UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **REGENERON PHARMACEUTICALS, INC.,** **Defendant.**	**Civil Action No. 20-11217-FDS**

MEMORANDUM AND ORDER ON THE GOVERNMENT'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND REGENERON'S MOTION FOR SUMMARY JUDGMENT

SAYLOR, C.J.

This is a case alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, by a pharmaceutical company. The United States has brought suit against Regeneron Pharmaceuticals, Inc., the manufacturer of a drug named Eylea, alleging that Regeneron improperly funneled millions of dollars to the Chronic Disease Fund ("CDF")—a purportedly independent charitable foundation—to subsidize patient copays for Eylea.

According to the government, the purpose of the payments was to induce physicians to increase prescriptions of the drug at the expense of the Medicare Part B program. Among other things, the government asserts that the contributions to the foundation were not motivated by a charitable purpose; instead, Regeneron employees solicited and received Eylea-specific data from CDF and improperly used that data to determine the specific amounts Regeneron would contribute, and their purpose in doing so, according to the government, was to increase sales of

Eylea. The amended complaint alleges that Regeneron's actions violated the AKS and caused the submission of false claims for payment to Medicare.

For its part, Regeneron contends that it donated to a *bona fide*, independent charity in a manner that complied with the government's own regulatory guidance. It further asserts that its donations did not result in or cause any false claims because it was not the only donor for a significant portion of the relevant period; CDF awarded assistance on a first-come, first-served basis without regard to whether patients used Eylea or another FDA-approved treatment; CDF had sufficient funds to cover all copay support provided to Eylea patients in 2013 and 2014 without any donations from Regeneron in each respective year; and a majority of Eylea patients in 2013 were allocated funds from CDF before Regeneron made a single donation.

The government has moved for partial summary judgment on the issues of materiality, causation, and damages under the FCA. Regeneron has moved for summary judgment as to all claims. For the following reasons, the government's motion will be denied, and Regeneron's motion will be granted in part and denied in part.

I. Background

Unless otherwise noted, the following facts are undisputed.

A. Factual Background

1. The Parties and the Medicare Copay Assistance Program

Regeneron Pharmaceuticals, Inc. is a pharmaceutical company. (Answer ¶ 10). It manufactures Eylea, a drug that treats neovascular (wet) age-related macular degeneration ("AMD"), an eye disease that primarily affects elderly people. (*Id.* ¶¶ 10, 29). Eylea is administered by injection into the eye at a physician's office. (*Id.* ¶ 29).

Throughout the period from 2012 through 2014, the other primary drugs used by physicians to treat wet AMD were Lucentis and Avastin, both of which are manufactured by

Genentech. (Am. Compl. ¶ 30; Def.'s SUF ¶ 4).

Medicare, including the Part B program, covers physician-administered drugs, including Eylea. (Answer ¶ 13). Eylea is a "buy and bill" drug, which means that physicians buy the drug before prescribing and administering it to patients, filing a claim with Medicare (and, if applicable, a claim with a charity for copay assistance for the patient), and receiving reimbursement. (*See* Docket No. 275, Ex. 2 ("Kiss Dep. Tr.") 328:14-329:3).

2. Regeneron's Donations to CDF

The Chronic Disease Fund ("CDF") is a patient-assistance foundation. (Gov't's SUF ¶ 6). More than 99% of CDF's funding comes from pharmaceutical manufacturers. (*Id.* ¶ 7; Docket No. 226, Ex. 3 ("Walley Dep. Tr.") 20:5-10).

From at least 2007 through 2014, CDF operated a fund to provide copay assistance to wet AMD patients (the "AMD fund"). (Def.'s SUF ¶ 15; Docket No. 247, Ex. 18 ("Walley Decl.") ¶ 5). The AMD fund covered copays, deductibles, and co-insurance for Medicare patients who were prescribed AMD drugs. (Gov't's SUF ¶ 9; Walley Dep. Tr. 26:5-27:14). Originally, the AMD fund covered three FDA-approved treatments for wet AMD: Lucentis, Macugen, and Visudyne. (Def.'s SUF ¶ 18; Walley Decl. ¶ 6). It did not, however, cover Avastin, which is used off-label for the treatment of wet AMD. (*See* Def.'s SUF ¶ 9). In 2011, after Eylea received FDA approval, the AMD fund added it as well. (Def.'s SUF ¶ 19; Walley Decl. ¶ 6).

Regeneron had no role in establishing the AMD fund. (Def.'s SUF ¶ 16; Walley Decl. ¶ 5). Before 2011, Genentech, the manufacturer of Lucentis and Avastin, was the only manufacturer-donor to the AMD fund; it remained its leading donor until the end of 2013. (Def.'s SUF ¶ 29; Walley Decl. ¶ 15). In 2014, Regeneron became the AMD fund's only manufacturer-donor. (Def.'s SUF ¶ 31; Walley Decl. ¶ 16). Patients who received copay assistance for treatments from the AMD fund were not provided any information from CDF

about the source of the assistance they received. (Def.'s SUF ¶ 28; Walley Decl. ¶ 13).

B. Procedural Background

As amended, the complaint alleges presentation of false claims in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (2009) (Count 1); making or using false records material to a false or fraudulent claim in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B) (2009) (Count 2); and unjust enrichment (Count 3). Essentially, the complaint alleges that Regeneron's efforts to funnel money into CDF specifically to reimburse the copays of Eylea patients violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). The resulting claims to Medicare were allegedly tainted by illegal kickbacks in violation of the FCA.

The government has moved for partial summary judgment on the issues of materiality, causation, and damages under the FCA. Regeneron has moved for summary judgment on all counts.

II. Standard of Review

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "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). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant, would permit a rational factfinder to resolve the issue in favor of either party." *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990) (citation omitted). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse

party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quotations omitted). The nonmoving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256-57.

III. Analysis

A. Regulatory Framework

The False Claims Act, 31 U.S.C. §§ 3729-33, imposes civil liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" 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)(1)(A), (a)(1)(B). A "claim" is "any request or demand . . . for money or property" presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2).

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, states that "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or recommend purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program" shall be guilty of a felony. 42 U.S.C. § 1320a-7b(b)(2).

In 2010, Congress amended the AKS to provide that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g); Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010). In other words, an "AKS violation that results in a federal health care payment is a per se false claim under the FCA." *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (quoting *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135

(4th Cir. 2017)).

B. Regeneron's Motion for Summary Judgment

Regeneron has moved for summary judgment on all claims. As to the claims under the FCA, it contends that the government (1) cannot prove a predicate AKS violation; (2) cannot show that its donations resulted in the submission of any false Medicare claim; and (3) cannot prove that Regeneron had the requisite knowledge and intent. Regeneron has also moved for summary judgment on the unjust-enrichment claim. Each will be addressed in turn.

1. Whether the Government Can Show an AKS Violation

The first question is whether the evidence is sufficient to establish a violation of the AKS. As noted, that statute makes it illegal to "offer[] or pay[] any remuneration . . . to induce [any] person . . . to purchase . . . or recommend purchasing . . . any . . . item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Liability under the AKS requires an "intent to induce a referral or recommendation"; "[a]n intent to induce referrals . . . means an intent 'to gain influence over the reason or judgment' of the [prescribing] physicians." *United States v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 268, 271 (D. Mass. 2016) (quoting *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000)). Put another way, "the heartland of what the AKS is intended to prevent [is] the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs," such as Medicare. *Guilfoile*, 913 F.3d at 192-93.

A person or company who offers or pays remuneration to a healthcare provider violates the AKS "so long as *one purpose* of the offer or payment is to induce Medicare or Medicaid patient referrals." *McClatchey*, 217 F.3d at 835 (emphasis added). However, a person or company "cannot be convicted merely because [he] hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes." *Id.* at 834. The

factfinder must make the "difficult factual determination" of a payor-company's intent in paying or offering remuneration to a healthcare provider: that is, is the prospect of inducing Medicare-funded patient referrals the "motivating factor" for the remunerative relationship, or is it simply a "collateral hope or expectation"? *Id.* at 834 n.7. The former would subject the payor-company to liability under the AKS, while the latter would not.

The practice of waiving copays, or making donations to offset the cost of copays, may violate the AKS. Copay discounts or waivers made directly to patients certainly implicate the AKS. The Seventh Circuit has found that a pharmacy's practice of forgiving the copays of Medicare customers, and providing them small gifts (such as tins of caviar), in order to induce them to fill their prescriptions there, rather than at competitor pharmacies, was a "kickback" under the AKS:

> The fraudulent character of giving discounts or refunds to the pharmacy's customers is less obvious—what is wrong with offering an inducement that reduces a product's cost to the consumer? The answer is that a discount or refund can become a "kickback" . . . because it artificially inflates the price that the government pays pharmacies for prescription drugs for Medicare or Medicaid beneficiaries . . . The [discount or] refund to the customer would thus have been a "kickback" . . . because it would have increased the pharmacy's sales (and presumably its profits, as otherwise it wouldn't provide refunds) at the government's expense. It would have had done so either by diverting customers from other pharmacies or by inducing customers to purchase drugs that they would not have been willing to purchase had they been responsible for the copay.

United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc., 772 F.3d 1102, 1104-05 (7th Cir. 2014).

Similarly, improperly structured donations to copay-assistance charities may violate the AKS if they are made with the intent to induce Medicare-funded referrals or drug purchases. *See, e.g.*, *United States v. Teva Pharms. USA, Inc.*, 2023 WL 4565105 (D. Mass. July 14, 2023).

In 2005, the Office of the Inspector General for the Department of Health and Human Services ("HHS-OIG"), the agency that administers Medicare, issued a "special advisory

bulletin" addressing how companies may contribute to copay-assistance programs without violating the AKS and FCA. *See* HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).[1] The 2005 bulletin advises that "pharmaceutical manufacturers can donate to bona fide independent charity PAPs [patient assistance programs], provided appropriate safeguards exist." *Id.* at 70625. The bulletin contains an illustrative list of such safeguards, stating that a pharmaceutical company's donations to an independent copay-assistance charity "should raise few, if any, anti-kickback statute concerns," as long as:

> (i) Neither the pharmaceutical manufacturer nor any affiliate . . . exerts any direct or indirect influence or control over the charity or the subsidy program;
>
> (ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (*i.e.*, the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);
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> (iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;
>
> (iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
>
> (v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

Id. at 70626. It adds in a footnote to section (v):

> We have previously approved a bona fide independent charity PAP arrangement that included only limited reporting of *aggregate* data to donors in the form of monthly or less frequent reports containing *aggregate* data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category . . . Reporting of data that is not

[1] While the bulletin is directed to enrollees of Medicare Part D, the guidance (how to contribute to copay-assistance foundations without violating the AKS and FCA) is applicable to both Parts B and D.

> in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the aggregate, related to the identity, amount, or nature of subsidized drugs.

Id. at 70626 n.16. The bulletin summarizes these safeguards by stating the operative rule or criteria for evaluating the legality of donations to PAPs as follows: "Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id.* at 70627.

As set forth below, here the government has proffered sufficient facts to withstand a motion for summary judgment as to whether Regeneron violated the AKS.

a. Remuneration

The first issue is whether the donations by Regeneron to CDF qualify as "remuneration" under the AKS. Regeneron asserts that it had no control over which AMD treatments or patients CDF assisted, and that its donations therefore do not fall within the statutory prohibition. As noted, however, "the AKS prohibits even the indirect receipt of prohibited remuneration." *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *3 n.8 (D. Mass. Aug. 23, 2016). Here, there is evidence that the promise of copay assistance through CDF indirectly provided remuneration to the physicians prescribing Eylea. Remuneration means "anything of value"; the copay assistance eliminates the financial risk to physicians if they prescribed a drug for which patients cannot pay. (*See, e.g.*, Docket No. 247, Ex. 52 ("Miller Decl.") ¶ 4 ("I have to be cognizant of the costs of these drugs; I cannot take on the cost of patient balances myself."); *id.* at ¶ 5 ("[T]he availability of copay assistance often gives me the option to administer Eylea if Eylea is the wet AMD drug that I prefer for a given patient.")).[2]

[2] This definition of "remuneration" derives from a 1994 HHS-OIG bulletin: "In certain cases, a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles also could be held liable under the Medicare and Medicaid anti-kickback statute. 42 U.S.C. 1320a-7b(b). The statute makes it illegal to offer, pay,

Under the circumstances, there is sufficient evidence that the government can prove that the donations constituted "remuneration" within the meaning of the AKS.[3]

b. Inducement of Claims

The second issue is whether the donations constituted an "inducement" to purchase an item within the meaning of the AKS. Regeneron asserts that the structure of CDF made it impossible for the donations to "improperly influence" or "impermissibly influence" doctors' and patients' decision to purchase Eylea. *See Guilfoile*, 913 F.3d at 192-93; 70 Fed. Reg. 70627. For example, it contends that CDF allocated its AMD grants to patients on a first-come, first-served basis, and that physicians therefore had no way of knowing whether a patient would eventually receive copay assistance from CDF when they made their prescribing decisions.

However, the record contains evidence suggesting that at least some doctors did know about the availability of copay assistance before administering Eylea, and that the expectation of copay assistance did, in fact, change their behavior. (*See, e.g.*, Docket No. 247, Ex. 47 ("Sarrafizadeh Decl.") ¶ 4 ("Co-pay assistance for Medicare patients is a huge help in removing financial considerations from treatment decisions. Many Medicare patients with concerns about the high cost of co-pays can get branded wet AMD treatment like Eylea because of foundation payments. I am able to prescribe whichever drug I would like to my Medicare patients because I know the co-pay foundation will cover or significantly reduce their co-pays for branded drugs.");

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solicit or receive *anything of value* as an inducement to generate business payable by Medicare or Medicaid." HHS-OIG, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65375 (Dec. 19, 1994) (emphasis added).

[3] There is sufficient evidence that the government can prove that the donations constituted "remuneration" within the meaning of the AKS even under the Sixth Circuit's interpretation of the term in *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023). The court in *Martin* considered whether renumeration "covers just payments and other transfers of value or any act that may be valuable to another." *Id.* at 1048. The court held that the term "renumeration" is limited to "payments and other transfers of value," reasoning that a broader definition both contravenes the "four corners of the statute" and "lacks a coherent end point." *Id*. at 1048, 1050-52. In reaching that conclusion, the court found that a hospital's decision not to hire a particular doctor did not amount to an "offer of referrals" to another doctor. *Id*. at 1052.

Docket No. 247, Ex. 48 ("Siegel Decl.") ¶ 4 (discussing the availability of copay assistance from CDF for "many of [her] patients"); Docket No. 247, Ex. 49 ("Khan Decl.") ¶ 5 ("I typically have freedom of choice when prescribing wet AMD drugs to Medicare Part B patients because I know the patients will be able to afford the drugs once they receive copay assistance."); Docket No. 275, Ex. 72 ("Subramanian Decl.") ¶¶ 4-5 ("Cost is a consideration for me when recommending treatment. I will not administer Eylea unless the patient's insurance will cover it or the patient receives assistance or wants to pay out of pocket . . . Copay assistance or full payment assistance is usually available for my patients. My understanding is that this assistance comes from Regeneron.")).

Accordingly, there is sufficient evidence that the remuneration structure "influence[d] decisions on the provision of health care," *Guilfoile*, 913 F.3d at 193, and thus induced Medicare claims for Eylea.

c. Intent to Induce Claims

The third question is whether there is evidence that Regeneron had the necessary intent to induce purchases of Eylea. The government has submitted evidence that at least some Regeneron employees understood that they were receiving Eylea-specific data from CDF, used CDF-provided data to perform ROI calculations that affected the amount of Regeneron's contributions to CDF, and sought to conceal their use of such data from internal auditors.

For example, William Daniels, who testified that he "was Regeneron's main point of contact to co-pay assistance foundations and managed the relationship between Regeneron and those foundations," stated that he "had been receiving data from CDF that was specific to Eylea" and that he used CDF data to perform ROI calculations. (Docket No. 275, Ex. 3 ("Daniels Dep. Tr.") 11:22-24, 97:5-6). In addition, there is evidence that Bob Terifay, Regeneron's former Vice President of Commercial, changed an email from Daniels before forwarding it to the

internal audit team (a change that the government contends was made in order to conceal from internal auditors that Regeneron possessed Eylea-specific data from CDF). (*See* Docket No. 315, Ex. 1).

That evidence could support an inference that Regeneron intended to use CDF as a conduit to reimburse patients and influence the choices of physicians, and therefore had more than a vague "hope or expectation" that Eylea purchases would increase following donations to CDF. *See McClatchey*, 217 F.3d at 834 n.7.[4] Ultimately, intent is a "difficult factual determination" that should be left for a jury to decide, rather than the court at the summary-judgment stage. *See id.*

In summary, viewing the entire record in the light most favorable to the government and drawing all reasonable inferences in its favor, there is evidence that Regeneron paid remuneration, through donations to CDF, in order to induce physicians to recommend Medicare-subsidized purchases of its drugs and to induce patients to purchase those drugs. Accordingly, summary judgment will not be granted on the basis that there is insufficient evidence to establish a violation of the AKS.

2. Whether the Government Can Show that Regeneron's Donations Resulted in False Claims

As noted, any claim for Medicare reimbursement "that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of

[4] Nor can Regeneron establish at this stage that its intent was categorically proper based on the "safe harbor" described in the 2005 HHS-OIG guidance. Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623. The government has proffered some evidence (which Regeneron challenges) that Regeneron's combined donations to CDF in 2013 and 2014 closely tracked the AMD fund's total Eylea assistance during that period, which, in turn, could permit an inference that CDF unlawfully "function[ed] as a conduit for payments by the pharmaceutical manufacturer to patients." *Id.* at 70627.

In addition, given evidence that "[p]atients granted copay assistance for a calendar year did not necessarily receive copay assistance during that year," at this stage, the Court declines to compare the amount of its donations and CDF's assistance only on an annual basis. (*See* Docket No. 247, Ex. 22 ("Resnick Report") at 8 ¶ 19).

[the FCA]." 42 U.S.C. § 1320a-7b(g) (emphasis added). In other words, an "AKS violation that results in a federal health care payment is a per se false claim under the FCA." *Guilfoile*, 913 F.3d at 190 (citing *Lutz*, 853 F.3d at 135).

The meaning of the term "resulting from" is not settled, and has led to differing interpretations. *See United States ex rel. Fitzer v. Allergan, Inc.*, 2022 WL 846211 at *9 (D. Md. Mar. 22, 2022) ("Courts around the country have struggled to define the standard of causation that is required to prove an FCA claim based on an AKS violation."). At a minimum, the language clearly suggests that there must be a causal relationship of *some* kind between the AKS violation and the medical decision that resulted in the false claim. To date, the only pronouncement by the First Circuit on the question has been in *Guilfoile*: "[I]f there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA." *Guilfoile*, 913 F.3d at 190 (citing *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96-98 (3d Cir. 2018)).

The precise requirements of that "sufficient causal connection" are unclear. Among the principal unsettled questions are (1) the legal standard (but-for causation, or some other, less demanding, standard); (2) the nature and amount of the evidence that the government must present to prove the causal connection; and (3) the extent to which the defendant can offer countervailing evidence of a lack of causation.

Before turning to an analysis of the caselaw, there are two threshold questions. The first is whether the Third Circuit's decision in *Greenfield* is effectively binding on this Court. According to the government, it is, because the First Circuit cited that decision in *Guilfoile* for the proposition that there must be "a sufficient causal connection" between the violation and the

submitted claim. *Id.* It is true that the court in *Guilfoile* cited—although it did not discuss—*Greenfield*. But the court expressly disclaimed making a decision on the "full implications" of the statute, and did not elaborate on what it meant by a "sufficient causal connection." *Id.*[5] The court explained that engaging in such an analysis would be superfluous, as the issue facing the court was "not the standard for proving an FCA violation based on the AKS, but rather the requirements for pleading an FCA retaliation claim." *Id.*[6] Under the circumstances, this Court does not find *Greenfield*, or the causation standard set forth in that opinion, to be binding.[7]

The second question is whether this Court is bound by its own earlier decision in this case, issued December 4, 2020, denying Regeneron's motion to dismiss. Again, the answer to that question is no. That opinion did address the issue of causation, but at a relatively superficial level; moreover, that discussion was not informed by the opinion of the Eighth Circuit in *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022), and the Sixth Circuit in in *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023), neither of which had yet been issued. *United States v. Regeneron Pharms., Inc.*, 2020 WL 7130004, at *14-15 (D. Mass. Dec. 4, 2020). Furthermore, and in any event, that decision was an interlocutory order, which is subject to reconsideration at any point.[8] This Court will therefore consider the causation issue

[5] The *Guilfoile* court noted: "We have previously declined to directly address the impact of § 1320a-7b(g) on FCA actions, *see Hutcheson*, 647 F.3d at 379 n.1, and we do not attempt to assess the full implications of the AKS provision today." *Guilfoile*, 880 F.3d at 190.

[6] That distinction is potentially significant, because pleading a retaliation claim under the FCA "does not require adequately pleading the submission of a false claim or meeting the Rule 9(b) standards for pleading fraud." *Guilfoile*, 880 F.3d at 189. Plaintiffs who allege retaliation must only "plausibly plead a reasonable amount of smoke — conduct that could reasonably lead to an FCA action based on the submission of a false claim." *Id.*

[7] At least two other courts in this district, however, have concluded that *Guilfoile* counsels following *Greenfield*. *See Teva*, 2023 WL 4565105, at *5 (D. Mass. July 14, 2023) (quoting *United States ex rel. Bawduniak v. Biogen Idec Inc.*, 2022 WL 2438971, at *2 (D. Mass. July 5, 2022)). The *Bawduniak* court, however, acknowledged that the "First Circuit's analysis may not be binding." *Bawduniak*, 2022 WL 2438971, at *2.

[8] The doctrine of law of the case is not implicated, because '[i]nterlocutory orders, including denials of motions to dismiss, remain open to trial court reconsideration, and do not constitute the law of the case.'" *Harlow v.*

anew, without being bound by its prior ruling.

To date, there are three circuit opinions directly addressing the meaning of the term "resulting from a violation." *See Greenfield*, 880 F.3d at 96-100; *Cairns*, 42 F.4th at 834-37; *Martin*, 63 F.4th at 1052-55. As set forth below, those three opinions adopt two different approaches.

In *Greenfield*, 880 F.3d 89, the Third Circuit rejected a standard that would require proof "that federal beneficiaries would not have used the relevant services absent the alleged kickback scheme." *Id.* at 100. The court did not perform a textual analysis of the term "resulting from," or consider how that phrase had been interpreted in other contexts. Instead, it concluded that a requirement of but-for causation "would dilute the False Claims Act's requirements vis-à-vis the Anti-Kickback Statute, as direct causation would be a precondition to bringing a False Claims Act case but not an Anti-Kickback Statute case." *Id.* at 97. It further reasoned that such a standard would be inconsistent with the intentions of the drafters of the AKS, who sought "to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs." *Id.* at 96 (quoting H.R. Rep. No. 95-393, at 1 (1977)). As a result, it concluded that the legislative history suggests that a but-for causation standard was not required. *Id*. at 96-98.

Instead, the *Greenfield* court determined that the phrase "resulting from" requires the plaintiff (there, a relator) to prove only "a *link* between the alleged kickbacks and the medical care received." *Id.* at 100 (emphasis added). Such a plaintiff need not "show that a kickback

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Children's Hosp., 432 F.3d 50, 55 (1st Cir. 2005) (quoting *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d 40, 42 (1st Cir. 1994)); *see also Daumont-Colón v. Cooperativa de Ahorro y Crédito de Caguas*, 982 F.3d 20, 26 (1st Cir. 2020) ("[T]he Civil Rules authorize district courts to revise their own orders and decisions at any time before entering final judgment." (citing Fed. R. Civ. P. 54(b))).

directly influenced a patient's decision to use a particular medical provider," but must demonstrate "some connection between a kickback and a subsequent reimbursement claim." *Id.* at 97, 100.[9] The court expressly rejected the "taint" theory proposed by the relator, stating that "the taint of a kickback" does not "render[] every reimbursement claim false." *Id.* at 100. Instead, it concluded that a kickback will not "morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Id.*[10]

In *Cairns*, 42 F.4th 828, the Eighth Circuit declined to follow *Greenfield*, and instead held that "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment, it must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks." *Id.* at 836.

The court approached the issue as one of statutory interpretation. It began by observing that "[w]hen a statute is unambiguous, interpretation both begins and ends with the text." *Id.* at 834 (citing *Food Mktg. Inst. v. Argus Leader Media*, 139 S.Ct. 2356 (2019)). It then noted that the Supreme Court had interpreted "a nearly identical phrase, 'results from,' in the Controlled Substances Act" in *Burrage v. United States*, 571 U.S. 204 (2014). *Id.* There, the Supreme Court interpreted the phrase "results from" in that Act to require but-for causation. *See Burrage*, 571 U.S. at 212 ("Where there is no textual or contextual indication to the contrary, courts regularly read phrases like 'results from' to require but-for causality."). Because that but-for

[9] The court concluded that establishing "temporal proximity" between the kickbacks and the submission of claims, without more, is not enough. *Id.* at 100.

[10] Although as yet there are no other circuit opinions following *Greenfield*, the opinion has been followed by other district courts outside of Massachusetts. *See, e.g., United States v. Teva Pharms. USA, Inc.*, 2019 WL 13244248, at *2-3 (S.D.N.Y. Apr. 11, 2019); *Fitzer*, 2022 WL 846211 at *9; *Kuzma v. N. Arizona Healthcare Corp.*, 2022 WL 2159027, at *10 (D. Ariz. June 15, 2022); *United States ex. rel. Wallace v. Exactech, Inc.*, 2020 WL 4500493, at *19 (N.D. Ala. Aug. 5, 2020).

causation standard is the "default" or "background" rule against which Congress legislates, and because there are no textual indications to the contrary in the 2010 amendments, the court declined to consider legislative history and the drafters' purported intentions. *Cairns*, 42 F.4th at 835-36.

Like the *Greenfield* court, the *Cairns* court expressly rejected the "taint" theory proposed by the government. *Id.* at 835. The government had argued that "all that is required is that the illegal kickbacks 'tainted' the 'claim[] for goods or services' or the anti-kickback 'violation itself *may* have been a contributing factor.'" *Id.* The court observed:

> These alternative standards, however, are hardly causal at all. A 'taint' could occur without the illegal kickbacks motivating the inclusion of *any* of the 'items or services.' Similarly, asking the jury if a violation '*may* have been a contributing factor' does not establish anything more than a mere possibility.

Id. It further observed that as a matter of statutory construction, the phrase "resulting from" is "unambiguously causal," and therefore it was unnecessary to substitute a different causal standard when Congress itself had not done so. *Id.* at 836. It noted that if Congress intended to codify an expanded understanding of AKS enforcement in the 2010 amendments, "it could have selected different language." *Id.*

Most recently, in *Martin*, 63 F.4th 1043, the Sixth Circuit followed *Cairns* and adopted a but-for causation standard, reasoning that "[w]here a statute 'yields a clear answer, judges must stop.'" *Id.* at 1053 (quoting *Argus Leader Media*, 139 S.Ct. 2356, 2364 (2019)). The court noted that "[t]he ordinary meaning of 'resulting from' is but-for causation," and legislative history does not "overcome the ordinary meaning of the text." *Id.* at 1052-53. In addition, it observed that "we generally do not consider legislative history in construing a statute with criminal applications, the idea being that no one should be imprisoned based on a document or statement that never received the full support of Congress and was presented to the president for

signature." *Id.* at 1054.[11] And it cautioned that "reading causation too loosely" would mean that "[m]uch of the workaday practice of medicine might fall within an expansive interpretation of the Anti-Kickback Statute." *Id.* at 1054. A looser theory of causation would fail to "protect doctors of good intent, sweeping in the vice-ridden and virtuous alike." *Id.* A standard of but-for causation, on the other hand, "still leaves plenty of room to target genuine corruption." *Id.* at 1055. Accordingly, the court granted a motion to dismiss where there was "not one claim for reimbursement identified with particularity in this case that would not have occurred anyway." *Id.* at 1053. ("[T]he alleged scheme did not change anything.").

Here, the government acknowledges that it has the burden of proving some form of causal connection. In substance, it contends that the "exposure" theory set forth in *Greenfield* is correct: that is, once it has proved that an AKS violation occurred, all that is required to prove a causal link is that "a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Greenfield*, 880 F.3d at 100. According to the government, proof of but-for causation is not required, and evidence that a kickback actually influenced (or did not influence) a physician's medical judgment is irrelevant. Regeneron, in turn, contends in substance that a "but-for" causation standard should apply, and that the government bears the burden of proving that an AKS violation occurred and that the remuneration actually caused the physician to provide different medical treatment (and thus caused the false claims).

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[11] In a discussion earlier in the opinion concerning the term "remuneration," the *Martin* court observed:

> Recall that the same language creates civil *and* criminal liability. In the context of dual-application statutes like this one, we give the same interpretation to the same words, whether applied in a civil or criminal setting. That means that, if ambiguity exists over the meaning of a provision, the rule of lenity favors a narrower definition.

63 F.4th at 1050.

In the court's view, the standard set forth in *Greenfield* is fraught with problems. To begin, and as the *Cairns* and *Martin* courts observed, that standard is divorced from the actual language of the statute and from basic principles of statutory interpretation. It is likewise disconnected from long-standing common-law principles of causation.[12] As a result, and because the standard uses a term ("exposed") that is not set forth in the statute and is not part of a familiar common-law framework, its meaning is unclear and its application in specific factual contexts is uncertain. A simple hypothetical will help to illustrate the point.

Suppose a doctor has two options for treating a patient with a particular condition: product A or product B. Each year for several years, she writes 50 prescriptions for A and 50 for B. One year, she receives unlawful remuneration from the manufacturer of A, and her prescriptions that year rise to 75 for A and drop to 25 for B. If permitted (and, presumably, immunized), she would testify that based on her medical judgment, and in the absence of any remuneration, that year she would have written 65 for A and 35 for B. All the prescriptions resulted in Medicare claims.

How many false claims "result[ed] from" that AKS violation? If the standard is but-for causation, and the doctor's testimony is both permitted and credited, the answer is likely 10 (75

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[12] In *Universal Health Services v. U.S. ex rel. Escobar*, 579 U.S. 176 (2016), the Supreme Court held that a theory of implied false certification could provide a basis for liability under the FCA. In doing so, the Court examined the principles of common-law fraud. It wrote:

> Congress did not define what makes a claim "false" or "fraudulent." But it is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses. And the term "fraudulent" is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.

Escobar, 579 U.S. 176, at 187 (citation omitted).

The Seventh Circuit in *United States v. Luce* drew upon that reasoning to find that "nothing in the FCA contains any indication of an intent to depart from the common-law understanding of causation in fraud cases." *United States v. Luce*, 873 F.3d 999, 1012 (7th Cir. 2017). While *Luce* does not concern the language from the AKS at issue in this case, the opinion highlights the principle that Congress is presumed to incorporate well-settled judicial interpretations of terms when it enacts legislation.

minus 65). If the standard is but-for causation, and the doctor's testimony is not permitted or not credited, the answer is likely 25 (75 minus 50). If the standard is "taint" (that is, once the government has proved that the unlawful remuneration occurred, all of the prescriptions written by the doctor for A must be deemed to have resulted in false claims), the answer is 75.[13]

But what if the standard is "exposure"? Again, the *Greenfield* court expressly rejected both a but-for causation standard, 880 F.3d at 96, and a "taint" standard, *id*. at 100. In the hypothetical, what is the number of claims in which patients were "exposed" to an AKS violation? If the answer is 75, what is the difference between the rejected "taint" standard and the permitted "exposure" standard? If the answer is more or less than 75, what is the analytic process that leads to that result?

The *Greenfield* opinion also effectively bars the defendant from contesting the government's evidence of causation once an AKS violation is proved. As noted, the court concluded that because the government need only prove a "link" between the violation and the claim (which, again, it defined as an "exposure'), it is not necessary for the government to prove actual causation—that is, that the AKS violation actually caused the provision of the medical services that led to the false claim. *Id*. at 98, 100.

Following *Greenfield*, another judge in this district described the standard as follows:

> [A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a *quid-pro-quo* exchange or would have been submitted even absent the kickback. *See Greenfield*, 880 F.3d at 96. Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the

[13] Of course, the matter becomes considerably more complicated once other variables are introduced, such as multiple physicians and multiple patients with differing medical circumstances. The matching of the remuneration from the manufacturer to the physician may also be quite difficult, particularly where (as here) the alleged remuneration was indirect, more than one manufacturer is potentially involved, and there are temporal and other variables that make one-to-one tracing challenging as an evidentiary matter.

> physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

United States ex rel. Bawduniak v. Biogen Idec, Inc., 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018). Thus, under *Greenfield*, it is "sufficient" for the government to prove that a kickback was paid to a physician and the physician then prescribed the product.

Greenfield, however, went further, and concluded that the intent of the prescribing physician and the treated patient are necessarily irrelevant. 880 F.3d at 98. It is by no means obvious that such an approach is correct. The Court need not decide that issue for purposes of the present motion; nonetheless, it is reasonable to ask why the defendant could never be permitted to put on any evidence, from any source, suggesting that a particular referral or treatment was not actually caused by the AKS violation. Indeed, if that is correct, an AKS violation could lead to liability even if all of the prescribing physicians were unaware of the violation, and even if the violation did not cause a single additional referral or prescription. If nothing else, it is unclear how such an inducement "resulted in" any false claims. Proof of a "link" thus becomes akin to an irrebuttable presumption: it leads to liability even if the facts show no actual causation of any kind.[14]

In any event, in the Court's view, the statutory construction analysis set forth in *Cairns* and *Martin* is persuasive. The adoption by Congress of the "resulting from" language in the statute requires a finding that the appropriate standard is but-for causation, and the Court will follow that approach here.

[14] As this Court noted in *United States ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, another possible approach might be to adopt a burden-shifting framework; once the government has proved a *prima facie* case of causation, the burden would shift to the defendant to prove the contrary. *Flanagan*, 2022 WL 17417577, at *18 (D. Mass. Dec. 5, 2022).

It does not necessarily follow, however, that the government's burden is thereby made insuperably difficult. To begin, under tort law, but-for causation does not normally require that an actor be the sole factual cause of a harm. *See, e.g., Bostock v. Clayton County*, 140 S.Ct. 1731, 1739 (2020) ("[O]ften, events have multiple but-for causes."). Under traditional principles, a negligent act will satisfy the but-for causation requirement if it was a "substantial factor in bringing about" the harm. *Bernier v. Boston Edison Co.*, 380 Mass. 372, 386 (1980); *see Tritsch v. Boston Edison Co.*, 363 Mass. 179, 182 (1973); *Falvey v. Hamelburg*, 347 Mass. 430, 435 (1964).[15] It is thus likely that the government will not need to prove that the AKS violation was the only cause of the resulting false claim.

As to the quantum of evidence necessary to prove a violation, the government is not required in a civil case to adduce proof beyond a reasonable doubt. Under a preponderance standard, it need only prove that it was more likely than not that the AKS violation was the cause of the false claim. And the government, like any litigant, is entitled to attempt to prove its case through circumstantial evidence and reasonable inferences. It cannot do so through speculation or conjecture (for example, by arguing that there "must have been" a false claim resulting from the AKS violation), but its proof need not be beyond all possible doubt. And the Court sees no reason why its evidence may not, in the right circumstances, include proof of temporal proximity—although, as in any case where causation is proved in that manner, it may not be sufficient, and the reasonableness of the inference may be attenuated as the time period grows longer. *See Greenfield*, 880 F.3d at 100 (stating that proof of temporal proximity is not enough

[15] The Supreme Judicial Court has recently criticized the term "substantial contributing cause," calling it "confusing" and identifying the standard "proposed in the Restatement (Third) for multiple sufficient cause cases" as a more favorable alternative. *Doull v. Foster*, 487 Mass. 1, 17-18 (2021). Nevertheless, it remains true that there can be "multiple, simultaneously operating, sufficient causes" of a harm. *Id.* at 18.

to show the requisite "link"); *Martin,* 63 F.4th at 1053 (stating that "[t]emporal proximity by itself does not show causation, and seven months would create few inferences of cause and effect anyway.").

With that framework in mind, the question then becomes whether the government here has proffered sufficient evidence to establish but-for causation. The government has submitted a report from Ian Dew, who analyzed CDF disbursement data in conjunction with Medicare claims data and performed a "matching" analysis identifying Medicare claims for which CDF paid some or all of the beneficiary's copay. (*See* Gov't's SUF ¶¶ 20-21).[16] In order to perform that analysis, Dew "filtered the Medicare claims to include only those that list a Wet AMD diagnosis code" and "filtered the CDF disbursements to include only those disbursements from CDF's Wet AMD fund." (*Id.*, Ex. 10 at 1). He found that "115,192 Medicare claims in 2013 and 2014 had part or all of the beneficiary copayment covered by one or more CDF disbursements, and these claims resulted in reimbursements of $68,029,431 to providers." (*Id.* at 7).

In addition, the government points to other evidence that physicians would not have submitted claims for Eylea absent the co-pay subsidies. The price of Avastin, an alternative therapy, was dramatically lower than the price of Eylea, and it is surely true that physicians and patients alike would take the out-of-pocket cost of a drug into account when making medical decisions. That would be particularly likely here, where Eylea was a buy-and-bill drug that would leave the physician's practice bearing the cost of any unpaid copay obligations.

Regeneron contends that Dew's analysis cannot prove a causal "link" between *its* donations and Medicare claims, because he only "matched" disbursements from *CDF* to Eylea

[16] Regeneron disputes that Dew accurately analyzed that data and determined the Medicare claims for which CDF paid some or all of the beneficiary's copays.

patients. He did so, it asserts, despite evidence that CDF had multiple donors and a surplus of funds from another donor at that time. Thus, according to Regeneron, his analysis proves nothing more than "temporal proximity" between the donations and the Medicare claims, which *Greenfield* concluded was insufficient to establish causation. *See* 880 F.3d at 100.[17]

A similar argument, however, was rejected by another court in this district. *See United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 422 (D. Mass. 2021) ("Teva's assertion that the government cannot link its donations to specific false claims because other donors contributed to the relevant MS funds is unpersuasive."); *see Teva*, 2023 WL 4565105, at *3 (D. Mass. July 14, 2023) (considering matched-claims analysis of Ian Dew in rejecting defendant's motion for summary judgment as to causation under the FCA).

The government also contends that Regeneron's claim of a "surplus" is "misleading" as to 2013 and "grossly deceptive" as to 2014; among other things, it notes that Regeneron's expert witness improperly used an end-of-year figure for 2013 of $33 million and a beginning-of-year figure for 2014 of $65 million, even though the two figures should have been identical. (Gov't Opp. at 25-26).

Based on the record before the Court, it cannot conclude that the government's evidence, including Dew's analysis, is so flawed or incomplete as to every alleged false claim that judgment must necessarily enter for Regeneron. Resolving all doubts in favor of the government as the non-moving party, and construing the evidence in the light most favorable to it, the factual

[17] Regeneron further contends that because Dew testified that he was not expressing an opinion on causation, his analysis cannot establish a causal link. (*See* Docket No. 261, Ex. 4 ("Dew Dep. Tr.") 78:12-21). Because an expert's role is to provide opinions on evidence—not on legal concepts such as causation under the AKS and FCA—his testimony does not change the Court's conclusion.

evidence is sufficient to withstand summary judgment on the issue of causation. *See O'Connor*, 994 F.2d at 907.

3. Whether Regeneron Lacked the Requisite Scienter Under the FCA

Regeneron next contends that the government cannot establish a knowing violation of the FCA because it lacks evidence that the relevant decisionmaker at Regeneron—the CEO, Dr. Schleifer—"knowingly" caused the submission of false claims.[18]

As a general matter, a corporation is bound by the acts of its employees acting within the scope of their employment. *United States v. Bank of New England, N.A.*, 821 F.2d 844, 856 (1st Cir. 1987).[19] That principle applies to claims arising under the AKS and the FCA. *See United States v. O'Connell*, 890 F.2d 563, 568 (1st Cir. 1989) (explaining that the FCA does not "contain[] language that would preclude, or has a purpose that would not be served by, applying vicarious liability"). Thus, the relevant scienter is not limited to that of the CEO (who, of course, may well have been deceived by his employees); if a single employee of Regeneron had the requisite knowledge and intent, that is sufficient.[20]

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[18] To the extent Regeneron originally asserted that it lacked the requisite scienter because its conduct was consistent with an objectively reasonable interpretation of the law, that argument appears to have been foreclosed by the Supreme Court's recent decision in *United States ex rel. Schutte v. SuperValu Inc.*, 143 S.Ct. 1391 (2023) (holding that the FCA's scienter element refers to the defendant's knowledge and subjective beliefs, not what an objectively reasonable person might have known or believed).

[19] Under the "collective knowledge" doctrine, the "knowledge" attributable to a corporation is the sum of all of the knowledge possessed by all of its employees, regardless of their position. *See Bank of New England*, 821 F.2d at 856. For purposes of establishing scienter under the FCA, however, the "collective knowledge" doctrine does not apply. *See, e.g.*, *Banigan*, 2016 WL 10704126, at *5 (D. Mass. Aug. 23, 2016) ("Courts within the First Circuit require at least one individual within a corporate entity to have acted knowingly . . . ."); *see also United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) ("[U]nder the FCA, 'collective knowledge' provides an inappropriate basis for proof of scienter because it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act's language, structure, and purpose.").

[20] To the extent the language in *United States ex rel. Dyer v. Raytheon Co.*, 2013 WL 5348571 (D. Mass. Sept. 23, 2013) could be read to suggest that ordinary principles of vicarious liability do not apply in FCA cases, the Court will decline to adopt that position.

Here, as noted, there is evidence that certain Regeneron employees believed that they were improperly receiving Eylea-specific data from CDF and sought to hide that information from internal auditors.[21] That is evidence from which a reasonable inference could be drawn that those employees knew about the remuneration and understood that it was wrongful. Accordingly, and under the circumstances, there is sufficient evidence to defeat summary judgment on the issue of scienter.

4. Unjust Enrichment

Regeneron has also moved for summary judgment on the unjust-enrichment claim, contending that the government should be limited to the remedy Congress authorized in the FCA. The Court agrees.

"[A] party with an adequate remedy at law cannot claim unjust enrichment." *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017). In addition, "[i]t is the availability of a remedy at law, not the viability of that remedy, that prohibits a claim for unjust enrichment." *Id.* Accordingly, courts in this district have routinely dismissed unjust-enrichment claims under similar facts to those presented here. *See, e.g.*, *Teva*, 560 F. Supp. 3d at 423-24 (dismissing unjust-enrichment count "[b]ecause an adequate remedy at law exists in the government's FCA claims"); *United States ex rel. Martino-Fleming v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 133 (D. Mass. May 19, 2021) (same). Accordingly, summary judgment will be granted as to the claim of unjust enrichment.

[21] Regeneron disputes that its employees were receiving Eylea-specific information from CDF. However, the Court need not resolve that issue at this stage, because "[t]he FCA's scienter element refers to [defendant's] knowledge and subjective beliefs." *SuperValu*, 143 S.Ct. at 1399; *see also id.* at 1400 ("[T]he FCA's standards focus primarily on what [defendant] thought and believed."). As noted, the government has put forth evidence that at least some employees subjectively believed that they were receiving Eylea-specific data.

C. The Government's Motion for Partial Summary Judgment

The government has moved for partial summary judgment on (1) the materiality of violations of the AKS under the FCA; (2) the legal standard for FCA causation for claims "resulting from" AKS violations; and (3) the minimum amount of damages that Regeneron owes, should the government prove that it violated the FCA.

1. Materiality

The government contends that healthcare claims that include items or services resulting from kickbacks in violation of the AKS are *per se* materially false for purposes of the FCA. The Court agrees.

As noted, the 2010 amendment to the AKS clarified that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g); *see also Guilfoile*, 913 F.3d at 190 ("We further read the AKS amendment as obviating the need for a plaintiff to plead materiality—that is, to plead that compliance with the AKS was material to the government's decision to pay any specific claim."). Accordingly, "a violation of the AKS is per se a violation of the False Claims Act," and the government need not prove materiality. *Bawduniak*, 2022 WL 2438971, at *1-2.

It does not follow, however, that summary judgment will be granted to the government as to any claim asserted in the complaint. The government must still prove that the AKS was violated; the fact that its burden of proof is made easier by the 2010 amendment does not entitle it, without more, to summary judgment.

2. Causation

The government has moved for summary judgment on the issue of causation, contending that it need only show under the *Greenfield* standard of "exposure" a "sufficient causal

connection" between Regeneron's contributions to CDF and the resulting copay-assisted Eylea claims that Medicare reimbursed. For the reasons set forth above, the Court disagrees, and concludes that the government must prove but-for causation. Accordingly, the government's motion for summary judgment as to causation will be denied.

3. Damages

Finally, the government contends that if it establishes at trial that Regeneron violated the FCA, the Court should award damages in the amount of at least $195,800,553—that is, the amount the government asserts is the trebled value of the claims it contends were tainted by improper copay assistance.[22]

As a general matter, courts do not entertain motions for partial summary judgment on damages where a party's liability has not yet been determined. *See, e.g.*, *Marshall Contractors, Inc. v. Peerless Ins. Co.*, 827 F. Supp. 91, 93 (D.R.I. 1993) (finding that confronting damages questions on summary judgment before liability is established "may be a waste of judicial time"); *Boden v. St. Elizabeth Med. Ctr., Inc.*, 2018 WL 4855210, at *4 (E.D. Ky. Oct. 5, 2018) (denying motion as premature where movant attempted to "sidestep the crucial issue in this case" and place "the Court in the untenable position of being asked to render an advisory opinion on a hypothetical determination of critical facts"); *Robson v. Duckpond Ltd.*, 2021 WL 1222429, at *8 (E.D. Mo. Mar. 31, 2021) (holding that partial summary judgment on damages claims "would constitute an improper advisory opinion").[23]

[22] Dew calculated that Regeneron would be liable for at least $65,266,851 in single damages, which, if trebled, would amount to $195,800,553. (*See* Gov't's SUF ¶ 26).

[23] Of course, motions for summary judgment as to damages are not barred in all circumstances. *See, e.g.*, *Rudy v. City of Lowell*, 777 F. Supp. 2d 255, 259 (D. Mass. 2011); *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 8 (D. Mass. 2006). However, in most cases where courts have granted such a motion, the parties did not "dispute the facts or the defendant's liability." *See Rudy*, 777 F. Supp. 2d at 259; *see also City of New York v. Golden*

Although the critical questions in this case—whether Regeneron violated the AKS and caused the submission of false claims for payment to Medicare—remain undecided, the government has asked the Court to rule on the minimum amount of damages assuming, as a hypothetical, that the violations of the AKS and FCA are conclusively established.[24] Although the Court acknowledges the benefits of resolving matters prior to trial, it is not convinced that judicial economy is served by ruling on hypothetical issues that may never have to be addressed. It will therefore deny the motion.

IV. Conclusion

For the foregoing reasons, the motion of the United States for partial summary judgment is DENIED, and the motion for summary judgment of defendant Regeneron Pharmaceuticals, Inc., is GRANTED as to the unjust-enrichment claim, and otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: September 27, 2023

Feather Smoke Shop, Inc., 2013 WL 3187049, at *33 (E.D.N.Y. June 20, 2013) ("A court may grant summary judgment as to damages *following a determination on liability* . . . .") (emphasis added)).

[24] This case is therefore unlike *Teva*, where the court granted summary judgment on the proper *standard* for measuring damages. *See Teva*, 2023 WL 4565105, at *5-6 ("[T]he Court will measure damages in this case as the entirety of the government's payments for the claims resulting from the illegal kickbacks."). As the government acknowledged at oral argument, it had not previously sought summary judgment on the legal standard for damages, but rather the minimum amount of damages. (Docket No. 339 ("Hearing Tr.") at 78).