CHATOM PRIMARY CARE, P.C. v. MERCK & CO., INC. Doc. 361

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

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION	:	
	:	**CIVIL ACTION**
	:	**Master File No. 12-3555**
THIS DOCUMENT RELATES TO: ALL ACTIONS	:	

MEMORANDUM

Kenney, J. **July 27, 2023**

Chatom Primary Care, P.C., Andrew Klein, M.D., and John I. Sutter, M.D. (collectively, "Plaintiffs") bring this proposed class action on behalf of direct purchasers of Defendant Merck & Co., Inc.'s ("Merck") mumps vaccines. Plaintiffs' remaining claims allege that they were overcharged for Merck's mumps vaccines as a result of Merck's unlawful monopolization of the Mumps Vaccine Market in violation of Section 2 of the Sherman Act and New Jersey and New York state laws. Plaintiffs' case arises from the same underlying allegations of fraud that spawned the related False Claims Act ("FCA") case, *U.S. ex rel. Krahling v. Merck & Co., Inc.*, 10-cv-4374 (E.D. Pa.). Presently before the Court are Merck's Motion for Summary Judgment (ECF No. 272) and Merck's Motion to Exclude Evidence from Dr. Thomas Copmann Pursuant to Federal Rule of Evidence 702 and *Daubert* (ECF No. 305). These motions have been fully briefed. For the reasons set forth below, Merck's Motion for Summary Judgment is granted in part and denied in part, and Merck's Motion to Exclude Evidence from Dr. Thomas Copmann is denied. An appropriate Order will follow.

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I. BACKGROUND

This Section will begin by providing a brief overview of the vaccine approval process in the United States. Then the Court will discuss Merck's mumps vaccines, mumps cases in the United States following the introduction of a vaccine, GlaxoSmithKline's ("GSK")[1] mumps vaccines, Merck's alleged unlawful conduct, and finally, GSK's path to approval of its mumps vaccine. The facts set forth in this Section are derived from the undisputed evidence of record submitted by the parties and the disputed evidence of record viewed in the light most favorable to Plaintiffs.[2]

A. The Vaccine Approval Process in the United States

Bringing a vaccine to market in the United States is an expensive, complex, and rigorous endeavor. In order to sell a vaccine in the United States, Food and Drug Administration ("FDA") approval and licensure are required. ECF No. 274 ¶ 58; ECF No. 277 ¶ 58. In deciding whether to license a vaccine, the FDA assesses the vaccine's safety, efficacy, manufacturing, and product

[1] GSK was previously known as "SmithKlineBeecham," "SKB," or "SB." *See* ECF 295 at 8 n.5.

[2] The Court notes that in response to many of the facts Plaintiffs put forth in their Corrected Statements of Disputed Material Facts concerning Merck's alleged anticompetitive conduct, Merck did not admit or dispute the facts, but rather, claimed the facts "do not bear on the issues material to Merck's Motion for Summary Judgment." *See* ECF No. 301 at 1. The Court finds Merck's position that its purported unlawful conduct is not material to the arguments contained in its Motion for Summary Judgment unconvincing. For example, Merck's first argument is that even if Merck had submitted fraudulent information to the government, this amounts to petitioning activity that is protected from antitrust liability under the *Noerr-Pennington* doctrine. However, Merck refused to admit or dispute the facts relating to those submissions to the government. Given the fact that Merck incorporated by reference its Motions for Summary Judgment in the FCA Action, many of the facts can be deemed undisputed. *See* ECF No. 273 at 9 n.1. In any event, the Court must view the evidence in the light most favorable to the nonmoving party and it will do so as to those facts Merck did not admit or dispute.

labeling. ECF No. 274 ¶ 60; ECF No. 277 ¶ 60. As to safety and efficacy, the FDA bases its analysis on three phases of clinical trials. ECF No. 274 ¶ 61; ECF No. 277 ¶ 61. However, before beginning any clinical trials, a pharmaceutical manufacturer must submit an Investigational New Drug application ("IND") to the FDA. ECF No. 274 ¶ 62; ECF No. 277 ¶ 62. An "IND describes the vaccine, the method of manufacture, [] quality control tests for release, [and also] . . . information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans." *Id.* Thereafter, three phases of clinical trials proceed as follows. In Phase I, "small groups of people receive the trial vaccine." ECF No. 274 ¶ 61; ECF No. 277 ¶ 61. "In Phase II, the clinical study is expanded and [the] vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended." *Id.* Finally, "[i]n Phase III, the vaccine is given to thousands of people and tested for efficacy and safety." *Id.* Once these three phases are completed, manufacturers submit a Biologics License Application (BLA) to the FDA for approval of the vaccine for use in the United States. ECF No. 274 ¶ 73; ECF No. 277 ¶ 73.

B. Merck's Mumps Vaccines

Merck was the first licensed mumps vaccine provider in the United States and the sole licensed mumps vaccine provider in the United States from 1967 until June 2022, when the FDA licensed GSK's mumps vaccine. ECF No. 267 ¶ 1; ECF No. 277 ¶ 1; FDA, June 3, 2022 Approval Letter – PRIORIX, https://www.fda.gov/media/158962/download (last visited July 25, 2023). Currently, Merck sells two vaccines which contain a mumps component: MMR-II and ProQuad. ECF No. 267 ¶ 2; ECF No. 277 ¶ 2. MMR-II was licensed in the United States in 1978 and is a trivalent product containing vaccines for measles, mumps, and rubella ("MMR"). ECF No. 267 ¶

1; ECF No. 277 ¶ 1. ProQuad was licensed in the United States in 2005 and is a quadrivalent product containing vaccines for measles, mumps, rubella, and varicella (chicken pox) ("MMRV"). *Id.*

C. Mumps Cases Following a Vaccine

The CDC reports that after Merck introduced the mumps vaccine in 1967, mumps cases in the United States decreased by more than 99%. ECF No. 274 ¶ 7; ECF No. 277 ¶ 7. Specifically, mumps cases decreased "from 152,209 in 1968 to 231 in 2003." CDC, Mumps Cases & Outbreaks, https://www.cdc.gov/mumps/outbreaks.html (last visited July 25, 2023). Notably, however, "mumps cases and outbreaks reported in the United States have increased since 2006" with most of these cases involving people who were vaccinated.[3] *Id.* The CDC currently reports that two doses of the mumps vaccine are 88% (range 31% to 95%) effective at preventing mumps. ECF No. 274 ¶ 6; ECF No. 277 ¶ 6. In April 2019, the director of the FDA's Center for Biologics Evaluation and Research ("CBER") issued a statement reaffirming that the FDA "work[s] diligently to assess safety and effectiveness of all licensed vaccines for their intended uses [and] [t]he MMR vaccine is very effective at protecting people against measles, mumps, and rubella." ECF No. 275-8 at 3.

[3] According to the CDC, in 2006, 6,584 cases of mumps were reported in the United States. In 2007, there were 800 reported cases of mumps. In 2008, 454 cases were reported. In 2009, 1,991 cases were reported. In 2010, 2,612 cases were reported. In 2011, 404 cases were reported. In 2012, 229 cases were reported. In 2013, 584 cases were reported. In 2014, 1,223 cases were reported. In 2015, 1,329 cases were reported. In 2016, 6,366 cases were reported. In 2017, 6,109 cases were reported. In 2018, 2,251 cases were reported. In 2019, 3,780 cases were reported. In 2020, 616 cases were reported. In 2021, 154 cases were reported. In 2022, 322 cases were reported. *See* CDC, Mumps Cases & Outbreaks, https://www.cdc.gov/mumps/outbreaks.html (last visited July 25, 2023); *see also* ECF No. 277 ¶ 7 n.3.

D. GSK's Mumps Vaccines

GSK, like Merck, manufactures two mumps-containing vaccines. First, GSK manufactures Priorix, an MMR (measles, mumps, rubella) vaccine, which was first licensed for sale in Europe in 1998 and was then licensed in the United States in 2022.[4] ECF No. 274 ¶¶ 49, 52; ECF No. 277 ¶¶ 49, 52. Second, GSK manufactures Priorix-Tetra, an MMRV (measles, mumps, rubella, varicella) vaccine, which is licensed *outside* the United States. ECF No. 274 ¶¶ 50–51; ECF No. 277 ¶¶ 50–51. The mumps strain contained in GSK's Priorix and Priorix-Tetra vaccines is derived from the mumps strain in Merck's mumps-containing vaccines. ECF No. 274 ¶ 54; ECF No. 277 ¶ 54. GSK does not view the mumps component in Priorix as different from the mumps component in Merck's MMR-II, and GSK's clinical studies show that GSK's mumps component is non-inferior to Merck's mumps component. ECF No. 274 ¶ 57; ECF No. 277 ¶ 57. In the FDA's Summary Basis for Regulatory Approval of Priorix, the Review Committee confirmed this, finding: "In clinical studies, vaccine-specific antibody responses to measles, mumps, and rubella viruses following administration of PRIORIX were shown to be non-inferior to antibody responses induced by the licensed M-M-R II vaccine." FDA, June 3, 2022 Summary Basis for Regulatory Action for PRIORIX, https://www.fda.gov/media/159545/download (last visited July 25, 2023).

E. Merck's Alleged Anticompetitive Conduct

Based on the allegations in the related FCA case, Plaintiffs contend that Merck's submissions to the FDA and, in turn, its labels for its mumps vaccines contain false and misleading information related to the efficacy and seroconversion rates of Merck's mumps vaccines and because of this conduct, Merck precluded GSK from obtaining a license to sell its MMR vaccine

[4] In June 2022, after the conclusion of briefing for the present motions, but prior to oral argument, the FDA approved GSK's Priorix vaccine. *See* FDA, June 3, 2022 Approval Letter – PRIORIX, https://www.fda.gov/media/158962/download (last visited July 25, 2023).

and caused Plaintiffs to be overcharged. *See generally* Amended Complaint, ECF No. 26. Outlined below is an overview of the specific evidence relating to Merck's competitive intelligence regarding GSK's potential entrance into the Mumps Vaccine Market and Merck's alleged false and misleading conduct as to its mumps vaccines.

1. Merck Learns of GSK's Potential Entrance

In the late 1990s, Merck recognized that MMR-II was under "imminent threat of a major competitive launch" in the United States from GSK's Priorix. ECF No. 295-1 ¶ 31; ECF No. 301 ¶ 31; *see also* ECF No. 286, Ex. 81. Internal Merck documents reveal that in the face of GSK's impending launch, in 1996, Merck established a "Competitive Defense Task Force for M-M-R II." ECF No. 295-1 ¶ 32; ECF No. 301 ¶ 32; ECF No. 286, Ex. 81. These documents indicate that the marketing elements for the MMR-II Competitive Defense Task Force were to: (1) "Pursue a proactive tactical plan including initiatives to delay and disrupt the launch of Priorix into the market"; (2) "Launch a marketing and positioning plan to maintain the [MMR-II] advantage by preserving share in priority segments and emphasizing the long-term safety and efficacy profile"; and (3) "Set the stage for a new product platform including the use of recombinant albumin and the introduction of MMRV." ECF No. 286, Ex. 81 at MRK-CHA00285279. In June 1999, the Competitive Defense Task Force for MMR-II reported that since the Task Force was created in 1996, the "team has succeeded in 'raising the bar' for the competition at every available opportunity including a successful presentation to CBER in January [and] [a]lthough, we will probably never know whether that presentation had the effect of raising issues for the Priorix file, we do know that [GSK] will most likely not launch in the U.S. until 4Q99." *Id.* at MRK-CHA00285278.

2. Merck's Mumps Vaccine Label Claim Issues

In the late 1990s, around the same time Merck learned of GSK's imminent threat of launch in the United States, Merck and CBER engaged in discussions concerning the potency figure on Merck's mumps label. ECF No. 295-1 ¶ 36; ECF No. 301 ¶ 36. At that time, the MMR-II label specified that "the dose . . . contains not less than . . . 20,000 $TCID_{50}$ of the . . . Mumps Virus" (the "Potency Claim"). *Id*. TCID stands for Tissue Culture Infectious Dose and is a measure of vaccine potency (*i.e.*, the volume of live cells in the vaccine), which vaccine manufacturers and the FDA typically convert to a $\log_{10}$ scale. *Id*. Thus, the potency on the label equated to 4.3 on a $\log_{10}$ scale. ECF No. 295-1 ¶ 37; ECF No. 301 ¶ 37. During Merck's communications with CBER, it became evident that "the agency did not agree with [Merck's] proposal that the specifications noted in [Merck's] label were the minimum release potencies for [MMR-II]. Instead, [CBER] defined these specifications as end-expiry potencies," meaning it wanted the labeled potency to be the amount of live virus in the vaccine at the end of its shelf life, which for MMR-II has always been 24 months. ECF No. 295-1 ¶ 36; ECF No. 286, Ex. 82 at MRK-CHA00207706. Accordingly, as an interim measure to comply with CBER's request, Merck "overfilled" its mumps vaccines (*i.e.*, put more live virus in each dose) in order to ensure that the vaccine would comply with the 4.3 $\log_{10}$

potency claim at the end of the 24-month shelf life. ECF No. 295-1 ¶ 41. Merck continues to overfill each mumps vaccine dose to this day. *Id.*

In 2000, after Merck implemented the "overfill," FDA inspectors visited Merck's manufacturing division and issued a Form 483,[5] which cited Merck's failures in reporting mumps vaccines lots that fell below the potency claim prior to the expiry of the 24-month shelf life. ECF No. 295-1 ¶ 42. Merck submitted a response to the Form 483, but the issues identified in the Form 483 were raised again by the FDA in a February 9, 2001, Warning Letter. ECF No. 295-1 ¶ 42; ECF No. 295-1 ¶ 42. A Warning Letter is issued to a manufacturer when the "FDA finds that a manufacturer has significantly violated FDA regulations." FDA, About Warning and Close-Out Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters (last visited July 25, 2023). The February 2001 Warning Letter indicated that "investigators reported that the data in [Merck's] files showed that a number of . . . lots manufactured before the formulation was changed during February 2000 failed to meet the minimum potency specification." ECF No. 286, Ex. 124 at MRK-CHA00209402. The Warning Letter directed Merck to "submit an analysis of Mumps stability data describing the range of potencies you would expect the various Mumps Vaccine products to reach at the two-year expiration date." *Id.* In creating this analysis, the FDA directed Merck to "assume the initial potency is the minimum release potency specification that was in effect before 2000" and "summarize the available data regarding product efficacy at the lower end of this

[5] "An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." FDA, FDA Form 483 Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last visited July 25, 2023).

potency range." *Id.* In concluding, the Warning Letter stated that "[f]ailure to promptly correct these deviations may result in regulatory action without further notice" which could include "license suspension and/or revocation." *Id.*

In developing its response to the Warning Letter, Merck internally identified it had, prior to increasing the release potency, released to market 225 lots of MMR-II that had an end-expiry potency potentially lower than 4.3 $\log_{10}$ minimum mumps potency specification, with 107 of these lots being "a compliance issue," as they were projected to, at 24 months, fall below 4.0 $\log_{10}$.[6] ECF No. 295-1 ¶ 43; ECF No. 286, Ex. 128. Merck instituted a "Fact Finding" ("a prelude to a potential product recall") to track down all 107 lots that were a potential compliance issue. ECF No. 286, Ex. 128. While drafts of Merck's Warning Letter response referenced these "sub-potent lots," Merck's final version of its response did not specifically mention these lots. ECF No. 295-1 ¶ 46; *see also* ECF No. 286, Ex. 130 (draft 2001 Warning Letter Response); ECF No. 286, Ex. 131 (draft 2001 Warning Letter Response); ECF No. 286, Ex. 132 (Merck's Mar. 8, 2001 Response to February 2001 Warning Letter). Instead, Merck responded to the FDA's Warning Letter by explaining:

> [I]f it is assumed that the initial potency is 4.3 log TCID50/dose, the minimum release potency specification in effect prior to February 2000, the expected average potency at expiry is 3.6 log TCID50/dose. In order to estimate the range of potencies around the average loss rate, the standard deviation of the loss rate was calculated and found to be 0.3 logs. Therefore, the 95% upper and lower confidence limits for mumps potency at the end of a two year expiry is estimated to be 3.9 and 3.3 log TCID50/dose, respectively.

[6] While Merck's email discussing the issue and its working drafts of its response to the February 2001 Warning Letter reference 223 lots being at risk of falling below 4.3 $\log_{10}$ and of those 223, 106 lots being at risk for falling below 4.0 $\log_{10}$, Plaintiffs point out that the spreadsheet attached to the email identifies 255 and 107 lots, respectively. *See* ECF No. 295-1 ¶ 43 n.78.

ECF No. 132 at MRK-CHA01537609. In March and April of 2001, Merck sent the FDA two Biologics Product Deviation Reports ("BPDRs"), reporting similar potency problems, but represented that the "overfill" solved the issue. ECF No. 295-1 ¶ 48; ECF No. 292, Ex. 269 (March 2001 BPDR), Ex. 270 (April 2001 BPDR). In April 2001, the FDA closed its Warning Letter without requiring any lots to be withdrawn from the market. ECF No. 302 at 15–16.

Internal correspondence in 2002 at Merck indicates, however, that Merck's "corrective actions (adding more mumps and increasing the release specification) did not ensure [Merck met] 4.3/dose at expiry as previously indicated." ECF No. 295-1 ¶ 48; ECF No. 287, Ex. 137. Instead, Merck calculated that "approx. 7% of the lots [were] expected to be <4.3 at expiry." *Id.* Merck questioned whether the FDA would have responded differently if it knew about the potency values below 4.3/dose. *Id.* Additional internal documents and correspondence from this time indicate that if Merck's potency claim were to remain at 4.3 $\log_{10}$ at expiry, the shelf life would need to be changed to 12 months or less, but that such adjustment would have a commercial impact, including "[i]nternational loss of share due to a competitive disadvantage ([GSK's proposed vaccine is] at 24 months)." ECF No. 295-1 ¶ 50; *see also e.g.,* ECF No. 287, Ex. 140.

Apart from implementing the overfill in 1999, beginning in 1997, Merck also discussed with the FDA conducting a clinical trial to support a label change of a mumps end-expiry potency lower than 4.3 $\log_{10}$. ECF No. 295-1 ¶ 57. This clinical trial would become known as Protocol 007, officially titled "A Study of M-M-R II at Mumps Expiry Potency in Healthy Children 12-18 Months of Age." ECF No. 295-1 ¶ 57. Two types of tests were used in Protocol 007: (1) a plaque reductions neutralization assay ("PRN") and (2) an enzyme linked immunosorbent assay ("ELISA"). Both of these tests are used to measure immunogenicity, which provides information about how a subject's immune system responds to different stimuli, including vaccination. ECF

No. 295-1 ¶¶ 4–6; *see also, e.g.*, ECF No. 283 at 208. The most common immunological response evaluated in vaccine studies is the development of antibodies induced by the vaccine. ECF No. 295-1 ¶ 4. One way to measure immunogenicity is "seroconversion," which refers to a person going from being "seronegative" prior to vaccination, which generally means lacking pathogen specific antibodies, to being "seropositive" after vaccination, which means possessing such antibodies. *Id.*

a) The PRN

A PRN indirectly measures antibodies based on their capacity to neutralize the virus of interest. ECF No. 295-1 ¶ 7. A PRN is considered a functional immunogenicity assay—meaning it evaluates the functioning of the antibodies, not merely their presence. ECF No. 283 at 210. In a PRN, a blood serum is incubated with the virus in a clear well (*i.e.*, a container). ECF No. 295-1 ¶ 8. If the virus is not neutralized, the virus causes "plaques" (or holes) in the cells. *Id.*; *see also* ECF No. 283 at 293–94. The theory is that if the test sample has neutralizing antibodies, they will prevent the virus from infecting the cells, meaning there would be fewer plaques. ECF No. 283 at 294. In the Protocol 007 PRN, pre-vaccinated serum samples are compared to post-vaccinated serum samples to determine if, as a result of vaccination, the child could be said to have seroconverted. ECF No. 295-1 ¶ 8. The PRN in Protocol 007 was designed to compare seroconversion rates across higher and lower potencies. ECF No. 295-1 ¶ 58. CBER set two statistical criteria that the experimental groups had to meet in order to consider the lower potency acceptable as compared to the existing potency. ECF No. 286, Ex. 95 at MRK-CHA00001468. First, the seroconversion rate in the group receiving the candidate end-expiry potency could not be more than 5% less than the seroconversion rate in the group receiving the control, and second, the

lower limit of the confidence interval of the seroconversion rate in the group receiving the candidate end-expiry potency would have to be above 90%. *Id.*

Initially, Merck engaged in initial testing using its mumps virus strain (*i.e.*, the Jeryl Lynn strain) and other "wild-type" virus strains, meaning those naturally occurring. ECF No. 295-1 ¶ 62. However, initial testing of the wild-type virus resulted in seroconversion rates well below 95%, so Merck used the Jeryl Lynn strain, which was yielding seroconversion above 90%. *Id.* Additionally, Merck included rabbit antibodies, specifically anti-human Immunoglobin G ("anti-IgG") in the serum samples. ECF No. 295-1 ¶ 65. This anti-IgG PRN was referred to as the Anti-IgG Enhanced Neutralization Test ("AIGENT"). *Id.*

After finalizing the design of the PRN, Merck performed the AIGENT in a research lab supervised by Dr. David Krah. ECF No. 295-1 ¶¶ 73–74. According to the relators in the related FCA case, Dr. Krah directed his lab staff to selectively recount pre-positive samples and change pre-positive samples to make them pre-negative, and also directed his staff to falsify data. *Id.* ¶ 74. Once the FDA was made aware of these allegations, FDA investigated and issued a Form 483, listing among other observations that "raw data [was] being changed with no justifications." *Id.* ¶ 80; *see also* ECF No. 289, Ex. 219 (August 6, 2001 Form 483).

b) The ELISA

The second test that was performed as part of Protocol 007 was an ELISA. In an ELISA, serum samples are added to a plastic microtiter wells coated with antigens—which are structures that bond to particular antibodies. ECF No. 283, Ex. 55 (Pasetti Report). If the serum contains antigen-specific antibodies, those antibodies bind to the antigens, triggering a secondary reaction that changes the color of the solution. *Id.* This color can be measured by a device called a

spectrophotometer to determine whether or not there has been sufficient color change to identify a positive result. *Id.*

c) Merck's MMR-II sBLA

Initially, to be allowed to support a supplemental Biologics License Application ("sBLA") to lower the minimum mumps potency specification on the MMR-II label with the Protocol 007 testing, Merck was instructed by the FDA to demonstrate a correlation between the results of Merck's ELISA and AIGENT tests. ECF No. 295-1 ¶ 70. Based on the data produced in the Protocol 007 study, Merck submitted an sBLA in January 2004 requesting a lower potency figure on its label. ECF No. 283, Ex. 39 (Kessler Report) ¶ 330. In 2007, CBER determined that "the information and data submitted are inadequate for final approval." *Id.* ¶ 333. CBER also noted: "[h]owever, the science related to immunogenicity of [MMR II] has substantially evolved since our initial testing requirements [and] use of ELISA data to evaluate the effect of difference in product potency is now acceptable." *Id.* ¶ 336. In response, Merck submitted an amendment providing additional information, including data from the Protocol 007 ELISA and ELISA data from previous Merck studies. In December 2007, the FDA approved Merck's sBLA to change the labeled potency from 4.3 to 4.1 $\log_{10}$ $TCID_{50}$. *Id.*

d) Merck's ProQuad BLA

In August 2004, Merck submitted its ProQuad BLA. ECF No. 283, Ex. 39 (Kessler Report) ¶ 330. To support this application, Merck used data from Protocol 007 and provided information about the correlation between the PRN and the ELISA from Protocol 007. ECF No. 288, Ex. 183 ¶ 116. In September 2005, the FDA approved Merck's ProQuad BLA. *Id.* ¶ 332.

F. GSK's Path to FDA Approval

To obtain approval of its mumps vaccine, GSK understood that it needed to conduct head-to-head clinical trials to study the immunogenicity and safety of MMR-II versus Priorix and demonstrate that Priorix was non-inferior to MMR-II. ECF No. 274 ¶¶ 63, 65; ECF No. 277 ¶¶ 63, 65. Accordingly, as GSK's corporate designee testified, the clinical development plan for Priorix was based on mirroring Merck's label. ECF No. 295-1 ¶ 131; ECF No. 301 ¶ 131. GSK understood this process would be very costly and time-consuming. ECF No. 274 ¶¶ 63, 65; ECF No. 277 ¶¶ 63, 65. For the Phase III clinical trials for Priorix, the FDA required GSK to conduct five separate studies: four non-inferiority studies and one safety study. ECF No. 274 ¶ 66; ECF No. 277 ¶ 66. As GSK explained, clinical trials involving children typically cost a minimum of $10 million and involve more burdensome documentation compared to clinical trials with only adults. ECF No. 274 ¶ 67; ECF No. 277 ¶ 67.

GSK began this process in July 1997 when it submitted an IND to the FDA to begin clinical trials for Priorix. ECF No. 274 ¶ 68; ECF No. 277 ¶ 68. However, in August 1997, the FDA put GSK's Priorix program "on clinical hold" due to concerns, including about GSK's safety data, indicating that the FDA needed additional data concerning "neurovirulence testing, the ELISA assay used to determine seronegativity and the reverse transcriptase assay testing of the viral seed and viral bulk." ECF No. 274 ¶ 69, ECF No. 277 ¶ 69; ECF No. 280-1 at 220; ECF No. 275-19 at 2. Thereafter, in March 1998, the FDA sent GSK a letter with fifty-two comments on GSK's proposed clinical development plan for Priorix. ECF No. 274 ¶ 70; ECF No. 277 ¶ 70. GSK internally summarized the FDA's comments as criticisms of its proposed United States IND study, including the proposed study's design and the types of assays to be used to test each vaccine component, and criticisms concerning other studies to be submitted in its BLA, including the

quality of data derived from GSK's clinical testing outside the United States, the safety of the mumps strain, and the sample sizes of those studies. *Id.* Following discussions between the FDA and GSK, in June 1998, the FDA lifted the clinical hold. ECF No. 274 ¶ 71; ECF No. 277 ¶ 71; ECF No. 280-1 at 227, 233.

Nonetheless, discussions between the FDA and GSK concerning the clinical development of Priorix continued with the FDA requesting information on, *inter alia*, vaccine lots, documentation of the measles virus strain development, and how GSK intended to validate assays used to test the measles, mumps, and varicella components. ECF No. 274 ¶ 72; ECF No. 277 ¶ 72. In March 1999, the FDA denied GSK's request for a "pre-BLA meeting," which typically occurs before a manufacturer submits a final BLA for vaccine approval. ECF No. 274 ¶ 73; ECF No. 277 ¶ 73. GSK believed the FDA denied their request for the pre-BLA meeting because the "FDA does not consider [the] safety database as acceptable" and "FDA needs [an] additional safety study." ECF No. 275-23 at 5. Then, in October 1999, GSK internally reported that the FDA's decision to require an additional safety study remained unchanged. ECF No. 275-13 at 11; ECF No. 274 ¶ 76; ECF No. 277 ¶ 76. GSK estimated that this safety study requested by the FDA would cost between $10 million to $20 million, and GSK wanted to "avoid" conducting such a large safety study. ECF No. 275-25 at 5–6; ECF No. 274 ¶¶ 75, 77; ECF No. 277 ¶¶ 75, 77. Comments from the FDA during this time period also indicate that the FDA required additional information on mumps serology. ECF No. 295-1 ¶ 137; ECF No. 301 ¶ 137; ECF No. 295-13 at 10–11.

Thereafter, between 2000 and 2001, GSK deprioritized development of its MMR vaccine. ECF No. 295-1 ¶ 139; ECF No. 301 ¶ 139. The reason for this de-prioritization was that Merck's MMRV vaccine, ProQuad, was expected to be on the market in 2001, and accordingly, GSK wanted to wait until the position of Merck with respect to MMRV was clear. ECF No. 274 ¶ 78;

ECF No. 277 ¶ 78. GSK planned to follow Merck's progress and if Merck's MMRV succeeded, GSK would revive its development of MMRV, but if Merck's MMRV failed, it would prioritize Priorix. ECF No. 247 ¶ 80; ECF No. 277 ¶ 80. Evidence from GSK's documents indicates that it would cease all work during the two-year period except it would address outstanding MMR and Varicella IND questions, answer FDA questions on neurovirulence, continue to work on the level of serology in order to validate its mumps and varicella assays for future U.S. trials, and conduct certain neurovirulence testing. ECF No. 275-28 at 19.

In March 2002, GSK completed a risk assessment for the development of Priorix and Priorix-Tetra in the United States, and its marketing team recommended GSK "[p]ursue MMRV" and "[r]e-address MMR only if MMRV has proven not viable from a development perspective." ECF No. 274 ¶ 81; ECF No. 277 ¶ 81; ECF No. 275-31 at 11. GSK estimated that it would cost $33.1 million to develop MMR, $34.8 million to develop MMRV, and a combined $23.2 million in additional costs across both products. ECF No. 274 ¶ 81; ECF No. 277 ¶ 81. But in 2003, GSK's United States development of Priorix was put on hold due to business reasons and GSK stated it would revisit in the end of 2004 in light of study results and competitive intelligence status. ECF No. 275-33 at 4; ECF No. 275-34 at 7; ECF No. 274 ¶ 83; ECF No. 277 ¶ 83. One of the business reasons for discontinuing development of Priorix was that Merck's MMRV vaccine was near licensure in the United States. ECF No. 274 ¶ 84; ECF No. 277 ¶ 84.

Following Merck's licensure of ProQuad in 2005, by 2006, there was a renewed interest by GSK to bring a mumps vaccine to the United States market. ECF No. 295-1 ¶ 143; ECF No. 301 ¶ 143. After ProQuad was approved in 2005, the CDC indicated it preferred the use of the quadrivalent MMRV vaccine over separate injections of MMR and varicella vaccines. ECF No. 274 ¶ 87; ECF No. 277 ¶ 87. [redacted]

[redacted]. ECF No. 274 ¶ 89; ECF No. 277 ¶ 89. Moreover, in 2009, the CDC updated its recommendation to prefer separate injections of MMR and varicella vaccines for the first dose, and MMRV, rather than separate MMR and varicella injections, for the second dose. ECF No. 274 ¶ 87; ECF No. 277 ¶ 87. Accordingly, GSK shifted its focus from Priorix-Tetra (MMRV) to Priorix (MMR), as it saw a potential opportunity for Priorix as a first dose option. ECF No. 274 ¶¶ 88–89; ECF No. 277 ¶¶ 88–89.

In 2009, Merck's ELISA became commercially available when Merck's lab was purchased by an independent research company, PPD. ECF No. 295-1 ¶ 148; ECF No. 301 ¶ 148. In April 2011, GSK decided to use Merck's ELISA and notified the FDA of this intention in December 2011. ECF No. 295-1 ¶ 149; ECF No. 301 ¶ 149. In April 2012, the FDA gave GSK permission to use Merck's ELISA. ECF No. 295-1 ¶ 150; ECF No. 301 ¶ 150. Accordingly, in 2012, GSK commenced five Phase III clinical studies for Priorix, which GSK estimated would cost between $57.1 million and $66.8 million to complete. ECF No. 274 ¶ 91; ECF No. 277 ¶ 91.

In 2014, when GSK learned of the complaint in the related FCA case, GSK internal correspondence questioned whether the allegations could enable GSK to bring its mumps vaccine to the United States market sooner. ECF No. 295-1 ¶ 152; ECF No. 301 ¶ 152; *see also* ECF No. 283 at 135 (email correspondence asking whether the allegations "could have implications on our 'non inferiority' benchmark for the US registration??"); *see also id.* at 139 (email correspondence wondering whether "anything will (or can) come of this??? Earlier introduction of Priorix and Varilrix in the US????").

Additionally, in preparing for an investor event in 2015, GSK's Chairman of Vaccines was informed internally that GSK's Phase III trials started so late because:

> [D]iscussions with CBER about the Eps [endpoints] and assays to be used in phase III . . . proved to be protracted, since we could not meet the serological acceptability criteria for mumps that CBER required for Phase III success with our mumps assay (they required "a lower bound . . . for the response rate ≥90%") . . . . [U]ltimately, having access to the Merck Mumps ELISA which they licensed to PPD facilitated these discussions.

ECF No. 295-1 ¶ 153; ECF No. 301 ¶ 153; *see also* ECF No. 283 at 56.

On January 4, 2018, GSK's corporate designee was deposed and explained various business and budgetary considerations relating to GSK's development of its mumps vaccine in the United States. ECF No. 275-46. Specifically, GSK explained that its leadership had "always grappled with this vaccine for a couple of reasons; the low sales, the impact on the portfolio is more qualitative than quantitative, and because the schedule in the US is such that you receive varicella the same time you would get MMR and we don't have a varicella[.]" ECF No. 275-46 at 137:5-13. Additionally, GSK identified five reasons why it did not yet have a mumps vaccine approved in the United States:

> 1. GSK deprioritized development of mumps-containing vaccines for business reasons, including budgetary concerns and opportunities with other products more in line with GSK's business strategy of focusing on adult vaccines;
>
> 2. GSK was concerned that Priorix sales would be low;
>
> 3. GSK did not actively pursue Priorix prior to 2009 because it believed that the market would shift from MMR to MMRV vaccines;
>
> 4. But then GSK did not pursue a MMRV vaccine either, because [redacted]; and
>
> 5. GSK believed a mumps-containing vaccine would have a qualitative, but no quantitative, impact on its overall product portfolio.

ECF No. 274 ¶ 97; ECF No. 277 ¶ 97. GSK stated that there were no other reasons that GSK was not on the market with a mumps-containing vaccine. ECF No. 274 ¶ 98; ECF No. 277 ¶ 98. GSK also testified that it was not aware of any statement on Merck's product labels for MMR-II or

ProQuad that foreclosed GSK from commercializing the mumps vaccine in the United States. ECF No. 274 ¶¶ 100–101; ECF No. 277 ¶¶ 100–101. However, GSK testified that the entire clinical development plan for Priorix was based on "mirroring" Merck's label claims. ECF No. 295-1 ¶ 131; ECF No. 301 ¶ 131.

In September 2019, a GSK executive told investors that it had completed the Phase III studies and it was "programming now the next step . . . submission of that asset to the regulators." ECF No. 295-1 ¶ 154; ECF No. 301 ¶ 154. Public approval documents from the FDA reveal that the FDA approved GSK's mumps vaccine Priorix in June 2022. FDA, June 3, 2022 Approval Letter – PRIORIX, https://www.fda.gov/media/158962/download (last visited July 25, 2023).

II. PROCEDURAL HISTORY

On June 25, 2012, Chatom Primary Care, P.C., filed a class action complaint against Merck based on the allegations of fraud alleged in the *qui tam* action, *U.S. ex rel. Krahling v. Merck & Co., Inc.*, 10-cv-4374 (E.D. Pa.). On July 9, 2012, Dr. Andrew Klein filed a class action complaint against Merck also based on the allegations in the *qui tam* action. On August 2, 2012, this Court consolidated *Chatom Primary Care, P.C. v. Merck & Co., Inc.*, No. 2:12-cv-03555 and *Dr. Andrew Klein and Merck & Co., Inc.*, No. 2:12-cv-03857. ECF No. 23. Thereafter, on September 20, 2012, Plaintiffs, Chatom Primary Care, P.C., Andrew Klein, M.D., and John I. Sutter, M.D., filed a Consolidated Amended Class Action Complaint. ECF No. 26. The Consolidated Amended Class Action Complaint set forth six claims for relief: (1) Monopolization in Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2; (2) Violation of State Consumer Protection Laws; (3) breach of contract; (4) violation of Pennsylvania's Express Warranty Law, Pa. Stat. Ann. Tit. 13, § 2313; (5) violation of Pennsylvania's Implied Warranty Law, Pa. Stat. Ann. Tit. 13, § 2314; and (6) unjust enrichment. *Id.*

On November 19, 2012, Merck filed a Motion to Dismiss Plaintiffs' Amended Complaint. ECF No. 40. On September 4, 2014, the Court granted in part and denied in part Merck's Motion to Dismiss. ECF Nos. 63, 65. The Court denied the motion to dismiss the antitrust claim, granted the motion to dismiss the state law claims, except those claims brought under the New York Deceptive Acts and Practices Act ("NYDAPA") and the New Jersey Consumer Fraud Act ("NJCFA"), and granted the motion to dismiss Count III, Count IV, Count V, and Count VI in their entireties. *United States ex rel. Krahling v. Merck & Co., Inc.*, 44 F. Supp. 3d 581, 558–59,609–610 (2014).

Years of discovery practice and accompanying motion practice followed until January 10, 2020, when Merck filed a Motion for Summary Judgment. ECF No. 272. Plaintiffs filed an Opposition on February 10, 2020 (ECF No. 279) and filed a corrected Opposition on February 20, 2020 (ECF No. 295). On March 10, 2020, Merck filed a Reply in Support of its Summary Judgment Motion (ECF No. 302), and Plaintiffs filed a Sur-Reply on March 17, 2020 (ECF No. 312).

Additionally, on March 12, 2020, Merck filed a Motion to Exclude Evidence from Dr. Thomas L. Copmann Pursuant to Federal Rule of Evidence 702 and *Daubert*. ECF No. 305. That Motion has also been fully briefed. *See* ECF Nos. 319 (Plaintiffs' Opposition); 323 (Merck's Reply); 324 (Plaintiffs' Sur-Reply).

On December 5, 2022, this case was reassigned from the Honorable C. Darnell Jones, II to the Honorable Chad F. Kenney. ECF No. 340. This Court heard oral argument on Defendant's Motion for Summary Judgment on January 24, 2023. ECF No. 342.

III. MERCK'S MOTION FOR SUMMARY JUDGMENT

A. Legal Standard

A district court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Indeed, "[s]ummary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Wright v. Owens Corning*, 679 F.3d 101, 105 (3d Cir. 2012) (quoting *Orsatti v. New Jersey State Police*, 71 F.3d 480, 482 (3d Cir. 1995)). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). There is a genuine issue of material fact if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

The party moving for summary judgment has the initial burden "of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). Once the moving party has met this burden, the non-moving party must counter with "specific facts showing that there is a *genuine issue for trial*." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotation marks and citation omitted); *see also* Fed. R. Civ. P. 56(c).

The non-movant must show more than the "mere existence of a scintilla of evidence" for elements on which the non-movant bears the burden of production. *Anderson*, 477 U.S. at 252. The non-movant opposing a motion for summary judgment may not "rely merely upon bare assertions, conclusory allegations or suspicions." *Fireman's Ins. Co. v. DuFresne*, 676 F.2d 965, 969 (3d Cir. 1982). Additionally, the non-moving party "cannot rely on unsupported allegations,

but must go beyond pleadings and provide some evidence that would show that there exists a genuine issue for trial." *Jones v. United Parcel Serv.*, 214 F.3d 402, 407 (3d Cir. 2000). Moreover, arguments made in briefs "are not evidence and cannot by themselves create a factual dispute sufficient to defeat a summary judgment motion." *Jersey Cent. Power & Light Co. v. Lacey Twp.*, 772 F.2d 1103, 1109–10 (3d Cir. 1985).

When determining the existence of a genuine issue of material fact, a court must "examine the evidence of record in the light most favorable to the party opposing summary judgment, and resolve all reasonable inferences in that party's favor." *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). The court need only decide whether "a fair-minded jury could return a verdict for the plaintiff on the evidence presented." *Anderson*, 477 U.S. at 252. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial'" and the court should grant summary judgment in favor of the moving party. *Matsushita Elec. Indus. Co.*, 475 U.S. at 587 (citation omitted).

B. Discussion

1. Antitrust Claim

Merck argues that it is entitled to summary judgment on Plaintiffs' antitrust claim for the following reasons. First, it argues that Plaintiffs' Section 2 Sherman Act claim is foreclosed by the *Noerr-Pennington* doctrine. Second, it argues that to the extent Plaintiffs base their Section 2 claim on any of Merck's public statements about its mumps-containing vaccines, those statements are not actionable. Third, it argues that Plaintiffs cannot prove causal antitrust injury. Lastly, it argues that Plaintiff Dr. John I. Sutter is not a direct purchaser and therefore lacks antitrust standing to bring a Sherman Act claim. The Court will address each argument in turn.

a) *Noerr-Pennington* Doctrine

"Under the *Noerr-Pennington* doctrine, '[t]hose who petition [the] government for redress are generally immune from antitrust liability.'" *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 359–60 (3d Cir. 2020) (quoting *Prof'l Real Estate Inv'rs., Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 56 (1993)). The doctrine applies to petitioning before "all departments of the Government," including the Executive Branch and its agencies, like the FDA. *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001) (quoting *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1979)); *see also In re Lipitor Antitrust Litig.*, 868 F.3d 231, 273 (3d Cir. 2017) ("Petitions to administrative agencies are consequently also immune from antitrust liability."). Nonetheless, this doctrine is not absolute; rather, the "scope of *Noerr-Pennington* immunity depends on the 'source, context, and nature of the competitive restraint at issue.'" *A.D. Bedell*, 263 F.3d at 251 (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 (1988)). "On the one hand, parties may be immune from liability for 'the antitrust injuries which result from the [government] petitioning itself' or 'the antitrust injuries *caused by* government action which results from the petitioning.'" *In re Lipitor Antitrust Litig.*, 868 F.3d at 264 (quoting *A.D. Bedell*, 263 F.3d at 251). "On the other hand, '[i]f the restraint directly results from private action there is no immunity.'" *Id.* (quoting *A.D. Bedell*, 263 F.3d at 251). This means that "immunity will not categorically apply to private actions somehow involving government action." *Id.* "Immunity applies to 'political activity with a commercial impact' but not 'commercial activity with a political impact.'" *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 622 F. Supp. 3d 22, 76 (E.D. Pa. 2022) (quoting *Ticor Title Ins. Co. v. FTC*, 998 F.2d 1129, 1138 (3d Cir. 1993)).

Courts have found *Noerr-Pennington* to not apply when the petitioning is a request to the government to perform "a ministerial act" or the petitioning is a "mere incident of regulation." *See, e.g.*, *In re Buspirone Pat. Litig.*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002); *Litton Sys., Inc. v. AT&T Co.*, 700 F.3d 785 (2d Cir. 1983) (holding AT&T's submission of its tariff rates to FCC for publication—that FCC did not need to review or approve prior to publication—did not warrant *Noerr-Pennington* immunity because decision to impose and maintain the interface tariff was made in the AT&T boardroom, not at the FCC). Therefore, "it is critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties." *In re Buspirone*, 185 F. Supp. 2d at 369. An example of a ministerial act is the listing of a patent with the FDA for publication in the Orange Book, which courts have repeatedly found is not petitioning activity eligible for *Noerr-Pennington* immunity as the FDA did not independently confirm that the patent listing was correct. *Id.* at 370; *see also American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) (FDA administers Orange Book listings in ministerial fashion).

Additionally, there is an exception to *Noerr-Pennington* immunity for "sham petitions." Under this exception, a "party is not entitled to immunity where the activity 'ostensibly directed toward influencing governmental action [ ] is a mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor . . . .'" *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 309 (E.D. Pa. 2011) ("*Flonase I*") (quoting *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1965)). A two-step test has been established to determine whether petitioning is a sham. *PRE*, 508 U.S. at 60–61. Courts consider government petitioning a sham if: (1) it is "objectively baseless in the sense that no reasonable [party] could

realistically expect success on the merits" and (2) it is "an attempt to interfere *directly* with the business relationships of a competitor, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id.* (internal quotation marks and citations omitted). And while the Third Circuit has expressly declined to recognize a "fraudulent misrepresentation" exception to *Noerr-Pennington* immunity, it has explained that "a material misrepresentation that affects the very core of a litigant's case" is relevant to the objectively baseless prong of the sham exception. *Cheminor Drugs, Ltd. V. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999).

In cases involving the pharmaceutical industry, application of the two-part test has often been invoked in the context of determining whether manufacturers' use of citizens petitions to the FDA are a sham and whether bringing patent litigation to invoke the 30-month stay under the Hatch-Waxman framework is a sham. *See, e.g.*, *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (applying *PRE* to a citizen petition filed with FDA and patent litigation and finding sham exception adequately pled); *AstraZeneca AB v. Mylan Labs. Inc.,* No. 00–cv–6749, 2010 WL 2079722, at *3 (S.D.N.Y. May 19, 2010) (applying *PRE* to patent infringement litigation and granting motion to dismiss as the activity was not a sham and thus immunized by *Noerr-Pennington*); *Flonase I*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (denying *Noerr-Pennington* immunity under the sham exception when defendant filed citizens petitions). While administrative petitions are "less susceptible than lawsuits to the sham exception, [they] still carry the potential for antitrust liability." *In re DDAVP*, 585 F.3d at 686; *see also Flonase I*, 795 F. Supp. 2d at 309–10 ("Although *PRE* only discussed the sham exception in the context of litigation, the test also generally applies to petitions to administrative agencies.").

Additionally, "[i]t is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *Calif. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972). "Where certain conduct is immunized from antitrust liability, a court must still 'consider evidence of the remaining challenged conduct in the aggregate to see if it is sufficient to support antitrust liability.'" *In re Suboxone*, 622 F. Supp. 3d at 77 (quoting *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 839 (7th Cir. 2011)).

Here, Merck asserts *Noerr-Pennington* immunity applies because, even if Merck submitted fraudulent information to the government, Plaintiffs' alleged injuries are caused by government action, *i.e.*, the standard the FDA required GSK to meet in designing clinical testing for its mumps vaccine. ECF No. 273 at 25. Plaintiffs argue that Merck's conduct is not petitioning activity; rather, it was a commercial decision to market its mumps vaccines with a false and misleading label and that Merck's response to FDA enforcement is a mere incident of regulation. *See* ECF No. 295 at 66–69. Merck replies by stating that it "has never argued that statements made to the public were immunized" by *Noerr-Pennington*, just that the submissions to the FDA allegedly containing false information that Plaintiffs' claim resulted in the agency holding GSK to a higher standard are immune. ECF No. 302 at 10–11.

The Court agrees that Merck's submission to the FDA could be considered petitioning activity. Additionally, the submissions at issue are not requests to the government to perform "a ministerial act" nor is the petitioning a "mere incident of regulation." As described above, the key consideration for this exception is whether the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties' acts or if the government renders a decision only after an independent review of the merits of a petition.

Considering the submissions to the FDA described in the parties' briefing—submission of Protocol 007 data, a white paper that Merck submitted to the FDA, a response to an FDA Form 483, a response to an FDA Warning Letter, and certain BPDRs—in all of these instances, the FDA is not acting in a merely ministerial or non-discretionary capacity based on the representations made by Merck. Instead, the FDA is independently reviewing the merits of each of the submissions. One does not have to look beyond the back-and-forth between the FDA and Merck to see that the FDA was actively reviewing Merck's submissions and exercising its discretion.

Turning to the sham exception, the Court must first examine whether the submissions to the FDA had an objective basis. However, "[t]he question of whether a petition is a sham is generally a question of fact for the jury" and "[a] court should only rule on the objective baselessness prong as a matter of law [w]here there is no dispute over the predicate facts of the underlying petitions." *Flonase I*, 795 F. Supp. 2d at 310 (internal quotations and citations omitted). Accordingly, the Court declines to grant summary judgment in favor of Merck on *Noerr-Pennington* grounds because genuine issues of material fact remain. Merck did not describe the petitioning at issue in its Statement of Undisputed Facts in Support of its Motion for Summary Judgment (ECF No. 274), but rather, just cited to the Plaintiffs' general allegations in the Amended Complaint. Additionally, in its response to the paragraphs in Plaintiffs' Additional Disputed Facts in Opposition to Summary Judgment that described the facts surrounding the submissions to the FDA, Merck stated: "The statements in this paragraph are not material to the issues in Merck's Motion for Summary Judgment because they do not bear on whether Plaintiffs' claims are barred by the *Noerr-Pennington* doctrine, whether Merck's conduct caused antitrust injury to Plaintiffs, or any other basis upon which Merck moved for summary judgment. Merck reserves the right to dispute the statements in this paragraph at any trial in this action." *See, e.g.*, ECF No. 301,

Response to ¶ 48. Because of this response, there remain disputes as to the predicate facts of the underlying petitions at issue.

Finally, the Court notes that even if Merck's petitioning conduct is immune under *Noerr-Pennington*, Plaintiffs allege that the anticompetitive business regime centered on Merck's false and misleading label claims, and as such, the petitioning may be relevant to showing Merck's intent.

For the foregoing reasons, this Court declines to grant summary judgment in favor of Merck on the grounds that the *Noerr-Pennington* doctrine bars Plaintiffs' antitrust claim.

b) Public Statements

In addition to arguing that its statements to the FDA are immune from antitrust liability, Merck also argues that to the extent Plaintiffs base their antitrust claim on purported misstatements to the public at large, that theory fails under the Sherman Act. Specifically, Merck asserts that even if its statements about its own MMR product to potential customers "may have been wrong, misleading, or debatable," such statements are not actionable as antitrust violations in the absence of coercion, and additionally, because a truthful disclosure would not have made a difference in the competitive process. ECF No. 273 at 42–43. In support of this argument, Merck relies on four cases that this Court finds distinguishable from the present case. ECF No. 273 at 42–43 (citing *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 133 (3d Cir. 2005); *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 524–25 (5th Cir. 1999); *Rambus v. FTC*, 522 F.3d 456, 466 (D.C. Cir. 2008); *Eisai Inc. v. Sanofi-Aventis U.S.*, No. 08-4168, 2014 WL 1343254 (E.D. Pa. Mar. 28, 2014)).

First, *Santana* held that wrong, misleading, or debatable statements by one competitor about another competitor's products are indicative of competition on the merits and therefore do

not constitute a "restraint of trade" for purposes of an antitrust violation. 401 F.3d at 132. Putting aside the fact that the Third Circuit has acknowledged that the *Santana* holding was phrased in "overly broad terms," *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010), *Santana* is distinguishable on the facts as it involved statements about a competitors' product; whereas here, Plaintiffs' claims focus on the allegedly fraudulent statements Merck made about its own product. Second, *Stearns* is also factually distinct from this case as it concerned competitors bidding on contracts to provide airline boarding bridges to municipal airports. 170 F.3d at 524. *Stearns* explained that there could be no exclusionary conduct as long as the decision on the choice of supplier remained "in the hands of the consumer," but the court also noted that "bribery and threats are not competition on the merits" and that "[s]everal cases have found violations of section 2 when the monopolist engages in what appears to be normal competitive behavior, but has manipulated representatives of the consumer to the point that the integrity of the decisional process has been violated." *Id.* at 526. Here, Plaintiffs did not have a choice of supplier, and therefore, this case does not directly support Merck's argument. Third, in *Rambus*, the court determined that the alleged deception did not harm the competitive process. 522 F.3d at 466. In contrast, as will be described *infra*, there is a dispute of material fact as to whether Merck's allegedly false and misleading label claims were a material cause of GSK's delayed market entry. Lastly, Merck points to *Eisai* for the proposition that "[w]hile it is theoretically possible that false statements about a rival to potential investors and customers can be a form of anticompetitive conduct, it would be a rare case in which such false statements in-and-of themselves would be sufficient to support an antitrust violation." 2014 WL 1343254, *37 (internal quotations and citation omitted). However, as the Court is unaware of any public statements Merck made about GSK's vaccine, the Court does not see how *Eisai* is applicable to this case.

In conclusion, there are disputes as to material fact as to whether Merck's alleged deception impaired the competitive process, and therefore, the Court declines to grant summary judgment to Merck on the aspects of Plaintiffs' antitrust claim based on Merck's statements to the public.

c) Antitrust Injury

In antitrust actions, plaintiffs are required to "establish antitrust standing, which is distinct from Article III standing." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163 (3d Cir. 2017). "To establish antitrust standing, [] plaintiff[s] must show they have suffered an antitrust injury—that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendant['s] acts unlawful.'" *Id.* (quoting *Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 233 (3d Cir. 2013)). Thus, plaintiffs must show that a defendant's antitrust violation was a "material cause" of their injuries. *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) ("*Flonase II*") (citations omitted). "An antitrust violation is a 'material cause' of an injury if it is a proximate cause of that injury." *Id.* (citations omitted).

"That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d at 165. However, "an antitrust violation can be the proximate cause of a plaintiff's injury even if there are additional independent causes of the injury." *In re Suboxone*, 622 F. Supp. 3d at 78 (citations omitted). Moreover, "[e]ven if an antitrust violation is not the material cause of an injury and the only material cause is some intervening conduct, courts have consistently found the causation requirement satisfied and the chain of causation intact where that intervening conduct was the foreseeable consequence of the original antitrust violation." *Flonase II*, 798 F. Supp. 2d at 628. Ultimately, "[w]hether conduct constitutes intervening conduct that breaks the chain of causation and whether intervening conduct

is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury." *Id.* (citation omitted).

In order to establish antitrust injury here, Plaintiffs must show that the harm they say they experienced—inflated prices for mumps vaccines—was caused by Merck's allegedly unlawful conduct. Plaintiffs allege that they have created a triable issue of fact as to whether Merck's conduct materially caused their harm because they have put forth evidence that: (1) Merck kept GSK off the market by maintaining false and misleading statements on the mumps vaccine labels; and (2) Merck kept GSK off the market by failing to disclose potency failures, staving off a massive recall. ECF No. 295 at 52–55. Merck on the other hand argues: (1) GSK's independent business decisions, not Merck's conduct, delayed GSK's development of Priorix; and (2) Plaintiffs' claims that FDA would have "lowered the bar" absent Merck's conduct is pure speculation that does not forge the necessary causal link. ECF No. 273 at 26–34.

The Court finds that there is sufficient evidence to raise a genuine issue of material fact as to whether it was Merck's conduct that was a material cause of Plaintiffs' injuries. Numerous pieces of evidence submitted with the briefings establish this dispute and the Court will point to a few herein. First, there is evidence that GSK had protracted discussions with the FDA on the serological acceptability criteria for mumps and it was only after Merck licensed their mumps ELISA (the test that Plaintiffs alleged was scientifically flawed) to PPD, and GSK was able to use Merck's ELISA, that GSK was finally able to complete its Phase III clinical trials and enter the market. *See, e.g.*, Jan. 24, 2023 Hr'g Tr. at 19:18–20:1. There is additional evidence contained in Merck's internal documents stating that they were out of compliance, but changing their label was unacceptable because it would allow GSK to enter the market. Moreover, after GSK got access to Merck's ELISA and the approval to use Merck's ELISA in 2012, GSK received approval in 2022,

which fits within the exact time frame, Plaintiffs' expert, Dr. Copmann, predicted GSK would receive approval once it received access to Merck's allegedly flawed ELISA. *See id.* at 20:18–20. Additionally, the fact that GSK's corporate designee testified as to different reasons for GSK not obtaining approval until 2022 does not, at summary judgment, break the causal connection between the alleged antitrust violation and Plaintiffs' injury, as the corporate designee also testified that GSK had to mirror Merck's allegedly false label claims. Moreover, the actions taken by the FDA and GSK in response to Merck's allegedly false label claims are foreseeable consequences of Merck's alleged misconduct.

Therefore, while a jury may well conclude that GSK's independent business reasons and the FDA decision-making process break the chain of causation, whether these reasons are the proximate cause of Plaintiffs' injury is a question of fact for the jury. Accordingly, the Court finds genuine issues of material fact remain as to the question of whether Merck caused Plaintiffs' alleged injury.

d) Antitrust Standing

To have standing to sue for damages under the antitrust laws, a private plaintiff must be a direct purchaser of the product from the defendant. 15 U.S.C. § 4; *Ill. Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977); *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 79 (3d Cir. 2011). Merck argues that Dr. Sutter does not have antitrust standing because although his practice, "John Ivan Sutter, MD, PA"—which is a distinct corporate entity and not a named plaintiff—made purchases of Merck's mumps vaccine, Dr. Sutter did not personally make those purchases. ECF No. 273 at 44. Dr. Sutter's deposition testimony and his records showing payment make it clear that it was his corporate entity, not him personally, that purchased the mumps vaccines from Merck. ECF No. 274 at 42; ECF No. 302 at 27. In response, Plaintiffs point to Merck's own sales data that does not reveal a customer named "John Ivan Sutter, MD, PA.;" rather, the sales data contained customers "John Ivan Sutter, MD" and "John Sutter," both in Clifton, New Jersey, that purchased $36,530 worth of MMRII and ProQuad between 1998 and 2007. ECF No. 277 ¶ 42. In reply, Merck argues that Plaintiffs' contention that because the sales data does not include the word "PA" to signify the corporate entity, it is referring to Dr. Sutter in his individual capacity, cannot defeat summary judgment because it is pure speculation. ECF No. 302 at 27–28 (citing, *inter alia*, *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 382 n.12 (3d Cir. 1990) ("speculation or conjecture does not create a material factual dispute sufficient to defeat entry of summary judgment")). While this Court agrees that Plaintiffs' argument that Dr. Sutter personally purchased the mumps vaccines seems speculative in the face of Dr. Sutter's own testimony and his documented evidence, the Court finds this to be an issue of fact, that it cannot resolve at summary judgment.

2. State Law Claims

Merck argues that it is entitled to summary judgment on Plaintiffs' New Jersey and New York consumer protection claims. Merck argues that Dr. Sutter's New Jersey consumer protection claim fails "because, by his own admission, the mumps vaccine is not sold to the public at large and thus is not a product covered by the statute." ECF No. 273 at 12. Additionally, Merck argues Plaintiffs failed to establish the essential element of causation for their consumer protection claims. *Id.* For the following reasons, the Court finds that Merck's mumps vaccines constitute merchandise under the NJCFA, but finds that Plaintiffs have not created a genuine issue of material fact that they would have acted any differently if Merck's label claims had said anything different.

a) "Merchandise" under the NJCFA

The NJCFA prohibits sellers of "merchandise" from engaging in any "unconscionable or abusive [commercial practice], deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression or omission of any material fact with intent that others rely upon such concealment." N.J. Stat. Ann. § 56:8-2. The NJCFA defines "merchandise" as "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." *Id.* § 56:8-1(c). New Jersey has interpreted "the public," as used in this definition of "merchandise," to refer to the "public at large." *Princeton Healthcare Sys. v. Netsmart New York, Inc.*, 29 A.3d 361, 365 (N.J. App. Div. 2011) (collecting cases). Notably, "it is the character of the transaction rather than the identity of the purchaser which determines if the Consumer Fraud Act is applicable." *J & R Ice Cream Corp. v. California Smoothie Licensing Corp.*, 31 F.3d 1259, 1273–74 (3d Cir. 1994) (citation omitted).

Accordingly, some courts have "dismissed NJCFA claims relying on services or goods that are only offered to a select group of individuals." *City of Atl. City v. Zemurray St. Capital, LLC*,

192 F. Supp. 3d 563, 568 (D.N.J. 2016) (citations omitted). On the other hand, however, "at least one judge in [the district of New Jersey] has determined that the NJCFA can encompass claims for merchandise that is 'expensive, uncommon, or only suited to the needs of a limited clientele.'" *Id.* (citing *Prescription Counter v. AmerisourceBergen Corp.*, No. 04-5802, 2007 WL 3511301, at *14 (D.N.J. Nov. 14, 2007)). Courts have summarized the distinction in this line of cases, stating that "where courts permitted claims to go forward seemingly about goods not available to the general public, those goods are generally standardized and did not require individual bargaining"; "[b]ut where claims were not permitted to proceed, those usually dealt with specific agreements and individualized negotiations." *Id.* (citing *Naporano Iron & Metal Co. v. Am. Crane Corp.*, 79 F. Supp. 2d 494, 509 (D.N.J. 1999)).

Merck argues that Plaintiffs' NJCFA claim fails because the mumps vaccines were not available "to the public at large," therefore, the mumps vaccines do not qualify as "merchandise" under the NJCFA. ECF No. 273 at 46–47. In support of this argument, Merck points to Dr. Sutter's deposition testimony stating that the mumps vaccine is not available "to the public at large," but rather, the vaccine must be purchased by licensed medical professionals. ECF No. 247 ¶ 43; ECF No. 277 ¶ 43. However, looking at the character of the transaction rather than the identity of the purchaser, the Court finds that Merck's mumps vaccines are standardized and not the result of individual bargaining. As indicated by Plaintiffs, Merck's mumps vaccines are made under standard formulas and conditions and are administered uniformly to the general public. ECF No. 295 at 80. The mumps vaccines are not customized to each patient, but rather are sold in a uniform package and administered in a uniform dose. *Id.* Additionally, Merck has not demonstrated that the transaction was subject to individualized negotiations.

Therefore, the Court finds that Merck's mumps vaccines are "merchandise" under the NJCFA and thus will deny summary judgment on this ground.

b) Causation Element of Plaintiffs' State-Law Claims

To prove their claims under the NYDAPA and the NJCFA, Plaintiffs must show causation. *See Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (explaining that the NJFCA requires a causal link between the practice and the harm); *In re Currency Conversion Fee Antitrust Litig.*, 230 F.R.D. 303, 310 (S.D.N.Y. 2004) (explaining that the NYDAPA requires a plaintiff to prove that the defendant's material deceptive act caused the injury). Under the NJCFA, "[c]ourts have generally found causation to be established for [NJCFA] purposes when a plaintiff has demonstrated a direct correlation between the unlawful practice and the loss; they have rejected proofs of causation that were speculative or attenuated." *Heyert v. Taddese*, 70 A.3d 680, 700 (N.J. App. Div. 2013); *see also Fleisher v. Fiber Composites, LLC*, No. 12-cv-1326, 2012 WL 5381381, at *10 (E.D. Pa. Nov. 2, 2012) (explaining under the NJCFA, plaintiffs must articulate a causal nexus between the defendant's conduct and plaintiffs' ascertainable loss). "Under the [NYDAPA], plaintiffs need not prove reliance, but at a minimum, the complaint must allege that the plaintiffs saw the deceptive statements prior to purchasing the defendant's product, and that the defendant's deceptive act or practice caused harm." *Fleisher*, 2012 WL 5381381, at *10 (cleaned up) (citations omitted).

Here, Plaintiffs allege in their Complaint that as "a direct and proximate result of Merck's misrepresentations and omissions, the Plaintiffs . . . were damaged" and Plaintiffs "would not have purchased or used Mumps Vaccine had they known the truth." ECF No. 26 ¶¶ 167–168. But the undisputed evidence shows that Plaintiffs would not have acted any differently if the labels said anything different. Dr. Klein does not dispute that he did not regularly review the package insert

for Merck's MMR-II vaccine, other than in the context of this case and to check the dosing schedule. ECF No. 274 ¶ 33; ECF No. 277 ¶ 33. Similarly, Dr. Sutter never investigated whether the statements in Merck's label related to efficacy, effectiveness, or seroconversion were false and misleading prior to reviewing the Complaint in the related FCA action. ECF No. 274 ¶ 44; ECF No. 277 ¶ 44. Accordingly, Plaintiffs cannot establish the causal nexus required to prove their state-law claims. *See, e.g.*, *Fleisher*, 2012 WL 5381381, at *10 (dismissing NJCFA and NYDAPA claims because "at the minimum" the plaintiff must have seen "the deceptive statements prior to purchasing the defendant's product"); *Gale v. Int'l Bus. Mach. Corp.*, 9 A.D.3d 446, 447 (N.Y. 2d Dep't 2004) ("If the plaintiff did not see any of these statements, they could not have been the cause of his injury.").

Plaintiffs argue that they had "no choice" but to buy Merck's product because there was no alternative. However, this is beside the point, as Plaintiffs must prove a causal nexus between the alleged false statement and their decision to purchase, and here, Plaintiffs never reviewed or evaluated the alleged misstatements in connection with a purchase, making proof of a causal nexus impossible.

Plaintiffs additionally argue that all that they need to show is that they did not receive the benefit of the bargain—*i.e.*, they bought a product that was ultimately worth less than the product that was promised. ECF No. 295 at 77–78. However, the cases Plaintiffs rely on in support of this argument are inapposite. *Smajlaj v. Campbell Soup Co.* found that a different element of the plaintiff's NJCFA claim, the ascertainable loss element, was satisfied if the plaintiff did not receive the benefit of the bargain. 782 F. Supp. 2d 84, 97, 99 (D.N.J. 2011). Additionally, *Rodriquez v. It's Just Lunch, Int'l* was a class certification decision which therefore has no bearing on this motion. 300 F.R.D. 125, 147 (S.D.N.Y. 2014).

Accordingly, because Plaintiffs have not shown that they would have acted any differently if the labels said anything different, Merck is entitled to judgment as a matter of law on Plaintiffs' state-law claims.

3. Conclusion

For the foregoing reasons, Merck's Motion for Summary Judgment as to the antitrust claim will be denied and Merck's Motion for Summary Judgment as to the NYDAPA and NJCFA claims will be granted.

IV. MERCK'S MOTION TO EXCLUDE EVIDENCE FROM DR. COPMANN

A. Legal Standard

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. This Rule places district courts in the role of the "gatekeeper," requiring courts to "ensure that any and all [expert] testimony . . . is not only relevant, but reliable." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)) (internal quotations omitted). Rule 702 has "a liberal policy of admissibility," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted), and accordingly, the "rejection of expert testimony is the exception and not the rule." *Dorman Prods. v. PACCER, Inc.*, 201 F. Supp. 3d 663, 689 (E.D. Pa. 2016) (quoting Fed. R. Evid. 702 Advisory Committee Note). The Third Circuit has explained that to survive a *Daubert* challenge, an expert must satisfy three "restrictions on expert testimony: qualification, reliability, and fit." *Schneider*

ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). The party offering the expert must prove each of these requirements by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999).

To qualify as an expert, Rule 702 requires the "expert witness to have 'specialized knowledge' regarding the area of testimony." *Betterbox Commc'ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 327 (3d Cir. 2002). The Third Circuit has instructed courts to interpret the qualification requirement "'liberally,' recognizing that 'a broad range of knowledge, skills, and training qualify an expert as such.'" *Thomas v. CMI Terex Corp.*, No. 07-3597, 2009 WL 3068242, *5 (D.N.J. Sept. 21, 2009) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994) ("*Paoli II*")). "[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." *Pineda*, 520 F.3d at 244 (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)).

The reliability requirement of *Daubert* "means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Paoli II*, 35 F.3d at 742 (citation omitted). "The reliability requirement is not to be applied 'too strictly' and is satisfied as long as the expert has 'good grounds' for his or her opinion." *Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 228 (E.D. Pa. 2017) (quoting *Holbrook*, 80 F.3d at 784). "[I]n making reliability determinations, courts must err on the side of admission rather than exclusion." *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 857 (3d Cir. 1990) ("*Paoli I*").

Lastly, Rule 702 requires the expert testimony fit the issues in the case. "Testimony 'fits' a case when it is 'relevant for the purposes of the case and . . . assist[s] the trier of fact.'" *In re*

Flonase Antitrust Litig., 884 F. Supp. 2d 184, 190 (E.D. Pa. 2012) ("*Flonase III*") (quoting *Schneider*, 320 F.3d at 404). Finally, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citing *Rock v. Arkansas*, 483 U.S. 44, 61 (1987)).

B. Discussion

Plaintiffs proffer Dr. Thomas L. Copmann ("Dr. Copmann") to provide an expert opinion on the possible effects of Merck's conduct on GSK's ability to obtain regulatory approval of its own mumps vaccine, Priorix, and to opine on when Priorix would have obtained regulatory approval in the United States if not for Merck's actions. ECF No. 309 at 8. Merck's Motion to Exclude Evidence from Dr. Thomas L. Copmann Pursuant to Federal Rule of Evidence 702 and *Daubert* argues that: (a) Dr. Copmann's opinion about how the FDA would have reacted to different disclosures by Merck is not admissible; (b) Dr. Copmann's opinions about how GSK would have reacted to different disclosures by Merck are not admissible; and (c) Dr. Copmann's estimate that it would take 8 to 10 years for GSK to secure FDA approval for a vaccine is baseless and unreliable. ECF No. 306.

1. Dr. Copmann's Qualifications

Dr. Copmann is qualified to offer expert testimony in this case. Dr. Copmann holds a bachelor's degree in biochemistry, a master's in endocrinology, and a doctorate in physiology. Additionally, Dr. Copmann has thirty years of experience helping to bring pharmaceutical products to market and in such role, he has worked closely with the FDA and CBER in handling NDAs, BLAs, and INDs for dozens of drugs and biological products, many of which involved non-inferiority analyses and ELISA testing. Dr. Copmann has authored dozens of comments to the

FDA and CBER and has met with the agencies hundreds of times. Additionally, Dr. Copmann has written various articles and comments about the development and regulation of biological products. Moreover, Dr. Copmann was nominated by a senior FDA official, Dr. Carolyn Hardegree, to serve on the CDC's Advisory Committee on Immunization Practices ("ACIP") as the liaison representative for the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which demonstrates the high regard FDA officials hold Dr. Copmann's experience and judgment.

Contrary to Merck's assertion, the fact that Dr. Copmann has not worked for the FDA does not disqualify him. Experience at the FDA is not required to opine about FDA regulations. *See Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 658–59 (E.D. Pa. 2012) (finding two experts that did not work at the FDA qualified to testify about FDA regulations); *AstraZeneca LP v. Breath Ltd.*, 88 F. Supp. 3d 326, 385 n.54 (D.N.J. 2015) (permitting testimony of "regulatory lawyer who [] practiced before the FDA for over 35 years, possess[ed] knowledge that [could] assist the Court in understanding the manner in which the FDA issues rules and regulations"). Moreover, the fact that Dr. Copmann has never previously served as an expert, does not undermine Dr. Copmann's qualifications. *See United States v. Lee*, 339 Fed. App'x 153, 159 (3d Cir. 2009) (noting that the fact that it was an individual's "first time testimony as an expert does not undermine [his] qualifications").

Accordingly, the Court finds that Dr. Copmann possesses specialized knowledge greater than the average layman and he is therefore qualified to testify under the Third Circuit's liberal requirements for expert testimony.

2. Reliability and Fit of Dr. Copmann's Opinions

Merck first objects to Dr. Copmann's opinion that if Merck had revised its label, "[t]his would have *likely resulted in the FDA taking a more flexible approach* in reaching an agreement with GSK on an appropriate serological assay to demonstrate how well Priorix protected children from disease," and would have allowed GSK to demonstrate non-inferiority using tests it had already developed and studies it had already conducted, resulting in GSK launching Priorix sooner. ECF No. 306 at 11 (citing Dr. Copmann Report at ¶ 19). Merck argues that this opinion is unreliable and untestable *ipse dixit* and that it is unhelpful because Dr. Copmann cannot, and does not, explain how likely the FDA would have been to take the actions he posits. *Id.* at 12.

The Court finds this opinion is reliable as it is well-grounded in Dr. Copmann's experience and the record. *See, e.g.*, *Center City Periodontist, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 202 (finding the "totality" of expert's knowledge and experience provides a reliable basis for opining on the FDA's regulatory and administrative requirements but excluding the opinion because it did not fit the facts of the case). Dr. Copmann considered over 600 documents produced in this matter; analyzed dozens of studies and publications; and reviewed or attended multiple depositions. Considering the intricacies of this case, his opinion on the process by which the FDA would review GSK's application would be helpful to the trier of fact.

Merck points to case law for the proposition that even a qualified expert cannot testify to state of mind or beliefs. ECF No. 306 at 13 (citing *Wolfe*, 881 F. Supp. at 660–62 (recognizing expert could not opine regarding the FDA's state of mind); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011) (noting "the opinions of [expert] witnesses on the intent, motives, or states of minds of corporations, regulatory agencies, and others have no basis in any relevant body of knowledge or expertise" (citation omitted))). However, the Court finds that Dr. Copmann is not opining on the FDA's state of mind; rather his opinion is how the FDA would

have likely responded under the operative statutes and regulations to disclosures Merck allegedly should have made, but did not. *See Flonase III*, 907 F. Supp. 2d at 644 (finding reliable expert report about how the FDA would have responded to certain submissions). Accordingly, the Court finds that Dr. Copmann's opinion regarding the FDA likely taking a more flexible approach is admissible as it is reliable and will assist the trier of fact.

The second opinion that Merck objects to is Dr. Copmann's opinion that if Merck revised its label and the FDA had relaxed its standards for vaccine approval, GSK would have launched its competing Priorix vaccine more quickly. ECF No. 306 at 15. Again, Merck argues that this opinion about what GSK would have done is untestable and unreliable *ipse dixit* that conflicts with uncontroverted testimony that Merck's labels had no effect on GSK's development of Priorix and that the opinion is unhelpful because Dr. Copmann cannot, and does not, explain how likely GSK would have been to launch Priorix any earlier. *Id.* at 15–16.

The Court finds this opinion reliable and that it fits the facts of the case. As discussed *supra* in the discussion of antitrust injury, the Court has found there is a dispute of material fact as to whether the labels played a role in the delay of Priorix coming to the market. While GSK's corporate designee did answer "no" when asked if Merck's labels stopped GSK from commercializing its mumps vaccine, her testimony also indicated that GSK based its development on what was publicly available on Merck's label. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012) (affirming denial of defendant's *Daubert* motion as "amount[ing] to nothing more than a complaint that [plaintiffs' expert] did not adopt [defendant's] view of the case"). Accordingly, the Court finds this opinion admissible as it is reliable and fits the facts of the case.

The last opinion that Merck objects to is Dr. Copmann's opinion that it would have taken GSK 8 to 10 years to obtain regulatory approval for Priorix once it reached agreement on an appropriate endpoint for a clinical study because Merck argues the opinion is baseless and unreliable. ECF No. 306 at 19. Merck takes issue with the fact that Dr. Copmann only reviewed four Merck vaccines and four GSK vaccines for this opinion and argues that such a review does not amount to a reliable basis to make his conclusion. Additionally, Merck takes issue with the fact that Dr. Copmann does not look at the specifics of those vaccines to assess if they are relevant comparators and his opinion does not take into account the fact that only a small percentage of vaccine products are actually approved by the FDA. Finally, Merck argues that one third of the vaccines he examined took 12.75 years or longer for approval and therefore his analysis is unreliable as it contains no explanation as to why GSK would have fallen within the low end of the range.

The Court finds this opinion reliable as estimating a competitor's entry date in the but-for world is a routine and necessary aspect of antitrust cases. *See, e.g.*, *Apotex*, 321 F.R.D. 220 (permitting expert to opine that if not for a patent settlement, at least one of the first-filer generics would have prevailed at summary judgment and entered the market in 2006); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144 (D. Mass. Jan. 25, 2018) (permitting expert testimony regarding but-for entry dates in antitrust matter where opinion was based on "industry surveys and [the parties] own representations"). Additionally, according to Plaintiffs, Dr. Copmann, looked at every clinical development start date and end date he could find for each prophylactic vaccine licensed in the United States to generate comparator vaccines and calculate his average development timeline. *See* ECF No. 319 at 29. Moreover, Dr. Copmann's eight-to-ten-year estimate is reliable because it accords with GSK's own estimate.

GSK began its Phase III studies for Priorix in the United States in 2012 and launched in 2022. Because there is a rational factual basis underlying Dr. Copmann's estimate that it would take 8 to 10 years for Priorix to come to the market, the Court finds his opinion admissible. Additionally, the Court finds it would be helpful to the trier of fact.

In sum, considering the fact that the Federal Rules of Evidence illustrate a preference for admitting evidence that might assist the trier of fact and this policy extends to the admissibility of expert testimony, the Court finds Dr. Copmann's opinions admissible at this time. Cross examination will be an appropriate means of challenging this expert testimony. The Court will therefore deny Merck's Motion to Exclude Evidence from Dr. Thomas L. Copmann (ECF No. 305).

V. CONCLUSION

For the reasons set forth above, Merck's Motion for Summary Judgment (ECF No. 272) is granted in part and denied in part and Merck's Motion to Exclude Evidence from Dr. Thomas L. Copmann (ECF No. 305) is denied. An appropriate Order will follow.

BY THE COURT:

/s/ Chad F. Kenney

CHAD F. KENNEY, JUDGE