23-2553

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA EX REL.,
STEPHEN A. KRAHLING; JOAN A. WLOCHOWSKI,

against

MERCK & CO, INC.,

STEPHEN A. KRAHLING; JOAN A. WLOCHOWSKI,

Appellants.

On Appeal from the United States District Court
for the Eastern of District of Pennsylvania,
The Honorable Chad F. Kenney, Case No. 2:10-04374-CFK

BRIEF FOR APPELLANTS AND VOLUME I OF JOINT APPENDIX Pages Appx1 to Appx 43 (Filed Under Seal)

Gordon Schnell, Esq.
CONSTANTINE CANNON LLP
355 Madison Avenue, 9th Floor
New York, New York 10017
212-350-2700

Jeffrey F. Keller, Esq.
KELLER GROVER, LLP
1965 Market Street
San Francisco, California 94103
415-543-1305

Attorneys for Relators-Appellants

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INTRODUCTION

This False Claims Act case centers around Merck's cascade of misrepresentations and omissions to the CDC surrounding Merck's sales of its MMR-II and ProQuad mumps vaccines. It started with Merck's discovery in the mid-1990's of mumps potency failures in MMR-II; which led to Merck's Protocol 007 clinical trial to demonstrate MMR-II still provided sufficient mumps protection at the lower potencies; which led to Merck's fraudulent Protocol 007 testing because Merck could not demonstrate this protection; which led to Merck's fraud in securing MMR-II and ProQuad vaccine licenses; all of which resulted in Merck's sales to the CDC of vaccines violating numerous prerequisites and material conditions to CDC purchase relating to mumps vaccine potency, protection, shelf life, licensing, and labeling. Indeed, Merck's misconduct goes to the very essence of the CDC's vaccine purchases and Merck's absolute duty to disclose any problems with its vaccines.

The False Claims Act is designed to protect the Government from this precise kind of fraud. But the District Court granted summary judgment for Merck, finding the plaintiffs here (Relators), who brought this case on behalf of the Government, "failed to establish" that Merck's misconduct was material to the Government's payment decision. The District Court made multiple errors in reaching this decision. It improperly flipped the summary judgment burden to

Relators. It gave no weight to the evidence supporting materiality. It gave no weight to the evidence that the Government lacked actual knowledge of Merck's violations. And it gave no weight to what the Government has done since Relators filed this lawsuit. Instead, the District Court gave dispositive weight to what the Government has *not* done, without considering any surrounding circumstances, including the crucial need to vaccinate millions of children each year against mumps, measles, and rubella, for which until late last year, Merck's vaccines were the only option.

The District Court violated the well-established summary judgment standards under which Merck has the burden to establish it is entitled to summary judgment, not the other way around; the evidence must be viewed in a light and with all reasonable inferences favoring Relators, not Merck; and the District Court may not weigh conflicting evidence, let alone ignore altogether the evidence favoring Relators. The District Court's errors were even more manifest in light of the materiality analysis required by *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016). As this Court recently held in *United States ex rel. Druding v. Care Alternatives*, 81 F.4th 361 (3d Cir. 2023), that analysis requires a "holistic, totality-of-the-circumstances inquiry" where no one factor is dispositive. *Id.* at 367 (cleaned up). The District Court did the opposite. So did

the lower court in *Druding*, which this Court flatly rejected and reversed. This Court should reach the same result here.

JURISDICTION

The District Court had subject matter jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). This Court has jurisdiction under 28 U.S.C. § 1291. This appeal is from a final judgment, entered on July 27, 2023, granting summary judgment to Merck and disposing of Relators' claims. Appx42-43. Relators timely filed their notice of appeal on August 24, 2023. Appx1.

ISSUES PRESENTED[1]

1. On summary judgment, it is the moving party's burden to show no genuine dispute as to any material fact and that it is entitled to judgment as a matter of law. *Druding*, 81 F.4th at 369. Did the District Court err in flipping this burden to Relators and "granting summary judgment for Merck on the basis that Relators have failed to establish materiality"? Appx25 n.4.

2. In *Druding*, the Third Circuit reversed the lower court's grant of summary judgment to the defendant, finding the court "overlook[ed] the factors that could have weighed in favor of materiality." 81 F.4th at 365. Did the District Court here err in doing the same thing?

[1] These issues were briefed (Dkts. 290, 292, 294, 299, 300, 309-310, 314, 319, 323-324, 328, 340, 343, 347), argued (Appx118-179 (SJ Transcript)), and ruled upon (Appx22-41 (Opinion)).

3. In *Druding*, the Third Circuit reversed the lower court's grant of summary judgment to the defendant, finding "an open dispute over the government's actual knowledge" of the defendant's violations. *Id.* (cleaned up). Did the District Court here err in ignoring the open dispute over the Government's actual knowledge of Merck's violations, including the Government's explicit denial of actual knowledge?

4. In *Druding*, the Third Circuit reversed the lower court's grant of summary judgment to the defendant, finding the court "assigned dispositive weight to a single *Escobar* factor, government action." *Id.* Did the District Court here err in doing the same thing?

RELATED CASES AND PROCEEDINGS

On October 10, 2023, the District Court granted Merck's motion for certification of interlocutory appeal of the District Court's denial of Merck's summary judgment motion in *Chatom Primary Care, P.C. v. Merck & Co., Inc.*, No. 2:12-cv-3555-CFK (E.D. Pa. filed June 25, 2012). The Third Circuit has not yet ruled whether it will accept the interlocutory appeal. That case and this one share some overlapping facts but the issues presented on this appeal are unique to this action. Relators are not aware of any other related case.

STATEMENT OF THE CASE

I. THE FALSE CLAIMS ACT

Congress enacted the False Claims Act in 1863 to combat widespread fraud during the Civil War. The statute is applied "expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (cleaned up). It authorizes and is designed to encourage whistleblowers (called relators) to bring actions on the Government's behalf, providing them a portion of any Government recovery, an award that *increases* when the Government does not intervene. 31 U.S.C. § 3730(d). *See State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 39, 34 (2016) (1986 reforms designed to "encourage more private enforcement" because lack of Government resources was "perhaps the most serious problem plaguing effective enforcement") (cleaned up); *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010) ("Congress passed the 1986 amendments … to strengthen the Government's hand … [and] encourage more private enforcement suits.") (cleaned up).

The statute imposes liability on "any person who … knowingly presents … a false or fraudulent claim for payment" to the Government or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or

fraudulent claim." 31 U.S.C. § 3729(a)(l). While "[a] false claim may take many forms," they all typically involve "a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011), *abrogated on other grounds by Escobar*, 579 U.S. 176 (quoting S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274). Central to this appeal is the statute's requirement that the violation be material to the Government's payment decision, meaning "having a natural tendency to influence, or be capable of influencing" that decision. *Escobar*, 579 U.S. at 192-93 (cleaned up).

II. REGULATORY BACKGROUND

The CDC's public health mission is to decrease vaccine-preventable infectious diseases. Appx1947, 1952 (CDC Letters). In furtherance of that mission, the CDC is responsible for purchasing vaccines on behalf of the Government and local health authorities for administration in vaccination programs around the country. It is also responsible for monitoring disease outbreaks. Appx302 (Rels. SUMF). The CDC's Advisory Committee on Immunization Practices ("ACIP") provides recommendations that guide the CDC in its vaccine purchase decisions. *Id*. The FDA is responsible for licensing vaccines. Appx300 (Rels. SUMF). It only licenses vaccines supported by clinical trials demonstrating

effectiveness and potency. Appx300-301 (Rels. SUMF). The FDA is not involved in the CDC's vaccine purchase decisions; it recuses itself "[t]o protect and preserve [its] scientific independence and judgment." Appx1959 (FDA Document).

Vaccine manufacturers have multiple duties to the Government. These include ensuring their vaccines are safe and effective; providing accurate and complete information to support vaccine licensure; ensuring their vaccines comply with the specifications on the label; and disclosing any problems relating to vaccine safety, effectiveness, or potency. Appx302-304 (Rels. SUMF). With respect to the duty to disclose, the Third Circuit has stressed this "responsibility is continuous, and [Merck] must therefore apprise the CDC of any risks it later discovers or, in the exercise of reasonable care, should have discovered." *Mazur v. Merck & Co.*, 964 F.2d 1348, 1366 (3d Cir. 1992).[2]

In 1967, Merck obtained the first license to sell a mumps vaccine in the United States. Appx305 (Rels. SUMF). MMR-II is Merck's combination measles, mumps, and rubella (MMR) vaccine, which Merck has been selling in various forms since 1978. *Id*. ProQuad is Merck's combination measles, mumps, rubella,

[2] Merck's duty of disclosure encompasses all the information the CDC needs to carry out its corollary duty to warn the public about the benefits and risks of vaccination. Merck specifically negotiated with the CDC for this *quid pro quo* delegation to protect against personal injury claims for failing to warn the public about the safety and effectiveness of its vaccines. *See Mazur v. Merck & Co.*, 767 F. Supp. 697, 701-03 (E.D. Pa. 1991) (describing Merck's delegation to CDC of its duty to warn public of benefits and risks of vaccination).

and varicella vaccine, which Merck has been selling since 2005. *Id*. The CDC purchases millions of doses of Merck's mumps vaccines each year, largely through the agency's Vaccines for Children Program. Appx302, 390 (Rels. SUMF). For more than fifty years, Merck was the only supplier of MMR vaccines in the United States, until late 2022 after GSK obtained a license to sell its Priorix MMR vaccine. Appx305, 390 (Rels. SUMF); Appx20 (Opinion). The CDC immediately began purchasing Priorix from GSK. Appx20 (Opinion).

III. FACTUAL BACKGROUND

A. Merck's MMR-II Mumps Potency Failures

Starting in the mid-1990's, Merck discovered mumps potency problems with MMR-II. Appx312 (Rels. SUMF). Merck was unable to maintain the minimum required mumps potency for the full 24-month shelf life specified on the product label. Appx310-311 (Rels. SUMF). Merck attempted to resolve this issue by significantly increasing the amount of mumps virus in each MMR-II dose, doubling the vaccine's manufactured mumps potency. Appx313 (Rels. SUMF). It did not fix the problem. According to Merck's calculations, even with this mumps overfill, Merck could only assure MMR-II would meet the minimum mumps potency specification on the vaccine label for roughly 12 months or less. Appx316-317 (Rels. SUMF).

Merck acknowledged at the highest levels of the company that MMR-II was "misbranded" and "out of compliance," and required "immediate corrective action" to avoid a product recall. Appx317-318 (Rels. SUMF). The record is full of this evidence from Merck's own documents, in Merck's own words:

- "**Critical Milestones** … label is out of compliance. **Timing of Critical Milestones** … **OVERDUE!**"). [Appx4052 (emphasis in original).]

- "**Mis[]branded – stability continues to be an issue, even with the increase in mumps** …." [Appx4025 (emphasis in original).]

- "[O]ur most recent stability analysis for mumps does not support the current label claim …." [Appx3877.]

- "8% of current product is expected to fail [minimum potency specification]." [Appx3912.]

- "[W]e are out of compliance." [Appx4033.]

- "**[M]aximum [] shelf life of 12 months.**" [Appx3930 (emphasis in original).]

- "[W]e do not have adequate (95%) confidence that the current manufacturing process supports the … label claim. As such, an immediate corrective action must be taken." [Appx3918.]

- Label claim "is wrong as we cannot guarantee this potency in our product." [Appx3903.]

- "[T]here continues to be an unacceptable risk of current product failure. This has serious implications for these vaccines, potentially culminating in a recall …." [Appx4082.]

- "[I]ssue of short s[h]elf life was of significant concern to marketing … - we may not have any other immediate solution to keep product on the market …." [Appx4118.]

- "[W]e wanted to salv[a]ge the product … alternative was a product recall." [Appx4062.]

Relators' expert Dr. David Kessler is a former FDA Commissioner and until last year, the Chief Science Officer of the White House COVID-19 Response Team. He characterized the MMR-II potency problem as "one of the most important public health conundrums," and "emphasize[d] in the strongest possible terms … [the] significant public health import" it raised. Appx1514, 1541 (Deposition). He opined that "[f]rom May 1998-December 2007, MMR II was adulterated because Merck was unable to assure the potency specification for mumps … for the shelf life of the vaccine." Appx1085 (Report). He also testified to his deep concerns that Merck's mumps potency problems have continued:

> I would be very happy to be reassured … that this problem was corrected. … Because [from] everything I see, that's not the case, and that's why I am very concerned here. … [Y]ou're dealing with one of the staples … of the American healthcare system, the MMR II vaccine. … No one wants to have to recall MMR II. Everybody wants a good product that works. Please fix this issue …. [Appx1537-1538 (Deposition).]

B. Merck's Fraud in Protocol 007

Merck nonetheless continued to sell MMR-II to the CDC without disclosing these critical potency, shelf-life, and label-compliance problems, or the risk of a product recall. Appx374 (Rels. SUMF). To bring the vaccine back into

compliance and protect Merck's MMR vaccine monopoly from the competitive threat GSK posed with its competing Priorix vaccine, Merck needed to lower its minimum mumps potency specification. Appx318-320 (Rels. SUMF). To make this product label change, Merck needed to provide the FDA data from a new clinical trial called Protocol 007 -- comprising an AIGENT and ELISA test -- demonstrating that the vaccine was as protective at the lower mumps potencies. Appx321, 325 (Rels. SUMF).

Merck was unable to demonstrate that protection through standard testing. Merck resorted to fraud instead. Relators worked on the AIGENT testing as virologists at Merck and witnessed this fraud firsthand. Appx337-340 (Rels. SUMF). It included manipulating how Merck designed and conducted the testing to ensure it reached the desired outcome. Appx328 (Rels. SUMF). In the words of the Merck supervisor in charge of the AIGENT testing: "[M]y goal and my understanding … was to have an assay that would allow us to have the capability of measuring 95 percent seroconversion … without considering the impact on accuracy." Appx5063 (Krah Deposition). *See also* Appx5606 (Krahling Deposition) (Merck selected "a methodology that they knew could give them 95 percent efficacy which is what they needed").

When Merck still could not demonstrate the necessary level of mumps protection, Merck resorted to altering or destroying unfavorable data. Appx337-

342 (Rels. SUMF) (citing evidence of data falsification, "overwhelming statistical evidence of bias," destruction of data, and active concealment of wrongdoing). When the FDA investigated some of this misconduct, Merck lied to the FDA and took other steps to cover up the fraud. Appx340-342 (Rels. SUMF). Merck's ELISA test was equally problematic because its reliability as a measure of protection against mumps -- as required by the FDA -- was entirely dependent on its correlation to the AIGENT. Appx326 (Rels. SUMF). As Merck's Director of Clinical Vaccine Research conceded: "[Y]ou cannot confirm that something is accurate with a lot of precision with something that in itself is imprecise." Appx4681 (Schodel Deposition).

The end result was a clinical trial that had no clinical relevance and failed to provide an accurate or reliable measure of how well low-potency MMR-II protected against mumps. Merck's key witnesses and experts admitted this:

- Merck's supervisor of the AIGENT testing admitted the test he developed and ran was not "designed to indicate whether [patients] were protected or not," and that he had no opinion on whether the test was even "accurate or not." [Appx5070 (Krah Deposition).]

- Merck's statistician who performed the AIGENT-ELISA correlation study and authored the AIGENT Validation Report admitted the AIGENT results did not "reflect protection," "[w]e don't really know what a clinically protective level is in either [test]," and "there is no clinical history/expectation/meaning that can be attached" to the AIGENT results. [Appx5819 (Antonello Deposition), 5322, 9269 (Merck Documents).]

- Merck's Director of Clinical Vaccine Research admitted Protocol 007 "does not give you a certainty that you're protected or not," the AIGENT was a "very unreliable assay," and he "could not overemphasize the weakness of the [test] (50% specificity!!!!!!)." [Appx4621, 4673 (Schodel Deposition), 5318 (Merck Document).]

- Merck's Director of Worldwide Regulatory Affairs reported speaking with the responsible statistician who "re-emphasized that the precision with the [AIGENT] was very poor …." [Appx5318 (Merck Document).]

- Merck's Director of Clinical Research and 30(b)(6) witness admitted she "really can't answer" whether the Protocol 007 results "have any relationship to protection from disease," or whether the AIGENT "results in any way inform Merck's understanding of how well its vaccine protects recipients from mumps." [Appx5360, 5367-5368 (Kuter Deposition).]

- One of Merck's experts testified the AIGENT "doesn't measure protection," and there was "no way" for the test to "distinguish between seroconversion results that were protective against mumps and those that were not." [Appx2707, 2710 (Durbin Deposition).]

- Another Merck expert testified Protocol 007 "did not measure protection," and "did not include a proper analysis of vaccine efficacy," meaning "protection or effectiveness." [Appx2667, 2669-2670 (Pasetti Deposition).]

- Still another Merck expert testified Protocol 007 "would not have really anything to do with effectiveness." [Appx7228 (Atkinson Deposition).]

Relators' experts agreed. *See, e.g.*, Appx1090 (Kessler Report) ("Neither the AIGENT nor [] ELISA measured protection against disease …."); Appx1575 (Kessler Deposition) ("[T]here was no clinical relevance whatsoever."); Appx2067 (Calcott Report) ("[T]he data [Merck] generated by [the Protocol 007] methods and

the correlation lacked technical validity. As such the data and conclusions are meaningless.").

C. Merck's Fraud in Securing Its MMR-II and ProQuad Licenses

The record thus powerfully demonstrates that Protocol 007 -- both the AIGENT and ELISA tests -- failed to measure protection against mumps. Nevertheless, Merck repeatedly represented that Protocol 007 measured how well low-potency MMR-II protected against mumps. That is what Merck told the parents of the children participating in the testing to secure their consent, the clinical investigators administering the vaccines to the children, and the public health community more broadly.[3] It also is what Merck told the DOJ when it investigated Relators' original Complaint:

> Protocol 007 was designed to determine whether Merck's MMR vaccine would remain effective against mumps if the potency (i.e. concentration) of the mumps component of the vaccine was reduced.

Appx4450. *See also id*. (Protocol 007 was to determine if low-potency vaccine was "comparably protective"); Appx4451 (Protocol 007 "measured the effectiveness of the vaccine at the potencies being studied.").

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[3] *See, e.g.*, Appx6502-6503 (Patient Consent Forms representing Protocol 007 results would determine "whether your child is protected from … mumps"); Appx4783 (Merck Presentation to Clinical Investigators: "positive mumps neutralization titer almost certainly ensures protection"); Appx6532 (Merck presentation at meeting of Infectious Disease Society of America representing AIGENT test "was used as a surrogate of vaccine efficacy").

Merck similarly misrepresented the test results to the FDA to support its application to lower MMR-II's minimum mumps potency specification on the vaccine label so it could get back into compliance and avoid a product recall. Throughout the application process, Merck falsely represented that -- contrary to what Merck knew to be true -- Protocol 007 demonstrated low-potency MMR-II still afforded sufficient protection against mumps. *See, e.g.,* Appx6480 (MMR-II Application) (claiming Protocol 007 data "indicate with a high level of assurance that decreasing the mumps [potency] … will ensure that M-M-R^{TM}II remains a highly effective vaccine."); Appx4350 (Clinical Study Report) (claiming Protocol 007 results "support the effectiveness" of low-potency MMR-II); Appx5171 (Merck Document) (characterizing AIGENT "as a surrogate marker for vaccine efficacy").

Merck likewise falsely pointed to the ELISA-AIGENT correlation as evidence of the "clinical relevance" of the ELISA test. Appx5181. This was in response to FDA requests for assurances that the ELISA test was "supported by data demonstrating some relevance with protective levels of antibody (e.g., neutralizing antibody)." Appx4474, 4478, 4481. Based on Merck's false assurances, "the FDA found … the vaccine would be adequately protective against mumps even if Merck were to reduce the potency of the mumps component." Appx4452 (Merck Document). Consequently, in December 2007, the FDA

approved Merck's application to lower the MMR-II mumps potency specification on the label.[4] Appx6644 (FDA Document).

D. Merck's Fraud in Its MMR-II and ProQuad Labeling

As a result of Merck's MMR-II potency problems and Merck's fraud in securing its MMR-II and ProQuad licenses, Merck's vaccine labels have misrepresented the mumps vaccines Merck has been selling since 2000. For MMR-II through December 2007, as Merck conceded internally, the vaccine was "misbranded" and "out of compliance" because it did not meet or lacked adequate assurances of meeting the label's potency and shelf-life specifications. *See supra* 8-10. And for MMR-II and ProQuad through the present, the labels have misrepresented the mumps protection the vaccines provide and their basis for licensure. They rely on outdated studies and statements of protection in no way linked to or supported by the AIGENT and ELISA tests Merck used to obtain its current licenses. Appx366-369 (Rels. SUMF).

[4] The FDA approved Merck's license application for ProQuad in September 2005 based on the same false assurances of "clinical relevance" and that the ELISA-AIGENT correlation "support[s] the use of the results of a[n] … ELISA as a correlate of protection." Appx6805-6829 (FDA Documents), 6675 (ProQuad Application), 5307-5308 (FDA Document).

E. MMR-II and ProQuad Have Not Provided Sufficient Protection to Prevent a Mumps Resurgence

Following Merck's introduction of its first mumps vaccine in 1967, there was a 99% reduction in mumps cases in the United States. Appx5 (Opinion). But starting in 2006, there has been a resurgence of mumps among individuals fully vaccinated with Merck's mumps vaccines. Appx370-371 (Rels. SUMF). And while the CDC has reported an 88% median 2-dose vaccine effectiveness rate from various mumps outbreak studies, the CDC has recognized the "limited" nature of these studies and how "[m]ore studies are needed to assess vaccine effectiveness over time." *CDC Manual for the Surveillance of Vaccine-Preventable Diseases*, Chapter 9: Mumps (2021), https://www.cdc.gov/vaccines/pubs/surv-manual/chpt09-mumps.html. Merck's supervisor of the AIGENT testing predicted this resurgence would occur because of the diminished level of mumps protection Merck's vaccines provide. Appx370 (Rels. SUMF). On multiple occasions, he told Relator Krahling "the efficacy rate of the mumps vaccine had significantly diminished since its original licensure." Appx5721 (Interrogatory Response).

The mumps resurgence is of significant concern to the CDC and has been the subject of extensive investigation, numerous academic studies, more than a dozen ACIP meetings, and a Working Group devoted exclusively to the subject. Appx375 (Rels. SUMF). It has caused ACIP to change its mumps vaccine recommendations twice in only ten years, moving from a one- to two-dose regimen

for children (in 2006), and adding a third dose for those at risk in outbreak situations (in 2017). Appx375-376 (Rels. SUMF). It is the only vaccine for which ACIP has changed its recommendations twice due to a resurgence in disease. Appx376 (Rels. SUMF). And it has caused the CDC to abandon its original goal of total mumps elimination by 2010. Appx372 (Rels. SUMF).

According to the CDC, this "surge" of mumps "is not understood and it is of serious public health concern for many reasons." Appx7271 (CDC Email). A CDC 30(b)(6) witness testified the outbreaks "do not have only a disruption for the institutions and populations affected, but you have children who are being hospitalized with complications, some of which include more serious conditions, like deafness …." Appx1752 (Pallansch Deposition). That is why leading vaccine experts (including from the CDC and FDA) have called for the development of a new mumps vaccine. Appx379 (Rels. SUMF). *See also* Appx7741 (NIH Grant Letter) (FDA's Dr. Steven Rubin: "the recent resurgence of mumps in highly vaccinated populations … mak[es] it quite clear that newer, more immunogenic vaccines are needed."). As one of the world's leading mumps authorities put it: "Although the practical difficulties are considerable, so is the cost of continued outbreaks of mumps." Appx7604 (Plotkin Commentary).

F. Merck's Fraud in Its MMR-II and ProQuad Sales to the CDC

Despite the mumps resurgence and widespread call for a new mumps vaccine, until late last year the CDC's only options for mumps, measles, and rubella vaccines for the millions of children covered by the Vaccines for Children Program were Merck's MMR-II and ProQuad. The CDC has made these purchases without actual knowledge of Merck's mumps vaccine potency, protection, shelf-life, labeling, and licensing issues. Appx374 (Rels. SUMF). Merck has failed to disclose these issues despite its clear duty to do so and its own concerns about how well its mumps vaccines protect against mumps. *See, e.g.,* Appx5359-5360 (Merck 30(b)(6) witness testifying she did not know the level of protection Merck's mumps vaccines provide); Appx4984 (Merck's supervisor of AIGENT testing testifying the same despite all the clinical testing he conducted); Appx5112-5113 (Merck Document) ("Additional concerns: … vaccine doesn't work").

IV. PROCEDURAL HISTORY

Relators filed their Complaint in August 2010. Appx21 (Opinion). The DOJ filed its notice of non-intervention in April 2012. *Id.* Relators filed their Amended Complaint the same day, which the District Court unsealed in June 2012. *Id.* Merck moved to dismiss the Amended Complaint in August 2012. *Id.* The DOJ filed a Statement of Interest challenging one of Merck's central arguments for dismissal and noting it "remains a real party in interest in this suit … with a strong

interest in the outcome." Appx77. The DOJ further stated its non-intervention "should not be interpreted as a comment on the merits" because of the many reasons that could be behind it, "including limited resources and confidence in a relator's attorney." Appx77 n.1, 81. The District Court denied Merck's motion to dismiss in September 2014. Appx21 (Opinion).

After years of fact and expert discovery, the parties submitted competing motions for summary judgment in October 2019. *Id.* The DOJ filed another Statement of Interest, rejecting Merck's materiality argument, stressing the Government lacked actual knowledge of Merck's violations and that "Merck is [] wrong to assign dispositive weight to the 'government action' *Escobar* factor." Appx104. On December 2, 2022, the case was reassigned to the Honorable Chad Kenney, who on January 24, 2023 held oral argument on the summary judgment motions. Appx22 (Opinion). The DOJ participated in the argument, reinforcing that it "does not have actual knowledge" of the challenged conduct and Merck's arguments to the contrary are "presumptuous" and based on "conjecture." Appx158, 169. The DOJ also underscored how much the "Government supports declined cases" and how the False Claims Act is designed "to allow the Government to rely on Relators and their counsel to develop a case and try to put it on in court." Appx172, 165.

V. THE DISTRICT COURT'S DECISION

The District Court issued its summary judgment decision on July 27, 2023, denying Relators' motion for summary judgment and granting Merck's motion "on the basis that Relators have failed to establish materiality." Appx25 n.4. The District Court not only turned the summary judgment standard on its head by imposing on Relators the burden of proving materiality, it also failed to view the evidence in a light and with all reasonable inferences favoring Relators. The District Court ignored much of the evidence altogether or improperly weighed the evidence against the dispositive weight it gave to the CDC's continued purchases of Merck's mumps vaccines. The District Court also reached its decision without even referencing (or presumably considering) the key attributes of Merck's fraud -- the mumps potency, shelf-life, and label-compliance problems; Merck's recognition it was "out of compliance" and selling a "misbranded" vaccine; Merck's recognition Protocol 007 did not measure mumps protection; Merck's fraudulent license applications; Merck's fraudulent labeling; and Merck's failure to disclose any of these issues to the CDC. *See supra* 8-19.

VI. THE THIRD CIRCUIT'S DECISION IN *DRUDING*

On August 25, 2023, the Third Circuit issued its decision in *Druding*, which addressed the same questions at issue here. The lower court there granted summary judgment to the defendant "for lack of materiality based principally on

the government's continued reimbursement of [defendant] even after being made aware of its deficient documentation required by regulation." 81 F.4th at 365. This Court reversed the decision "[b]ecause the District Court assigned dispositive weight to a single *Escobar* factor, government action, while overlooking the factors that could have weighed in favor of materiality -- and despite an open dispute over the government's 'actual knowledge.'" *Id*. (quoting *Escobar*, 579 U.S. at 195). The District Court in this case made precisely the same errors, and with a record that has significantly more evidence supporting materiality.

SUMMARY OF THE ARGUMENT

The District Court made four fundamental errors in granting summary judgment to Merck, each of which provides an independent ground for reversal.

First, it improperly flipped the summary judgment burden from Merck to Relators, requiring Relators to prove materiality rather than requiring Merck to establish no genuine issue of material fact as to a lack of materiality and that it is entitled to judgment as a matter of law. *Second*, it gave no weight to the evidence and factors supporting materiality. *Third*, it gave no weight to the evidence the Government lacked actual knowledge of Merck's violations, including the Government's explicit denial of actual knowledge. *Fourth*, it gave no weight to the actions the Government has taken and instead gave dispositive weight to certain actions the Government has *not* taken. And it did so without considering any

surrounding circumstances, including the need (until recently) for the CDC to purchase Merck's mumps vaccines or cut off mumps, measles, and rubella vaccines for millions of children each year.

Underlying these multiple errors was the District Court's failure to conduct a proper summary judgment analysis. It viewed the evidence in a light and with all inferences favoring Merck (not Relators) at every turn. It weighed conflicting evidence in favor of Merck, supplanting the jury's fact-finding function. Or it ignored the evidence altogether, much of it powerfully supporting materiality. The District Court exacerbated these errors by failing to follow the "holistic" approach to materiality *Escobar* requires, where the "totality" of facts and circumstances relevant to materiality must be considered. In casting aside these central summary judgment standards, imposing on Relators the ultimate burden of proof they are supposed to face at trial (not in defending against summary judgment), and assuming the role of the factfinder, the District Court erred in granting Merck summary judgment on materiality.

STANDARD OF REVIEW

The District Court's grant of summary judgment to Merck is subject to plenary review by this Court. *Druding*, 81 F.4th at 369. Merck has the burden to show "no genuine dispute as to any material fact," and that it is "entitled to judgment as a matter of law." *Id.* (cleaned up). In deciding whether Merck has

met this burden, the Court must draw "all reasonable inferences from the record … in favor of [Relators]," and "may not weigh the evidence or assess credibility." *Id.* (cleaned up). It also is required to view the record "in the light most favorable to [Relators]." *Forrest v. Parry*, 930 F.3d 93, 105 (3d Cir. 2019). In other words, "the evidence of the [Relators] is to be believed …." *Tolan v. Cotton*, 572 U.S. 650, 651 (2014) (cleaned up). In "granting summary judgment for Merck on the basis that Relators have failed to establish materiality," the District Court failed to follow these essential summary judgment standards. Appx25 n.4.

The District Court likewise failed to apply the governing standard for assessing materiality the Supreme Court set forth in *Escobar*. That requires a "'holistic,' totality-of-the-circumstances inquiry" where no one factor is dispositive. *Druding*, 81 F.4th at 367. It "turns on a variety of factors such as: (1) whether the government has expressly designated the legal requirement at issue as a 'condition of payment'; (2) whether the alleged violation is 'minor or insubstantial' or instead goes to the 'essence of the bargain' …; and (3) whether the government made continued payments, or does so in the 'mine run of cases,' despite 'actual knowledge' of the violation." *Id.* (quoting *Escobar*, 579 U.S. at 193 n.5, 194-95). The District Court did not give weight to any of the evidence supporting materiality. Instead, it gave dispositive weight to certain evidence within a single *Escobar* factor, Government action, without crediting the circumstances

surrounding that action or the Government's repudiation of actual knowledge of Merck's violations.

ARGUMENT

I. THE DISTRICT COURT ERRED IN IMPOSING ON RELATORS THE BURDEN OF PROVING MATERIALITY

The District Court erred in failing to follow the applicable summary judgment standards. Most fundamentally, it flipped the burden, imposing on Relators the burden of proving materiality, when it was Merck's burden to show no genuine dispute of fact as to a lack of materiality and it was entitled to judgment as a matter of law. The District Court's failure is evident from its glaring admission that it granted summary judgment for Merck "on the basis that Relators have failed to establish materiality." Appx25, n.4. *See also* Appx41 ("Relators have failed as a matter of law to satisfy the 'rigorous' and 'demanding' standard for materiality as set forth in *Escobar* and this Court will therefore grant Merck's Motion for Summary Judgment"); Appx27 ("Relators cannot show that any of these so-called false claims were material to the CDC's purchasing decisions"); Appx38 ("[Relators'] cases do not support a finding of materiality here").

Given this critical failure in applying the most basic of summary judgment standards, the District Court should be reversed on this ground alone. *See, e.g.*, *Druding*, 81 F.4th at 375-76 (reversing summary judgment where district court

improperly flipped burden to relators, noting "on a motion for summary judgment, it is the *moving party* who bears the burden of demonstrating the absence of a genuine issue of material fact") (emphasis in original); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986) (nonmovant "need only present evidence from which a jury *might* return a verdict in [its] favor") (emphasis added); *Brewer v. Quaker State Oil Ref. Corp.*, 72 F.3d 326, 330 (3d Cir. 1995) (reversing summary judgment, noting nonmovant need only "provide[] sufficient evidence to allow a reasonable jury to find for [nonmovant] at trial").

II. THE DISTRICT COURT ERRED IN GIVING NO WEIGHT TO THE EVIDENCE SUPPORTING MATERIALITY

Reversal is also warranted because the District Court failed to apply the other summary judgment standards in assessing the evidence relevant to materiality. The District Court was supposed to draw all reasonable inferences in Relators' favor, view the evidence in the light most favorable to Relators, and refrain from weighing the evidence. Again, the District Court did the opposite. It ignored much of the evidence altogether. And for the evidence it did consider, the District Court viewed the evidence in the light most favorable to Merck, not Relators. Or it improperly weighed conflicting evidence, usurping the role of the jury to resolve factual disputes. The District Court's failure was compounded by its additional failure to perform the required "holistic" materiality analysis, where no one factor is dispositive.

A. Essence of the Bargain

This case centers around Merck's failure -- spanning more than twenty years -- to disclose vital information to the CDC about how well MMR-II and ProQuad protect against mumps. The violations at issue "simply are not minor or insubstantial" by any stretch in either scale, scope, or duration. *See Druding*, 81 F.4th at 371 (cleaned up). That is why the CDC has stressed its "clear interest in the outcome" of this case because of its "[c]ritical" need for "accurate information from [] vaccine manufacturers" like Merck. *See infra* 30-31 (quoting Appx1947, 1952) (CDC Letters). Vaccine effectiveness is central to this critical need and goes to the very essence of the CDC's vaccine contracts with Merck and other suppliers. It is a concession Merck and its experts made throughout Merck's summary judgment briefing and argument. *See*, *e.g.*, Appx176 (SJ Transcript) ("effectiveness [is] the most important factor for the CDC"); Appx201-202 (Merck's SUMF) (vaccine effectiveness is CDC's "single-most important measure"). As one of Merck's experts -- a former head of CDC procurement -- underscored, "vaccine effectiveness is obviously kind of the most important thing that we deal with." Appx7224 (Atkinson Deposition). The District Court conceded it too, citing Merck's briefs: "[T]he CDC considers vaccine effectiveness the most important factor when evaluating a vaccine." Appx30.

Yet the District Court gave no weight to this factor in its materiality assessment, giving dispositive weight to certain evidence within the Government action factor instead: "[T]he CDC, despite this suit having been litigated for over ten years at this point, has continually recommended Merck's mumps vaccines and has continually asserted that two doses of the vaccine are 88% (range: 31%-95%) effective." *Id*. The District Court also limited its essence-of-the-bargain analysis to "one internal model of potency loss" and "the results of Protocol 007," finding "no evidence" they went to the essence of the bargain. *Id.* The District Court provided no analysis or discussion explaining how it jumped to this conclusion. But more importantly, it shows the District Court did not even consider Merck's potency, protection, shelf-life, licensing, and labeling violations. This is the pivotal misconduct at issue. All of it critical to the CDC vaccine payment decision. None of it included in the District Court's assessment of this factor.

B. Prerequisites to the CDC's Vaccine Purchases

Merck's potency, protection, shelf-life, licensing, and labeling violations implicate multiple contractual and regulatory obligations, including: (i) cGMP compliance, which requires adequate assurances of sufficient potency; (ii) 12 months of shelf life remaining upon delivery; (iii) compliance with a valid license; (iv) ACIP recommendation; and (v) fit for purpose and merchantability. Appx385-386 (Rels. SUMF). Complying with these obligations is not only material to the

CDC's payment decision. As Merck's own experts confirm, they are absolute prerequisites to the CDC's purchase, without which the CDC will not even enter into a contract. *See, e.g.*, Appx3219, 3221-3222 (Merck expert testifying cGMP compliance, minimum 12-month shelf life, valid license, ACIP recommendation, and merchantability, are "prerequisites to a CDC purchase" without which "CDC would not initiate procurement for a product").

The District Court gave no weight to this evidence, dismissing it in a single sentence without crediting that they are prerequisites to the CDC purchase decision or explaining why they could not support materiality: "Just because the Government … found a particular issue important enough to regulate speaks little to the intended consequence of noncompliance." Appx29-30 (cleaned up). The District Court likewise gave no weight to vaccine effectiveness even though it recognized it as a condition of payment. Appx29. Instead, it again gave dispositive weight to some of the evidence under the Government action factor, finding it trumped the condition-of-payment factor (and every other factor) that supported materiality: "[T]he CDC has continued to recommend that two doses of the mumps vaccine are 88% effective (range 31%-95%) against mumps. Thus, Merck did not violate a condition of payment relating to vaccine effectiveness." *Id.*

C. Other Critical Considerations to the CDC's Vaccine Purchases

The CDC witnesses, as well as former CDC employees Merck retained as experts, identified several other critical considerations to the CDC's payment decision that Merck's misconduct directly implicates, including: (i) accurate labeling; (ii) vaccine potency; and (iii) manufacturer fraud. *See, e.g.*, Appx7397 (CDC 30(b)(6) witness testifying that improperly labeled vaccine is "very problematic"); Appx7257-7258 (Merck expert testifying that CDC's understanding of product licensure, shelf life, and potency comes from the label); Appx1755 (another CDC 30(b)(6) witness testifying that a potency change could "[a]bsolutely" be relevant to vaccine effectiveness); Appx3241 (another Merck expert testifying "I don't think the CDC would want to contract with a vendor … found guilty of committing fraud"). The District Court gave no weight to this additional evidence that the violations at issue are not "minor or insubstantial" but go to the essence of Merck's bargain with the CDC. *Druding*, 81 F.4th at 37. The District Court ignored it completely.

D. The CDC's "Clear Interest" in the Outcome of this Case

The CDC -- on two separate occasions -- expressed its "clear interest in the outcome of [this case] given its public health mission to decrease vaccine-preventable infectious diseases." Appx1947, 1952 (CDC Letters). In doing so, the CDC highlighted how "[c]ritical" it is to "receiv[e] accurate information from the

vaccine manufacturers to better inform CDC/ACIP guidance." *Id.* This "critical" need for "accurate information" is at the core of Merck's duty -- as this Court laid out in *Mazur* -- to "apprise the CDC of any risks it later discovers or, in the exercise of reasonable care, should have discovered" with its vaccines. 964 F.2d at 1366. The duty is especially important with respect to clinical trial results, which ACIP is "mandated" to review and on which ACIP's vaccine recommendations are "largely dependent."[5] It is likewise vital with regard to accurate labeling as the CDC looks to the vaccine label as a primary source for its understanding of key product information like shelf life and potency. Appx365 (Rels. SUMF). *See Mazur*, 964 F.2d at 1367 ("The [vaccine label's] intended audience is … the CDC, who [is] contractually obligated to develop a meaningful warning for vaccinees or their parents.").

The District Court gave no weight to this duty so central to the CDC/Merck contractual relationship and the violations at issue, which so clearly support materiality. *See Druding*, 81 F.4th at 373 (finding materiality supported where "reasonable jury could conclude" violations were not "isolated instances" or "minor

[5] *See* Appx7535 (Merck expert report: "[n]ew vaccine recommendations … are largely dependent on the results of studies conducted by the manufacturer"); Appx2034 (Merck expert testifying that ACIP is "mandated" to "review those clinical trials and the efficacy and safety data resulting from those trials and uses that information in assessing what recommendations, if any, it's going to make."); Appx2371 (another Merck expert report: "ACIP recommendations … will be based upon pre-licensure clinical trials performed by the manufacturer.").

or insubstantial," but went to the "essence of the bargain"). The District Court did not even address this duty or *Mazur*. It likewise gave no weight to the CDC's pronouncements on its vital need for accurate vaccine information and why this case is therefore of such "clear interest." The District Court, once again, gave dispositive weight to certain evidence under the Government action factor instead. And it did so, viewing the evidence in the light *least* favorable to Relators and drawing all reasonable inferences *against* them. *See* Appx33 ("The CDC's so called 'clear interest' during the discovery period illustrates that it takes appropriate steps in response to serious allegations that a vaccine is not effective. But now that all the allegations as to Merck's misconduct have been directly submitted to the CDC, the CDC's lack of response is strong evidence of lack of materiality.").

E. The DOJ's "Strong Interest" in the Outcome

The District Court made the same fundamental errors in giving no weight to the DOJ's participation in this case. The DOJ filed Statements of Interest opposing Merck's arguments at both the motion to dismiss and summary judgment stages, making clear its "strong interest in the outcome." Appx77, 101. And it participated at the summary judgment hearing, forcefully rejecting Merck's materiality arguments and expressing its strong support for declined cases:

> [T]hat is the design of the [FCA], to allow the Government to rely on Relators and their counsel to develop a case and try to put it on in court. … And I'd just point out, Your Honor, that declined cases, the

> Government has collected since 1986, I think, 3.5 billion dollars in declined cases. The Government supports declined cases.

Appx165, 172. The District Court dismissed this evidence, again turning the summary judgment standard on its head by viewing the evidence in a light, and with all reasonable inferences, favoring Merck: "While Relators argue that the DOJ has repeatedly 'injected themselves into this case' and that this shows materiality, the DOJ's involvement *could* indicate simply the DOJ's continuing advocacy in the interpretation of a statute which generates significant recovery for the Government." Appx34 (emphasis added). A reasonable jury *might* agree. It also *might* disagree, finding the evidence supports materiality. The District Court took that decision from the jury.

F. Prior False Claims Act Cases

The DOJ has brought and settled numerous False Claims Act cases involving the same type of misconduct at issue here -- providing the Government pharmaceutical products that did not comply with key contractual provisions; did not comply with their potency or quality specifications; did not comply with cGMP requirements; were not supported by clinical data; did not have the efficacy represented; or did not comply with the product label.[6] In one such case, the DOJ

[6] *See, e.g.*, DOJ Press Releases (Appx9412 (DOJ claimed Ranbaxy "manufactured, distributed, and sold drugs whose strength, purity, or quality differed from the drug's specifications"); Appx9415 (DOJ claimed GSK "sold

claimed the defendant (McKesson) violated CDC vaccine contracts which -- just like in this case -- impacted the potency, protection, and shelf life of the vaccines. The DOJ could not have been clearer on the significant Government and public health interests at stake:

> Companies must comply with the requirements they agree to when they contract with the government to provide products that protect the public. … If a contractor does not adhere to the terms it negotiated, its conduct not only hurts taxpayers but also could jeopardize the integrity of products, like vaccines, that Americans count on to be safe. … Ensuring the integrity and performance of government contracts is paramount, especially when they impact programs intended to protect young children.

Appx9444 (DOJ Press Release). The DOJ reinforced the materiality of these types of violations in another case (against Shire) which -- just like this case -- involved the sale of drug products unsupported by clinical data and with overstated efficacy: "The Department of Justice will be vigilant to hold accountable pharmaceutical companies that provide misleading information regarding a drug's safety or efficacy." Appx9421 (DOJ Press Release).

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certain … lots of drugs, the strength of which differed materially from, or the purity or quality of which fell materially below, the strength, purity or quality specified in the drugs' FDA applications or related documents"); Appx9418 (DOJ claimed Baxter's "failure to follow cGMPs" in the manufacture of certain drugs); Appx9421 (DOJ claimed Shire promoted its drug "for certain uses despite a lack of clinical data to support such claims and overstated the efficacy"); Appx9424-9425 (DOJ claimed Quest subsidiary sold test kits that produced "materially inaccurate and unreliable" results and were not the subject of "accurate claims in their labeling"); Appx9444 (DOJ claimed McKesson "improperly set temperature monitors used in shipping vaccines under its contract with [CDC]")).

This presents the exact "mine run of cases" the Supreme Court pointed to as "proof of materiality" because it shows the Government has refused to pay claims or brought an enforcement action in the face of similar misconduct. *Escobar*, 579 U.S. at 194-95. Yet the District Court gave no weight to this evidence, again improperly giving it a one-sided view in Merck's favor. While the District Court specifically referenced the *McKesson* and *Shire* actions (but none of the others), it dismissed them as inapposite because they were settled with no admission of liability. *See* Appx38 ("Importantly, parties settle lawsuits for many different reasons, and particularly with a statute like the FCA, … defendants have a huge risk and significant costs if they chose to litigate such a case."). The District Court did not explain why the fact the cases settled makes these prior False Claims Act enforcement actions irrelevant to the materiality assessment. A reasonable jury could, and almost certainly would, go the other way, especially if they faithfully followed *Escobar*.

G. Adulteration/Misbranding

Adulterated or misbranded products may not be sold or purchased in the United States. 21 U.S.C. § 331(a). Merck's potency, protection, shelf-life, licensing, and labeling issues relate directly to whether Merck has been selling the CDC adulterated or misbranded mumps vaccines. It was a problem Merck repeatedly acknowledged at the highest levels. *See supra* 8-10 (citing evidence of

Merck's internal recognition that MMR-II was "misbranded" and "out of compliance," and facing a risk of recall). It is not only material to the CDC's payment decision. It dictates whether the CDC can purchase these vaccines at all. DOJ has routinely enforced this prohibition against selling or buying adulterated or misbranded products. *See* Appx389 (Rels. SUMF) (citing numerous criminal and civil Government enforcement actions imposing fines, forfeitures, and injunctions for sales of misbranded or adulterated products). The District Court gave no weight to this evidence, not even addressing it in its decision.

H. The Expert Opinions of Former FDA Commissioner Kessler

Dr. David Kessler is a former FDA Commissioner and most recently the head of the Government's COVID task force, making him one of the leading vaccine experts in the country. He submitted an expert report for Relators in this case which comprised 533 pages of opinion and roughly 300 additional pages of supporting analyses. Appx552-1482. Merck deposed Dr. Kessler for roughly ten hours, yielding a transcript of more than 400 pages. Appx1484-1587. In both his report and at his deposition, Dr. Kessler stressed his deep concerns over the misconduct at issue:

- "From May 1998-December 2007, MMR-II was adulterated because Merck was unable to assure the potency specification for mumps … for the shelf life of the vaccine." [Appx1085.]

- "Let me again emphasize in the strongest possible terms … this matter … has significant public health import." [Appx1514.]

- "I could assure you … had Merck … [been] forthcoming[] that 23 million doses were below specification … bells would have been set off at the [FDA]." [Appx1540.]

- "[If] I knew that a staple of the American healthcare framework was subpotent …, and certainly if I knew seroconversion rates were less in the range that Merck was getting … I would be caucusing with my senior staff about what to do about this because … it would create to me one of the most important public health conundrums." [Appx1541.]

- "I would be very happy to be reassured … that this problem was corrected. I see nothing in the record that says … FDA was informed of this … and that these children received potent vaccine …. Because [from] everything I see, that's not the case, and that's why I am very concerned here." [Appx1537.]

- "[Y]ou're dealing with one of the staples … of the American healthcare system, the MMR II vaccine. … Please fix this issue." [Appx1538.]

The District Court gave no weight to this evidence supporting materiality. *See Druding*, 81 F.4th at 372 (citing in support of materiality relators' expert opinion that defendant's violations were "longstanding problems" from which "a reasonable jury could find … were part of a pattern of significant noncompliance"). It did not even reference the roughly 800 pages of Dr. Kessler's expert opinions and analyses or his ten hours of deposition testimony where he stated in the strongest possible terms why the fraud alleged in this case is so material and why Merck needs to take action to address it.

* * *

In failing to credit any of this evidence -- by viewing it in a light and drawing all reasonable inferences *against* Relators; weighing it against evidence of Government action; or ignoring it altogether -- the District Court violated the central summary judgment standards and the holistic, consider-all-evidence approach *Escobar* demands. The District Court compounded this failure by improperly setting the bar for Relators' evidence at definitively proving materiality rather than what a reasonable jury could find by a preponderance of the evidence. It is a distinction this Court highlighted in *Druding*: "For purposes of appellate review, we acknowledge that some of *Escobar's* factors 'could support a materiality finding' not because the evidence definitively points towards materiality -- it does not -- but because on this record, a reasonable jury could conclude that [the defendant's] alleged violations were material." 81 F.4th at 373, n.11.

The District Court's failures here, just like in *Druding*, present another independent ground for reversing its summary judgment decision. *See also Tolan*, 572 U.S. at 656 (vacating summary judgment because appellate court "failed to view the evidence … in the light most favorable to [the nonmovant]," "fail[ed] to credit evidence that contradicted some of its key factual conclusions," "improperly weigh[ed] the evidence," and "resolved disputed issues in favor of the moving party") (cleaned up); *Faush v. Tuesday Morning, Inc.*, 808 F.3d 208, 215 (3d Cir. 2015) (reversing summary judgment where district court "overstated the extent to

which [certain] factors" of multifactor test "cut against [nonmovant]"); *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 62-68 (3d Cir. 2009) (reversing summary judgment where district court "overlook[ed]," "ignored," and "did not give adequate weight" to nonmovant's evidence); *Lawrence v. Nat'l Westminster Bank N.J.*, 98 F.3d 61, 67 (3d Cir. 1996) (reversing summary judgment where district court weighed disputed evidence and discounted nonmovant's evidence); *Brewer*, 72 F.3d at 328, 331 (reversing summary judgment where district court "discounted [nonmovant's] evidence"); *United States ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1346-47, 1352 (11th Cir. 2021), *cert. denied* 141 S. Ct. 2632 (2021) (reversing summary judgment on materiality where district court "impermissibly resolved factual disputes by weighing conflicting evidence" and where certain factors favored materiality).

III. THE DISTRICT COURT ERRED IN GIVING NO WEIGHT TO THE EVIDENCE OF THE CDC'S LACK OF "ACTUAL KNOWLEDGE"

A Government action defense to materiality must be premised on the Government's actual knowledge of the violation. This requirement comes directly from *Escobar* where the Supreme Court was explicit that Government action in the form of continued payments or otherwise is only relevant to materiality where the Government has "actual knowledge that certain requirements were violated." 579 U.S. at 195. *See also Druding*, 81 F.4th at 375 ("*Escobar* focuses on whether the government had '*actual knowledge*' of a violation when it made a payment")

(emphasis in original); *United States ex rel. Heath v. Wis. Bell, Inc.*, 75 F.4th 778, 788 (7th Cir. 2023) (finding defendant's "actual knowledge" argument "seeks to erase the difference between allegations and conclusive proof"); *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 517 (6th Cir. 2022) ("there is a difference between alleged fraud and actual fraud," and "the alleged facts show only that USN4U informed NASA of its allegations, not that NASA necessarily believed the allegations to be true"); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance").

At the summary judgment hearing before the District Court, the Government forcefully denied having actual knowledge of Merck's violations:

> The Government does not have actual knowledge. … Merck states, throughout its briefing, that the Government must have concluded that Relators' allegations are untrue or otherwise not material, because the Government has actual knowledge of all of the facts and all of the evidence relating to this matter. That's just not true. [Appx158.]
>
> So, when Merck says, the CDC and FDA, and I'm quoting here, "have all of the evidence to evaluate it," and they say that, "the DOJ, CDC and FDA know the entirety of Relators' falsity claims, including every pertinent piece of evidence that Relators say was withheld from the agency" … that's just simply not true. [Appx162.]

The Government stressed it "has not made any determination or drawn any conclusions" with respect to Merck's misconduct and any finding to the contrary

would necessarily "inject [] conjecture into the materiality analysis." Appx158. The CDC's two 30(b)(6) witnesses were in complete accord, both testifying the agency had not reached any determination on whether Merck had engaged in the misconduct at issue. Appx1758, 7372.

One of them went even further, testifying the CDC has no knowledge of any of the misconduct at issue, not even the pervasive mumps potency problems that have been plaguing Merck's MMR-II vaccines for the past twenty years. *See, e.g.,* Appx1753 (testifying CDC has no knowledge of any mumps potency changes); Appx1747 (testifying CDC has no knowledge of details of Protocol 007); Appx1747-1748 (testifying CDC has no knowledge of any clinical trial fraud). That is why the CDC has not even considered vaccine potency issues in investigating the possible causes for the mumps resurgence:

> We have not looked at potency because of the lack of any awareness of a change of potency. Therefore, as far as our assumptions is the vaccine that was originally licensed for MMR is still the vaccine that we're evaluating for vaccine effectiveness.

Appx1755 (Pallansch Deposition). It also explains why the CDC recently misstated MMR-II's actual potency levels in a public report it publishes as part of its duty to provide information about the safety and effectiveness of vaccines. *See* Elisabeth Krow-Lucal, et al., *Measles, Mumps, Rubella Vaccine (PRIORIX): Recommendations of the Advisory Committee on Immunization Practices — United States*, 71 Morbidity & Mortality Weekly Report, No. 46, at 1467 (Nov. 28, 2022),

https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7146a1-H.pdf ("2022 MMWR") (2022 CDC publication cites the wrong MMR-II mumps potency, incorrectly pointing to the potency from more than 20 years ago before Merck significantly increased it to try (unsuccessfully) to address its pervasive mumps potency problems).

The District Court gave no weight to this evidence. It rejected outright the Government's denial of actual knowledge and did not even consider the CDC testimony and evidence affirming it. Instead, the District Court substituted its views for the Government's and found "the Government does have knowledge of all of the facts, but these facts were simply not persuasive to the CDC, or any other agencies, to prompt them to take any action." Appx36. Merck made the same argument below, which the Government called "presumptuous" because "[t]hey do not have knowledge -- they do not have a basis to know why the Government did what it did." Appx169. The District Court does not either. And it certainly does not know more about what the Government knows than the Government itself. This Court emphasized this reality in *Druding* when it acknowledged "we simply do not know what the government knew and when." 81 F.4th at 375. It thus refused to "equate the government's awareness of allegations of fraud with 'actual knowledge' that fraud occurred," recognizing "the Government may not want to

prematurely end a relationship with a contractor over unproven allegations." *Id.* (cleaned up).

Like in *Druding*, the District Court plainly erred in finding there was no dispute the Government had actual knowledge when so much evidence goes against it, including the Government's explicit denial of such knowledge.[7] This error presents another independent ground for reversal. *See Heath*, 75 F.4th at 789 ("The government's knowledge of a pending lawsuit making allegations simply does not indicate actual knowledge of actual violations. … At the very least, a genuine question of material fact exists on this issue.").

IV. THE DISTRICT COURT ERRED IN GIVING DISPOSITIVE WEIGHT TO GOVERNMENT ACTION

Even assuming there was no evidence that the CDC lacked actual knowledge of Merck's violations -- and the District Court had not improperly flipped the

[7] In finding no dispute as to "actual knowledge," the District Court heavily relied on a joint submission Dr. Kessler and Merck made to the CDC and FDA shortly before the start of the COVID pandemic. Appx32-33. But the District Court gave no weight to the diversion of public health resources needed for the Government's COVID response. Rather, it assumed the Government fully reviewed this information, and consistent with its improper burden shifting, imposed on Relators the burden to prove otherwise. *See* Appx33 ("it is plaintiff's burden to show that the agency did not review the record") (cleaned up). The District Court also ignored the limited scope of Dr. Kessler's portion of the submission (just 27 pages compared to his roughly 800 pages of expert opinions), and that it largely focused on just a portion of Merck's alleged fraud. The District Court further ignored that Merck's competing submission to the Government vigorously disputed Dr. Kessler's views, raising numerous contested issues of fact. Appx15655 (Joint Submission).

summary judgment burden to Relators, weighed the evidence in Merck's favor, viewed the evidence in a light favoring Merck, and ignored evidence a reasonable jury could find supports materiality -- the District Court still erred in giving dispositive weight to the Government action factor.

A. Government Action Is Irrelevant for Merck's MMR-II Sales Through 2007

From at least 2000 through 2007, Merck's MMR-II vaccine was misbranded because it did not comply with the mumps minimum potency and shelf-life specifications on the label. *See supra* 8-10. This technically ended in December 2007 when Merck secured a label change (albeit through its Protocol 007 fraud) decreasing the minimum potency specification and bringing the vaccine back into compliance. Accordingly, the CDC's action (or lack of action) in response to the lawsuit is irrelevant to the materiality analysis for these purchases made years before Relators even filed this lawsuit (in 2010). The District Court ignored these *pre-lawsuit* purchases, not even addressing them in its decision.

B. Government Action Supports Materiality

In giving dispositive weight to what actions the CDC *has not* taken, the District Court also erred in failing to give any weight to the actions the CDC *has* taken. The CDC has engaged in multiple measures in response to the unprecedented mumps resurgence, including holding numerous meetings and a

Working Group devoted exclusively to the subject, changing its mumps vaccine recommendations, abandoning its original goal of total mumps eradication, and calling for a new mumps vaccine. *See supra* 17-18. In addition, as soon as an alternative to Merck's mumps-measles-rubella vaccine became available in late 2022 with GSK's Priorix vaccine, the CDC immediately began shifting purchases from Merck to GSK. Appx39 (Opinion). The CDC's sister agency responsible for the Government's research priorities, the NIH, also has taken action by funding scientists to develop a new mumps vaccine. Appx7713 (NIH Letter). *See also* FDA, *An Attenuated Live Mumps Virus Vaccine Candidate Expressing F and HN Protein Genes from Genotype G*, https://www.fda.gov/science-research/licensing-and-collaboration-opportunities/attenuated-live-mumps-virus-vaccine-candidate-expressing-f-and-hn-protein-genes-genotype-g (2020) (FDA announcing its work to develop new mumps vaccine because "[t]here is a need for the development of newer, more efficacious mumps vaccines to address the growing cases of a once dormant disease.").

The District Court gave no credit to the evidence of Government action supporting materiality. With respect to the CDC actions to address the mumps resurgence, the District Court ignored them altogether. With respect to the CDC's recent shift to GSK's mumps vaccines, the District Court again failed to view the evidence in the light most favoring Relators. To the contrary, the District Court

found the CDC's shift away from Merck supported immateriality because of the District Court's view that the CDC believes the GSK and Merck mumps vaccines are "fully interchangeable." Appx39-40. The District Court usurped the jury by weighing this contrasting evidence. Even worse, it did so while disregarding all the evidence supporting materiality and showing the CDC lacks actual knowledge of Merck's mumps potency and protection issues. This evidence includes testimony from multiple CDC witnesses and the very CDC publication the District Court cited for the CDC's view on the supposed interchangeability of the Merck and GSK vaccines. Appx20 (citing 2022 MMWR where the CDC reports the wrong MMR-II mumps potency).

The District Court's failures here present yet another independent ground for reversal. *See Druding*, 81 F.4th at 376 ("[N]otwithstanding the government's prolonged inaction in the wake of Relator's fraud allegations, it was erroneous to treat this factor as determinative of immateriality. A jury must be permitted to weigh the government's inaction alongside *Escobar*'s other factors."); *Bibby*, 987 F.3d at 1352 (reversing summary judgment, finding even if Government action presented "strong evidence of immateriality, that evidence is not unrebutted [and a] factfinder would still have to weigh that factor against others") (cleaned up); *Heath*, 75 F.4th at 788-89 (reversing summary judgment, finding defendant "does not come close to mustering the kind of evidence that would defeat a False Claims

Act case at summary judgment on such a [continuing payments] theory regarding materiality," and that "[a]t the very least, a genuine question of material fact exists on this issue").

C. Government Action Is Explained by Surrounding Circumstances

The District Court also erred in failing to consider three key facts surrounding the CDC's purchase of Merck's mumps vaccines that shed light on why, even if it had actual knowledge of Merck's fraud, the CDC would want (or need) to continue purchasing them. First, the vaccines the CDC has continued buying are critical products that impact the health of millions of children. Second, Merck's mumps vaccines are not stand-alone products but are bundled with Merck's measles and rubella vaccines. Third, until recently, Merck was the only supplier of mumps vaccines in the United States. According to one Merck consultant, this made Merck's purchasers "customers by force" not "by choice." Appx8410 (Merck Document). In other words, for virtually the entirety of this case, had the CDC stopped purchasing Merck's mumps vaccines, it would have completely severed the only source of mumps vaccines -- and measles and rubella vaccines too -- for millions of children each year. This limits, if not entirely removes, any materiality inference that can be drawn from the CDC's continued purchase of Merck's mumps vaccines.

The District Court gave no weight to these pivotal facts surrounding the CDC's mumps vaccine purchases. The District Court merely stated, "the CDC prefers vaccines that protect against multiple diseases," without addressing the difficulty and broader ramifications of the CDC cutting off mumps, measles, and rubella vaccines for millions of children. Appx39. Or without at least trying to explain (or even consider) how that significant fact impacts the materiality analysis. The District Court was equally dismissive of the "customers by force" language from Merck's consultant because "the document does not mention the CDC," only "private sector" purchasers. Appx39 n.6. But the District Court ignored that both the CDC and private purchasers have been subject to the exact same sole-source supply limitations. All that mattered to the District Court was that the CDC has "consistently paid for and recommended Merck's mumps vaccines." Appx39.

Courts have consistently rejected the District Court's constrained approach to materiality, recognizing the many reasons the Government might continue dealing with a contractor that engaged in fraud. The Government made this point in its Statement of Interest:

> In any event, even where the government has *actual* knowledge of a defendant's wrongful conduct and continues to pay claims, such action does not necessarily undermine a materiality finding. There are many reasons, including important public health and safety considerations (such as the need to ensure adequate access to health care, or the

> unavailability of similar products from different providers), why the government might continue to pay claims in such circumstances.

Appx107-108 (emphasis in original). The Government reaffirmed it at oral argument: "there are many, many reasons that the Government may act, despite having knowledge, actual knowledge." Appx173. Even the District Court acknowledged (though ultimately disregarded) this reality: "Courts have recognized that even where the Government has actual knowledge of noncompliance, there may be other good reasons for the Government to continue paying these claims." Appx31.

As one court aptly put it, "[t]he more essential the continued execution of a contract is to an important government interest, the less the government's continued payment weighs in favor of the government knowledge defense." *United States v. Pub. Warehousing Co.*, No. 1:05-cv-2968, 2017 WL 1021745, at *6 (N.D. Ga. Mar. 16, 2017). *See also United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 737-38 (5th Cir. 2023) (agreeing with Government contention that "where it was important for potential patients of [defendant hospital] to continue to have access to healthcare," continued payments to hospital "do[] not neutralize the evidence supporting the jury's finding of materiality"); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) (observing Government might have good reason to pay despite

violation because "the contract might be so advantageous to the government" or too far along to terminate without excessive costs).[8]

This case presents a compelling example of why these considerations must be part of the materiality analysis. There are few things more essential than protective vaccines, and few Government interests more important than the public health of millions of children. Even if the CDC had actual knowledge of Merck's violations, it still must account for Congress's mandate through the Vaccines for Children Program to purchase vaccines for millions of children who rely on the CDC for mumps, measles, and rubella vaccines. The District Court ignored all of this.

[8] *See also United States ex rel. Muhawi v. Pangea Equity Partners*, No. 1:18-cv-02022, 2023 WL 6311470, *9 (N.D. Ill. Sept. 28, 2023) ("Even if the [Government] knew of [defendant's] false claims, it could have other reasons for the decision to continue payments to [defendant], such as keeping voucher holders safely housed …."); *United States ex rel. Hueseman v. Pro. Compounding Ctrs. of Am., Inc*., No. 5:14-cv-00212, 2023 WL 2669879, at *19 (W.D. Tex. Mar. 27, 2023) ("The Court declines to endorse a theory of materiality that would, at a minimum, force the Government to deny care to people who have made sacrifices for their country, and, at worst, create a national security risk."); *United States ex rel. Rahimi v. Rite Aid Corp.*, No. 2:11-cv-11940, 2019 WL 1426333, at *8 (E.D. Mich. Mar. 30, 2019) ("Government may have continued to pay to avoid adversely affecting the millions of Medicaid beneficiaries who rely on Rite Aid to meet their prescription needs") (cleaned up).

D. The District Court Relied on Inapposite Cases and Misplaced Policy Concerns

The District Court's reliance on *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017) as "[p]articularly instructive to [its] analysis" further shows how the District Court did not undertake the holistic approach *Escobar* demands. Appx36. In *Petratos*, the Third Circuit affirmed the lower court's dismissal on the element of materiality. But the Court did not get there by flipping the summary judgment burden to the relator, giving no weight to the evidence or factors supporting materiality, or ignoring the circumstances surrounding the Government's purchases, all of which the District Court did here. Rather, there was no materiality in *Petratos* because the relator "concede[d] that the Government would have paid the claim with full knowledge of the alleged noncompliance," and "concede[d] that the expert agencies and government regulators have deemed these violations insubstantial (or at least would do so if made aware)." 855 F.3d at 490.

These key relator concessions and the absence of any countervailing evidence supporting materiality show how inapposite *Petratos* is and how the District Court's reliance on it as "[p]articularly instructive" is so misplaced. Several courts, including this one in *Druding*, have distinguished *Petratos* for exactly this reason. 81 F.4th at 375 (citing *Petratos* for "affirming summary judgment where Relator conceded the Government would have paid the disputed

claims with full knowledge of the alleged noncompliance") (cleaned up). *See also United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (distinguishing *Petratos* where "relator did not dispute that [Government] would reimburse these claims even with full knowledge" because "no such concession is made here") (cleaned up); *United States v. Honeywell Int'l Inc.*, 502 F. Supp. 3d 427, 458-59 (D.D.C. 2020), *reversed on other grounds by* 47 F.4th 805 (D.C. Cir. 2022) (distinguishing *Petratos* based on same); *United States v. Johnson & Johnson*, No. 3:12-cv-7758, 2017 WL 2367050, *6 (D.N.J. May 31, 2017) (same).

The same is true for the other decision on which the District Court principally relied, *United States ex rel. Bennett v. Bayer Corp.*, No. 2:17-cv-04188, 2022 WL 970219 (D.N.J. Mar. 31, 2022).[9] The district court there dismissed the complaint, finding the relator "cannot satisfy materiality" because it did not plead what "material statutory, regulatory, or contractual requirement" defendants

[9] The other two cases the District Court cited -- *Nargol* and *D'Agostino* -- are equally inapt as they both are fraud-on-the-FDA cases where there was "a break in the causal chain between the alleged misstatements and the payment of any false claim [that] render[ed] a claim of materiality implausible." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017). *See also D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (finding no "causal link between the representations made to the FDA and the payments made to CMS"). By contrast, this case is about Merck's misrepresentations and omissions *to the CDC*, violating multiple contractual and regulatory obligations *to the CDC*, causing Merck's submission of false claims *to the CDC*.

allegedly violated. *Id.* at *9. The court further found the Government was fully aware of all the facts surrounding the alleged fraud. *Id.* at *10. Indeed, the court highlighted how the relator "appear[ed] to concede" that he and the Government's "*own scientists* uncovered the *full extent*" of these facts. *Id.* (emphasis in original). While *Bennett* and *Petratos* may be "almost on all fours" with each other, they are not with this case and do not "stand[] on the same principles," as the District Court found.[10] Appx37.

Equally misplaced was the District Court's policy concern of creating "a perverse incentive for the Government to decline to intervene and then stick their heads in the sand and ignore the progression of the case." Appx40-41. Congress purposely designed the False Claims Act to allow relators to litigate without Government intervention. This gives the Government the option to best allocate its limited resources and rely on the efforts of private litigants, especially when they

[10] The four facts of this case the District Court pointed to as aligning with *Petratos* and *Bennett* further illustrate the District Court's flawed reasoning. *See* Appx37 (pointing to: the Government knowing the allegations since 2010; the lack of FDA response; the Government's continued purchases; and the Government's declination). None of these facts support the District Court's decision. *Druding* dismisses two of them outright, finding it "will not equate … awareness of allegations … with actual knowledge," and that Government declination "is at best, of minimal relevance." 81 F.4th at 374 n.14, 375 (cleaned up). As to any FDA response, that is not the relevant agency, especially since it recuses itself from the CDC purchase decision. Appx1959 (FDA Document). As to the CDC's continuing purchases -- given the lack of actual knowledge, the "customer by force" nature of the purchases, and the recent shift to GSK's vaccines -- they are of minimal (or at least, disputed) import.

are represented by capable relator's counsel. *See Rigsby*, 580 U.S. at 34 (citing Congressional purpose to "encourage more private enforcement" given lack of Government resources) (cleaned up); *Wilson*, 559 U.S. at 298 (citing same); *United States ex rel. Cantekin v. Univ. of Pittsburg*, 192 F.3d 402, 408 (3d Cir. 1999), *superseded on other grounds by* FERA, Pub. L. No. 111-21 (2009) (citing Congressional recognition that Government "lacks the resources to investigate and prosecute all false claims even when the Government has information revealing fraud"); *USN4U*, 34 F.4th at 518 ("The very fact that the FCA allows private relators to enforce the Act … implies a recognition that the Government may have limited resources or may choose to focus its enforcement efforts elsewhere.").

The District Court's concern cannot be reconciled with this fundamental statutory design and if accepted would set a very dangerous precedent.[11] It would require Government agencies to change their purchasing behavior without full information or a firm conclusion on actual wrongdoing, or risk losing their rights under the False Claims Act. The facts of this case highlight the potential dangers with this approach. It would have required the CDC to stop purchasing (or recommending) what until very recently were the only vaccines for mumps, measles, and rubella in the United States without knowing whether the violations

[11] The District Court's concern of creating a "perverse incentive" for Government declination is further belied by the statute which substantially *reduces* the Government's recovery if it declines to intervene. 31 U.S.C. § 3730(d).

actually occurred. Or now, to shift all its purchases to a different supplier selling a just-approved vaccine despite the CDC's self-described "[redacted]" need for multiple suppliers "[redacted]" Appx8213 (GSK Document). "The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. 9:14-cv-00230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017). *See also Hueseman*, 2023 WL 2669879, at *19 (quoting same, noting "Government must ensure the delivery of health care to many millions of Americans").

But that is exactly what the District Court's reasoning would foist on the CDC and any similarly situated agency to preserve the right to recover under the False Claims Act. This is not what Congress intended with the False Claims Act, especially when it expressly permits relators to pursue cases the Government declines to join and incentivizes them with an even greater share of the Government's recovery. It also cannot be what the Supreme Court had in mind in *Escobar* with its call for a holistic approach to materiality.

CONCLUSION

For the reasons set forth above, this Court should reverse the District Court's decision granting summary judgment to Merck. Given the fundamental nature of the District Court's errors, any one of which provides ample grounds for reversal,

Relators do not request oral argument for this appeal, and do not believe one is necessary. This is especially true given this Court's decision in *Druding* reversing the lower court's summary judgment decision based on the same errors the District Court made here.

Respectfully submitted this 1st day of November 2023.

/s/ Gordon Schnell
Gordon Schnell
(NY State Registration #2502136)
Robert L. Begleiter
Hamsa Mahendranathan
Elizabeth Soltan
CONSTANTINE CANNON LLP
335 Madison Avenue
New York, NY 10017
Telephone: (212) 350-2700
gschnell@constantinecannon.com
rbegleiter@constantinecannon.com
hmahendranathan@constantinecannon.com
esoltan@constantinecannon.com

Marlene Koury
CONSTANTINE CANNON LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Telephone: (415) 639-4001
mkoury@constantinecannon.com

Jeffrey F. Keller
Kathleen R. Scanlan
KELLER GROVER, LLP
1965 Market Street
San Francisco, CA 94103
Telephone: (415) 543-1305
jfkeller@kellergrover.com
kscanlan@kellergrover.com

Counsel for Appellants-Relators Stephen Krahling and Joan Wlochowski

COMBINED CERTIFICATIONS

1. **Bar Membership** – I hereby certify that Gordon Schnell, Jeffrey Keller, Kathleen Scanlan, Robert Begleiter, Marlene Koury, Hamsa Mahendranathan, and Elizabeth Soltan, counsel for Appellants-Relators Stephen Krahling and Joan Wlochowski, are members in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. **Word Count/Typeface Requirements** – I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), and contains 12,941 words, excluding the parts exempted by Fed. R. App. P. 32(f). Furthermore, this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) as this brief has been prepared in proportionately spaced typeface using Microsoft Word in 14-point Times New Roman style.

3. **Identical Compliance of Briefs** – I hereby certify that the text of the PDF file and the hard copies of this brief are identical.

4. **Virus Check** – I hereby certify that the PDFs of the electronic Brief for Plaintiff-Appellant and Appendix Volumes I through XLV have been

scanned for viruses using SentinelOne, Version 23.1.5.886. The anti-virus program has indicated the PDFs are free of any viruses.

Dated: November 1, 2023

/s/ Gordon Schnell

Gordon Schnell

CERTIFICATE OF SERVICE

I hereby certify that, on November 1, 2023, I electronically filed this Brief and Appendix (Volumes I through XLV) for Appellants-Relators Stephen Krahling and Joan Wlochowski with the Clerk of the United States Court of Appeals for the Third Circuit using the CM/ECF system, which will send notification of such filing to the counsel of record in this case who are registered on the CM/ECF.

In addition, seven true and correct copies of Volume I and four true and correct copies of Volumes II through XLV were mailed to the Court.

Dated: November 1, 2023

/s/ Gordon Schnell

Gordon Schnell

VOLUME I OF JOINT APPENDIX

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Volume I

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

UNITED STATES OF AMERICA *ex rel.*, STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI, *Plaintiffs*, v. MERCK & CO., INC., *Defendant.*	Civil Action No. 10-4374 (CFK) **RELATORS' NOTICE OF APPEAL**

Relators Stephen A. Krahling and Joan Wlochowski ("Relators") hereby appeal to the United States Court of Appeals for the Third Circuit from the final judgment dated and entered on July 27, 2023 (ECF No. 351) and the accompanying Memorandum dated and entered on July 27, 2023 (ECF No. 350).

Dated: August 24, 2023

Respectfully Submitted,

/s/ Gordon Schnell

Gordon Schnell
Robert L. Begleiter
Daniel J. Vitelli
Hamsa Mahendranathan
Elizabeth Soltan
CONSTANTINE CANNON LLP
335 Madison Avenue
New York, NY 10017
Tel: (212) 350-2700
Fax: (212) 350-2701
gschnell@constantinecannon.com
rbegleiter@constantinecannon.com
dvitelli@constantinecannon.com
hmahendranathan@constantinecannon.com
esoltan@constantinecannon.com

Marlene Koury
CONSTANTINE CANNON LLP

150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Fax: (415) 639-4002
mkoury@constantinecannon.com

Jeffrey Keller
Kathleen R. Scanlan
KELLER GROVER LLP
1965 Market St.
San Francisco, CA 94103
Tel: (415) 543-1305
Fax: (415) 543-7861
jfkeller@kellergrover.com
kscanlan@kellergrover.com

Counsel for Relators

CERTIFICATE OF SERVICE

I, Gordon Schnell, am employed in the County of New York, State of New York. I am over the age of eighteen and I am not a party to this action. My business address is 335 Madison Avenue, 9th Floor, New York, NY 10017. On August 24, 2023, I caused a true and correct copy of the foregoing **RELATORS' NOTICE OF APPEAL** to be served on the interested parties, as set forth below, by ECF filing and electronic mail:

Lisa Dykstra
Eric Sitarchuk
R. Brendan Fee
Margaret E. Rodgers Schmidt
Zachary Johns
MORGAN LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
ldykstra@morganlewis.com
esitarchuk@morganlewis.com
bfee@morganlewis.com
mrodgersschmidt@morganlewis.com
zjohns@morganlewis.com

Dino Sangiamo
Sally Bryan
Craig Thompson
Kathleen Hardway
Christina L. Gaarder
VENABLE LLP
750 E. Pratt Street, Suite 900
Baltimore, MD 21202
dssangiamo@venable.com
srbryan@venable.com
cathompson@venable.com
khardway@venable.com
clgaarder@venable.com

Counsel for Defendant Merck & Co., Inc.

Neal Kumar Katyal
Jessica Ellsworth
HOGAN LOVELLS US LLP
555 Thirteenth Street, Columbia Square
Washington, DC 20004
neal.katyal@hoganlovells.com
jessica.ellsworth@hoganlovells.com

Counsel for Defendant Merck & Co., Inc.

Dated: August 24, 2023

/s/ Gordon Schnell
Gordon Schnell
Counsel for Relators

UNDER SEAL

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

UNITED STATES OF AMERICA *ex rel.*, STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI,	:	**CIVIL ACTION**
***Plaintiffs*,**	:	**NO. 10-4374**
v.	:	
MERCK & CO., INC.,	:	
***Defendant*.**	:	

MEMORANDUM

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

Relators Stephen Krahling and Joan Wlochowski ("Relators") bring this *qui tam* action against their former employer Defendant Merck & Co., Inc. ("Merck"). Relators contend that Merck violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, by submitting false and fraudulent claims to the Centers for Disease Control and Prevention ("CDC") in connection with Merck's sale of its MMR-II and ProQuad mumps vaccines to the CDC. Presently before the Court are fully briefed cross-motions for summary judgment. ECF Nos. 281, 283, 285, 287, 294. For the reasons set forth below, Relators' Motion for Summary Judgment is denied. ECF No. 294. Merck's Motions for Summary Judgment based on an Efficacy Theory and the Kessler-Based Theory (ECF Nos. 281 and 287) are granted and, accordingly, summary judgment is entered in favor of Defendant Merck. An appropriate Order will follow.

I. BACKGROUND

Mumps was once a ubiquitous childhood disease. ECF No. 290-1 ¶ 28; ECF No. 300-1 at 8 ¶ 28. The disease generally presents as a fever and inflammation of salivary glands, and one

frequent complication is meningitis, which, in rare cases, can result in death. ECF No. 290-1 ¶¶ 28, 30; ECF No. 300-1 at 8 ¶¶ 28, 30. Prior to a vaccine being introduced in 1967, "mumps was the leading cause of viral encephalitis [brain inflammation] and sudden onset deafness in the United States." ECF No. 290-1 ¶ 29; ECF No. 300-1 at 8 ¶ 29. After the mumps vaccine was introduced, mumps cases in the United States decreased by more than 99%. ECF No. 290-1 ¶ 36; ECF No. 300-1 at 9 ¶ 36. 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 among vaccinated individuals.[1] *Id.*

A. Merck's Mumps Vaccines

Until 2022, Merck was the only licensed manufacturer of a mumps vaccine in the United States. Merck first entered the United States market in 1967 when it obtained a license for its monovalent mumps vaccine, MUMPSVAX ("Mumpsvax"). ECF No. 290-1 ¶ 31; ECF No. 300-1 at 8–9 ¶ 31. Merck supported this licensure of the Mumpsvax vaccine with clinical trials conducted by Dr. Maurice Hilleman and his colleagues in 1965–1966. ECF No. 290-1 ¶ 40; ECF No. 300-1 at 12 ¶ 40. These investigators found: "The reduction of cases of natural mumps (that is, protective efficacy) resulting from the vaccine was 97 per cent if only the laboratory-proved cases are considered. If, however, the later cases that occurred in families and have not yet been diagnosed

[1] 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).

in the laboratory are included, the protective efficacy would be about 95 per cent." *Id.* (citations omitted).

Thereafter, in 1971, Merck obtained a license for its M-M-R ("MMR") vaccine, which combined its mumps, measles, and rubella vaccines into a single trivalent vaccine. ECF No. 290-1 ¶ 32; ECF No. 300-1 at 9 ¶ 32. Then, in 1978, Merck obtained a license for its MMR-II vaccine, which contained the same mumps and measles components as MMR, along with a different rubella vaccine. ECF No. 290-1 ¶ 33; ECF No. 300-1 at 9 ¶ 33. In 2005, Merck obtained a license for ProQuad, a quadrivalent vaccine comprised of the same measles, mumps and rubella vaccines that are in MMR-II, as well as a varicella (chicken pox) vaccine. ECF No. 290-1 ¶ 34; ECF No. 300-1 at 9 ¶ 34. All of Merck's mumps vaccines contain the "Jeryl Lynn" strain of the mumps virus. ECF No. 294-2 ¶ 17; ECF No. 299-1 ¶ 17. Merck discontinued the sale of Mumpsvax in 2009, leaving only MMR-II and ProQuad as the available mumps vaccines on the United States market until 2022. *Id.*

B. Potency on Merck's Mumps Vaccine Label

In 1986, Congress passed the National Childhood Vaccine Injury Act ("NCVIA"). *See* 42 U.S.C. §§ 300aa-1–34. Pursuant to the NCVIA, the FDA engaged in a review of a large number of vaccine labels, one of which was Merck's MMR-II vaccine label. ECF No. 294-2 ¶ 27; ECF No. 299-1 ¶ 27. The FDA began its review of MMR-II in the mid-1990's and, as part of this review, the FDA and Merck engaged in discussions regarding mumps potency on the MMR-II label. ECF No. 292-1 ¶ 130; ECF No. 300-1 at 171–72 ¶ 130; ECF No. 294-2 ¶ 27; ECF No. 299-1 ¶ 27.

1. Release Potency Increase

As the mumps vaccine is a live virus containing live viral cells, the volume of live cells in the vaccine (*i.e.*, potency) is known to decrease over time. ECF No. 292-1 ¶ 52; ECF No. 300-1 at

138 ¶ 52. Potency on the MMR-II label describes the concentration of virus in each dose of vaccine and is reported in units of "tissue culture infection dose" ("$TCID_{50}$"). ECF No. 290-1 ¶¶ 67–68; ECF No. 300-1 at 25 ¶¶ 67–68. At the time of the FDA's review in the late 1990s, the MMR-II label specified that "[e]ach 0.5 mL dose contains not less than . . . 20,000 $TCID_{50}$ of the . . . Mumps Virus." ECF No. 294-2 ¶ 28; ECF No. 299-1 ¶ 28; ECF No. 290-1 ¶ 70; ECF No. 300-1 at 25 ¶ 70. This minimum potency equates to 4.3 on a $\log_{10}$ scale, which is how the FDA and vaccine manufacturers typically describe $TCID_{50}$ potency measurements. ECF No. 294-2 ¶¶ 28–29; ECF No. 299-1 ¶¶ 28–29. In 1996 and 1997, Merck and the FDA engaged in discussions concerning the mumps potency figure on the MMR-II label. ECF No. 292-1 ¶ 130; ECF No. 300-1 at 171–72 ¶ 130. Merck asserts that, at that time, it "understood the MMR-II label to state the minimum 'release potency'—i.e., the amount of live virus in the vaccine when the vaccine is approved for release to the market by" the FDA's Center for Biologics Evaluation and Research ("CBER"). ECF 290-1 ¶ 158; ECF No. 300-1 at 65–66 ¶ 158. The FDA stated that going forward it wanted the labeled potency to reflect the end-expiry potency—*i.e.*, the amount of live virus in the vaccines at the end of its shelf life, which for MMR-II has always been 24 months. ECF 290-1 ¶ 158; ECF No. 300-1 at 65 ¶ 158; ECF No. 294-2 ¶ 28; ECF No. 299-1 ¶ 28. Contemporaneous correspondence between the FDA and Merck substantiates those positions. *See, e.g.*, ECF No. 295-155 at 2 (Feb. 26, 1996 Email stating that Merck historically has provided release specification and that CBER believes the label implies expiry, so CBER would accept a label change to reflect end-expiry); ECF No. 295-195 at 2 (Dec. 5, 1997 Letter from Merck to CBER noting that it "was apparent from [their] meeting that there are different interpretations regarding the 'release' and 'shelf-life' titer for mumps"); ECF No. 295-183 at 7 (Mar. 8, 2001 Warning Letter Response noting

"we historically considered the M-M-R II labeled titers to reflect minimum release specifications").

Thereafter, the FDA and Merck discussed how to address the potency on the MMR-II label. ECF No. 290-1 ¶ 159; ECF No. 300-1 at 66 ¶ 159. On August 20, 1999, the FDA sent a letter to Merck indicating that the minimum release potency of its mumps vaccine must be 5.0 $\log_{10}$ $TCID_{50}$ in order to be 95% confident that the lot would comply with an end-expiry potency of 4.3 $\log_{10}$ $TCID_{50}$, consistent with the FDA's interpretation of the potency statement on the label. ECF No. 290-1 ¶ 160; ECF No. 300-1 at 66–67 ¶ 160; ECF No. 292-1 ¶ 162; ECF No. 300-1 at 193 ¶ 162. In order to ensure the minimum release potency of 5.0 $\log_{10}$ $TCID_{50}$, the FDA instructed Merck to "formulate all mumps-containing vaccine lots manufactured (filled) on and after September 13, 1999, to contain at least 5.2 $\log_{10}$ $TCID_{50}$." ECF No. 292-1 ¶ 162; ECF No. 300-1 at 193 ¶ 162. The FDA also indicated that those "lots will be released by CBER with a dating period of 24 months," and that "regardless of manufacturing date, will be subject to the described CBER release requirement as of November 8, 1999." ECF No. 292-1 ¶ 162; ECF No. 300-1 at 193 ¶ 162. In September of 1999, Merck submitted a Prior Approval Supplement to the FDA to formalize the increase in the release potency to 5.0 $\log_{10}$ $TCID_{50}$, which the FDA approved in February 2000. ECF No. 292-1 ¶¶ 165–166; ECF No. 300-1 at 195 ¶¶ 165–166. Merck has continued to manufacture and use 5.0 $\log_{10}$ $TCID_{50}$ as the minimum potency for release ever since. ECF No. 292-1 ¶ 150; ECF No. 300-1 at 185 ¶ 150.

2. FDA's 2001 Warning Letter

Between August and October 2000, after Merck increased the release potency, a different division of the FDA—that is, a different one from the division that discussed the increase with Merck—inspected Merck's manufacturing division. ECF No. 292-1 ¶ 167; ECF No. 300-1 at 195–

196 ¶ 167; ECF No. 295-146. Following this inspection, the FDA issued a Form 483. ECF No. 292-1 ¶ 167; ECF No. 300-1 at 195–196 ¶ 167. A Form 483 "notifies the company's management of objectionable conditions . . . and encourages the company to respond and, if necessary, correct the cited conditions." ECF No. 290-1 ¶ 242; ECF 300-1 at 103 ¶ 242. The Form 483 issued to Merck cited, among other things, failures to provide Error and Accident Reports related to certain lots of mumps vaccines that had failed stability tests at various intervals. ECF No. 292-1 ¶ 167; 300-1 at 196–197 ¶ 167. The failures cited in the Form 483 related solely to lots of vaccines manufactured prior to the increase in release potency. *Id.*

Merck submitted a response to the Form 483; however, the issues identified in the Form 483 were raised again in a February 9, 2001, Warning Letter issued by the FDA. *Id.* 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). A Warning Letter "identifies the violation" and "makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform FDA of its plans for correction." *Id.*; *see also* ECF No. 292-1 ¶ 167; 300-1 at 196–197 ¶ 167. The February 2001 Warning Letter issued to Merck stated that "investigators reported that the data in your firm'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. 295-146 at 5. The Warning Letter explained that "[p]roduct manufactured before February 2000 may still be on the market because the expiry period is two years." *Id.* 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 February 2000" and "summarize the available data regarding product efficacy at the lower end of this potency range." *Id.* In concluding, the Warning Letter stated that "[f]ederal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts" and 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 preparing its response to the FDA's Warning Letter, Merck internally identified that it had, prior to increasing the release potency, released to market 225 lots of MMR-II with 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 $\log_{10}$.[2] ECF No. 294-63 at 2–5; *see also* ECF No. 294-2 ¶ 36; ECF No. 299-1 ¶ 36. Merck then instituted a "Fact Finding" ("a prelude to a potential product recall") to track down all 107 lots that were potential compliance issues. ECF No. 294-63 at 5; *see also* ECF No. 294-64. 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. *See* ECF No. 294-65 (draft 2001 Warning Letter Response); ECF No. 294-66 (draft 2001 Warning Letter Response); ECF No. 294-69 (Merck's Mar. 8, 2001 Response to Feb. 2001 Warning Letter). Instead, Merck responded to the FDA's Warning Letter by explaining:

[2] 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 $\log_{10}$, Relators point out that the spreadsheet attached to the email identifies 255 and 107 lots, respectively. ECF No. 294-2 ¶ 36; ECF No. 299-1 ¶ 36.

> [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.

ECF No. 294-69 at 7–9. In April 2001, the FDA closed its Warning Letter without requiring any lots to be withdrawn from the market. ECF No. 292-1 ¶ 178; ECF 300-1 at 203 ¶ 178.

3. Protocol 007

Although Merck increased the minimum release potency of the mumps vaccine 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 $\log_{10}$ $TCID_{50}$. ECF No. 290-1 ¶ 162; ECF No. 300-1 at 67 ¶ 162. This study would become Protocol 007, officially titled "A Study of M-M-R II at Mumps Expiry Potency in Healthy Children 12 to 18 Months of Age," the study on which Relators worked during their time at Merck. ECF No. 290-1 ¶¶ 6, 17–18, 164; ECF No. 300-1 at 3–4 ¶ 6, 6 ¶¶ 17–18, 69 ¶ 164. Protocol 007 was designed to study "the effect of vaccination on children who had not yet received the vaccine and who would be randomized to receive vaccine lots at different potencies." ECF No. 290-1 ¶ 165; ECF No. 300-1 at 70–71 ¶ 165.

Two types of tests, or assays, were used in Protocol 007: (1) a plaque reductions neutralization assay ("PRN") and (2) an enzyme linked immunosorbent assay ("ELISA"). ECF No. 290-1 ¶ 170; ECF No. 300-1 at 73 ¶ 170. Both of these laboratory tests are used to measure immunogenicity, which provides information about how a subject's immune system responds to different stimuli, including vaccination. ECF No. 294-2 ¶ 21; ECF No. 299-1 ¶ 21; ECF No. 290-1 ¶ 55; ECF No. 300-1 at 20–21 ¶ 55. The most common immunological response evaluated in vaccine studies is the development of antibodies induced by the vaccine. ECF No. 290-1 ¶ 56; ECF

No. 300-1 at 21 ¶ 56. 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. ECF No. 290-1 ¶ 57; ECF No. 300-1 at 21 ¶ 57.

a) The PRN

A PRN indirectly measures antibodies based on their capacity to neutralize the virus of interest. ECF No. 290-1 ¶ 174; ECF 300-1 at 74 ¶ 174. In a PRN, a blood serum is incubated with the virus and then the mixture is added to a cell monolayer in a clear well. ECF No. 290-1 ¶ 175; ECF No. 300-1 at 74 ¶ 175. If the virus is not neutralized, the virus causes "plaques" (or holes) in the cell monolayer. ECF No. 290-1 ¶ 176; ECF No. 300-1 at 74 ¶ 176. The theory is that if there are more plaques, fewer functional antibodies are present. *Id.*

Merck consulted the FDA in designing the PRN that was used in Protocol 007. ECF No. 290-1 ¶¶ 182–199; ECF No. 300-1 at 77–86 ¶¶ 182–199. In the PRN, pre-vaccinated serum samples were compared to post-vaccinated samples to determine if, as a result of vaccination, the child could be said to have seroconverted. ECF No. 290-1 ¶ 179; ECF No. 300-1 at 75 ¶ 179. The PRN in Protocol 007 was developed to compare a control group, which received MMR-II containing 4.8 $\log_{10}$ $TCID_{50}$ per dose of mumps, with experimental groups, which received MMR-II at lower-potency doses. ECF No. 290-1 ¶ 180; ECF No. 300-1 at 75–76 ¶ 180. CBER set two statistical criteria that the experimental groups had to meet in order to consider the lower potency vaccines acceptable as compared to the existing potency. ECF No. 290-1 ¶ 182; ECF No. 300-1 at 77 ¶ 182. 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 had to be above 90%. *Id.*

Initially, Merck engaged in testing using its mumps virus strain (*i.e.*, the Jeryl Lynn strain) and other "wild-type" virus strains, meaning those naturally occurring. ECF No. 292-2 ¶ 60; ECF No. 299-1 ¶ 60; ECF No. 290-1 ¶¶ 185–186; ECF No. 300-1 at 78–79 ¶¶ 185–186. However, initial testing of the wild-type virus resulted in seroconversion rates well below 95%, so Merck used the Jeryl Lynn strain which yielded seroconversion above 90%. ECF No. 294-2 ¶¶ 60, 62; ECF No. 299-1 ¶¶ 60, 62; ECF No. 290-1 ¶¶ 187–191; ECF No. 300-1 at 79–80 ¶¶ 187–191. Additionally, Merck included rabbit antibodies, specifically anti-human Immunoglobin G ("anti-IgG") in the serum samples. ECF No. 290-1 ¶¶ 192–195; ECF No. 300-1 at 82–84 ¶¶ 192–195; ECF 294-2 ¶ 62; ECF No. 299-1 ¶ 62. This anti-IgG PRN was referred to as the Anti-IgG Enhanced Neutralization Test ("AIGENT"). ECF 294-2 ¶ 62; ECF No. 299-1 ¶ 62.

After the design of the PRN was finalized, Merck performed the AIGENT in a research lab supervised by Dr. David Krah. ECF No. 290-1 ¶ 171; ECF No. 300-1 at 74 ¶ 171. Relators Krahling and Wlochowski worked in this lab. ECF No. 294-2 ¶ 97; ECF No. 299-1 ¶ 97. In their positions, Relators, among other things, counted the plaques in the pre- and post-vaccination samples. *Id.*

In June and July of 2001, Relator Krahling had "four or five teleconferences calls or telephone meetings" with the FDA where he raised allegations of misconduct in Dr. Krah's lab. ECF No. 290-1 ¶¶ 222–223; ECF No. 300-1 at 97 ¶¶ 222–223. Specifically, Krahling alleged that "the lab was committing fraud," "data was being destroyed," and the lab was "instituting a policy to fraudulently lower the pre-positive rate" in the PRN (*i.e.*, lowering the rate at which unvaccinated blood samples were classified as seropositive to make it easier to then say they

seroconverted after vaccination). ECF No. 290-1 ¶¶ 222–226; ECF No. 300-1 at 97–98 ¶¶ 222–226.

After hearing these allegations, FDA investigators conducted an on-site inspection of the Merck laboratory performing the PRN assay under Dr. Krah's supervision on August 6, 2001. ECF No. 290-1 ¶ 228; ECF No. 300-1 at 99 ¶ 228. The purpose of the inspection, which lasted nearly eight hours, was to "assure that the raw data" from the PRN "was accurate and reliable." ECF No. 290-1 ¶¶ 229–230; ECF No. 300-1 at 99 ¶ 229–230. At the conclusion of the inspection, the FDA issued Merck a Form 483. ECF No. 290-1 ¶ 241; ECF No. 300-1 at 103 ¶ 241. In this August 6, 2001 Form 483, the FDA listed four observations: (1) raw data was being changed with no justifications; (2) there was no procedure to assess whether a research lab is suitable for clinical testing prior to the start of testing; (3) spreadsheets used to determine questionable results and retesting had not be validated; and (4) notebooks did not identify each technician performing each task. ECF No. 295-10; ECF No 290-1 ¶ 243; ECF No. 300-1 at 103 ¶ 243.

One of the investigators that performed the initial FDA August 6, 2001 investigation of Dr. Krah's lab returned to the lab on August 10 and September 14 to collect more information. ECF No. 290-1 ¶¶ 244, 247; ECF No. 300-1 at 103–104 ¶ 244, 247. Merck cooperated in this investigation by providing documentation in response to FDA requests and participating in telephone conferences. ECF No. 290-1 ¶¶ 248–256; ECF No. 300-1 at 104–109 ¶¶ 248–256. In Merck's formal written response to the Form 483, Merck indicated, among other things, that it had retrained all personnel involved in Protocol 007 on proper documentation practices, reviewed the historical changes to the assay data and conducted a reanalysis of the data set, and was retraining all staff who performed testing of samples from vaccine clinical trials. ECF No. 295-10 at 13–15. Merck's response also stated that the reanalysis of the data set revealed "no evidence of a

difference between the corrected and uncorrected data sets with respect to seroconversion." *Id.* at 13. In addition to formally responding with this information, Merck had further written and telephone conversations with the FDA to address the FDA's concerns regarding the PRN. ECF No. 290-1 ¶ 256; ECF No. 300-1 at 109 ¶ 256. The FDA, however, rejected the corrected data, electing instead to accept Merck's proposal to use the originally recorded results from the PRN to support its potential label change. ECF No. 290-1 ¶¶ 260–261; ECF No. 300-1 at 110–111 ¶¶ 260–261.

b) The ELISA

The second test conducted as part of Protocol 007 was an ELISA assay. ECF No. 290-1 ¶ 170; ECF No. 300-1 at 73–74 ¶ 170. This test ran in parallel to the PRN assay and was conducted in a separate lab. *Id.* In an ELISA, serum samples are added to plastic microtiter wells coated with antigens—which are structures that bond to particular antibodies. ECF No. 290-1 ¶ 201; ECF No. 300-1 at 87–88 ¶ 201. 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 in order to determine whether there has been a sufficient color change to identify a positive result. *Id.*

4. Merck's MMR-II Potency sBLA

Based on the immunogenicity data produced in the Protocol 007 study, Merck submitted a supplemental Biologics License Application ("sBLA") to the FDA in January 2004 requesting a change in the label's potency figure from 4.3 $\log_{10}$ $TCID_{50}$ per dose to 4.1 $\log_{10}$ $TCID_{50}$ per dose. ECF No. 290-1 ¶ 263; ECF No. 300-1 at 113 ¶ 263. After CBER and Merck engaged in several rounds of comments and responses regarding this sBLA, in May 2007, CBER definitively notified Merck that it would not approve the sBLA. ECF No. 290-1 ¶ 264; ECF No. 300-1 at 113–14 ¶

264. CBER found that "the information and data submitted are inadequate for final approval at this time" and noted it could not "accept use of multiple imputation analyses of the PRN data to support the lowering of mumps vaccine end-expiry potency." ECF No. 295-128. 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 differences in product potency on immunogenicity is now acceptable." *Id.* Accordingly, CBER indicated Merck could amend its Supplement and provide support for the Supplement with a new analysis pooling the control group for the Protocol 007 ELISA with control groups from previous studies in order to create a new control group against which to evaluate the lower-potency immunogenicity. ECF No. 290-1 ¶ 264; ECF No. 300-1 at 113–114 ¶ 264; ECF No. 295-128.

In the summer of 2007, Merck submitted an amendment responding to CBER's requests. ECF No. 290-1 ¶ 266; ECF No. 300-1 at 115–116 ¶ 266. Specifically, the amendment provided an analysis pooling the control group for the Protocol 007 ELISA and ELISA data from previous Merck studies and concluded that the lower potency of 4.1 $\log_{10}$ $TCID_{50}$ lot was comparably immunogenic to the control group. *Id.*; *see also* ECF No. 294-212. In December 2007, CBER approved Merck's sBLA to change the labeled potency from 4.3 to 4.1 $\log_{10}$ $TCID_{50}$. ECF No. 290-1 ¶ 267; ECF No. 300-1 at 116 ¶ 267; ECF No. 295-127. Although this label change was approved, Merck has never reduced its minimum release potency from the 5.0 $\log_{10}$ $TCID_{50}$ it began using in 1999. ECF No. 290-1 ¶ 268; ECF No. 300-1 at 116 ¶ 268.

5. Merck's MMR-II with rHA sBLA

Merck submitted an additional sBLA for MMR-II in June 2004. ECF No. 294-2 ¶¶ 168, 171; ECF No. 299-1 ¶¶ 168, 171. This sBLA was submitted to switch making MMR-II with pooled human derived serum albumin ("HSA") to making it with recombinant human albumin ("rHA").

ECF No. 294-2 ¶ 168; ECF No. 299-1 ¶ 168. Merck supported this sBLA with an ELISA study comparing the seroconversion rates of the HSA-containing and rHA-containing vaccines. ECF No. 294-2 ¶ 172; ECF No. 299-1 ¶ 172. The FDA approved Merck's sBLA for MMR-II with rHA in August 2005. ECF No. 294-2 ¶ 174; ECF No. 299-1 ¶ 174.

6. Merck's ProQuad BLA

In August 2004, Merck submitted its ProQuad Biologic License Application ("BLA"). ECF No. 294-2 ¶ 158; ECF No. 299-1 ¶ 158. In evaluating the ProQuad BLA, CBER requested information about the degree of agreement between the PRN and ELISA assay from Protocol 007 because it would be helpful in providing information on the clinical relevance of the chosen ELISA cutoff for seropositivity (*i.e.*, the value distinguishing seronegative from seropositive). ECF No. 290-1 ¶ 271; ECF No. 300-1 at 117 ¶ 271; *see also* ECF No. 295-179. Ultimately, on the basis of Merck's submissions, CBER concluded that Merck had demonstrated "good correlation" between the mumps PRN assay and the ELISA and that Merck's "studies indicated that the ELISAs used to assess antibody response to each of the vaccine antigens in ProQuad would parallel responses that correlated with protection in other studies." ECF No. 290-1 ¶ 273; ECF 300-1 at 119 ¶ 273. In September 2005, the FDA approved Merck's ProQuad BLA. ECF No. 290-1 ¶ 275; ECF No. 300-1 at 120 ¶ 275.

C. CDC's Purchasing of Mumps Vaccines

The Government purchases Merck's mumps vaccines primarily through the Vaccines for Children ("VFC") entitlement program administered by CDC, which helps provide vaccines to children whose parents or guardians may not be able to afford them. ECF 290-1 ¶¶ 72–74; ECF No. 300-1 at 26 ¶¶ 72–74. In order to protect and preserve its scientific independence and judgment, the FDA does not involve itself in the CDC's vaccine purchase decisions. ECF No. 294-

2 ¶ 9; ECF No. 299-1 ¶ 9. The CDC's Advisory Committee on Immunization Practice ("ACIP") provides recommendations that guide the CDC on its vaccine purchase decisions. ECF No. 294-2 ¶¶ 9–10; ECF No. 299-1 ¶¶ 9–10. The ACIP's decision to include an FDA-licensed vaccine in the VFC program is made after a detailed assessment of the "burden of the disease, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed, economic analyses and implementation issues." ECF No. 290-1 ¶ 78; ECF No. 300-1 at 28 ¶ 78. In 1977, the ACIP recommended one dose of mumps vaccine for all children twelve months or older. ECF No. 295-49 at 2. In 1989, following measles outbreaks in the late 1980s, the ACIP recommended routine administration of two doses of MMR for children, with the first dose administered at ages twelve through fifteen months and the second at ages four through six years. *Id.* In 2006, in response to mumps outbreaks primarily affecting populations with high coverage of two doses of MMR in midwestern states and colleges, the ACIP formally recommended a routine two-dose mumps vaccination policy for school-aged children and adults at high risk. *Id.* In 2017, the ACIP recommended a third dose of a mumps-containing vaccine for those persons previously vaccinated with two doses "who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak." *Id.* In making this recommendation, the ACIP stated in its Summary of Key Findings that the "median effectiveness of [two] doses of MMR vaccine in preventing mumps is 88%, with estimates ranging from 31% to 95%." *Id.* at 3.

The CDC also routinely evaluates "vaccine effectiveness for both old and new products." ECF No. 290-1 ¶ 81; ECF 300-1 at 29 ¶ 81. The CDC has conducted multiple mumps effectiveness studies. ECF No. 290-1 ¶ 84; ECF No. 300-1 at 32 ¶ 84. The CDC has noted that while the original clinical studies conducted prior to Merck's mumps vaccine licensure found a single dose of mumps

vaccine to be approximately 95% effective in preventing the disease, vaccine effectiveness estimates have been lower in post-licensure studies. ECF No. 290-1 ¶ 85; ECF No. 300-1 at 32 ¶ 85. For example, in 1998, the CDC observed that while controlled clinical trials found one dose of the vaccine to be approximately 95% efficacious in preventing mumps diseases, the effectiveness of the vaccine observed in field studies was lower, ranging from 75% to 95%. ECF No. 290-1 ¶ 86; ECF No. 300-1 at 32 ¶ 86. The CDC has reaffirmed its finding that the effectiveness of the vaccine in real-world application is lower than the efficacy found in the original clinical trials. ECF No. 290-1 ¶¶ 84, 85, 87, 88; ECF No. 300-1 at 32–33 ¶¶ 84, 85, 87, 88. Nonetheless, the CDC recommends that two doses of the mumps vaccine are 88% effective (range 31%–95%) against mumps. ECF No. 290-1 ¶ 145; ECF No. 300-1 at 61 ¶ 145.

Merck and the CDC negotiate contracts for the purchase of mumps vaccines annually, with the contracts lasting for one-year terms. ECF No. 290-1 ¶ 90; ECF No. 300-1 at 33 ¶ 90. For the CDC to consider a vaccine, it must be recommended by the ACIP, compliant with all applicable current Good Manufacturing Practices ("cGMP"), and have a valid FDA license. ECF No. 294-2 ¶¶ 244–245, 247; ECF No. 299-1 ¶¶ 244–245, 247. Additionally, Merck's contracts with the CDC for MMR-II from 1998 to 2016 have contained a requirement for a 12-month shelf life remaining upon delivery to the consignee, and Merck's 2006 contract for ProQuad required a minimum shelf life of 8 months remaining upon delivery to the consignee. ECF No. 290-1 ¶¶ 85–87; ECF No. 300-1 at 155–156 ¶¶ 85–87. The CDC also requires Merck to submit invoices, which include information such as: Merck's name and invoice date, contract number, a description, cost and quantity of the goods delivered, shipping and payment terms, name and contact information for person to whom payment is to be sent, lot number of vaccine vials shipped, and expiration date of vaccines vials shipped. ECF No. 290-1 ¶ 91; ECF No. 300-1 at 157 ¶ 91.

Since Relators filed this case more than a decade ago, the CDC has continued to purchase Merck's mumps-containing vaccines pursuant to annual VFC contracts with Merck. ECF No. 290-1 ¶¶ 149–151; ECF No. 300-1 at 62–63 ¶¶ 149–151.

D. GSK's Mumps Vaccine

In June 2022, the FDA approved GSK's mumps vaccine, Priorix. *See* FDA, June 3, 2022 Approval Letter – PRIORIX, https://www.fda.gov/media/158962/download (last visited July 25, 2023). In GSK's clinical trials to support its mumps vaccine, the FDA allowed GSK to use the same ELISA assay used by Merck for its MMR-II potency sBLA and ProQuad BLA. ECF No. 290-1 ¶ 262; ECF No. 300-1 at 111 ¶ 262. After the FDA approved GSK's mumps vaccine, the ACIP recommended Priorix because it found "[b]oth PRIORIX and M-M-R II are fully interchangeable for all indications for which MMR vaccination is recommended." ECF No. 340 (quoting Elisabeth Krow-Lucal, Mona Marin, Leah Shepersky, Lynn Bahta, Jamie Loehr & Kathleen Dooling, *Measles, Mumps, Rubella Vaccine (PRIORIX): Recommendations of the Advisory Committee on Immunization Practices — United States*, 71 Morbidity & Mortality Weekly Report, no. 46, Nov. 28, 2022 at 1465, https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7146a1-H.pdf.). The ACIP's view is that "[t]wo interchangeable vaccines from different manufacturers will help safeguard vaccine supply in the United States to maintain measles and rubella elimination and mitigate mumps cases and outbreaks." *Id.*; *see also* ECF No. 294-2 ¶ 234. Accordingly, in the United States today, there are two manufacturers of mumps vaccines (GSK and Merck), and the CDC purchases mumps vaccines from both manufacturers.

II. PROCEDURAL HISTORY

Relators filed this *qui tam*[3] suit under seal on August 27, 2010. ECF No. 20. As with all *qui tam* actions under the FCA, the United States Department of Justice ("DOJ") was given time to conduct an investigation to determine whether the United States would intervene. On April 27, 2012, the Government declined to intervene in this action. ECF No. 14. On that same day, Relators filed an Amended Complaint, which was unsealed on June 21, 2012. ECF No. 12. The crux of Relators' allegations in the Amended Complaint are that Merck "fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine." *United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 586 (E.D. Pa. 2014). Specifically, Relators allege that Merck "deliberately obfuscated information about the vaccine's lessening efficacy" and withheld "information about the alleged lessened efficacy of the vaccine." *Id.* at 591, 594. On August 31, 2012, Defendant moved to dismiss Relators' Amended Complaint. ECF No. 45. The Court denied Defendant's Motion to Dismiss on September 4, 2014. ECF No. 60.

Years of discovery followed until October 25, 2019, when both parties filed motions for summary judgment. ECF Nos. 281, 283, 285, 287, 294. Relators filed one motion for summary judgment (ECF No. 294) and Merck filed the following four motions for summary judgment: (1) Defendant Merck's First Dispositive Motion for Summary Judgment on Relators' Claims Based on An Efficacy-Based Theory of Falsity (ECF No. 281); (2) Defendant Merck's Second

[3] "*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur,* which means 'who pursues this action on our Lord the King's behalf as well as his own.'" *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 n.1 (2000). Under the FCA, "a private person (the relator) may bring a *qui tam* civil action 'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.'" *Id.* at 769 (quoting 31 U.S.C. § 3730(b)(1)).

Dispositive Motion for Summary Judgment Against Relator Krahling (ECF No. 283); (3) Defendant Merck's Third Dispositive Motion for Summary Judgment on the Time-Barred Claims and Damages (ECF No. 285); and (4) Defendant Merck's Fourth Dispositive Motion: to Strike or, in the Alternative, for Summary Judgment on, the Unpled Kessler Theory (ECF No. 287). All five of the pending summary judgment motions were fully briefed. *See* ECF Nos. 299, 300, 300-3, 300-7 (Oppositions), 309, 311, 312, 313, 314 (Replies). The DOJ also filed a statement of interest addressing the materiality standard under the FCA (ECF No. 319), to which the parties responded (ECF Nos. 323, 325, 328).

On December 2, 2022, this case was reassigned from the Honorable C. Darnell Jones, II to the Honorable Chad F. Kenney. ECF No. 332. This Court held oral argument on the five pending motions for summary judgment on January 24, 2023. ECF No. 335. Following oral argument, on January 31, 2023, Merck filed a post-hearing submission (ECF No. 340) to which Relators responded on February 7, 2023 (ECF No. 343), to which Merck replied on February 14, 2023 (ECF No. 347).

III. LEGAL STANDARD

A district court "shall grant summary judgment if the movant shows that there is no genuine issue 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. 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 (1986). 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. Township of Lacey*, 772 F.2d 1103, 1109–10 (3d Cir. 1985).

When determining the existence of a genuine issues of material fact, the 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).

IV. DISCUSSION

"The primary purpose of the FCA is to indemnify the government—through its restitutionary penalty provisions—against losses caused by a defendant's fraud." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304 (3d Cir. 2011) (internal quotations and citations omitted). Pursuant to the FCA, individuals, known as relators, can "bring enforcement actions, known as *qui tam* actions, on behalf of the United States to recover funds which were fraudulently obtained, and to share in any resulting damages award." *United States ex rel. Dhillon v. Endo Pharms.*, 617 F. App'x 208, 211 (3d Cir. 2015) (citing 31 U.S.C. § 3729, *et seq*.). The FCA prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" or "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). To establish an FCA violation, four elements must be proven: "falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citations omitted).

Relators argue that they have proven all four elements, while Merck argues Relators have shown none of the elements.[4] *See* ECF Nos. 290, 292, 294-1. There is significant overlap in the arguments made in the motions, the accompanying oppositions, and the replies. Accordingly, the Court will address the motions together in the following fashion. First, the Court will briefly mention the false claims Relators argue they have shown before moving to the materiality element. As detailed below, because the Court finds that the Relators have failed to establish a triable fact regarding the materiality of the alleged false claims, the Court concludes that no reasonable jury could return a verdict for Relators and will grant summary judgment in favor of Merck.

A. False Claims

The first element of an FCA violation is a false claim. "There are two categories of false claims under the FCA: a factually false claim and a legally false claim." *Wilkins*, 659 F.3d at 305 (citation omitted). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* Legal falsity can take two forms: express false certification and implied false certification. *United States ex rel. Whatley v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016). Under an express false certification theory, a defendant "is liable under the FCA for falsely certifying that it is in compliance with a material statute, regulation, or contractual provision." *Id.* (internal quotations and citation omitted). Under an implied false certification theory, a defendant is liable for "mak[ing] specific representations about the goods or

[4] Merck has also moved for summary judgment: (1) on the claims brought by Relator Krahling on the grounds that Krahling signed an enforceable release of claims (ECF No. 283); and (2) on time-barred claims and damages (ECF No. 285). The Court declines to address these arguments as it is granting summary judgment for Merck on the basis that Relators have failed to establish materiality.

services provided" where the defendant's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016)) (internal quotations omitted). Finally, "[a]lthough the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *United States ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014) (citations omitted).

Relators' Motion for Summary Judgment argues that Relators have shown that Merck's claims to the CDC are factually false, legally false by implied certification, and that they are false under a fraudulent inducement theory.[5] ECF 294-1 at 49–53; ECF No. 309 at 26–38. First, as to their factually false theory, Relators allege that this is a case where there was both an incorrect description of goods and goods never provided, and more specifically that: (a) there was factual falsity with respect to potency and shelf-life; and (b) there was factual falsity with respect to mumps protection and licensure. ECF No. 309 at 26–33. As to the former, Relators argue that at least from 2000 through 2007, Merck sold the CDC "tens of millions of" MMR-II doses that did not meet the minimum level of potency required by the label throughout the doses' shelf life. Relators maintain that as a result, Merck violated the 12-month shelf life (upon delivery) contract requirement, cGMP contract requirements (including assuring minimum potency), and multiple duties to ensure its vaccines are effective and comply with the product specifications on the label. ECF No. 294-1 at 43–44. As to Relators' factual falsity claim regarding reported protection as a

[5] Relators have expressly disclaimed a "Fraud-on-the-FDA" theory of falsity. *See* ECF No. 309 at 37–38; *see also* ECF No. 337, Jan. 24, 2023 Hr'g Tr. 11:18–25.

basis for licensure, Relators argue that various MMR-II and ProQuad label statements concerning mumps protection and supporting clinical studies all derive from fifty-year-old studies with no connection to the AIGENT or ELISA testing that Merck actually used to support the vaccines it currently sells. ECF No. 309 at 29–30.

Second, in support of their legal falsity theory, Relators argue that Merck's claims to the CDC are legally false by implied certification because the product representations included in claims to the CDC for payment for MMR-II and ProQuad represent to accurately convey central features of the product, and therefore, were misleading half-truths because Merck provided them "'while omitting critical qualifying information' relating to the vaccines' potency, shelf life, protection and licensing failures and Merck's numerous efforts to conceal them." ECF 294-1 at 51 (citation omitted).

Lastly, in support of their fraudulent inducement theory, Relators argue Merck induced the CDC to enter contracts through various misrepresentations and omissions regarding: (1) mumps potency and shelf life; and (2) mumps protection and the basis for product licensure, which are both critical to the CDC's contracting decisions. ECF No. 294-1 at 51-53; ECF No. 309 at 37.

Merck argues Relators are unable to satisfy any false claim theory. ECF No. 290 at 32–38; ECF No. 292 at 36–40. But even assuming *arguendo* that Relators satisfy one of these categories of false claims, Merck is still entitled to summary judgment because, as explained below, Relators cannot show that any of these so-called false claims were material to the CDC's purchasing decisions.

B. Materiality

Under the FCA, a false claim is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

Materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 579 U.S. at 193 (internal quotations and citation omitted). The Supreme Court has emphasized that "[t]he materiality standard is demanding" and that strict enforcement is necessary to prevent the statute from becoming "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 194. The Supreme Court has also explicitly rejected the "assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." *Id.* at 195 n.6.

The materiality inquiry is a "holistic, totality-of-the circumstances examination." *United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315, 342 (3d Cir. 2021). In *Escobar*, the Supreme Court identified the following nonexclusive factors that are relevant to the materiality inquiry: (1) whether compliance with a particular requirement is expressly identified as a "condition of payment"; (2) whether the violation is substantial and goes to "the essence of the bargain" or is "minor [and] insubstantial"; and (3) whether the government pays or declines to pay a "particular claim" or "particular type of claim" when it has "actual knowledge that certain requirements were violated." *Escobar*, 579 U.S. at 194–95; *see also United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, 500 F. Supp. 3d 345, 361 (E.D. Pa. 2020) (summarizing materiality factors discussed in *Escobar*). As these factors are nonexclusive, other indications of materiality may be considered.

Additionally, "courts need not opine in the abstract when the record offers insight into the Government's actual payment decisions." *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1032 (D.C. Cir. 2017) (citing *Escobar*, 579 U.S. at 193). Here, the extensive record offers substantial insight into the Government's actual payment decisions. Accordingly, in the following analysis of the *Escobar* factors, the Court does not need to opine in the abstract.

1. Condition of Payment

One factor identified by the Supreme Court as relevant to the materiality analysis is "[t]he Government's decision to expressly identify a provision as a condition of payment." *Escobar*, 579 U.S. 194. The Supreme Court has indicated that whether the Government has expressly identified "a provision as a condition of payment is relevant, but not automatically dispositive" to the materiality analysis. *Id.*; *see also id.* ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment."). While the parties dispute whether efficacy is a procurement criterion in the CDC's contracts with Merck, both parties agree that the CDC considers vaccine effectiveness to be the most important factor when evaluating the impact a vaccine has on disease in the population. *See* ECF No. 299 at 37; ECF No. 309 at 42. In that regard, the undisputed evidence shows that the CDC conducts its own effectiveness studies and has acknowledged that the effectiveness measured in field studies has been lower than the effectiveness reported in the clinical studies that supported licensure of Merck's mumps vaccine. *See supra* Section I.C. Nonetheless, the CDC has continued to recommend that two doses of the mumps vaccine are 88% effective (range 31%–95%) against mumps. *See id.* Thus, Merck did not violate a condition of payment relating to vaccine effectiveness.

Relators also argue that "Merck's potency, shelf-life, protection, licensing and labeling violations implicate multiple contractual and regulatory obligations, including: (i) cGMP compliance, which require adequate assurances of sufficient potency; (ii) 12 months of shelf life remaining upon delivery; (iii) compliance with a valid license; (iv) ACIP recommendation; and (v) fit for purpose and merchantability." ECF No. 309 at 42. However, just because "the Government or a federal agency found a particular issue important enough to regulate speaks little

to the intended consequence of noncompliance." *United States ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, No. 11-cv-4607, 2017 WL 1133956, at *7 (E.D. Pa. Mar. 27, 2017). Accordingly, the Court finds this factor does not weigh in favor of a finding of materiality.

2. Essence of the Bargain

The next non-exclusive factor identified by the Supreme Court in *Escobar* is whether the "non-compliance is minor or insubstantial" or "the extent to which the requirement that was violated is central to, or goes to the very essence of, the bargain." *Escobar*, 579 U.S. at 194 (citation omitted); *see also id.* at 193 n.5; *United States ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1347–48 (11th Cir. 2021) (internal quotations and citations omitted) (cleaned up). Relators argue that "[t]he CDC has made it very clear—*in this lawsuit*—that Merck's misrepresentations and omissions at issue here go to the very essence of the CDC's vaccine purchase decision and its ultimate mission of controlling disease through safe and effective vaccines." ECF 294-1 at 57. However, as this Court has mentioned, the CDC considers vaccine effectiveness the most important factor when evaluating a vaccine. *See* ECF No. 299 at 37; ECF No. 309 at 42. And the CDC, despite this suit having been litigated for over ten years at this point, has continually recommended Merck's mumps vaccine and has continually asserted that two doses of the vaccine are 88% (range: 31%–95%) effective. *See supra* Section I.C. Furthermore, there is no evidence to show that either the one internal model of potency loss or the results of Protocol 007 went to the essence of the bargain. Accordingly, this factor gives further weight to the conclusion that no jury could rule in Relators' favor on materiality.

3. Government (In)action

The Government's reaction to a defendant's violation is an important factor in the materiality inquiry. *See Bibby*, 987 F.3d at 1347–48 (citing *Escobar*, 579 U.S. at 194–95). "[P]roof

of materiality can include, but is necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 194–95. "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 195. Further, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* Courts have recognized that even where the Government has actual knowledge of noncompliance, there may be other good reasons for the Government to continue paying these claims. *See, e.g.*, *United States v. Aegerion Pharms., Inc.*, No. 13-CV-11785-IT, 2019 WL 1437914, at *7 (D. Mass. Mar. 31, 2019).

At the outset it is important to note that this case is not at the motion-to-dismiss stage with an undeveloped record. *See, e.g.*, *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 542 n.13 (10th Cir. 2020) ("It is not inconsistent to state that knowledge of allegations is insufficient, alone, to warrant dismissal under Rule 12(b)(6) and yet constitutes some evidence of immateriality under Rule 56(a)"). Therefore, this Court "need not opine in the abstract [as] the record offers insight into the Government's actual payment decisions." *McBride*, 848 F.3d at 1032. Here, the Court has "the benefit of hindsight" and it "should not ignore what actually occurred." *Id.* at 1034.

What did occur is as follows. In 2001, the FDA issued a Warning Letter addressing the potency issues raised by the Relators in this case. *See supra* Section I.B.2. The Warning Letter noted that "[f]ederal agencies are advised of the issuance of all Warning Letters about drugs and

devices so that they may take this information into account when considering the award of contracts." ECF No. 295-146 at 5. This Warning Letter was closed in April 2001. *See supra* Section I.B.2. Then, in 2001, Relator Krahling brought his allegations to the FDA regarding issues with Merck's Protocol 007. *See supra* Section I.B.3. In response to Krahling's allegations, the FDA thoroughly investigated. *See id*.

Moreover, in 2010 when this Complaint was filed, the Government investigated Relators' allegations prior to declining to intervene. *But see Int'l Bhd. of Elec. Workers Loc. Union No.*, 5 F.4th at 346 ("But intervention decisions are, at best, of minimal relevance."). Since then, the Government—including the FDA and CDC—has been involved in the years of discovery and has had access to the evidence. Particularly notable is that upon Relators' request, the Court authorized Relators' expert and former FDA Commissioner Dr. David Kessler to submit his "opinions and conclusions to the appropriate officials at the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and the Center for Disease Control and Prevention (CDC) so that those officials can determine what response, if any, is appropriate to address any potential public health issue." ECF No. 250 ¶ 2. In authorizing this, the Court explained: "Such disclosure will permit the appropriate public health officials to assess, in the first instance, whether a public health issue exists, and to adopt measures, if any, in response to any such issue." ECF No. 250 at 2 n.2.

In October 2019, Dr. Kessler's submissions with detailed analyses of Merck's supposed lack of transparency and Dr. Kessler's potency and efficacy concerns about Merck's mumps vaccine based on his review of the discovery record in this case, along with Merck's responses to Dr. Kessler's submissions, were provided to the Commissioner of the FDA, the Director of the CDC, the Secretary of the HHS, along with other high-ranking public health officials at those

agencies. ECF No. 295-211. Nonetheless, the CDC has continued to pay for Merck's mumps vaccines and to recommend that two doses of MMR are 88% effective (range 31%--95%). Similarly, the FDA has not taken any action in response to this lawsuit or Dr. Kessler's submissions. Because these agencies are under a duty to review the information before them, the lack of response by both the FDA and CDC strongly indicate that Relators' allegations are not material. *Advanced Disposal Servs. E., Inc, v. N.L.R.B.*, 820 F.3d 592, 604 (3d Cir. 2016) (noting it is plaintiff's burden "to show that the [agency] did not review the record" in administrative proceedings); 21 U.S.C. § 355(o)(4)(A) (requiring the FDA to promptly notify the responsible person if it "becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the [FDA] determines should be included in the labeling of the drug"); *see also Petratos*, 855 F.3d at 490 (affirming dismissal of FCA suit on materiality grounds).

In response to this strong evidence, Relators point to the CDC's statement in authorizing the depositions of its current and former employees as indicating that the CDC has a "clear interest in the outcome" of the case and to the United States having "on numerous occasions . . . injected itself into this case." ECF No. 294-1 at 60; Jan. 24, 2023 Hr'g Tr. 36:13–15, 36:18–19. However, the fact that the CDC and the DOJ have shown an interest in this case demonstrates that these Government agencies are appropriately discharging their duties. The CDC's so called "clear interest" during the discovery period illustrates that it takes appropriate steps in response to serious allegations that a vaccine is not effective. But now that all the allegations as to Merck's misconduct have been directly submitted to the CDC, the CDC's lack of response is strong evidence of lack of materiality.

Similarly, the DOJ's injection into the case has been limited and the DOJ has specified that it "takes no view on the sufficiency of the evidence in this case." Jan. 24, 2023 Hr'g Tr. 47:8–11; *see also* ECF No. 54 (United States' Statement of Interest Addressing Merck's Motion to Dismiss); ECF No. 319 (United States' Statement of Interest in Response to the Parties' Summary Judgment Briefing). Rather, as represented by the DOJ at oral argument, the DOJ wished to indicate its view on the interpretation of the FCA and more specifically, the materiality element. Jan. 24, 2023 Hr'g Tr. 47:8–11. The FCA is an important Government tool in preventing fraud, as evidenced by the fact that in 2022 FCA settlements and judgments exceeded $2.2 billion. *See* DOJ, Feb. 7, 2023 Press Release, False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022, available at: https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 (last visited July 25, 2023). Therefore, the DOJ's advocacy in the legal interpretation of the FCA is no surprise. While Relators argue that the DOJ has repeatedly "injected themselves into this case" and that this shows materiality, the DOJ's involvement could indicate simply the DOJ's continuing advocacy in the interpretation of a statute which generates significant recovery for the Government.

Turning specifically to the DOJ's arguments concerning materiality, the DOJ argued in its materiality submission and at oral argument that the Government does not have actual knowledge of the facts; rather, it knows about the *allegations* made by Relators but has no *actual knowledge* and, thus, the Government's response or lack thereof to Merck's alleged violation has no bearing on the materiality analysis. Jan. 24, 2023 Hr'g Tr. 48:8–18 (emphasis added). The DOJ stated that, after it declined to intervene, Relators filed an Amended Complaint containing new allegations, and when the case proceeded into years and years of discovery, "[t]he Government was aware of some of what was happening"; "[t]he Government participated in some of what was happening";

"[b]ut the Government did not take this case on . . . [it] did not digest every bit of evidence[;] [w]e watched as the case progressed." *Id.* at 50:15–51:1. Relators echoed this argument in their briefings and at oral argument. *See, e.g.*, ECF No. 300 at 63–69; Jan. 24, 2023 Hr'g Tr. 68:1–69:9.

In support of this argument, the DOJ's and Relators' briefings contain many out-of-circuit and thus non-controlling cases. Additionally, many of the cases that the DOJ and Relators cite to in support of this argument were at the motion-to-dismiss stage. *See, e.g.*, *United States v. Rahimi v. Rite Aid Corp.*, No. 2:11-cv-11940, 2019 WL 1426333, at *7–9 (E.D. Mich. Mar. 30, 2019) (denying defendant's motion to dismiss FCA case, noting that defendant conflated "actual knowledge that certain requirements were violated" with "actual knowledge of allegations that certain requirements were violated" and that defendant must concede it did violate the requirements and the government possessed actual knowledge of its violations to succeed on such an argument); *United States ex. rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831–37 (6th Cir. 2018) (reversing district court's dismissal of case finding materiality sufficiently pled and noting "[w]ithout actual knowledge of the alleged non-compliance, the government's response to the claims submitted by the defendants . . . has no bearing on the materiality analysis"); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (reversing district court's dismissal noting "mere awareness of allegations concerning noncompliance is different from knowledge of actual noncompliance" and that "it may be the case that MassHealth continued to pay claims to UHS despite becoming aware that they were not in compliance with the patient regulations, and this information may come to light during discovery"); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 904–06 (9th Cir. 2017) (reversing district court's dismissal of case, but noting "[i]t is undisputed that at all times relevant, the drugs at issue were FDA-approved, and that the government continues to make direct

payments and provide reimbursements for the sale of the [drugs]" and consequently "[r]elators face an uphill battle in alleging materiality sufficient to maintain their claim").

But the argument that the Government merely has knowledge only of allegations and not actual knowledge of the facts is belied by the extensive record in the case. The reality is that the Government does have knowledge of all of the facts, but these facts were simply not persuasive to the CDC, or any other agencies, to prompt them to take any action. The CDC has "regularly" paid for Merck's mumps vaccines and "has signaled no change in position, [which is] strong evidence that the requirements are not material." *Escobar*, 579 U.S. at 195; *see also Lawrence Mem'l Hosp.*, 949 F.3d at 542 n.13 (affirming summary judgment on materiality grounds and noting "in *Escobar* the allegations only noted that the Government continued to pay claims up to the filing of litigation. Here CMS has continued to pay claims—and has requested no changes in [defendant's] data reporting or Emergency Room practices—for years despite ongoing litigation").

Particularly instructive to the Court's analysis here is the Third Circuit's decision in *United States ex rel. Petratos v. Genentech Inc.*, wherein the Third Circuit affirmed dismissal of a relator's complaint alleging a drug manufacturer concealed health risk information about a drug and engaged in a "campaign of misinformation." 855 F.3d at 490. The Third Circuit explained that the FDA's decision—after learning of these allegation—not to "initiate proceedings to enforce its adverse-event reporting rules or require [the defendant] to change [the drug's] FDA label," and the DOJ's decision to decline to intervene or otherwise take action against the manufacturer based on the allegations, left the relator unable to show materiality. *Id.* at 490; *see also, e.g.*, *United States ex rel. Nargol v. DePuy Orthopaedics*, 865 F.3d 29, 34 (1st Cir. 2017) (FDA's continued approval of product years after learning of relators' allegations that a manufacturer made false statements to obtain that approval "renders a claim of materiality implausible"); *D'Agostino v. ev3, Inc.*, 845

F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement for [the device] in the wake of [relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [relator] alleges.").

Similarly, in *United States ex rel. Bennett v. Bayer Corp.*, the court dismissed a relator's complaint alleging that drug manufacturers misbranded two antibiotics. No. 17-4188, 2022 WL 970219, at *1 (D.N.J. Mar. 31, 2022). Relator there argued that the FDA was unaware of the potential safety issues of the drugs, but the Court found that the case stood "almost on all fours with *Petratos* [as:] (i) the FDA was aware of all the safety information concerning both drugs; (ii) the FDA declined to change the label as Relator would like; (iii) CMS continued to pay reimbursements; and (iv) the Government declined to intervene in the *qui tam* action." *Id.* at *10 (citing *Petratos*, 855 F.3d at 490). Like the *Bennett* court, this Court finds that the present case stands on the same principles as *Petratos* because: (i) the Government has known about Relators' allegations since 2010; (ii) the FDA has not taken any actions in response to these allegations; (iii) the Government has continued to pay for the drug; and (iv) the Government has declined in intervene.

At oral argument, Relators highlighted two cases, *United States ex rel. Fox v. McKesson Corp.*, No. 3:12-cv-00766 (M.D. Tenn.) and *United States ex rel. Torres v. Shire Specialty Pharms.*, No. 08-4795 (E.D. Pa.), which they argued evidenced the same type of misconduct at issue here and in which the DOJ brought FCA enforcement actions and eventually obtained settlements, thus, showing that the Government considers the conduct at issue in the present case material. Jan 24, 2023 Hr'g Tr. 38:13–39:15; ECF No. 294-2 ¶ 259 n.301; ECF No. 294-308; ECF No. 294-305. In *McKesson*, the defendant contracted with the CDC under its Vaccines for Children program to provide distribution services, but allegedly failed to abide by the provisions of the

contract by not ensuring that, during shipping, the vaccines were maintained at proper temperatures through, among other measures, including electronic temperature monitors set to detect when the air temperature in the box reached a certain range. ECF No. 294-308 at 2. In announcing this settlement, the DOJ's press release stated: "Ensuring the integrity and performance of government contracts is paramount, especially when they impact programs intended to protect young children." *Id. Shire* concerned, among other allegations, promotion of several drugs despite a lack of clinical data to support such claims and overstated efficacy of defendant's drug, particularly relative to other manufacturers' drugs. ECF No. 294-305. In announcing this settlement, the DOJ's press release stated that the DOJ "will be vigilant to hold accountable pharmaceutical companies that provide misleading information regarding a drug's safety or efficacy." ECF No. 294-305 at 2. Notably, however, both *McKesson* and *Shire* were resolved by settlement and both of the press releases by the DOJ specifically stated: "The claims resolved by the settlement are allegations only; there has been no determination of liability." ECF No. 294-305 at 3; ECF No. 294-308 at 3. Importantly, parties settle lawsuits for many different reasons, and particularly with a statute like the FCA, where treble damages are available, defendants have a huge risk and significant costs if they chose to litigate such a case. Moreover, both *McKesson* and *Shire* are factually distinct and do not represent a determination of liability. Therefore, the Court finds that those cases do not support a finding of materiality here.

Relators also argue that the CDC's continued purchases of Merck's mumps vaccines do not defeat the materiality of Merck's misconduct because MMR-II (measles, mumps and rubella) and ProQuad (measles, mumps, rubella and varicella) are not stand-alone mumps vaccines, and

consequently, the Government is a "customer by force, not by choice."[6] ECF No. 343 at 3; *see also* Jan. 24, 2023 Hr'g Tr. 42:15–21. However, the CDC prefers vaccines that protect against multiple diseases. *See* CDC, Vaccines for Your Children, Combination Vaccines, "Benefits of combination vaccines," https://www.cdc.gov/vaccines/parents/why-vaccinate/combination-vaccines.html (last visited July 25, 2023) (noting "[c]ombining vaccines into fewer shots may mean that more children will get recommended vaccinations on time. And that means fewer delays in disease protection."). Additionally, the fact remains that, if the Government considered anything material, it would have raised the issue with Merck and required them to take corrective action. Again, rather than take such action, the agencies have consistently paid for and recommended Merck's mumps vaccines.

Finally, it is important to note that since the initial summary judgment briefing in this case concluded but prior to the Court's hearing on the motions, the FDA approved GSK's mumps vaccine and GSK entered the United States market. At oral argument and in their post-hearing submission, Relators point to the CDC's purchasing of GSK's mumps vaccine as evidence of CDC action illustrating the CDC's dissatisfaction with Merck's mumps vaccine. Jan. 24, 2023 Hr'g Tr. 68:15-19; ECF No. 343 at 2. But the fact that the CDC has "started to shift some of its purchases away from Merck" to GSK following the licensure of GSK's mumps vaccine does not show that the CDC is dissatisfied with Merck's mumps vaccines. In fact, in recommending GSK's mumps

[6] This phrase used by Relators throughout their briefing and in oral argument originates from a Merck consultant's 2008 pitch proposal to assist Merck with its "Pediatric Vaccines Competitive Simulation." ECF No. 294-265 at 2. In the list of ten "of the key questions that *may* be addressed as part of this project," one question (number five) states: "How can Merck transition from 'customers by force' to 'customers by choice' as the company loses sole source exclusivity in 2010? How can Merck make sure that customers are buying as many Merck pediatric vaccines as possible?" *Id.* at 3. But the document does not mention the CDC. In fact, in the "project scope," the consultant defines "customers" as "private sector, pediatric focus." *Id.* at 4. Accordingly, the Court recognizes that this catchy phrase was inapplicable to the CDC when initially used by Merck.

vaccine, Priorix, the ACIP found that Priorix and MMR-II are considered fully interchangeable. *See supra* Section I.D. Relators argue that Merck's vaccine is not safe and effective, but if that were the case, the CDC and the ACIP would not have found Merck's vaccine to be fully interchangeable with GSK's vaccine, rather the ACIP would have made a preferential recommendation. This is, therefore, further evidence of the CDC's continued support of Merck's mumps vaccines, and accordingly, is additional evidence of the lack of materiality in Relators' case.

In sum, the Government's inaction in this case weighs strongly in favor of a finding that Relators have failed to create a triable issue of materiality.

4. Materiality Summary

On review of the voluminous record in this case, considering the totality of the circumstances, no reasonable jury could conclude that the alleged false claims were material to the CDC's purchasing decisions. This Court has the "benefit of hindsight and should not ignore what actually occurred," which is that the Government has had actual knowledge of the alleged false claims and has continued to purchase Merck's mumps vaccines. *Halliburton*, 848 F.3d at 1034. This Court declines to turn the FCA into "a tool with which a jury of six people" could "second-guess agencies' judgments." *D'Agostino*, 845 F.3d at 8. The CDC, the FDA, and the DOJ have been given all the evidence. And with knowledge of this evidence, the CDC has continued to purchase Merck's mumps vaccines and recommend the vaccines as effective, and the FDA has continued to license Merck's mumps vaccines. To hold that these agencies do not have actual knowledge would mean that courts could never consider materiality at summary judgment unless the defendant has conceded to violating a statute, regulation, or contract provision, or alternatively the Government concedes it has knowledge of all the facts. This would create a perverse incentive

for the Government to decline to intervene and then stick their heads in the sand and ignore the progression of the case. The Court declines to allow that to happen. Accordingly, this Court finds that Relators have failed as a matter of law to satisfy the "rigorous" and "demanding" standard for materiality as set forth in *Escobar* and this Court will therefore grant Merck's Motion for Summary Judgment.

V. CONCLUSION

For the foregoing reasons, the Court will: (1) grant summary judgment in favor of Merck (ECF Nos. 281, 287); (2) deny Relators' Motion for Summary Judgement (ECF No. 294); and (3) deny as moot Merck's Second and Third Motions for Summary Judgment (ECF Nos. 283, 285). An appropriate Order will follow.

BY THE COURT:

/s/ Chad F. Kenney

CHAD F. KENNEY, JUDGE

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

UNITED STATES OF AMERICA *ex rel.*, STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI,	:	**CIVIL ACTION**
***Plaintiffs*,**	:	**NO. 10-4374**
v.	:	
MERCK & CO., INC.,	:	
Defendant.	:	

ORDER

AND NOW, this **27th** day of **July 2023**, upon consideration Relators' Motion for Summary Judgment (ECF No. 294) and Defendant Merck's Motions for Summary Judgment (ECF Nos. 281, 283, 285, 287), along with the responses and replies thereto, it is **hereby ORDERED** that for the reasons stated in the accompanying Memorandum:

1. Relators' Motion for Summary Judgment (ECF No. 294) is **DENIED**.
2. Merck's Motions for Summary Judgment based on an Efficacy Theory and the Kessler-Based Theory (ECF Nos. 281 and 287) are **GRANTED**.
3. Merck's Second Motion for Summary Judgment Against Relator Krahling (ECF No. 283) and Merck's Third Motion for Summary Judgment on the Time-Barred Claims and Damages (ECF No. 285) are **DENIED as moot.**
4. Judgment is **ENTERED** in favor of Defendant Merck and Relators' Amended Complaint is **DISMISSED IN FULL WITH PREJUDICE**.
5. The accompanying Memorandum **shall remain under seal for seven days**. Any party or non-party seeking to preclude public access to the accompanying Memorandum shall **show**

particularized good cause[1] in a memorandum not exceeding five pages to be filed no later than **12:00 p.m. on August 3, 2023** as to why the Court should preclude public access as to each word/line sought to be precluded from public access and shall email the underlying Memorandum with the proposed redactions to Chambers contemporaneous with filing the show cause Memorandum.

BY THE COURT:

/s/ Chad F. Kenney

CHAD F. KENNEY, JUDGE

[1] *See Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662 (3d Cir. 2019) (explaining that a party seeking to overcome the presumption of access to a judicial document bears the burden of showing "that the interest in secrecy outweighs the presumption" and that "the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure"); *see also In re: Application of Storag Etzel GmbH for an Order, Pursuant to 28 U.S.C. § 1782, to Obtain Discovery for Use in a Foreign Proceeding*, No. 19-mc-209-CFC, 2020 WL 2949742 (D. Del. Mar. 25, 2020).