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

UNITED STATES OF AMERICA,	:	
***ex rel.* SARAH BEHNKE,**	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	**NO. 14-cv-824**
v.	:	
	:	
CVS CAREMARK CORPORATION,	:	
***et al.*,**	:	
	:	
Defendants.	:	

UNITED STATES' STATEMENT OF INTEREST REGARDING MATERIALITY

In this False Claims Act (FCA) *qui tam* action, Sarah Behnke ("Relator Behnke" or "Behnke") alleges that the Caremark Defendants caused submission of false statements and claims to the Centers for Medicare and Medicaid Services (CMS) for Medicare Part D drugs.

Although it did not intervene in the action, the United States remains a real party in interest, entitled to share substantially in any recovery that Relator Behnke obtains. *See* 31 U.S.C. § 3730(d); *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 934-35 (2009). The United States' interests extend to the Court's interpretation both of the FCA, which is the Government's primary civil tool for fighting fraud, and of the Medicare Part D program.

On the FCA element of "materiality," the United States is aware of the parties' trial arguments, including their oral and written closing arguments and submissions. *See, e.g.*, ECF 495 (Caremark's June 17, 2025 letter submission), ECF 497 (Behnke's June 24, 2025 letter submission). The United States is also aware of the Court's sound reasoning on materiality at the summary judgment stage. *See* ECF 339 (Memorandum

Decision), reported at *United States ex rel. Behnke v. Caremark Corp.*, 2024 WL 1416499, at *38-39 (E.D. Pa. Apr. 2, 2024) ("Behnke Summary Judgment Decision").

In October 2023, while summary judgment motions were pending, the United States filed a Statement of Interest in this case. *See* ECF 312. That Statement stressed in part that, especially in the context of the Medicare Part D program, because CMS is usually not privy to contracts among Plan Sponsors, PBMs, and/or pharmacies, it is reasonable for the Government to wait for facts to be fully developed before taking appropriate action. *See* ECF 312, at p. 10; *see generally United States ex rel. Ellsworth Assocs., LLP v. CVS Health Corp.*, 660 F. Supp. 3d 381, 403-04 (E.D. Pa. 2023) ("The Government designed the Medicare Part D system to decrease costs through market competition. It did not envision a system where the Government's costs were purposefully increased by potential bad actors or merged companies who colluded and took steps at every level of the corporate Medicare reimbursement chain to profiteer at the Government's expense and prevent detection. . . . This is what Relator's allegations boil down to.").

The Statement further highlighted *United States ex rel. Druding v Care Alternatives*, 81 F.4th 361 (3d Cir. 2023) ("*Druding*"), in which the Third Circuit concluded that Government inaction is not automatically a valid defense, even where—on a record quite different from the record in this case—the Government was aware of allegations for 15 years and took no post-investigation action against a provider. *See* ECF 312, at pp. 9-12; *see also Druding*, 81 F.4th at 375 (in reversing summary judgment, stating that "we simply do not know what the government knew and when"); Behnke Summary Judgment Decision, 2024 WL 1416499, at *39 (citing *Druding* and reasoning that "Government inaction in the face of alleged fraud is 'not dispositive . . . evidence of

immateriality,' particularly given that 'awareness of allegations of fraud' is not the same as 'actual knowledge that fraud occurred,' and the Government may have reasons not to 'prematurely end a relationship with a contractor over unproven allegations.'").

Under 28 U.S.C. § 517, the United States now respectfully submits this Statement of Interest to address three topics that the parties' trial arguments on materiality raise.

First, the United States' non-intervention election should not be used as a basis to defeat materiality in this action.

The United States styled its April 2, 2018 decision not as a "declination" but rather as a "Notice of the United States that it is Not Intervening at this Time." *See* ECF 24 (Notice). The Notice explained that (1) in February 2018, the Court had ordered the United States to make its intervention decision on or before April 2, 2018 (this was approximately four years after the United States' investigation began), and (2) "[t]he court has not granted any extension of that deadline." *See id.* at p. 1 ("Because the United States is still evaluating this case, it is not yet able to decide whether to proceed with the action.").[1]

[1] The April 2, 2018 deadline occurred during a period when the parties were making presentations to the United States on their allegations and defenses. After the United States filed its Notice, and until the Court's April 2023 summary-judgment ruling, five years of litigation ensued (including years of discovery, and Relator Behnke further amending her Complaint). Apart from monitoring the public filings, the United States' role during that period involved discussing with CMS counsel a limited document request to CMS from one of the parties. Neither party sought to depose any CMS or other government agency witness or to call a government witness at trial. *See generally, e.g.*, *Druding*, 81 F.4th at 375 ("As a general matter, relators are not required to conduct discovery on government officials to demonstrate materiality[.]"); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (noting that summary judgment record included CMS employee testimony).

The United States' non-intervention election is at most "of minimal relevance" to the Court's materiality findings. *See, e.g.*, *United States ex rel. International Brotherhood of Elec. Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 346 (3d Cir. 2021); *United States ex rel. Class v. Bayada Home Health Care, Inc.*, No. 16-cv-680, 2018 WL 4566157, at *11 (E.D. Pa. Sept. 24, 2018) (Goldberg, J.) (collecting cases).

The Caremark Defendants argue that any such "minimal relevance" should be viewed in the context of the "full record." *See* ECF 495 (Caremark letter brief), at p. 1. But the allegations and records of government action, knowledge, and function in Third Circuit cases in which a United States declination was weighed as part of judicial decisions to dismiss actions or to find for defendants on materiality grounds make those decisions inapposite here where the context is quite different.

For example, many of those rulings involved not merely a government payor agency such as CMS but also a government regulatory agency such as the FDA that had responsibility for assessing and approving product safety and effectiveness and for protecting the public from unsafe and ineffective products. Actual government agency knowledge of particular safety or effectiveness issues in the context of allowing products to remain on the market merited particular weight that is not relevant here.

In *United States ex rel. Krahling v. Merck & Co., Inc.*, No. 10-cv-4374, 2023 WL 8367939 (E.D. Pa. July 27, 2023), for example, the two relators' allegations focused on the effectiveness and potency of Merck's MMR-II vaccine. In granting summary judgment in favor of Merck, Judge Kenney stressed the "extensive record" showing that (1) in 2001, the FDA issued a warning letter on the MMR-II potency issue, (2) later that year, one of the relators reported his concerns to the FDA, which the FDA "thoroughly" investigated before any *qui tam* action was filed, (3) the relators then filed their *qui tam*

complaint in 2010, (4) the United States declined to intervene in 2012, (5) the FDA, the CDC, and DOJ were actively involved in post-declination discovery in the case, which (as the Third Circuit would later clarify) included Rule 30(b)(6) depositions of CDC witnesses, (6) during a late stage in the litigation, one of relators' expert witnesses (a former FDA Commissioner) shared his conclusions with high-ranking officials of the U.S. Department of Health and Human Services, the CDC, and the FDA, which the Court allowed in order to "permit the appropriate health officials to assess . . . whether a public health issue exists, and to adopt measures, if any, in response," and (7) despite all of this, "the CDC . . . continued to pay" for the vaccines and the FDA did not take any action. The Court thus concluded: "Because these agencies are under a duty to review the information before them, the lack of response . . . strongly indicates that Relators' allegations are not material." *See Krahling*, 2023 WL 8367939, at *12-15 ("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."), *citing, e.g.*, 21 U.S.C. § 355(o)(4)(A) (requiring the FDA to promptly notify the responsible person if it becomes aware of new safety information or reduced-effectiveness information that the FDA determines should be included in labeling).

In affirming Judge Kenney's decision, the Third Circuit (1) ruled that "no reasonable jury could conclude" that the Government lacked knowledge of the relevant facts, and (2) stressed that the CDC continued to represent to the public that the MMR-II vaccine was effective. *United States ex rel. Krahling v. Merck & Co., Inc.*, No. 23-2553, 2024 WL 3664648, at *8 (3d Cir. Aug. 6, 2024).

Both Judge Kenney and the affirming Third Circuit panel cited to a Third Circuit decision, *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017).

See ECF 495 (Caremark's letter brief), at p. 1 (citing *Petratos*). In *Petratos*, the Third Circuit affirmed dismissal of allegations that Genentech suppressed adverse-event data for its cancer drug. As the Third Circuit summarized in *Krahling*, the *Petratos* court's reasoning was 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."). *Krahling*, 2024 WL 3664648, at *7. *See also Petratos*, 855 F.3d at 489-90 (noting that the relator "concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance," and that since his disclosures to the FDA, the agency "has not merely continued its approval" of the drug "but has added three more approved indications for the drug," all while not requiring any label change); *Krahling*, 2023 WL 8367939, at *15 (Judge Kenney finding the *Petratos* decision "[p]articularly instructive" and also relying on two other decisions involving "FDA's continued approval of product years after learning of relator's allegations that a manufacturer made false statements to obtain that approval," and drug misbranding tied to alleged safety issues).

In this quite different case (*Behnke*), however, the United States' non-intervention does not evidence Government knowledge or approval of the Caremark Defendants' practices rising to the level of even minimal relevance to the Court's materiality findings.

Second, it is a defendant's trial burden to prove a lack of materiality based on Government knowledge. *See U.S. ex rel. Int'l Bhd. of Elec. Workers v. Farfield Co.*, 5 F.4th 315, 346 (3d Cir. 2021) (affirming bench verdict where a relator made a "prima facie materiality showing," which the defendant failed to rebut with evidence that the

Government routinely pays claims despite actual knowledge) (citing *U.S. ex rel. Doe v. Heart Sol., P.C.*, 923 F.3d 308, 318 (3d Cir. 2019), a decision that affirmed summary judgment on materiality grounds where the Government met its "initial burden" to show materiality, and the defendant failed to rebut that with evidence that the Government normally pays challenged claims).

Third, any perceived Government "failure" to date to "claw back" from Caremark payments associated with falsely submitted claims should not bear on a materiality finding.

The United States frequently relies on relators to obtain recovery. At all stages of this litigation, sophisticated law firms have represented Behnke and the Caremark Defendants. When the Court did not extend the United States' evaluation period past April 2018, it was reasonable for the United States, before taking further action: (1) to rely on Relator Behnke and her counsel to represent the interests of the United States; (2) to rely on the litigation to shed light on Caremark's practices; and (3) to await the Court's ultimate findings and conclusions on whether the Caremark Defendants have violated the FCA. *See generally, e.g. Druding*, 81 F.4th at 374 n. 14 (Third Circuit stating: "As we recognized in *Farfield*, '[if] relators' ability to [meet] the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the [False Claims] Act,' which is explicitly designed to permit private litigants to litigate suits in lieu of the government.").

Relatedly, the Government's non-intervention decision should not be given weight on materiality because the Government may have lacked knowledge of relevant facts that were developed only during discovery, after the Government made its non-intervention decision. *See, e.g.*: (1) *Druding*, 81 F.4th at 375 n.16 (citing *United States ex*

rel. Foreman v. AECOM, 19 F.4th 85 (2d Cir. 2021) for the proposition that "[I]t makes sense not to place much weight on the government's response in the wake of [] litigation because, prior to discovery and a formal court ruling, the relator's allegations are just that—allegations, and the government may not necessarily have knowledge of all the material facts."); (2) *id.* at 374 ("if we credit . . . Relators' testimony that Care Alternatives' providers charted to 'paint a picture' of hospice eligibility . . . then the government would not have known that Care Alternatives was certifying patients who were potentially appropriate for hospice care."); (3) Behnke Summary Judgment Decision, 2024 WL 1416499, at *38 ("[A] factfinder might disagree that Caremark's reference to 'a few pharmacies' adequately apprised CMS of the scale of the situation. . . . And even if Caremark is correct that the phrase 'across the book of business' would have alerted CMS that Caremark's average price applied to both Part D and commercial purchases, it does not necessarily follow that CMS would understand that above-average payments on Part D purchases could be used to offset below-average payments on commercial purchases."); (4) *United States ex rel. Gohil v. Sanofi U.S. Servs.*, 2020 WL 4260797, at *16 (E.D. Pa. Jul. 24, 2020) (Brody, J.) (reasoning that, despite Government's knowledge of *allegations* of illegal conduct for 17 years, awareness of allegations does not equate to actual knowledge, and "Enforcement decisions and payment decisions do not line up perfectly. They are made by different government officials and involve different considerations."); (5) *United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 466-467 (W.D. Tex. 2020) (reasoning that: (a) the irrelevance of a Government declination "logically flows from the structure of the FCA, which expressly permits *qui tam* lawsuits in which a private citizen proceeds on behalf of the United States"; (b) the "Government's declination to

intervene does not indicate a decision was made by the Government that Relators' claims must fail"; (c) "the Court cannot speculate about what information the Government actually knows, especially in Medicare fraud lawsuits in which the Government has declined to intervene"; and (d) "It is equally likely that Medicare saw value in continuing to reimburse PVA for its services until the legality of its actions could be properly adjudicated."), *aff'd in part and rev'd in part*, 133 F.4th 395 (5th Cir. 2025); and (6) *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017) (in denying summary judgment, recognizing that allegations of wrongdoing are not conclusive, particularly where the defendant continues to deny liability).

In sum, it has been reasonable for the United States to wait to weigh the full set of facts developed through this litigation and the Court's forthcoming ultimate findings and conclusions before taking action in response to Relator Behnke's allegations. Accordingly, the Court should reject any assertion that the Government's non-intervention weighs against materiality.

CONCLUSION

The United States respectfully requests the Court to take notice of the United States' above-stated views.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date the foregoing Statement of Interest was electronically filed and is available for viewing and downloading via the Court's ECF system.

/s/ *Gerald B. Sullivan*
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Date: June 24, 2025