UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO DISMISS

SAYLOR, C.J.

This is a case alleging violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and False Claims Act, 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 a purportedly independent foundation to subsidize patients' copays for Eylea, inducing physicians to increase prescriptions of the drug at the expense of the Medicare Part B program and subverting the program's copay requirement. The complaint alleges that Regeneron's actions violated the Anti-Kickback Statute and caused the submission of false claims for payment to Medicare.

Regeneron has moved to dismiss the complaint for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), for failure to allege fraud with particularity as required by Fed. R. Civ. P. 9(b), and based on constitutional challenges under the First and Fifth Amendments. For the following reasons, the motion will be denied.

I. Factual and Procedural Background

Unless otherwise noted, the following facts are as alleged in the complaint.

A. The Parties and the Medicare Copay Assistance Program

Regeneron Pharmaceuticals is a pharmaceutical company founded in 1988. (Compl. ¶ 28). It manufactures Eylea, a drug to treat neovascular (wet) age-related macular degeneration ("AMD"), an eye disease that primarily affects elderly people. (*Id.* ¶ 29). Eylea is administered by injection into the eye at a physician's office. (*Id.*). It costs approximately $1,850 per dose. (*Id.*). The recommended dose is one injection per eye, once a month for the first 12 months, and 6-7 injections per year thereafter. (*Id.*). Eylea is presently the best-selling drug in the United States for AMD. (*Id.* ¶ 31).

Eylea has two primary competitors, Avastin and Lucentis, both made by Genentech. (*Id.* ¶ 30). All three drugs have comparable efficacy. (*Id.*). Lucentis costs $2,000 per dose. Avastin costs $55 per dose, but it is only FDA-approved to treat certain types of cancer. Some physicians nonetheless use it "off-label" to treat AMD. (*Id.*).

Medicare is a federally funded insurance program for people aged 65 or older and for people with certain disabilities or afflictions. (*Id.* ¶ 11). Medicare Part B covers outpatient medical services and physician-administered drugs, like Eylea. (*Id.* ¶ 13). Once a beneficiary meets his or her annual deductible (currently $198), Medicare Part B pays 80% of the cost of covered prescription drugs, while the beneficiary is responsible for the remaining 20% copay. (*Id.* ¶ 14). Some Medicare beneficiaries purchase supplemental insurance, called Medigap, to cover the copays. (*Id.*).

The purpose of requiring Medicare beneficiaries to pay copays is to give them an incentive to choose the most cost-effective treatment. (*Id.* ¶ 15). When a physician administers

a drug covered by Medicare Part B, he or she submits claim to Medicare for the drug, and then receives a reimbursement from Medicare of 106% of the average sales price of the drug less the 20% copay. (*Id.* ¶ 16). The physician is then responsible for collecting the copay from the patient. (*Id.*).[1]

The Chronic Disease Fund ("CDF"), now operating as Good Days, is a non-profit foundation that solicits donations from, among others, pharmaceutical companies, and uses that money to cover Medicare copays for prescription drugs. (*Id.* ¶ 32). Since 2010, CDF has operated an "AMD fund" that covers Medicare copays for patients prescribed AMD drugs. (*Id.*). Before the FDA approved Eylea in 2011, Genentech, the maker of Lucentis, alone financed the AMD fund. (*Id.* ¶ 33). Following FDA approval for Eylea in 2011, Regeneron also began to finance the AMD fund, which began to cover copays for Eylea and Lucentis, but not Avastin. (*Id.*). If a physician administers Eylea to a Medicare patient who indicates that they will have trouble affording the copay, the physician may submit a claim to CDF for the applicable Medicare copay, and CDF will pay that amount directly to the physician. (*Id.* ¶ 35). Thus, if CDF approves a copay grant for an Eylea patient, the physician does not need to collect the copay from the patient and does not bear the financial risk if the patient cannot afford to pay it. (*Id.*).

In 2013 and 2014, Regeneron contributed tens of millions of dollars to the AMD fund. (*Id.* ¶¶ 1, 4). The complaint alleges that Regeneron did so in order to induce physicians to prescribe and submit claims for Eylea, which Medicare then reimbursed. (*Id.* ¶¶ 3-4). The complaint further alleges that Regeneron continuously communicated with CDF to ensure that it

[1] Eylea is a "buy and bill" drug, which means that physicians buy the drug in bulk and store it in their offices 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 reimbursements. (Def. Mem. at 5).

was donating enough to cover the Medicare copays of Eylea patients only. (*Id.*). According to the complaint, Regeneron employed a business model under which any increase in the list price of Eylea could benefit Regeneron, at taxpayer expense, if it funneled matching donations to a foundation to cover copays: for every $100 increase in the price of the drug, Regeneron could contribute $20 to a copay assistance foundation to eliminate the financial burden on patients of the 20% copay, while receiving $80 in Medicare reimbursements.

The complaint alleges that the promise, or implicit guarantee, of copay assistance from CDF significantly altered the decision-making of patients and physicians. Because CDF covers copays for Eylea and Lucentis, which cost $1,850 and $2,000 per dose respectively, but not Avastin, which costs $55 per dose, Eylea and Lucentis are actually cheaper out-of-pocket than Avastin for Medicare patients. (*Id.* ¶ 30). According to the complaint, when physicians knew that copay assistance was not available for Eylea or Lucentis, they often prescribed the cheaper Avastin, in order to avoid the risk of burdening their patients with expensive copays or being unable to collect the copays. (*Id.*).

Regeneron contends that its donations were charitable in nature and not made to improperly induce patients or physicians to purchase Eylea. (Def. Mem. at 19). It asserts that the AMD fund was structured in such a way as to make it impossible for its donations to influence physicians' prescribing behavior. (*Id.* at 12). CDF allocated its AMD grants to patients on a first-come, first-served basis. (*Id.*). Therefore, according to Regeneron, physicians had no way of knowing whether a patient would eventually receive copay assistance from CDF when they made their prescribing decisions. (*Id.*).

B. Regeneron's Allegedly Improper Behavior

The complaint describes several events from 2011 to 2014 that allegedly demonstrate that

Regeneron donated certain amounts to CDF in order to improperly influence, induce, and increase prescriptions and claims for Eylea in violation of the Anti-Kickback Statute, causing false claims to be submitted to Medicare.

1. The Xcenda Report

Prior to the commercial launch of Eylea in 2011, Regeneron commissioned a report from Xcenda, an outside consultant, to analyze the proposed pricing and reimbursement structures for the drug. (Compl. ¶ 36). Xcenda concluded, based on projected sales and the estimated proportion of patients who would need Medicare copay assistance, that Regeneron should donate approximately $3 million to copay assistance foundations in 2012 to offset the cost of Eylea copays. (*Id.*).

At that time, Regeneron was considering a price of $1,500 per injection. (*Id.* ¶ 37). Xcenda's report found that increasing the price to $1,950 would benefit Regeneron financially, because the 43% increase in donations to copay assistance foundations that Regeneron would need to make would be offset by revenue increases from Medicare reimbursements. (*Id.*). Ultimately, Regeneron set the price of Eylea at $1,850. (*Id.* ¶ 38).[2]

The Xcenda report also recommended that Regeneron refer Medicare patients who could not afford Eylea to a copay foundation, rather than providing them with free Eylea. (*Id.*). The reasoning was that although those two options would both eliminate out-of-pocket expenses for patients, offering free Eylea would generate no revenue for Regeneron, while offering copay assistance would generate revenue from the resulting Medicare claims. (*Id.*). To date, Regeneron offers free Eylea to patients who cannot afford it only if they do not have insurance

[2] According to Regeneron, it has not changed the price of Eylea from $1,850 per dose since its launch. (Def. Mem. at 5).

coverage for Eylea, while barring Medicare patients from its free-drug program. (*Id.*).

2. Regeneron's Donations to and Communications with CDF[3]

The FDA approved Eylea for treatment of wet AMD on November 28, 2011. (*Id.* ¶ 41). Regeneron gave CDF $125,000 in 2011 and $600,000 in 2012. (*Id.*). Cynthia Sherman, the former senior director for reimbursement at Regeneron, testified that the company did "not provide a lot of money the first year because you just didn't know how many—what the uptake of Eylea would be, and Regeneron did not want to pay for Lucentis's copay." (*Id.*). Eylea sales in 2012 greatly exceeded expectations, causing Regeneron to consider increasing their donations to CDF. (*Id.* ¶ 42).

On July 9, 2012, Robert Krukowski, a senior manager for reimbursement at Regeneron, asked his direct report, William Daniels, if Daniels had spoken to Clorinda Walley, CDF's executive director, about increasing Regeneron's contribution to CDF and by what amount. (*Id.* ¶ 44). On July 23, Daniels emailed Walley requesting a meeting, stating that he would "need to justify [his] request for [Regeneron's] 2013 donation." (*Id.*). On July 24, Walley provided Daniels with a spreadsheet entitled "Regeneron Projections 2013," which projected the number of Eylea patients assisted by the AMD fund and the amount of copay assistance they would need over 2013, concluding that CDF needed $40 million in contributions from Regeneron to cover the cost of Eylea copays. (*Id.* ¶ 45).

[3] A substantial portion of the government's allegations concern alleged internal communications among Regeneron and CDF staff. The list of relevant people includes the following: Clorinda Walley, the executive director of CDF; Robert Krukowski, a Senior Manager for Reimbursement at Regeneron; William Daniels, Krukowski's direct report and Walley's point of contact at Regeneron; Cynthia Sherman, the former Senior Director for Reimbursement at Regeneron; Bob Terifay, Regeneron's Vice President, Commercial; Stephen Dressel, a Regeneron financial analyst; Robert Davis, Regeron's Executive Director and Head of Trade, who reported directly to Terifay; Cathy Casey, Regeneron's Senior Director for Reimbursement Strategy; Christopher Fenimore, Regeneron's Vice President of Financial Planning; John Calabro, Regeneron's Vice President of Internal Audit; and Thibaux Corbin de Mangoux, Regeneron's Manager of Internal Audit and Calabro's direct report.

Daniels, believing it unlikely that Regeneron senior management would approve a $40 million donation to CDF, performed his own analysis to estimate the amount that CDF would need to cover Eylea patients' Medicare copays in 2013. (*Id.* ¶ 46). He concluded that CDF would need about $5.6 million to cover "rollover patients" (that is, renewals of copay-assistance grants that CDF gave Eylea patients in 2012) and $11.5 to $19 million to cover new patients. (*Id.*). In anticipation of an October 8, 2012 meeting of senior management to discuss Regeneron contributions to CDF, Daniels sent several emails, slides, and documents comparing his and Walley's projections. (*Id.* ¶¶ 47-51). One such document projected "millions of dollars of potential lost sales" if Regeneron did not donate enough to CDF to cover the Medicare copays of potential new Eylea patients. (*Id.* ¶ 48). Another warned, "CDF management has communicated that for 2013, if every donor doesn't cover their market share the fund will be closed." (*Id.* ¶ 50). A slide that Daniels circulated on August 27 reported that Regeneron's share of the AMD fund was 6,200 patients, as quoted by CDF, and that Regeneron would face potential lost revenue of approximately $10.9 million if the fund were to shut down in 2013. (*Id.*). Notwithstanding those projections, at the meeting on October 8, 2012, the senior management team decided that Regeneron would pay CDF only $2.5 million in 2013, a number that Daniels subsequently conveyed to Walley. (*Id.* ¶ 52).

On December 29, 2012, Walley e-mailed Daniels a warning that a contribution of $2.5 million would not enable the AMD fund to stay open past early 2013. (*Id.* ¶ 53). Walley attached a revised projection showing that the AMD fund would need approximately $25 million to cover Medicare copays for Eylea patients in 2013. (*Id.*).

On January 3, 2013, Daniels and Krukowski had another meeting with senior Regeneron officials to discuss donations to CDF. (*Id.* ¶ 55). After the meeting, Krukowski sent attendees

an email reiterating that "the additional $2.5 million we were planning on funding in Q1 was not enough based up[on] the current number of EYLEA patients CDF has already rolled over and enrolled for 2013 . . . we need to up our funding in Q1 significantly and make Bob [Terifay, Regeneron's Vice President, Commercial] aware that we potentially need ~$25mil to adequately fund our patient responsibility for 2013." (*Id.*). On January 4, Christopher Fenimore, Regeneron's Vice President of Financial Planning, requested that Stephen Dressel, a financial analyst, "walk us through with Bob [Terifay] the economics of how much we contributed last year vs. [Genentech], how much got paid out to Lucentis v. Eylea patients last year, and based on this info what we think we'll need to do this year to keep the fund solvent." (*Id.* ¶ 56). That same day, Fenimore reported that "Bob [Terifay] just walked me through the logic . . . we agree to put $25 million in the plan." (*Id.*). The complaint alleges that this donation of $25 million exactly matched the amount that CDF requested to cover Eylea copays in 2013. (*Id.*).

On February 13, 2013, Regeneron paid CDF $5 million, and on May 1, Regeneron paid CDF $7.5 million. (*Id.* ¶ 58). That donation of $12.5 million in the first half of 2013 was exactly half of the $25 million that CDF projected it would need to cover Eylea copays in 2013.

On June 18, 2013, Walley e-mailed Daniels an updated "Regeneron Projections 2013" spreadsheet, which showed that CDF would now need $35 million to cover Eylea copays in 2013, given recent claim activity—an increase from the previous $25 million estimate. (*Id.* ¶ 59). Daniels created an internal slide presentation to justify the increased request for $35 million, which reported the following, based on Eylea-specific information provided by Walley: CDF had paid $32.6 million in claims through June 3, 2013; renewals for Eylea patients accounted for 41% of the AMD fund; and Regeneron could expect a return on investment (ROI) of 465%, or $198.5 million in potential Eylea sales, from paying CDF $35 million in 2013. (*Id.*

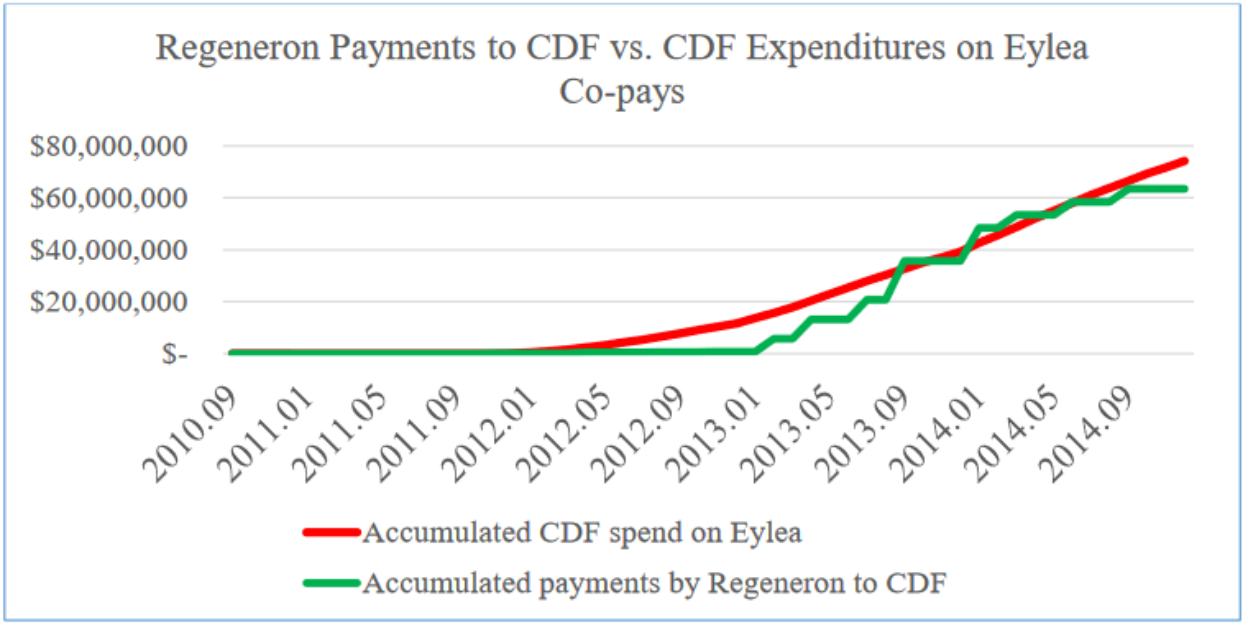
¶ 60). On June 26, 2013, upon viewing these slides, senior managers at Regeneron announced that they agreed to pay CDF the full $35 million requested in 2013 to cover copays for Eylea patients. (*Id.* ¶ 61).

On August 21, 2013, Regeneron paid CDF $7.5 million; on September 25, Regeneron paid CDF $10 million; and on October 1, Regeneron paid CDF $5 million. (*Id.* ¶ 63). Those donations, coupled with the $12.5 million donated in the first half of 2013, totaled $35 million in 2013, equal to the amount that CDF reported was necessary to cover Eylea copays. (*Id.*).

On January 3, 2014, Walley sent Daniels an estimate that Regeneron would need to donate $25.5 million to cover CDF's copay assistance to Eylea patients in the first quarter of 2014. (*Id.* ¶ 65).[4] Daniels later testified that he understood this request was meant to cover costs for Eylea patients only. (*Id.*). On January 6, Daniels sent an email to senior management, including Bob Terifay, Regeneron's Vice President, Commercial, and Stephen Dressel, the financial analyst, recommending that Regeneron donate $25.5 million to CDF in the first quarter of 2014, in two equal installments of $12.75 million each. (*Id.* ¶ 66). On January 10, Daniels and his manager Krukowski learned from a Regeneron sales representative that CDF was "out of funds" and as a result, a large retina clinic was "putting patients only on Avastin." (*Id.* ¶ 67). On January 15, Regeneron paid CDF $12.75 million, as recommended by Daniels as half of what was requested by Walley. (*Id.* ¶ 69).

In sum, from 2011 through 2014, Regeneron's payments to CDF matched very closely to CDF's spending on Eylea copay assistance, as demonstrated in the following chart:

[4] This represented the sum of $29.5 million to renew grants for Eylea patients and $5.5 million for new grants, less $9.5 million credited to Regeneron for its 2013 donations to CDF that had not yet been paid out in grants. (*Id.* ¶ 65).



(*Id.* ¶ 90).

The complaint does not allege that the pattern of communication and matching donations between CDF and Regeneron continued past early 2014, but states that "the scrutiny of CDF and other co-pay foundations intensified" and caused the parties to become "more circumspect in their written communications and patterns with respect to funding requests and payments." (*Id.* ¶ 70). Nonetheless, based on the pattern established over 2011-2014, the complaint alleges that by 2014, "Regeneron understood from CDF that CDF was using Regeneron's money to ensure that physicians did not need to consider the impact of Medicare copays when deciding to purchase and prescribe Eylea." (*Id.*).

3. <u>Resulting False Claims to Medicare</u>

The complaint alleges that Regeneron's funding of CDF induced "thousands" of Medicare-reimbursed purchases of Eylea, resulting in "tens of millions of dollars" of Medicare claims. (*Id.* ¶¶ 97-98). Since 2013, Medicare Part B has spent over $11.5 billion on Eylea reimbursements; in 2013 and 2014 alone, Medicare spent $1.9 billion for the drug. (*Id.* ¶ 1).

When CDF approved applications for Eylea subsidies, it would pay the 20% copay directly to prescribing physicians, and the physicians submitted associated claims to Medicare to cover the remaining 80% of the cost of the drug. (*Id.* ¶ 99). The complaint provides representative examples of eleven Massachusetts patients who received Eylea injections in 2013 and 2014, for whom CDF covered the $392.20 copays in full and Medicare paid the remaining $1,537.42 cost to the physician. (*Id.* ¶ 101).[5]

C. Regeneron's Alleged Knowledge of Wrongdoing and the Internal Audit

The complaint alleges that Regeneron knew that it should not use CDF as a conduit for Eylea patient reimbursements and that it should not solicit Eylea-specific data from CDF in order to set its donation amounts. Further, it alleges that Regeneron executives knew their actions were unlawful and attempted to hide evidence of their communications with CDF from internal auditors.

For example, in 2011, Cynthia Sherman, then the senior director for reimbursement at Regeneron, warned her superiors that it was illegal to seek out a "breakdown of [CDF] spend by Eylea users" and to get "actual utilization data" for the number of Eylea reimbursements from the CDF fund. (Compl. ¶ 72). Following the October 8, 2012 meeting where William Daniels reported that CDF had funded 6,200 Eylea patients, Robert Davis, Regeneron's Executive Director and Head of Trade, warned Daniels and his supervisor Robert Krukowski that Regeneron should not be receiving or using Eylea-specific data from CDF. (*Id.* ¶ 73). On December 5, 2012, Daniels e-mailed Krukowski a copy of a Special Advisory Bulletin issued by the Office of the Inspector General to the Department of Health and Human Services ("HHS-

[5] For one of these patients, Medicare paid $1,511.81 and the copay amount was $385.66, but the parties do not explain why the list price of Eylea was slightly lower for this patient.

OIG") in November 2005, which cautioned pharmaceutical companies against "solicit[ing] or receiv[ing] data from [copay assistance] charit[ies] that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products" so as to not run afoul of the Anti-Kickback Statute. *See* HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005). (*Id*. ¶ 74).

In February 2013, Regeneron's internal auditors John Calabro and Thibaux Corbin de Mangoux began an audit of the company's financial assistance programs, including its relationship with CDF. (*Id.* ¶ 76). Corbin e-mailed Daniels, requesting "detail around the rationale for the amount paid [to CDF]," including any "analysis" of the amount and "feedback reports . . . on how money given by Regeneron is actually being spent." (*Id.* ¶ 77). Daniels forwarded the request to Krukowski, Davis, and Terifay, commenting, "Please see below. I am not really comfortable providing the documentation he is requesting." (*Id.*). Terifay responded to the audit team: "Pharmaceutical companies cannot provide reimbursement assistance of any kind to patients covered in any way by a government insurance program. . . [D]onors have no rights to information of any sort of disposition of funds . . . We cannot ask for any information from the CDF. We gave a charitable donation." (*Id.* ¶ 79). Terifay's response also included an altered version of Daniel's original comment, which now read: "I am not really comfortable *asking for* [formerly 'providing'] the documentation he is requesting." (*Id*. ¶ 80).

In November 2013, Regeneron reopened the internal audit. Following a November 22, 2013 meeting between the auditors, Davis, Krukowski, and Casey, Calabro sent the participants an email seeking to confirm that Daniels "ha[d] not had any conversations with CDF concerning product level data" and requesting "a copy . . . of the monthly report of aggregate data we

receive from CDF." (*Id.* ¶ 84). Regeneron, however, had only received one "monthly report of aggregate data" about the AMD fund, in February 2012; instead, it had mainly been receiving spreadsheets from CDF showing non-aggregate, Eylea-specific numbers and expenditures within the AMD fund. (*Id.*). Upon receiving that request from the auditors, Daniels asked Walley for the "monthly CDF activity report" and sent it to Calabro, without disclosing that he had only once before received such "aggregate monthly" data and typically received different, Eylea-specific data from CDF instead. (*Id.* ¶ 85).

Calabro followed up by asking Daniels: "Do you receive any other reports or data in emails from CDF? If so, please provide. How does CDF make a request for additional funding? Is it verbal or by email? How do they justify it? Please provide any documentation you might have regarding such requests." (*Id.* ¶ 86). Daniels forwarded the e-mail to Terifay, asking, "How should [we] answer second question from [Calabro]?" (*Id.*). Terifay responded, "Isn't the answer that she estimates what she needs for the year verbally and then we divide across the year when we can afford it," an answer that the complaint alleges Terifay knew was false. (*Id.*). Accordingly, Daniels responded to Calabro: "No, I don't receive any other reports or data. My contact estimates what she needs for the year verbally and then we divide across the year when we can afford it. If she is running low, she calls and indicates what more she needs." (*Id.* ¶ 87). Daniels later testified that his statement, "I don't receive any other reports or data," was false, and that he said it because he was told to; he also testified that the remainder of his e-mail was a summary of Terifay's answer, which Daniels considered to be incomplete. (*Id.*).

Calabro followed up again in an email to Daniels, Davis, Krukowski, and Casey, asking, "When [Walley] makes a request for funding, how does she justify it? Can you send me an example email?" (*Id.* ¶ 88). Davis responded, "It is all verbal." (*Id.* ¶ 88). Again, this was a

false statement, according to the allegations of the complaint, which states that Walley requested funding using e-mails and spreadsheets showing the exact amounts requested to compensate Eylea patients.

D. Procedural Background

The United States filed a complaint on June 24, 2020, alleging 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 False Claims Act, 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 tainted by illegal kickbacks in violation of the False Claims Act.

Regeneron has moved to dismiss the complaint on the grounds that (1) the complaint fails to state a claim for violation of the Anti-Kickback Statute; (2) the complaint fails to state a claim that Regeneron's donations caused the submission of false claims; (3) the complaint fails to plead the violations of the Anti-Kickback Statute and False Claims Act with the sufficient particularity necessary to satisfy Fed. R. Civ. P. 9(b); and (4) the government's prosecution violates the First Amendment and the due-process rights guaranteed by the Fifth Amendment.

II. Legal Standard

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its

face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Medico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

Under Rule 9(b), the standard for allegations of fraud is higher than the normal pleading standard. To survive a motion to dismiss, a complaint alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

III. Analysis

A. Regulatory Framework

The False Claims Act ("FCA"), 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 ("AKS"), 42 U.S.C. § 1320a-7b, states that "whoever 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 clarify that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the 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 *U.S. ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017)).

B. Whether the Complaint States a Violation of the Anti-Kickback Statute

Defendant contends that the complaint fails to state a violation of the AKS because its donations to CDF were not intended to—and could not—induce patients or physicians to purchase Eylea.

The AKS 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 . . . 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," and "[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," like Medicare. *Guilfoile v. Shields*, 913 F.3d 178, 192-93 (1st Cir. 2019) (finding allegations that healthcare conglomerate paid referral fees to a consultant to refer hospital contracts to the conglomerate and then billed Medicaid and Medicare for its services were sufficient to state a claim under the AKS).

The intent of the entity providing remuneration is critical to proving an AKS violation. 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." *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) (emphasis added) (upholding criminal conviction based on this jury instruction and rejecting defendants' argument that government must prove their *primary* purpose was to induce referrals). 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. A jury 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 subjects the payor-company to liability under the AKS, while the latter does not.

Under this legal framework, companies' practices of waiving copays or making donations to offset the cost of copays may violate the AKS, as case law and guidance from the Office of the Inspector General for the Department of Health and Human Services ("HHS-OIG"), the agency that administers Medicare, have established. Copay discounts or waivers made directly to patients certainly implicate the AKS. The Seventh Circuit has found that a pharmacy's practice of forgiving Medicare customers' copays, 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.

U.S. ex rel. Grenadyor v. Ukrainian Village Pharmacy, Inc., 772 F.3d 1102, 1104-05 (7th Cir. 2014). *See also U.S. ex rel. Riedel v. Boston Heart Diagnostics Corp.*, 332 F. Supp. 3d 48 (D.D.C. 2018) (allegation that pharmaceutical company waived patient copays to induce physicians to use its lab services sufficiently stated AKS and FCA violation); *United States v. Berkeley Heartlab*, 225 F. Supp. 3d 487 (D.S.C. 2016) (waiver of copays is "remuneration" for purposes of AKS); *U.S. ex rel. Goodman v. Arriva Medical, LLC*, 2020 WL 3840446 (M.D. Tenn. July 8, 2020) (waivers of Medicare copays can violate the AKS and FCA).

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., U.S. ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717 (E.D. Pa. Jan. 22, 2020) (complaint stated AKS violation sufficient to survive motion to dismiss where pharmaceutical company allegedly donated to CDF fund designated solely to subsidize copays for one drug, produced by the company); *U.S. ex rel. Vitale v. MiMedx Group, Inc.*, 381 F. Supp. 3d 647 (D.S.C. 2019) (complaint stated AKS violation sufficient to survive motion to dismiss where defendant donated to copay-assistance charity to induce patients on Medicare to purchase

defendant's products).

On November 22, 2005, HHS-OIG 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).[6] The 2005 bulletin advises, "[P]harmaceutical 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);
>
> (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):

[6] The bulletin is directed to enrollees of Medicare Part D, which imposes cost-sharing (copay) obligations upon patients receiving prescription drugs, not specifically enrollees of Medicare Part B, which imposes copays for prescription drugs administered in an outpatient setting. However, the guidance (how to contribute to copay assistance foundations without violating the AKS and FCA) is applicable to both Parts B and D.

> 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 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 PAP's 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 choice." *Id.* at 70627.

Here, the facts alleged in the complaint and the reasonable inferences from the facts are sufficient to state a plausible claim of an AKS violation.

1. Remuneration

First, defendant indirectly provided remuneration to patients prescribed Eylea, by making donations to CDF that offset patients' copays. Arguably, the promise of copay waivers through CDF also provided remuneration to the physicians prescribing Eylea, where remuneration means "anything of value," by saving physicians' time that might be spent on explaining copays and assessing patients' financial hardship, removing the financial risk to physicians if they prescribed a drug that patients could not pay them back for, appeasing staff and patients, and generating increased business due to satisfied patients.[7] In several recent cases, district courts have found

[7] 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, solicit or receive *anything of value* as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them." HHS-OIG, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372 (Dec. 19, 1994) (emphasis added).

that alleged agreements to reduce or waive lab-testing copays for patients could constitute remuneration to the physicians referring test to those labs, sufficient to state a claim under the AKS. *See U.S. ex rel. STF, LLC v. Vibrant America, LLC*, 2020 WL 4818706, at *13 (N.D. Cal. Aug. 19, 2020) ("[A] benefit conferred directly on third parties, such as patients in the case of fee waivers . . . can also indirectly confer a benefit on physicians sufficient to support a claim under the Anti-Kickback Statute . . . [because] physicians are able to pay their staff less, appease their staff, and in some instances, obtain a portion of the medical staff's kickbacks."); *United States v. Crescendo Bioscience, Inc.*, 2020 WL 2614959, at *10 (N.D. Cal. May 23, 2020) ("[N]o patient likes additional costs; if a lab waives patients' fees . . . thus allowing physicians to reassure their patients that that they will not be responsible for more than $25, that is something of value to physicians and they might be induced to send more patients to that lab."); *Riedel*, 332 F. Supp. 3d at 66 ("Waiving patients' insurance co-payments and deductibles is of significant benefit to physicians and their patients: physicians are not forced to explain expensive deductible and co-payment requirements to angry patients . . . Physicians market free testing to their patients to make their offices more appealing, thereby improving the physicians' revenues.").

2. Inducement of Claims

Next, the complaint plausibly alleges that this remuneration structure induced Medicare claims for Eylea. It alleges that because "CDF was using Regeneron's money to ensure that physicians did not need to consider the impact of Medicare co-pays when deciding to purchase and prescribe Eylea," patients had every incentive to choose the $1,850-per-dose Eylea, without even considering the (allegedly) comparably effective, $55-per-dose off-label drug Avastin. (Compl. ¶¶ 30, 70). That this "influence[d] decisions on the provision of health care," *Guilfoile*, 913 F.3d at 193, or "impermissibly influence[d] beneficiaries' drug choice," 70 Fed. Reg. 70627,

is a reasonable inference: physicians, being practical, do not wish to prescribe medications that patients cannot afford, especially with a "buy and bill" drug where physicians themselves bear the financial risk of not being able to collect the copay. (Compl. ¶ 30). It is also supported by the complaint's allegation that in 2014, a shortfall in CDF funds caused a "large retina clinic" to switch its patients to Avastin—a fact that Regeneron senior management regarded with alarm and used to justify increasing the company's CDF donations. (Compl. ¶ 67).

Defendant contends that the complaint fails to allege that the CDF donations actually did "improperly influence" or "impermissibly influence" doctors' and patients' decision to purchase Eylea. *See Guilfoile*, 913 F.3d at 192-93; 70 Fed. Reg. 70627. First, it contends that the structure of CDF made this impossible: because CDF allocated its AMD grants on a first-come, first-served basis, and defendant did not control CDF or earmark its donations solely for Eylea patients, it argues that the prospect of copay-assistance remuneration to patients could not "induce" physicians to prescribe Eylea, because physicians could not guarantee to patients that their Eylea prescriptions would be covered by CDF copay assistance. Nor, it argues, could it "induce" patients to purchase Eylea, because physicians submitted the application for CDF copay assistance *after* prescribing and administering the injection to the patient. But the complaint plausibly alleges that the expectation of copay assistance through CDF *did* change prescriber behavior, as evidenced by physicians' practice of switching to the cheaper Avastin when CDF warned that copay assistance would not be available.

Defendant further contends its CDF donations did not "improperly influence decisions on . . . health care," because Eylea was the best clinical choice, cheaper than Lucentis and not "off-label" like Avastin. *Guifoile* at 192-93. However, to state an AKS violation, the complaint need not allege that the kickbacks actually corrupted clinical decision-making or provide "proof that

the underlying medical care would not have been provided but for a kickback." *U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3rd Cir. 2018). *See also U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the 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."); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014) ("[I]t is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement. The illegal [that is, tainted by kickbacks] recommendations . . . do not have to actually convince someone to purchase the drugs who would not have otherwise done so."). Here, it is sufficient that the complaint plausibly alleges that the copay-assistance system established by CDF and defendant involved the payment of kickbacks or remuneration to patients and physicians. Some of those kickback-tainted prescriptions then led to Medicare claims for Eylea—in part by removing financial considerations, a factor that the Medicare copay program intended for patients to consider, from patients' decision-making.

Defendant also contends that the complaint fails to allege a *quid pro quo* between defendant and patients or physicians. The AKS bars companies from offering remuneration or kickbacks "to induce" a person to purchase or recommend a Medicare-subsidized product, and it bars physicians and patients from receiving remuneration "in return for" making those purchases or recommendations. 42 U.S.C. § 1320a-7b(b)(1)(B), (b)(2)(B). According to defendant, the complaint must allege a *quid pro quo* exchange, such as an allegation that CDF would provide copay reimbursements *only if* a physician prescribed Eylea. However, the AKS does not require evidence of an explicit *quid pro quo*, or a guarantee that all of the remuneration flowing to the

physician or patient must directly subsidize prescriptions for defendant's drugs, as defendant appears to claim here. *See, e.g., Bawduniak*, 2018 WL 1996829, at *3 (to plead AKS violation, "[r]elators need not show that a quid pro quo exchange occurred"); *United States v. Teva Pharm. USA, Inc.*, 2019 WL 1245656, at *10 (S.D.N.Y. Feb. 27, 2019) (same). At any rate, the complaint does plausibly allege that patients received copay-assistance grants "in return for" purchasing Eylea, and physicians received remuneration in the form of satisfied patients, time saved on explaining copays, and lowered financial risk of not being able to collect copays, "in return for" prescribing Eylea—one of two drugs that physicians knew could be subsidized by the CDF fund.

Defendant cites *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016) for the proposition that absent "evidence that [defendant's] donations [to CDF] were contingent on the foundation's agreement to purchase or recommend [defendant's] drugs . . . [it] cannot be liable [under the AKS] for giving money to co-pay foundations." But *Celgene* is of course not binding upon this Court, and in any event is clearly distinguishable. First, in *Celgene*, the CDF sub-fund subsidized ten medications, only three of which were manufactured by the defendant, *id.* at 1057 n.33; here, the CDF fund subsidized only Eylea and Lucentis, and CDF provided defendant with specific information about the proportion of the fund subsidizing Eylea. Second, the complaint here plausibly alleges that defendant refused to provide substantial funding to CDF until it received data about its subsidies of Eylea, both historic and projected. (Compl. ¶¶ 40-45). In short, the complaint has alleged that even absent an explicit agreement that defendant would fund CDF only if it subsidized Eylea, practically speaking, the limited scope of the two-drug fund and defendant's use of Eylea-specific data to set its contribution amounts made its donations functionally contingent upon CDF's Eylea subsidies.

3. Defendant's Intent to Induce Claims

Next, the complaint plausibly alleges that defendant intended for its CDF donations to induce Medicare claims for Eylea. Sherman, a former senior director for reimbursement, testified that Regeneron's senior management did not wish for its CDF donations to go toward copays for Lucentis, its competitor. (Compl. ¶¶ 39-41). To that end, CDF regularly sent defendant drug-specific data about the number and cost of Eylea prescriptions funded by CDF, and precise requests for just enough donation money to fund its projected expenditures on Eylea patients—not Lucentis patients—going forward. (Compl. ¶¶ 42-70). According to the complaint, defendant's donations in the period 2011-2014 closely tracked CDF's donation requests, which Daniels, an employee working in the reimbursements department, testified were tailored "to cover costs for Eylea only." (Compl. ¶¶ 45, 65). Defendant incorporated the expectation of CDF-funded Eylea copay waivers into its business decisions, calculating the "return on investment" in Medicare payments for every dollar donated to CDF, and relying on CDF-funded copay assistance in setting its retail price of Eylea high in order to maximize Medicare reimbursements. (Compl. ¶¶ 36-38, 46-47, 60). Furthermore, the alleged efforts by senior managers to conceal their use of drug-specific data from internal auditors could be evidence of defendant's improper intent to use CDF as a conduit to reimburse patients and influence their drug choice. (Compl. ¶¶ 75-88). Those allegations, if proved, could support an inference that defendant's intent was more than a vague "hope or expectation" that Eylea purchases would increase following donations to CDF. *McClatchey*, 217 F.3d at 834 n.7.

Defendant contends its only intent in making CDF donations was charitable: it meant to keep the AMD fund solvent so that patients could receive assistance, regardless of therapy. It characterizes its communications with CDF, including discussion of ROI (return on investment),

as entirely proper business discussions of "how the charity operated, whether donations were spent responsibly, and what level of funding would help accomplish the charity's goals." (Def. Mem. at 19). It relies upon *United States v. Pfizer* for the principle that monitoring return on investment of a program is unremarkable for a for-profit corporation, and is not necessarily evidence that the program is meant to induce improper referrals. 188 F. Supp. 3d 122, 134 (D. Mass. 2016), *aff'd*, 847 F.3d 52 (1st Cir. 2017). Therefore, according to defendant, the prospect of copay assistance to subsidize Eylea was a "collateral hope or expectation" resulting from its CDF donations, not a "motivating factor" for those donations. *McClatchey*, 217 F.3d at 834 n.7.

While that may be a reasonable interpretation of the facts alleged, the complaint also alleges facts that give rise to a reasonable inference that defendant's intent was improper. Although the "return on investment" analysis of CDF donations, without more, may not be sufficient to suggest improper intent, the complaint sufficiently alleges other indicia of improper intent, such as the data-sharing and donation-matching coordination between CDF and defendant and an attempt to conceal that coordination from internal audit. Ultimately, defendant's intent is a "difficult factual determination" that should be left for a jury to decide, rather than the court at the motion-to-dismiss stage. *McClatchey*, 217 F.3d at 834 n.7.

Nor can defendant establish at this stage that its intent was categorically proper based on the "safe harbor" described in the 2005 HHS-OIG guidance. Under that provision, a pharmaceutical company whose donations to copay-assistance charities follow certain procedural safeguards would "raise few, if any, anti-kickback statute concerns." HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005). One of those safeguards is that "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. The bulletin specifically calls the sharing of drug-specific, non-aggregate data between a charity and a pharmaceutical company "problematic" in terms of AKS concerns. *Id* at 70626 n.16. Here, the complaint alleges that defendant solicited and received drug-specific, non-aggregated data from CDF about Eylea patients' utilization of the Fund in order to correlate the amount and frequency of its donations with the number of CDF-subsidized Eylea prescriptions. While "guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation," DOJ Justice Manual § 1-20.100, and defendant cannot be found liable simply for the *act* of violating guidance, its failure to follow HHS-OIG guidance can certainly be *evidence* of unlawful intent to violate the AKS. The complaint plausibly alleges a claim that defendant's practices of sharing data with CDF and matching its donations to CDF's Eylea-specific requests, in violation of HHS-OIG guidance, made CDF unlawfully "function as a conduit for payments by the pharmaceutical manufacturer to patients." 70 Fed. Reg. 70627.

Other courts have concluded that pharmaceutical companies' donations to copay-assistance charities may violate the AKS when they act as a conduit for money from the company to the patient and impermissibly influence patients' drug choice. A complaint alleging that a pharmaceutical company's donations to a CDF sub-fund designated to cover copays for only one drug, manufactured by that company, survived a motion to dismiss in *U.S. ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717 (E.D. Pa. Jan 22, 2020). That company, like defendant here, allegedly "received financial reports from CDF containing information regarding the number of patients enrolled, the amount the fund paid out, the percentage of patients who were approved for subsidies, the average copay amount for those patients, and more"—all in

violation of HHS-OIG guidance concerning non-aggregated data sharing. *Id.* at *3. Because the pharmaceutical company's drug was the only one covered by the CDF fund, the company was able to ensure that its CDF donations directly correlated with the number of subsidized drug prescriptions. *Id.* In *U.S. ex rel. Vitale v. MiMedx Group, Inc.*, the complaint sufficiently alleged an AKS violation where it claimed that defendant, a pharmaceutical manufacturer, "knowingly and willfully paid a remuneration, here Medicare coinsurance and copays, indirectly via its correlated charitable contribution funding of PAN [a copay-assistance foundation], to induce patients on Medicare to purchase [the] defendant's products," a line of drugs called EpiFix. 381 F. Supp. 3d 647, 659 (2019). The pharmaceutical manufacturer would encourage sales representatives to fill out applications for copay assistance for patients, receive data from the sales representatives about the number of patients seeking copay assistance for prescriptions of EpiFix, fund the foundation in exact amounts correlated to that number, and then tell the sales representatives to rush to submit their copay-assistance applications for EpiFix to PAN after the donations were finalized, in order to maximize the likelihood that the manufacturer's donations would flow directly to subsidizing its own drugs. *Id.*

It is true that here, defendant's coordination with the charity appears to be less close, and its anticipation that charitable donations would flow through to subsidize its own products less certain, than in those cases. Unlike *Mallinckrodt*, which concerned a single-drug fund, defendant's donations to CDF's AMD fund contributed to offsetting the copays of both its own drug, Eylea, and its competitor's drug, Lucentis; unlike *MiMedx*, there is no evidence that defendant's employees helped patients prepare applications to CDF for copay assistance or gave them strategic advice about when to submit them. But while defendant's alleged behavior here does not quite rise to the level of those cases, the complaint nonetheless is sufficient to allege a

plausible claim of a violation.

In summary, the complaint alleges that defendant paid remuneration to patients, through donations to CDF, in order to induce physicians to recommend Medicare-subsidized purchases of defendant's drugs and to induce patients to purchase those drugs. The complaint thus alleges sufficient facts to support each material element of an AKS violation.

C. Whether the Complaint Sufficiently Pleads that Defendant's Donations Resulted in False Claims

Any claim for Medicare reimbursement "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). 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 *U.S. ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017)).

Defendant contends that the complaint does not alleges that its donations to CDF, even if they were a violation of the AKS, *resulted in* any false claims being filed. Essentially, because Regeneron was not the only donor to the CDF fund, it contends that the government cannot show that any specific Medicare claim for Eylea "result[ed] from" an AKS-violating donation by it (as opposed to a donation from its competitor, Genentech). 42 U.S.C. § 1320a-7b(g).

That argument reads a specificity into the False Claims Act that is unsupported by the text of the statute or case law. The AKS bars both direct and indirect payment of remuneration in return for purchases or referrals. 42 U.S.C. § 1320a-7b. Here, there were only two donors to the fund. (Compl. ¶ 33). Moreover, the complaint alleges that defendant was a principal donor to the fund, without whose contributions the fund would cease to exist altogether. (*Id*. ¶¶ 48, 50, 53). Thus, but for defendant's contributions, patients would not receive Eylea copay subsidies from CDF. And those contributions "result[ed] in" Medicare claims, because patients who

illegally received Eylea copay assistance from CDF subsequently presented claims to Medicare for the remainder of the drug price. Therefore, the complaint has adequately alleged the existence of "AKS violation[s] that result[] in a federal health care payment," which are "per se false claim[s] under the FCA." *Guilfoile*, 913 F.3d at 190.

Defendant's reliance on *U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3rd Cir. 2018), is unavailing. In that case, the complaint sufficiently pleaded an AKS violation where it alleged that defendant Medco donated to a hemophilia charity in return for that charity recommending Medco's services to patients. *Id.* at 97-98. The charity's referral list was an "illegal referral or recommendation" tainted by kickbacks. *Id.* at 99. However, the court found that the complaint did not plead an FCA violation because there was no evidence that any of the patients who submitted allegedly-suspect Medicare claims for Medco's services had actually viewed the charity's (illegal) referral list or otherwise communicated with the charity. *Id.* at 100. That was fatal at the summary judgment stage, because the plaintiff needed to "point to at least one [Medicare] claim that covered a patient" who had actually been "exposed" to the illegal referral program, and failed to do so. *Id.* at 99. Here, in contrast, the complaint identifies at least eleven distinct claims for patients that were "exposed" to an "illegal referral or recommendation." (Compl. ¶¶ 98-101). The complaint alleges that those eleven claimants received illegal copay subsidies from CDF, and submitted Medicare claims for the remainder of the price of Eylea.

Other district courts have concluded, based on *Medco*, that a complaint sufficiently states a violation of the FCA if it alleges that "[d]efendant paid kickbacks to physicians . . . to induce those physicians to prescribe particular medications, and that the physicians then prescribed those medications, causing claims to be submitted to Medicare and Medicaid." *U.S. ex rel.*

Bawduniak v. Biogen Idec, Inc., 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018); *see also U.S. ex rel. Wallace v. Exactech, Inc.*, 2020 WL 4500493 (N.D. Ala. Aug. 5, 2020) (complaint sufficiently stated FCA violation where it alleged that defendant provided illegal kickbacks to physician, who subsequently prescribed defendant's devices for twelve patients and submitted Medicare claims for them); *United States v. Medtronic*, 189 F. Supp. 3d 259, 272-73 (D. Mass. 2016) (complaint sufficiently stated FCA violation where it identified specific doctors who billed Medicare for defendant's products after receiving kickbacks from defendant). Similarly, the complaint's allegations that at least eleven claimants who received the tainted copay subsidies submitted claims to Medicare are sufficient to state an FCA violation at the motion to dismiss stage.

D. Whether the Complaint Pleads the AKS Violation and Resulting False Claims with Particularity Required by Rule 9(b)

Because the False Claims Act is a statute directed at fraudulent conduct, Rule 9(b) "requires both that the circumstances of the alleged fraud and the claims themselves be alleged with particularity." *Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 130 (1st Cir. 2016); Fed. R. Civ. P. 9(b). The plaintiff must "set forth with particularity the who, what, when, where, and how of the alleged fraud." *U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013) (internal citations and quotation marks omitted). Where it is alleged that defendant caused a third party to submit a false claim to the government, rather than submitting the false claim itself, a "more flexible" standard applies, under which Rule 9(b) is satisfied by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim submitted." *U.S. ex rel. Kelly v. Novartis Pharm. Co.*, 827 F.3d 5, 13 (1st Cir. 2016) (quoting *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)). Rule 9(b) may be satisfied

"where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009).

While there is no "checklist of mandatory requirements that each allegation in a complaint must meet to satisfy Rule 9(b)," *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016), the First Circuit has identified some examples of specific allegations that may suffice to state a claim with the requisite particularity. In an FCA case, these may include "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices." *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). Here, the complaint has provided identifying information about eleven specific false claims submitted to Medicare: their date, location, product and billing code for which reimbursement was sought, patient identity, the amount billed to Medicare, and the amount billed to CDF. (Compl. ¶ 101).

The First Circuit has found that a complaint satisfies Rule 9(b) even when it fails to identify specific false claims, as long as it describes "each of the eight medical providers [that submitted fraudulent claims] (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves," although this was a "close call." *U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009). The complaint here similarly identifies eleven claimants who submitted kickback-tainted

Medicare claims (the who), the illegal kickbacks through CDF-funded copay subsidies (the what), defendant's coordination with CDF to ensure that Eylea prescriptions were adequately funded (the how), and the locations and dates of the Eylea injections that spurred Medicare claims (the when and where). It is true that the complaint does not identify the medical providers who administered the injections and submitted the Medicare claims on behalf of the identified patients. However, as a whole, the complaint provides more detail than *Duxbury* in identifying each specific false claim made, which is sufficient to satisfy Rule 9(b).

In sum, by describing defendant's allegedly illegal coordination with CDF to provide Eylea-specific copay subsidies in violation of the AKS in 2011-2014, and identifying eleven specific Medicare claims made by CDF-subsidized patients in 2013-2014, the complaint has alleged "both the circumstances of the alleged fraud and the claims themselves" with the particularity necessary to satisfy Rule 9(b). *Lawton*, 842 F.3d at 130.

E. Whether the Government is Restricting Charitable Speech in Violation of Defendant's First Amendment Rights

Defendant contends that this lawsuit constitutes an impermissible restriction on its charitable speech under the First Amendment. According to defendant, under the government's theory, donations to CDF would be perfectly legal in a vacuum, but they become illegal when coupled with the communication between CDF and defendant about CDF's funding needs. Therefore, defendant contends, the government is essentially penalizing speech.

Charitable solicitation is "fully protected speech," *Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 474 (1989), and the "protection afforded is to the communication, to its source and to its recipients both." *Va. State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976). Laws that impose speech limitations "restricting the solicitation of contributions to charity" are subject to strict scrutiny, and may only pass

constitutional muster if they are narrowly tailored to serve a compelling government interest. *Williams-Yulee v. Florida Bar*, 575 U.S. 433, 442 (2015) (citing *Riley v. National Federation of the Blind of N.C., Inc.*, 487 U.S. 781, 789 (1988)).

Defendant contends that the "restrictions" placed on its communications with CDF do not survive strict-scrutiny review, because they are not narrowly tailored to prevent fraud and abuse in the health care system, an aim that could be accomplished by less restrictive means, namely enforcing the AKS based on conduct and not speech. Defendant characterizes the "restrictions" as impermissibly content-based, because they proscribe the sharing of content that "would facilitate the manufacturer in correlating . . . its donations with . . . prescriptions," 70 Fed. Reg. 70626, and viewpoint-based, because they proscribe pharmaceutical manufacturers (but not other parties) from sharing this type of content with charities. "Content-based regulations are presumptively invalid." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1999). In *Sorrell v. IMS Health Inc.*, the Supreme Court struck down a state statute prohibiting the sharing of prescriber-identifying information between pharmacies and pharmaceutical manufacturers for marketing purposes as an impermissibly content-based restriction on speech. 564 U.S. 552 (2011).

However, this case is about restrictions on conduct—donations to CDF that functioned as kickbacks—not restrictions on speech. The complaint does not allege that defendant violated the law when it solicited and shared data from CDF concerning Eylea subsidies. Rather, the complaint alleges that defendant violated the law when it made financial contributions to CDF that were carefully tailored to fund Eylea prescriptions. A pharmaceutical manufacturer has no First Amendment right to pay kickbacks intended to induce prescriptions and purchases of its drugs. Unlike the cases cited by defendant, which involved the imposition of criminal or civil penalties for speech and information-sharing *itself*, this complaint only alleges that defendant's

donations, not its communications, were illegal. *See, e.g., Speet v. Schuette*, 726 F.3d 867 (6th Cir. 2013) (statute that criminalized begging); *Williams-Yulee*, 575 U.S. 433 (local bar rule banning judicial candidate from soliciting campaign donations); *Riley*, 487 U.S. 781 (regulations requiring paid fundraisers to disclose their fee to potential donors and barring them from soliciting donations absent a license); *Sorrell*, 564 U.S. 552 (statute prohibiting data-sharing between pharmaceutical companies and pharmacies).

The complaint treats specific communications between defendant and CDF not as the violation itself, but rather, as evidence of defendant's intent to violate the AKS. "The First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (upholding sentencing enhancement because defendant intentionally selected his victim on account of his race and permitting introduction of defendant's statements targeting a specific race). Nor does the First Amendment protect "speech or writing used as an integral part of conduct in violation of a valid criminal statute." *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 498 (1949) (upholding injunction restraining defendants from picketing, where picketing was integral part of a scheme to violate state anti-trade restraint law). The complaint has sufficiently alleged that defendant's constant, close communications with CDF (not the proscribed conduct) demonstrate its improper intent for its CDF donations to impermissibly influence patients' drug choices and to pass through CDF as a mere conduit for payments to patients, in violation of the AKS (the proscribed conduct).

Other courts considering First Amendment challenges to alleged AKS violations have rejected them on the basis that the AKS criminalizes conduct (remunerations), not speech. *See, e.g., U.S. ex rel. Nevyas v. Allergan, Inc.*, 2015 WL 3429381, at *1 n.1 (E.D. Pa. May 26, 2015)

("Relators allege a scheme by Allergan to induce physicians to write prescriptions for Allergan products in violation of the AKS; it is Allergan's conduct in providing 'illegal remuneration' to physicians and optometrists and not its speech that is at issue in the AKS claim."); *United States v. Mathur*, 2012 WL 4742833, at *4 (D. Nev. Sept. 13, 2012), *report and recommendation adopted*, 2012 WL 4711960 (D. Nev. Oct. 3, 2012) ("Courts have uniformly rejected the notion that bribery is protected speech . . . The Indictment alleges Mathur made payments ranging from $1,500 to $5,400 in exchange for patient referrals. The Anti–Kickback Act criminalizes corrupt payments in exchange for referrals, not statements related to those payments."). Defendant has cited no cases in which a court has found that an AKS prosecution violates the First Amendment.

It is hardly a novel legal theory that speech may provide evidence of a crime, or be an integral part of a crime, without running afoul of the First Amendment. For example, communicating confidential information about a company may be protected speech, but insider trading based on that information is not. Soliciting donations for a political campaign may be protected speech, but making a deal to award government contracts to donors is not. Describing an urge to attack members of a certain race may be protected speech, but actually inciting imminent violence, or attacking them, based on racial hatred is not. *See Mitchell*, 508 U.S. 476. Similarly, communicating with charities about their spending on specific drugs may be protected speech, but making donations to induce claims for one's own drugs based on that information is not. Accordingly, this action will not be dismissed on the ground that it seeks to impose liability in violation of the First Amendment.

F. Whether the Lawsuit Violates Defendant's Fifth Amendment Due Process Rights

Finally, defendant contends that this action violates its due-process rights under the Fifth Amendment because the government's theory of liability rests on non-binding OIG guidance,

which is impermissibly vague and fails to provide fair notice of prohibited behavior.

"Guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation." DOJ Justice Manual § 1-20.100. Defendant contends that it is being charged with violating non-binding HHS-OIG guidance, rather than the Anti-Kickback Statute itself, 42 U.S.C. § 1320a-7b. However, the complaint does not allege that defendant's failure to comply with 2005 HHS-OIG guidance concerning data-sharing with CDF, 70 Fed. Reg. 70623, was the conduct that violated the law. Rather, defendant's donations to CDF as a conduit to pay remuneration to physicians and patients, in order to induce Medicare claims for Eylea, was the offending conduct. The complaint cited the 2005 guidance for two purposes: first, to show that defendant had received warnings that its conduct was illegal, therefore supporting the AKS element of "knowing and willing" *mens rea*; and second, to provide evidence of defendant's intent for its donations to function as kickbacks.

Defendant also argues that the 2005 HHS-OIG guidance, 70 Fed. Reg. 70623, is impermissibly vague and fails to give fair notice of prohibited conduct in violation of its due-process rights. *See United States v. Paz-Alvarez*, 799 F.3d 12, 28 (1st Cir. 2015) ("[T]he Fifth Amendment Due Process Clause gives [defendants] a right to fair warning of [the] conduct which will give rise to criminal penalties . . . [T]he vagueness doctrine . . . bars enforcement of a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application."); *United States v. Lachman*, 387 F.3d 42, 56 (1st Cir. 2004) (an offense must be defined with "sufficient definiteness that ordinary people can understand what conduct is prohibited"). Specifically, defendants challenge the HHS-OIG statement that "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" in order to avoid AKS concerns as impermissibly vague, failing to describe what data a pharmaceutical company may or may not share with a charity. 70 Fed. Reg. 70626.

However, the vagueness doctrine may not apply, as the guidance does not "give rise to criminal penalties," *Paz-Alvarez* at 28, or define a "criminal offense," *Lachman* at 56. It is not a statute, nor even a regulation. Furthermore, and in any event, the guidance is not unduly vague. Its plain text suggests that sharing data about the "number of subsidized prescriptions for [the pharmaceutical company's] products" may implicate the AKS. 70 Fed. Reg. 70626. And the accompanying footnote specifically warns that sharing data that is "patient specific," "related to the identity, amount, or nature of subsidized drugs," or "not in the aggregate" could raise "problematic" AKS concerns. *Id.* n.16. The guidance is specific enough to warn an ordinary person of prohibited conduct.

In short, defendant had fair notice of the prohibited conduct, and the action will not be dismissed on the ground that the enforcement of the statute violates its due-process rights under the Fifth Amendment.

IV. Conclusion

For the foregoing reasons, defendant's motion to dismiss the complaint is DENIED.

So Ordered.

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

Dated: December 4, 2020