantor to comply with any obligation under a written warranty or implied warranty, or other various obligations established under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*

138. Boostrix is a "consumer product" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).

139. Plaintiff and the other members of the Class are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3).

140. GSK is a "supplier" and "warrantor" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301(4) & 2301(5).

141. GSK's marketing states that the product will reduce the potential that someone receiving the product will transmit pertussis is a statement made in connection with the sale of the product that relates to the nature of the product and affirms and promises that it would work in the manner warrantied—*i.e.*, will reduce the likelihood of transmitting pertussis—and, as such, is a warranty within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(6)(A).

142. As alleged herein, GSK has breached this written warranty by selling consumers a product that does not, as warranted, reduce the likelihood its recipient will transmit pertussis and thus does not conform to GSK's written warranty, violating the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*, and causing Plaintiff and the other members of the Class injury and damage in an amount to be proven at trial.

143. Furthermore, as alleged herein, GSK breached the above-described written warranty by selling consumers a product that, in fact, increases the likelihood of asymptomatic transmission of pertussis. The marketing and advertising of this product constitutes an affirmation and a promise that it will make its recipient less likely to transmit pertussis. Given that the product's true effect is to render an individual a potentially repeat asymptomatic spreader of pertussis, the product violates its warranty and GSK has violated the Magnuson-Moss Warranty Act, 15 U.S.C. §2301 *et seq.*, causing Plaintiff and other members of the Class injury and damage in an amount to be proven at trial.

COUNT VI

BREACH OF EXPRESS WARRANTY
ON BEHALF OF PLAINTIFF AND THE CLASS

144. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

145. GSK provided the Plaintiff and members of the Class an express warranty in the form of written and oral affirmations of fact in promising and representing that its product would reduce the potential for transmission of pertussis from the recipient to another person.

146. This affirmation of fact was not couched as "belief" or "opinion," and was not a "generalized statement[] of quality not capable of proof or disproof."

147. This affirmation of fact became part of the basis for the bargain and was material to the transactions of the Plaintiff and of members of the Class.

148. Plaintiff and members of the Class reasonably relied upon GSK's affirmation of fact and justifiably acted in ignorance of the material facts omitted or concealed when they decided to be injected with the product.

149. Within a reasonable time after they knew or should have known of GSK's breach, Plaintiff—on behalf of herself and the other members of the Class—placed GSK on notice of its breach, giving GSK an opportunity to cure its breach, which it refused to do.

150. Contrary to GSK's affirmation of fact, GSK breached the express warranty because its product, in direct contravention to its advertised claim, in fact increases the likelihood its recipients asymptomatically transmit pertussis to other individuals, thereby also breaching the following states' warranty laws:

a. ALA. CODE § 7-2-313;

b. ALASKA ST. § 42.02.313;

c. ARIZ. REV. STAT. ANN. § 47-2313;

d. ARK. CODE ANN. § 4-2-313;

e. CAL. COMM. CODE § 2313;

f. COLO. REV. ST. § 4-2-313;

g. CONN. GEN. STAT. ANN. § 42A-2-313;

h. DEL. CODE ANN. TIT. 6, § 2-313;

i. D.C. STAT. § 28:2-313;

j. FLA. STAT. ANN. § 672.313;

k. GA. CODE ANN. § 11-2-313;

l. HAW. REV. STAT. § 490:2-313;

m. IDAHO CODE ANN. § 28-2-313;

n. ILL. ST. CH. 810 § 5/2-313;

o. IND. CODE § 26-1-2-313;

p. IOWA CODE ANN. § 554.2313;

q. KAN. STAT. ANN. § 84-2-313;

r. KY. REV. STAT. ANN. § 355.2-313;

s. LA. CIV. CODE ANN. ART. 2520;

t. ME. REV. STAT. TIT. 11, § 2-313;

u. MD. CODE ANN., COM. LAW. § 2-313;

v. MASS. GEN. LAWS ANN. 106 § 2-313;

w. MICH. COMP. LAWS ANN. § 440.2313;

x. MINN. STAT. ANN. § 336.2-313;

y. MISS. CODE ANN. § 75-2-313;

z. MO. REV. STAT. § 400.2-313;

aa. MONT. CODE ANN. 30-2-313;

bb. NEB. REV. STAT. § 2-313;

cc. NEV. REV. STAT. § 104.2313;

dd. N.H. REV. STAT. § 382-A:2-313;

ee. N.J. STAT. ANN. 12A:2-313;

ff. N.M. STAT. ANN. § 55-2-313;

gg. N.Y. U.C.C. LAW § 2-313;

hh. N.C. GEN. STAT. ANN. § 25-2-313;

ii. N.D. CENT. CODE ANN. § 41-02-330 (2-313);

jj. OHIO REV. CODE ANN. § 1302.26;

kk. OKLA. STAT. ANN. TIT. 12A, § 2-313;

ll. OR. REV. STAT. § 72.3130;

mm. PA. STAT. ANN. TIT. 13, § 2313;

nn. RD. STAT. § 6A-2-313;

oo. S.C. § 36-2-313;

pp. S.D. COD. LAWS. § 57A-2-313;

qq. TENN. CODE ANN. § 47-2-313;

rr. TEX. BUS. & COM. CODE ANN. § 2.313;

ss. UTAH CODE ANN. § 70A-2-313;

tt. VT. STAT. ANN. § 2-313;

uu. VA. CODE ANN. § 8.2-313;

vv. WASH. ANN. 62A.2-313;

ww. W.VA. CODE § 46-2-313;

xx. WIS. STAT. ANN. § 402.313; and

yy. WYO. STAT. 34.1-2-313.

151. As a direct and proximate result of GSK's breaches of express warranty, Plaintiff and the other members of the Class were damaged in amounts to be proven at trial.

COUNT VII

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
ON BEHALF OF PLAINTIFF AND THE CLASS

152. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

153. GSK is in the business of manufacturing, producing, distributing, and selling biological products, including Boostrix.

154. Under the Uniform Commercial Code's implied warranty of merchantability, GSK warranted to Plaintiff and the members of the Class that Boostrix prevented its recipients from becoming infected with and transmitting pertussis to others.

155. GSK breached the implied warranty of merchantability in that Boostrix does not prevent its recipients from becoming infected with and transmitting pertussis and therefore materially deviates from the product description in GSK's marketing and advertising of the product, and reasonable consumers expected a product that conforms with GSK's representations regarding the product and would not have been injected with the product if they knew these representations were not accurate.

156. GSK breached the implied warranty of merchantability. The product does not disclose that it does not prevent infection and transmission of pertussis, or that it renders those

receiving the product more likely to be asymptotic carriers and transmitters of pertussis. Furthermore, the product advertising falsely states that the product prevents its recipient from becoming infected with and transmitting pertussis to others.

157. Reasonable consumers expecting a product that conforms to the representations related to this product by GSK would not accept the product if they knew the truth about its efficacy.

158. GSK breached the implied warranty of merchantability in that the product does not conform to the promises or affirmations of fact made on the product's marketing, advertising or literature.

159. Within a reasonable time after the Plaintiff discovered that the product is not what it purports to be, Plaintiff notified GSK of such breach.

160. The inability of the product to confer the protection promised by GSK was wholly due to GSK's fault and without Plaintiff's fault or neglect, and was solely due to GSK's manufacture and distribution of the product to the public.

161. At all times relevant to this action, GSK has breached its implied warranty of merchantability regarding Boostrix in violation of state implied warranty laws, including:

a. ALA. CODE § 7-2-314;

b. ALASKA ST. § 42.02.314;

c. ARIZ. REV. STAT. ANN. § 47-2314;

d. ARK. CODE ANN. § 4-2-314;

e. CAL. COMM. CODE § 2314;

f. COLO. REV. ST. § 4-2-314;

g. CONN. GEN. STAT. ANN. § 42A-2-314;

h. DEL. C. 6, § 2-314;

i. D.C. STAT. § 28:2-315;

j. FLA. STAT. ANN. § 672.314;

k. GA. CODE ANN. § 11-2-314;

l. HAW. REV. STAT. § 490:2-314;

m. IDAHO CODE ANN. § 28-2-314;

n. ILL. ST. CH. 810 § 5/2-314;

o. IND. CODE § 26-1-2-314;

p. IOWA CODE ANN. § 554.2314;

q. KAN. STAT. ANN. § 84-2-314;

r. KY. REV. STAT. ANN. § 355.2-314;

s. ME. REV. STAT. TIT. 11, § 2-314;

t. MD. CODE ANN., COM. LAW § 2-314;

u. MASS. GEN. LAWS ANN. CH. 106 § 2-314;

v. MICH. COMP. LAWS ANN. § 440.2314;

w. MINN. STAT. ANN. § 336.2-314;

x. MISS. CODE ANN. § 75-2-314;

y. MO. ANN. STAT. § 400.2-314;

z. MONT. CODE ANN. § 30-2-314;

aa. NEB. REV. STAT. U.C.C. § 2-314;

bb. NEV. REV. STAT. ANN. § 104.2314;

cc. N.H. REV. STAT. ANN. § 382-A:2-314;

dd. N.J. STAT. ANN. § 12A:2-314;

ee. N.M. STAT. ANN. § 55-2-314;

ff. N.Y. U.C.C. LAW § 2-314;

gg. N.C. GEN. STAT. ANN. § 25-2-314;

hh. N.D. GEN. STAT. ANN. § 25-2-314;

ii. OHIO REV. CODE ANN. § 1302.27;

jj. OKLA. STAT. ANN. TIT. 12A, § 2-314;

kk. OR. REV. STAT. § 72.3140;

ll. PA.CONS. STAT. ANN. § 2314

mm. R.I. GEN. LAWS ANN. § 6A-2-314;

nn. S.C. CODE ANN. § 36-2-314;

oo. S.D. COD. LAWS. § 57A-2-314;

pp. TENN. CODE ANN. § 47-2-314;

qq. TEX. BUS. & COM. CODE ANN. § 2.314;

rr. UTAH CODE ANN. § 70A-2-314;

ss. VT. STAT. ANN. TIT. 9A, § 2-314;

tt. VA. CODE ANN. § 8.2-314;

uu. WASH. REV. CODE ANN. § 62A.2-314;

vv. W.VA. CODE ANN. § 46-2-314;

ww. WIS. STAT. ANN. § 402.314; and

xx. WYO. STAT. ANN. § 34.1-2-314.

162. As a result of the foregoing, Plaintiff and the members of the Class have been damaged in an amount to be determined at trial.

COUNT VIII

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
ON BEHALF OF PLAINTIFF AND THE CLASS

163. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

164. Plaintiff and other members of the Class sought out and were injected with the product with the specific purpose of modifying their immune system so that they could not become infected with and transmit pertussis to other people.

165. GSK knew or had reason to know that Plaintiff and other members of the Class were buying a product with the specific purpose of obtaining this protection. GSK knew this because it made this promise in its marketing, advertising and literature to prompt consumers to demand and obtain this product.

166. Plaintiff and other members of the Class, intending to protect themselves from being able to become infected with and transmit pertussis, relied on GSK to select the product to fit the specific, intended use.

167. GSK held itself out as having particular knowledge of the product's values and content.

168. The reliance by Plaintiff and other members of the Class on GSK to select a product to fit the particular purpose was reasonable given GSK's statements and representations in its advertising, marketing and literature.

169. The reliance by Plaintiff and other members of the Class on GSK to select a product to fit the particular purpose was reasonable given GSK's particular knowledge of the product it manufactures and distributes.

170. At all times relevant to this action, GSK has breached its implied warranty of fitness for a particular purpose regarding Boostrix in violation of states' implied warranty laws, including:

a. ALA. CODE § 7-2A-213

b. ALASKA STAT. § 45.02.315

c. ARIZ. REV. STAT. ANN. § 47-2315

d. ARK. CODE ANN. § 4-2A-213

e. CAL. COM. CODE § 2315

f. COLO. REV. STAT. § 4-2-315

g. CONN. GEN. STAT. ANN. § 42A-2-315

h. DEL. C.6 , CODE § 2-315

i. FLA. STAT. § 672.315

j. GA. CODE ANN. § 11-2-315

k. HAW. REV. STAT. § 490:2-315

l. IDAHO CODE ANN. § 28-2-315

m. ILL. ST. CH. 810 § 5/2-315

n. IND. CODE § 26-1-2-315

o. IOWA CODE ANN. § 554.2315

p. KAN. STAT. ANN. § 84-2-315

q. KY. REV. STAT. ANN. § 355.2-315

r. LA. CIV. CODE § 2524

s. ME. REV. STAT. TIT. 11, § 2-315

t. MD. CODE AN., COM. LAW § 2-315

u. MASS. GEN. LAWS ANN. CH. 106 2 § 2-315

v. MICH. COMP. LAWS ANN. § 440.2315

w. MINN. STAT. § 325G.19

x. MISS. CODE ANN. § 75-2-315

y. MO. REV. STAT. § 400.2A-213

z. MONT. CODE ANN. § 30-2-315

aa. NEB. REV. STAT. U.C.C.§ 2-315

bb. NEV. REV. STAT. ANN. § 104.2315

cc. N.H. REV. STAT. ANN. § 382-A:2-315

dd. N.J. REV. STAT. ANN. § 12A:2-315

ee. N.M. STAT. ANN. § 55-2-315

ff. N.Y. U.C.C. LAW § 2-314; 810

gg. N.C. GEN. STAT. ANN. § 25-2-315

hh. N.D. CENT. CODE §41-02-32 (2-315)

ii. OHIO REV. CODE ANN. § 1302.28

jj. OKLA. STAT. ANN. TIT. 12A § 2-315

kk. OR. REV. STAT. § 72.3150

ll. 13 PA CONS. STAT. § 2315

mm. R.I. GEN. LAWS ANN. § 6A-2-315

nn. S.C. CODE ANN. § 36-2-315

oo. S.D. CODIFIED L § 57A-2-315

pp. TENN. CODE ANN. § 47-2-315

qq. TEX. BUS. & COM. CODE ANN. § 2.315

rr. UTAH CODE ANN. § 70A-2-315

ss. VT. STAT. ANN. TIT. 9A, § 2-315

tt. VA. CODE ANN. § 8.2-315

uu. WASH. REV. CODE ANN. § 62A.2-315

vv. W.VA.CODE ANN. § 46-2-315

ww. WIS. STAT. ANN. § 402.315

xx. WYO. STAT. ANN. § 34.1-2-315

171. As a result of the foregoing, Plaintiff and other members of the Class have been damaged in an amount to be determined at trial.

COUNT VIII

COMMON LAW UNJUST ENRICHMENT
ON BEHALF OF PLAINTIFF AND THE CLASS

172. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

173. Plaintiff, on behalf of herself and Class members, brings a common law claim for unjust enrichment.

174. GSK's conduct violated federal and state consumer protection statutes by manufacturing, advertising, marketing and selling Boostrix while misrepresenting and omitting material facts.

175. Worse, GSK engaged in a marketing campaign intended to generate fear that without receiving its product adults could seriously injure or kill young children, when in reality the product made it more likely this would occur.

176. GSK's unlawful conduct as described in this Complaint allowed GSK to knowingly realize substantial revenues from selling the product, which benefited and enriched GSK at the

expense of and to the detriment of Plaintiff and Class members. GSK has thereby violated the fundamental principles of justice, equity, and good conscience.

177. Under common law principles of unjust enrichment, it is inequitable for GSK to retain the financial benefits conferred by Plaintiff's and the Class members from GSK's sales of Boostrix.

178. Plaintiff and Class members seek disgorgement of all profits resulting from its sales of Boostrix and establishment of a constructive trust from which Plaintiff and Class members may seek restitution.

COUNT IX
COMMON LAW FRAUD
ON BEHALF OF PLAINTIFF AND THE CLASS

179. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

180. GSK knew that individuals receiving Boostrix could not only continue to become infected and transmit pertussis, but also knew that by receiving Boostrix, this would occur more frequently and with the individual having no or less symptoms.

181. Despite this knowledge, GSK falsely represented affirmatively and by omission in a nationwide advertising campaign to consumers, including Plaintiff and the Class, that receiving Boostrix would protect from becoming infected and transmitting pertussis to others, notably infants. GSK bombarded Plaintiff and the Class with advertisements, marketing and literature which affirmed that without receiving Boostrix, they could transmit pertussis and cause serious injury or death to an infant. GSK made these representations about Boostrix with knowledge of their falsity or with reckless and wanton disregard for the truth.

182. Plaintiff and the Class relied on GSK's false representations, including in the television advertisements by GSK, believed that these claims were true, and based on this reliance sought out and received an injection of Boostrix.

183. Plaintiff and the Class members have been injured by, *inter alia*, expending time and resources to seek out and obtain Boostrix, paying, directly or indirectly, in whole or in part, for Boostrix, and after GSK lead them to fear that without Boostrix they were in danger of spreading pertussis to infants, receiving the product has actually rendered them more likely to spread pertussis to infants and hence only increased the fear created by GSK. Accordingly, Plaintiff and the Class members did not receive what they bargained for.

184. Receiving Boostrix is not without risk. In clinical trials of Boostrix, "[s]erious adverse events were reported to occur by 4.2% … of subjects who received Boostrix … during the 6-month period after vaccination." For example, GSK has disclosed that Boostrix can, among other serious potential harms, cause encephalopathy (brain damage), coma, decreased level of consciousness and prolonged seizures.

185. Plaintiff and Class members seek actual damages, punitive damages, interest, costs and attorneys' fees in an amount to be determined at trial and an order compelling GSK to cease their practice of making misrepresentations about the product.

COUNT X

NEGLIGENT MISREPRESENTATION
ON BEHALF OF PLAINTIFF AND THE CLASS

186. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

187. GSK knew or should have known that individuals receiving Boostrix could not only continue to become infected and transmit pertussis, but also that this would occur more frequently and with the individual having no or less symptoms.

188. Despite same, GSK falsely represented affirmatively and by omission in a nationwide advertising campaign to consumers, including Plaintiff and the Class, that receiving Boostrix would protect from becoming infected and transmitting pertussis to others, notably infants. GSK's advertising bombarded Plaintiff and the Class with advertisements, marketing and literature which affirmed that without receiving Boostrix, they could transmit pertussis and cause serious injury or death to an infant. GSK made these representations about Boostrix with knowledge of their falsity or with reckless disregard for the truth.

189. Plaintiff and the Class relied on GSK's false representations, including in the television advertisements by GSK, believed that these claims were true, and based on this reliance sought out and received an injection of Boostrix.

190. Plaintiff and the Class members have been injured by, *inter alia*, expending time and resources to seek out and obtain Boostrix, paying, directly or indirectly, in whole or in part, for Boostrix, and after GSK lead them to fear that without Boostrix they were in danger of spreading pertussis to infants, receiving the product has actually rendered them more likely to spread pertussis to infants and hence only increased the fear created by GSK. Accordingly, Plaintiff and the Class members did not receive what they bargained for.

191. Receiving Boostrix is not without risk. In clinical trials of Boostrix, "[s]erious adverse events were reported to occur by 4.2% … of subjects who received Boostrix … during the 6-month period after vaccination." For example, GSK has disclosed that Boostrix can, among

other serious potential harms, cause encephalopathy (brain damage), coma, decreased level of consciousness and prolonged seizures.

192. Plaintiff and Class members seek actual damages, punitive damages, interest, costs and attorneys' fees in an amount to be determined at trial and an order compelling GSK to cease their practice of making misrepresentations about the product.

DEMAND FOR PRESERVATION

193. Plaintiff also specifically demands that GSK retain and preserve all records related to the allegations in this Complaint. Specifically, Plaintiff's demand for preservation includes, but is not limited to, the following documents and information:

a. Research regarding the efficacy of Boostrix or any other biological product against pertussis;

b. The ability of Boostrix, or any other biological product against pertussis, to prevent infection and/or transmission of pertussis;

c. Research that contributed to the marketing for Boostrix;

d. The marketing of Boostrix generally;

e. The Big Bad Cough advertising campaign;

f. Information regarding the individuals who received Boostrix;

g. The income generated by sales of Boostrix;

h. All documents and communications regarding linked epitope-suppression;

i. All documents and communications regarding the efficacy, immunogenicity, immunity, and/or protection from administration of Boostrix or any other pertussis containing biological product; and

j. All documents and communications, including emails, regarding or relating to Boostrix, including the marketing, promotion, and sales of Boostrix and/or any and all potential or actual issues with regard to Boostrix.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and as representative of all other persons similarly situated, prays for judgment against GSK, awarding relief as follows:

a. An order certifying this action as a class action under Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiff as class representative, and her counsel of record as class counsel;

b. A declaration that GSK's conduct is in violation of the state consumer protection, false advertising and warranty laws, and the Magnuson-Moss Warranty Act;

c. A declaration that GSK engaged in conduct constituting negligent misrepresentation and fraud;

d. A declaration that GSK was unjustly enriched by its unlawful conduct;

e. Restitution and/or damages to Plaintiff and the Class members for the purchase of Boostrix;

f. Treble, actual, statutory, punitive, and such other damages or other relief as provided by the statutes cited herein;

g. Equitable relief in the form of restitution and/or disgorgement of all unlawful or illegal profits received by GSK as a result of the illegal conduct alleged herein;

h. Injunctive relief barring GSK from making further misrepresentations regarding the efficacy of Boostrix;

i. Pre-judgment and post-judgment interest on monetary relief awarded;

j. Reasonable attorneys' fees and costs; and

k. All other relief, including all general, special and equitable relief, to which Plaintiff and the members of the Class are entitled to by law.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts so triable.

Dated: May 20, 2020

SIRI & GLIMSTAD LLP

Aaron Siri
Elizabeth Brehm
Jessica Wallace (*pro hac vice* motion to be filed)
200 Park Avenue, Seventeenth Floor
New York, New York 10166
Tel: (212) 532-1091
E: aaron@sirillp.com

Attorneys for Plaintiff and the Putative Classes