NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 23-2553

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UNITED STATES OF AMERICA ex rel.,
STEPHEN A. KRAHLING; JOAN A. WLOCHOWSKI,
Appellants

v.

MERCK & CO, INC.

_____

Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. No. 2-10-cv-04374)
District Judge: Honorable Chad F. Kenney

_____

Argued July 9, 2024

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Before: SHWARTZ, PHIPPS, and MONTGOMERY-REEVES, Circuit Judges.

(Filed: August 6, 2024)

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OPINION*

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* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

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SHWARTZ, Circuit Judge.

The Centers for Disease Control and Prevention ("CDC") buys vaccines, including Merck & Co., Inc.'s ("Merck") MMR-II and ProQuad vaccines, for individuals who lack the means to purchase them. Relators Stephen Krahling and Joan Wlochowski bring this qui tam action against Merck, their former employer, claiming that Merck violated the False Claims Act ("FCA") by making false representations to the CDC about its vaccine. The District Court held that, even assuming the representations were false, none were material to the CDC's purchasing decision, and thus granted summary judgment in Merck's favor. We agree and will affirm.

I

A

The Food and Drug Administration ("FDA") is tasked with licensing vaccines sold

in the United States. Merck received a license to distribute its MMR vaccine, which combined its mumps, measles, and rubella vaccines into a single trivalent vaccine, in the 1960s and, for more than fifty years, was the only entity licensed to sell the product in the United States. The vaccine underwent several iterations, but relevant here are: (1) the MMR-II vaccine, which was licensed in 1978; and (2) the ProQuad vaccine, which was licensed in 2005.[1]

The FDA-approved labels on Merck's vaccine provides information about the vaccine's potency and efficacy,[2] along with statements about its seroconversion rate[3] and immunogenicity,[4] both of which "can be indirect measures for protection."[5] Potency "describes the concentration of virus in each dose of vaccine" expected to trigger antibodies to fight the disease.[6] It is measured by the units of tissue culture infectious

[1] The MMR-II vaccine contained the same mumps and measles components as the MMR vaccine, along with a different rubella vaccine. The ProQuad vaccine contained the same measles, mumps, and rubella vaccines that are in the MMR-II, as well as a varicella (chicken pox) vaccine. Vaccines protecting against mumps, measles, and rubella are generally referred to as "MMR" vaccines, while those with the added varicella protection are generally referred to as "MMRV" vaccines.

[2] Efficacy refers to "[t]he ability of a vaccine to provide protection against disease under ideal circumstances." FCA App. Vol. 25 at 11252.

[3] Seroconversion 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." FCA App. Vol. 40 at 18771 ¶ 57 (internal quotation marks and citation omitted).

[4] "Immunogenicity provides information about how a subject's immune system responds to different stimuli, including vaccination." FCA App. Vol. 40 at 18770-71 ¶ 55.

[5] FCA App. Vol. 40 at 18771 ¶ 58.

[6] FCA App. Vol. 40 at 18775 ¶ 67.

dose ("$TCID_{50}$"), which is, put simply, the amount of live virus placed in a vaccine.[7] Because the potency of a vaccine decreases over time, a vaccine's potency at expiration ("end-expiry") is less than that at its initial release.

In the mid-1990s, the FDA began to review vaccine labels, including the MMR-II label, pursuant to the National Childhood Vaccine Injury Act ("NCVIA"). As a result, Merck and the FDA's Center for Biologics Evaluation and Research (the "CBER")[8] discussed the product's shelf-life based on the potency figure on Merck's vaccine label, which, at the time, represented that each dose contained 4.3 $\log_{10}$ $TCID_{50}$ of the virus and had a twenty-four month shelf life. The CBER determined that potency should be measured at end-expiry, whereas Merck defined the potency based on its level at the time the vaccine was released, and the CBER told Merck that, going forward, the labeled potency should reflect the end-expiry potency—i.e., the amount of live virus in the vaccine at the end of the labeled shelf life.

To address the potency information on the label, the CBER told Merck to increase the minimum release potency of its mumps vaccine to at least 5.0 $\log_{10}$ $TCID_{50}$ (and accordingly, to formulate any vaccine manufactured on or after September 13, 1999, to contain at least 5.2 $\log_{10}$ $TCID_{50}$) to be 95% confident that the vaccine would comply

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[7] Potency values expressed using TCID "represent the viral concentration necessary to induce cell death or pathological changes in 50% of inoculated cell cultures." FCA App. Vol. 40 at 18775 ¶ 68.

[8] The CBER "evaluat[es] scientific and clinical data submitted by manufacturers to determine whether the product meets CBER's standards for approval." FCA App. Vol. 40 at 18814 ¶ 156 (internal quotation marks and citations omitted). "After a thorough assessment of data, [the] CBER makes a decision based on the risk-benefit for the intended population and the product's intended use." Id.

with the labeled 4.3 $\log_{10}$ $TCID_{50}$ potency at the end-expiry date. In February 2000, Merck increased the TCID in its vaccine in an effort to ensure a 4.3 $\log_{10}$ potency at the end-expiry date (a process referred to as "overfilling").

In 2000, after Merck increased the potency, a different division of the FDA inspected Merck's manufacturing division and issued Merck a Form 483 for failing to report that certain vaccine lots, manufactured prior to the increase in potency, failed to satisfy 4.3 $\log_{10}$ potency by end-expiry. Merck responded, but the FDA raised the same issues in a 2001 Warning Letter[9] that: (1) observed that some vaccine lots manufactured before the overfilling began in February 2000 failed to meet the minimum potency specification and could still be on the market because the expiry period is two years, (2) directed Merck to submit data about the expected potencies at the end-expiry dates, (3) cautioned Merck that its failure to comply or correct errors could result in license suspension or revocation, and (4) informed Merck that federal agencies are notified about all Warning Letters and could take this information into account when considering whether to award future contracts.

In preparing its response to the Warning Letter, Merck determined that, before it began overfilling in February 2000, it released 225 lots[10] of MMR-II with an end-expiry potentially lower than 4.3 $\log_{10}$, 107 of which were projected to be below 4.0 $\log_{10}$ at end-

[9] Based on the FDA's website, "[a] Warning Letter is issued to a manufacturer when the FDA finds that a manufacturer has significantly violated FDA regulations." U.S. ex rel. Krahling v. Merck & Co., No. 10-cv-4374, 2023 WL 8367939, at *3 (E.D. Pa. July 27, 2023) (internal quotation marks and citation omitted).

[10] The 225 lots equals approximately 23 million doses.

expiry. Although Merck tracked down the 107 lots, and drafts of Merck's Form 483 response referenced those lots, Merck's response to the FDA did not specifically mention them. Instead, it simply noted that if it is assumed that the initial potency is 4.3 $\log_{10}$ $TCID_{50}$, then after twenty-four months, its expected average potency would be 3.6 $\log_{10}$. Merck also represented to the FDA that since implementing the overfill, the vaccine "products have end-expiry specifications consistent with their label."[11] In April 2001, the FDA closed the Warning Letter without any requirement that lots be withdrawn from the market. However, internal Merck documents suggest that the company was concerned that it could not ensure that the potency would remain at or above 4.3 $\log_{10}$ for more than approximately twelve months. Nevertheless, Merck's MMR-II label continued to reflect a shelf life of twenty-four months, and Merck did not report that information to the FDA.[12]

B

Although Merck increased the minimum potency of the mumps vaccine in 2000, beginning in 1997, Merck discussed with the FDA a clinical trial, known as "Protocol 007," to support a label change to reduce the end-expiry potency below 4.3 $\log_{10}$. To obtain approval for a label change, Merck was required to demonstrate that the seroconversion rate in the experimental groups (those receiving the lower potency doses),

[11] FCA App. Vol. 10 at 3700.

[12] Merck contends that its internal documents indicating that it could not ensure 4.3 $\log_{10}$ potency with overfilling was based on preliminary data before its stability tests were finalized, and that in reality, no lot manufactured after the potency increase ever tested below 4.3 in Merck's actual stability testing at any timepoint before the twenty-four-month expiry.

was (1) at least 90%, which was the lower bound of a 95% confidence interval based on MMR-II's label of a 96% seroconversion rate at its existing 4.3 $\log_{10}$ potency; and (2) not more than 5% less than that in the control group. The FDA allowed the trial to proceed but required that the test be performed using a wild-type virus, which is likely to be more similar to the virus strain encountered in the real world, as opposed to the virus strain (Jeryl Lynn strain) used to manufacture the vaccine.

As part of this trial, Merck used two tests to measure seroconversion: (1) a plaque reductions neutralization assay ("PRN"), which gauged immunogenicity by measuring the ability of antibodies to neutralize the virus, and (2) an enzyme linked immunosorbent assay ("ELISA"), which measured immunogenicity to determine how the immune system responds to vaccination.

The PRN testing initially used the Jeryl Lynn strain as well as wild-type virus strains. Although Merck's PRN testing yielded 91-96% seroconversion rates for the Jeryl Lynn strain, the rates for the wild-type virus strains ranged from 56% (or lower) to 76%. This means that Merck's tests showed that the vaccine was not likely to provide the same protection against strains more likely to be encountered outside the clinical setting. Merck then proposed using the passage 8 Jeryl Lynn strain, which is considered to be a wild strain,[13] and changed select PRN data, including by introducing rabbit antibodies ("anti-IgG") in the serum samples in a PRN test referred to as ("AIGENT"). The FDA acknowledged that Merck would use the AIGENT assay with the passage 8 Jeryl Lynn

[13] The CBER "concurred" with Merck's representation that the 8 Jeryl Lynn strain was a wild strain. FCA App. Vol. 26 at 11769.

strain.

Relators worked in the lab that performed the AIGENT test, and in 2001, one of them reported to the FDA that: (1) "data was being destroyed[,]" and (2) the lab was "instituting a policy to fraudulently lower the pre-positive rate" in the PRN (i.e., lowering the rate at which blood samples were classified as seropositive to make it easier to report they seroconverted).[14] In response, the FDA inspected the lab and thereafter issued a Form 483, in which it observed that: (1) raw data was being changed with no justification, (2) there was no procedure to assess whether a research lab was suitable for clinical testing prior to the start of testing, (3) spreadsheets used to determine questionable results and retesting had not been validated, and (4) notebooks did not identify the technician who performed each task.

In Merck's formal response, Merck represented that (1) it retrained staff involved in the Protocol 007 on proper testing and documentation practices, (2) it reanalyzed the data set, and (3) the reanalysis of the data set revealed "no evidence of a difference between the corrected and uncorrected data sets with respect to seroconversion."[15] The FDA rejected the reanalyzed data set[16] but accepted Merck's proposal to use the originally recorded results from the PRN to support its potential label change. However, when Merck submitted its application to change the label in 2004, the CBER would not approve it, finding that "the information and data submitted are inadequate for final

[14] FCA App. Vol. 40 at 18847-48 ¶¶ 222-26.

[15] FCA App. Vol. 22 at 9817.

[16] The FDA declined to accept the reanalyzed data set because no protocol for reanalysis of the data (i.e., plaque counts) had been set in advance.

approval at this time[,]" while noting that it could not "accept use of multiple imputation analyses of the PRN data to support the lowering of mumps vaccine end-expiry potency."[17]

As discussed above, the FDA allowed Merck to use PRN or ELISA assays, but the FDA put conditions on the use of the ELISA test. Based on scientific developments, however, the CBER later allowed Merck to use the ELISA assay only,[18] and in 2007 approved the label change, which reduced the listed potency of the virus from 4.3 $\log_{10}$ to 4.1 $\log_{10}$ by end-expiry with a twenty-four month shelf life.[19] Notwithstanding receiving permission to make this label change, Merck has never reduced its minimum release potency from the 5.0 $\log_{10}$ $TCID_{50}$ it began using in 1999.

C

The CDC purchases vaccines through the Vaccines for Children entitlement program, which provides vaccines to children whose parents or guardians may not be able to afford them. For the CDC to consider a vaccine, it must be licensed by the

[17] FCA App. Vol. 26 at 11651.

[18] Specifically, the CBER found that "the science related to immunogenicity testing of [the vaccine] ha[d] substantially evolved since [the] initial testing requirements" and "[u]se of ELISA data to evaluate the effect of differences in product potency on immunogenicity is now acceptable." FCA App. Vol. 26 at 11651.

[19] Separately, the FDA approved Merck's ProQuad MMRV vaccine in 2005 based in part on Merck's submission of data that used the same ELISA test and serostatus cutoff as was used in Protocol 007.

FDA,[20] compliant with applicable current Good Manufacturing Practices ("cGMP"),[21] and recommended by the CDC's Advisory Committee on Immunization Practices (the "ACIP").[22] The ACIP's purchasing recommendations are based on its review of the "burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses and implementation issues."[23] The ACIP has adjusted its recommendations concerning dosage amounts and sequence over the years, and, in making its 2017 recommendation, stated that the "median effectiveness of [two] doses of MMR vaccine in preventing mumps is 88%, with estimates ranging from 31% to 95%[,]"[24] which is based on "multiple studies that have been conducted both in the United States and in other countries[.]"[25] ACIP also conducts its own effectiveness studies, which measure how vaccines perform in the "real world as opposed to clinical

[20] Apart from the FDA license requirement, to preserve its scientific independence and judgment, the FDA is not involved in the CDC's vaccine purchase decisions. .

[21] cGMP regulations govern the "manufacture, processing, packing, or holding of a drug[.]" 21 C.F.R. § 210.1(a). The contract does not expressly provide that cGMP compliance is a condition of payment, only that cGMP "will be the standard [] applied for manufacturing, processing and packing of drugs, chemicals, biologicals, and reagents[,]" FCA App. Vol. 23 at 10486. Moreover, the CDC's 30(b)(6) witness testified that cGMP compliance refers to an FDA requirement, and that the CDC defers to the FDA as to the contractor's compliance.

[22] ACIP is a statutorily authorized committee of scientists. 42 U.S.C. § 1396s; see also CDC, ACIP Charter, https://www.cdc.gov/vaccines/acip/committee/charter.html (last visited July 18, 2024).

[23] CDC, ACIP Charter, https://www.cdc.gov/vaccines/acip/committee/charter.html (last visited July 18, 2024).

[24] FCA App. Vol. 23 at 10347.

[25] FCA App. Vol. 6 at 1724.

trial data."[26] Over the years, the CDC has observed and reaffirmed its findings that the effectiveness rate of the vaccine in real world studies is lower than the efficacy rate found in pre-licensure clinical trials.

Since the 1990s, the CDC and Merck have negotiated annual contracts to purchase the mumps vaccine and continue to do so today. Per these contracts, the vaccine was to maintain a certain shelf life upon delivery to the consignee, with the contracts for MMR-II from 1998 through 2016 containing a twelve-month shelf-life requirement, and the 2006 ProQuad contract containing an eight-month shelf-life requirement.

In 2022, the FDA approved competitor GlaxoSmithKline plc's ("GSK") mumps vaccine, and the ACIP thereafter recommended it to the CDC, concluding that GSK and Merck's vaccines "are fully interchangeable for all indications for which MMR vaccination is recommended."[27] In line with this recommendation, the CDC now purchases mumps vaccines from both manufacturers.

D

In April 2010, Relators filed a complaint alleging that Merck misled the CDC by

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[26] FCA App. Vol. 6 at 1722. Effectiveness, defined as a vaccine's real-world performance, is the most important measure for federal health authorities, and effectiveness studies are generally not conducted by manufacturers. Relevant here, the CDC has conducted mumps effectiveness studies and determined that as of 2017, there had been no significant change in the median effectiveness of the vaccine for more than ten years.

[27] 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 at 1465 (Nov. 28, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7146a1-H.pdf) ("Measles, Mumps").

omitting, concealing, and misrepresenting material information regarding its mumps vaccines in violation of the FCA. Two years later, the United States declined to intervene, and Relators filed an amended complaint.

After discovery, the parties cross-moved for summary judgment.[28] The District Court denied Relators' motion and granted Merck's motion, holding that even assuming Merck made false claims, no reasonable jury could conclude that they were material to the CDC's purchasing decision, which is a predicate for liability. U.S. ex rel. Krahling v. Merck & Co., No. 10-cv-4374, 2023 WL 8367939, at *10 (E.D. Pa. July 27, 2023). In reaching its conclusion, the Court evaluated the three non-exhaustive materiality considerations outlined in Universal Health Services, Inc. v. United States and Massachusetts, ex rel. Escobar, 579 U.S. 176 (2016), namely whether: (1) compliance with a particular requirement is expressly identified as a "condition of payment," (2) the violation is "minor [and] insubstantial," and (3) the Government pays or declines to pay a "particular claim" or "type of claim" when it has actual knowledge that certain requirements were violated." Krahling, 2023 WL 8367939, at *11 (citing Escobar, 579 U.S. at 194-95).

The District Court reasoned that (1) Merck did not violate a condition of payment

[28] In response to Merck's summary judgment motion, the DOJ filed a Statement of Interest, which contended, among other things, that the Government lacked actual knowledge of Merck's violation. The Government repeated this assertion at oral argument before the District Court but also acknowledged that it "had a lot of information available to [them]," FCA App. Vol. 2 at 163, but lacked actual knowledge because it had not yet "distilled and synthesized everything" provided three-and-a-half years prior such that it has been able to take a position on whether there is falsity, FCA App. Vol. 2 at 165.

relating to the effectiveness of the vaccine because the record demonstrates that the CDC (a) conducted its own effectiveness studies, (b) acknowledged that effectiveness in its field studies was lower than what Merck reported in the original clinical studies that supported Merck's licensing, and (c) nevertheless continued to represent that two doses of the mumps vaccine were 88% effective, id. at *11;[29] (2) the misrepresentations did not go to the "essence of the bargain" because (a) vaccine effectiveness is central to the bargain, and here, notwithstanding the decade-long litigation, the CDC continued to recommend the vaccine and advise that two doses of it are 88% effective, and (b) no evidence shows that misrepresentations about potency or the results of Protocol 007 were central to the CDC's bargain, id. at *12; and (3) the Government (a) had actual knowledge of the facts, given that it received Relators' expert witness disclosures and Merck's responses, among other documents, and the FDA and CDC are duty-bound to review the information made available to them, and (b) nevertheless continued to recommend and purchase the vaccine and sought no corrective action,[30] id. at *13-16.

[29] The District Court also rejected Relators' contention that "Merck's potency, shelf-life, protection, licensing and labeling violations implicated multiple contractual and regulatory obligations, including: ([1]) cGMP compliance, which require[s] adequate assurances of sufficient potency, ([2]) 12 months of shelf life remaining upon delivery, ([3]) compliance with a valid license, ([4]) ACIP recommendation, and ([5]) fit for purpose and merchantability," Krahling, 2023 WL 8367989, at *12 (citing Dist. Ct. Dkt. No. 309 at 42), and created a dispute as to materiality. The Court explained that "just because the Government or a federal agency found a particular issue important enough to regulate speaks little to the intended consequence of noncompliance." Id. at *12 (internal quotation marks and citations omitted).

[30] As to the Government action consideration, the District Court added that (1) although the CDC stated that it had a "clear interest in the outcome of the case," such interest demonstrates an appropriate discharge of duties, and does not warrant a contrary

Relators appeal.

II[31]

Relators filed suit under the FCA, which is meant to "reach all types of fraud . . . that might result in financial loss to the Government." United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 486 (3d Cir. 2017) (internal quotation marks and citations omitted). Pursuant to the FCA, relators can bring lawsuits, known as qui tam actions, on behalf of the United States to recover funds that were fraudulently obtained from the United States, and share in any resulting damages award. See 31 U.S.C. § 3729, et seq. The FCA, however, is not "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." Escobar, 579 U.S. at 194 (internal quotation marks and citation omitted). Instead, the FCA "requires that the

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materiality determination given its inaction, Krahling, 2023 WL 8367989, at *13; (2) Relators' argument that the Government was a "customer by force, not by choice" is not persuasive because (a) the CDC prefers vaccines that protect against multiple diseases, and (b) had the Government considered the information material it would have raised the issue with Merck and required corrective action, id. at *16; and (3) the CDC's finding that Merck's vaccine is "fully interchangeable" with the GSK vaccine likewise weighs against a finding of materiality because if the claims were material, ACIP would have made a preferential recommendation for the GSK vaccine, id. (citation omitted).

[31] The District Court had jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). We have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review of the District Court's order granting summary judgment. Resch v. Krapf's Coaches, Inc., 785 F.3d 869, 871 n.3 (3d Cir. 2015). We apply the same standard as the District Court, viewing facts and drawing all reasonable inferences in the non-movant's favor. Hugh v. Butler Cnty. Fam. YMCA, 418 F.3d 265, 266-67 (3d Cir. 2005). Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). There is a genuine issue of fact if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986).

contractor's alleged violation be, among other things, 'material' to the [G]overnment's decision to pay." United States ex rel. Druding v. Care Alts., 81 F.4th 361, 365 (3d Cir. 2023) (quoting Escobar, 579 U.S. at 192-93). An alleged violation is "material" to the Government's decision to pay 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). Therefore, the materiality inquiry is "holistic," Druding, 81 F.4th at 367, and "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," Escobar, 579 U.S. at 193 (alteration in original) (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston)).

In Escobar, the Supreme Court described the materiality element as "demanding" and "rigorous" and provided guidance as to how to apply it.[32] Escobar, 579 U.S. at 194, 195 n.6. It explained that to determine whether a representation is material, we may consider, among other things, (1) whether the representation went to a condition of payment (i.e., an express condition or an implied condition for which the Government would have the option to decline payment, though neither is dispositive); (2) whether the

[32] Escobar explained that noncompliance is not material merely because "the Government would have the option to decline to pay if it knew of the defendant's noncompliance." 579 U.S. at 194. Nor is the Government's decision to "expressly identify a provision as a condition of payment . . . automatically dispositive," although it is "relevant." Id. Likewise, the materiality element cannot be satisfied where the defendant's "noncompliance is minor or insubstantial." Id. Accordingly, proof that the Government "pays a particular claim in full despite its actual knowledge that certain requirements were violated" will be "very strong evidence" of immateriality. Id. at 195. Conversely, proof that "the defendant knows the Government consistently refuses to pay claims in the 'mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" may support a finding of materiality. Id.

representation was "minor or insubstantial"; and (3) if the Government knew the facts surrounding the representation, the Government's reaction to it (i.e., whether it continued to pay the claim in full).[33] See id. at 194-95.

Even if we assume, as the District Court did, that Merck made misrepresentations (i.e., false claims), based on our de novo review of these considerations, no reasonable jury could conclude that the representations were material to the CDC's purchasing decisions. As to condition of payment, Relators contend that the CDC had certain "prerequisites to . . . purchas[ing]," Appellant Br. at 29, namely (1) licensure; (2) ACIP recommendation; (3) shelf-life; (4) fitness for purpose; and (5) cGMP compliance. Each were met. First, there is no dispute that the FDA licensed the vaccine, and because Relators have disclaimed any argument that there was a fraud on the FDA, they do not assert that the license was fraudulently obtained. Second, ACIP recommended the vaccine knowing that its own studies demonstrated a lower effectiveness in the real world than the efficacy rate in pre-licensure clinical trials. Third, the contract only required a twelve-month shelf-life, and there is no evidence that the shelf life was ever below twelve

[33] Although in Druding, 81 F.4th at 367, we seemingly identified these considerations as a three-factor test, Escobar does no more than note that they are non-exhaustive considerations. This makes sense given the inherent overlap among them. For example, it is likely that if noncompliance with a certain contractual or regulatory provision was "minor or insubstantial" to the bargain, the Government would continue to pay the claim in full notwithstanding its actual knowledge of the noncompliance.

We note this factor/consideration distinction because Relators argue that the District Court erred by conflating the "factors" (namely, by relying on evidence that went to the Government action factor when evaluating the other two factors), but because this is not a three-part test, we are only faced with one question: whether the Court properly held that no reasonable jury could conclude that the misrepresentations were material to the CDC's purchasing decision.

months.[34] There is also no evidence that the vaccine was not fit for its purpose. Finally, even if we assume that the cGMP regulations (which are FDA regulations) were a condition of payment, and that this condition was violated, the record does not support the conclusion that such violations were material to the CDC's purchasing decision because Relators' argument—that (1) Merck violated this condition by misrepresenting the potency and effectiveness and (2) effectiveness is material to the CDC's purchasing—overlooks the undisputed fact that the CDC was aware, through its own studies, that the vaccine proved less effective in the real world than in the clinical trials yet it continued to purchase and recommend it. Thus, this consideration would not provide a reasonable jury a basis to conclude that the representations were material. See Petratos, 855 F.3d at 492 (holding that for an alleged violation to be "actionable," it "must affect the United States' payment decision"); see also Escobar, 579 U.S. at 194 ("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.").

Next, Merck's misrepresentations as to potency and its Protocol 007 testing were "minor or insubstantial" with respect to the CDC's purchasing decisions, and hence not material to such decisions. It is undisputed that (1) the ACIP conducted its own

[34] Instead, the record supports only that Merck had projected that 7-8% of vaccine lots may not satisfy a twenty-four-month shelf life. See FCA App. Vol. 10 at 3912 (Merck Deck) (noting as an "inference[] from [s]imulations" that "8% of current product is expected to fail 4.3"); but see FCA App. Vol. 9 at 3016 (Stannard Dep.) (confirming that Merck's stability reports did not yield any "out-of-spec stability finding[s]" for any "[p]roduct[s] on the market," within the twenty-four month period after the release-potency increase); FCA App. Vol. 25 at 11189-90 (Gulati Expert Report) (representing that no lots tested in the stability studies fell below their represented end-expiry potency).

effectiveness studies and recommended purchasing the vaccine based on them; (2) the ACIP made this recommendation knowing that effectiveness rates in its own studies (which measured real world effectiveness) were lower than the efficacy reported in the clinical trials; and (3) the CDC's purchases are based on ACIP's recommendations. Thus, no reasonable jury could find that Merck's alleged misrepresentations as to potency and testing were material to the CDC's purchasing decision, which was based on its own effectiveness studies and ACIP's recommendations, as opposed to Merck's misrepresentations.

Finally, the Government had actual knowledge of the facts—not just allegations.[35] The "Government" refers both to the paying agency and the agencies with oversight and enforcement authority, such as the FDA. See Petratos, 855 F.3d at 490 (reasoning that misrepresentations to CMS were not material where the relator "concede[d] that the expert agencies and [G]overnment regulators have deemed [the alleged] violations insubstantial," the FDA "continued its approval" of the drug, and DOJ declined to intervene); see also United States ex rel. Nargol v. DePuy Orthopedics, Inc., 865 F.3d 29, 34-35 (1st Cir. 2017) (holding that "[e]ven in an ordinary situation not involving a misrepresentation of regulatory compliance made directly to the agency

[35] At the summary judgment hearing, the Government reiterated what it argued in its Statement of Interest—that it lacks "actual knowledge" because it "cannot represent" that the Government has "distilled and synthesized everything" such that it has been able to take a position on whether there is falsity. FCA App. Vol. 2 at 165. The "actual knowledge" requirement, however, is satisfied by just that: actual knowledge. That the Government had not yet "distilled and synthesized" the information provided to it three-and-a-half years before the summary judgment hearing does not change that. FCA App. Vol. 2 at 165.

paying a claim, when '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.'" (quoting Escobar, 579 U.S. at 195)).

Here, no reasonable jury could conclude that the Government lacked knowledge of facts because, among other things: (1) in 2001, the FDA gained knowledge of the potency and Protocol 007 issues; (2) in 2010, this matter was filed and the Government began investigating; (3) since 2012 (when the Government declined to intervene and the matter was unsealed), the Government has been involved in discovery, including preparing Rule 30(b)(6) deponents like CDC officials who were tasked to review facts about which it had knowledge on the identified topics relevant to the claims in this case; and (4) in 2019, at Relators' request, portions of their expert witness's report and deposition (which outlined their view about the vaccine), and Merck's responses thereto, were provided to the Director of the CDC, Commissioner of the FDA, and Secretary of the Department of Health and Human Services.[36] fact, when pressed by the District Court at oral argument on the summary judgment motion, the Government acknowledged that it "had a lot of information available to [it]." FCA App. Vol. 2 at 163. Thus, no reasonable jury could conclude that the Government lacked knowledge of facts relevant to materiality.[37]

[36] This request was granted to "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." FCA App. Vol. 3 at 182 (Order).

[37] Because the Government obtained this knowledge before many contracts for purchase were made, the case at hand is distinguishable from Druding, where there was a dispute about when the Government obtained knowledge of the issues the relators there raised. In Druding, we vacated the district court's grant of summary judgment in favor of

Even with knowledge of the facts concerning the alleged misrepresentations and fraudulent acts as to testing, potency, shelf-life and the like, the CDC continued to purchase Merck's vaccine and "signaled no change in position." Escobar, 579 U.S. at 195. From the time Relators first reported their concerns to the FDA in 2001 through 2019 (when the parties moved for summary judgment), the CDC negotiated approximately eighteen annual contracts with Merck. See generally Docket, United States ex rel. Krahling v. Merck & Co., No. 2:10-cv-04374 (E.D. Pa.). The CDC paid each contract in full, despite the reports about the shelf-life, and did not attempt to renegotiate the price in light of the purported violations. The CDC, moreover, continued to represent to the public that the vaccine is "effective[.]" FCA App. Vol. 40 at 18810 ¶ 144 (quoting CDC, Mumps Vaccination, https://www.cdc.gov/vaccines/vpd/mumps/index.html (last visited July 18, 2024)). This makes sense, given that the CDC's own effectiveness studies and analysis of real-world data demonstrate that the vaccines continued to be effective. Thus, even if the CDC was

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the defendants because (1) there was "an open dispute over the [G]overnment's 'actual knowledge'" at the time the claims were paid, 81 F.4th at 365, 374 (quoting Escobar, 579 U.S. at 195), and (2) the district court nevertheless erroneously assigned "dispositive weight" to the Government action, "while overlooking the factors that could have weighed in favor of materiality" (i.e., condition of payment and minor or insubstantial violation), id. at 365. Here, (1) there is no dispute that the CDC paid its contracts with Merck in full after the Government obtained actual knowledge of Merck's alleged misrepresentations, and (2) the District Court considered the condition of payment and "minor or insubstantial" considerations, and found that they weighed against a finding of materiality because the CDC's most important purchasing consideration is vaccine effectiveness and the CDC made its purchasing decisions based on its own effectiveness studies, which it knew reflected lower effectiveness in the real world than that represented by Merck. Thus, this case is distinguishable from Druding.

a "customer[] by force," Appellee Br. at 52, in that it had no other sources for the vaccine, the Government's actions show that any misrepresentations were immaterial to its decision to purchase the vaccine. Indeed, even after an alternative vaccine source became available in 2022, the CDC still bought Merck's product and has represented that the two products are "fully interchangeable."[38]

In short, no reasonable jury could conclude that Merck's alleged misrepresentations were material to the CDC's purchasing decision because the Government (1) had actual knowledge of the facts concerning potency, shelf-life, and the like; (2) satisfied itself as to the effectiveness of the vaccine based on real world studies, which it acknowledged showed lower effectiveness rates than the efficacy that Merck reported from clinical trials; (3) entered into contracts with Merck that required the product to have only a twelve-month shelf-life (and there is no evidence that Merck's vaccine did not meet this condition); and (4) continued to purchase Merck's vaccine, even when another option became available. Thus, for the reasons set forth herein and those set forth by the District Court, summary judgment was properly granted in Merck's favor.

III

For the foregoing reasons, we will affirm.

[38] Measles, Mumps, 71 Morbidity & Mortality Weekly Report, No. 46 at 1465.