UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, et al., *ex rel.* JULIE LONG,	)	
Plaintiffs,	)	**Civil Action No. 16-12182-FDS**
v.	)	
JANSSEN BIOTECH, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER
ON DEFENDANT'S MOTION TO DISMISS

SAYLOR, C.J.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free services to physicians who prescribed its medications. Relator Julie Long has brought suit against defendant Janssen Biotech, Inc., a company that manufactures and sells Remicade and Simponi ARIA, two infusible medications used to treat a variety of diseases.

The second amended complaint ("SAC") alleges that Janssen provided a variety of free business advisory services to rheumatology and gastroenterology practices that prescribed and infused Remicade and Simponi ARIA. Janssen allegedly employed teams of practice advisors, including relator, and hired outside consultants to provide those services, which included presentations, advice, and customized analysis on how to run a profitable infusion business. The SAC alleges that by providing these services, Janssen violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare and Medicaid in violation of the False Claims Act, 31 U.S.C. § 3729(a).

Defendant has moved to dismiss the SAC under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted and under Fed. R. Civ. P. 9(b) for failure to plead fraud with particularity. For the reasons set forth below, the motion will be granted in part and denied in part.

I. Background

A. Factual Background

The facts are stated as set forth in the SAC unless otherwise noted.

1. The Parties

Janssen Biotech, Inc. is a corporation based in Horsham, Pennsylvania. (SAC ¶ 17). It is a wholly-owned subsidiary of Johnson & Johnson. (*Id.*). Janssen manufactures and sells pharmaceutical products, including the biopharmaceuticals Remicade and Simponi ARIA. (*Id.*).

Julie Long was an employee of Janssen from 2003 to February 2016. (*Id.* ¶ 16). She worked as an Area Business Specialist, which involved "advising and assisting physician practices with, among other things, establishing and operating in-office infusion suites where Remicade and Simponi ARIA infusions were administered." (*Id.*).

2. Government Healthcare Programs and Anti-Kickback Statutes

Medicare is a health-insurance program administered by the United States Department of Health and Human Services ("HHS"). (*Id.* ¶ 14). Medicare provides payment for, among other things, medical services and equipment to persons over 65 years of age and those who are 18 years of age or older and are eligible for disability benefits. (*Id.* ¶ 18). For inpatient treatment, Medicare reimburses hospitals and other treating facilities through Medicare Part A. (*Id.*). For outpatient treatment, Medicare reimburses physicians and healthcare providers through Medicare Part B. (*Id.*). Under Medicare Part C, private companies may offer Medicare Advantage plans that "include, at a minimum, all benefits covered by Parts A and B." (*Id.*). Finally, Medicare

Part D provides prescription drug benefits for beneficiaries of Part B or Part C. (*Id.*).

Medicaid is a health-insurance program administered by HHS jointly with agencies in each state. (*Id.* ¶ 19). It is designed to assist states in providing medical services, medical equipment, and prescription drugs for low-income or disabled persons who qualify for the program. (*Id.*).

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits "knowingly and willfully" soliciting, receiving, offering, or paying any "remuneration (including any kickback, bribe, or rebate) . . . to induce [a] person" to purchase, order, or recommend purchasing or ordering a good, service, or item "for which payment may be made in whole or in part under a Federal health care program." (*Id.* ¶ 23 (quoting 42 U.S.C. § 1320a-7b(b))). A violation of the Anti-Kickback Statute is a felony and is punishable by fines and imprisonment. (*Id.* ¶ 22 (citing 42 U.S.C. § 1320a-7b(b))).

Several states have enacted similar statutes that prohibit the payment or acceptance of kickbacks in connection with the purchase of medical goods or services covered by their Medicaid programs. (*Id.* ¶ 24 (collecting statutes)).

The SAC alleges that, in order to participate in Medicare and receive reimbursement, healthcare providers must certify that they will comply with the Anti-Kickback Statute. (*Id.* ¶ 26). Similarly, it alleges that, in order to participate in each state's Medicaid program, healthcare providers must certify that they will comply with the Anti-Kickback Statute and that state's equivalent laws. (*Id.* ¶ 27). It further alleges that on each claim submitted for payment to Medicare or Medicaid, a provider must again certify that the claim "complies with all applicable Medicare and/or Medicaid laws, . . . including but not limited to the [f]ederal [A]nti-[K]ickback [S]tatute." (*Id.* ¶ 28).

3. Remicade and Simponi ARIA

Remicade is the brand name for infliximab, a type of medication known as a tumor necrosis factor-alpha ("TNF-alpha") inhibitor. (*Id.* ¶ 45). In basic terms, Remicade targets TNF-alpha, a substance in the body that causes inflammation. (*Id.*). It has been approved by the FDA for treating a variety of indications, including rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and active ankylosing spondylitis. (*Id.*).

Simponi ARIA is the brand name for golimumab, which is also a TNF-alpha inhibitor. (*Id.* ¶ 52). It has been approved by the FDA for treating rheumatoid arthritis, psoriatic arthritis, and active ankylosing spondylitis. (*Id.*).

Both Remicade and Simponi ARIA are administered intravenously, a delivery process known as infusion. (*Id.* ¶¶ 46, 53).[1] An infusion takes 30 minutes (for Simponi ARIA) or two hours (for Remicade), which a patient receives approximately once every eight weeks. (*Id.*). Infusions can be performed at doctors' offices, hospital outpatient departments, private infusion clinics, or at patients' homes by mobile infusion providers. (*Id.* ¶ 46).

According to the SAC, "[t]he largest and most important market for Remicade and Simponi ARIA sales is rheumatology and gastroenterology practices that operate an in-office infusion suite [("IOI")]." (*Id.* ¶ 118). The SAC alleges that those practices can earn greater profits by prescribing and administering infusions of Remicade and Simponi ARIA than they could by prescribing comparable medications that would be taken orally or by injection. (*Id.* ¶ 117).

[1] According to the SAC, Simponi (as opposed to Simponi ARIA) is a formulation of golimumab that is administered by subcutaneous injection rather than by infusion. (SAC at 20 n.1). Simponi is sold by different sales representatives, and the SAC does not allege any violations of state or federal law arising out of its marketing. (*See id.*).

4. Janssen's Business Advisory Services

The SAC alleges that "[o]ne of Janssen's principal, longtime strategies for expanding the [IOI] market and growing sales of Remicade and Simponi ARIA was to advise rheumatology and gastroenterology practices about how these drugs offer a lucrative business opportunity" that does not exist with comparable medications. (*Id.* ¶ 120). It further alleges that from at least 2003 through 2016, and as part of this strategy, Janssen hired two sets of business advisers to "help [rheumatology and gastroenterology practices] establish and set up the infusion suites and also help them operate and grow these infusion businesses once opened." (*Id.* ¶ 121).

First, Janssen "employed a large team of highly-trained medical practice advisers," a position known as an Area Business Specialist ("ABS"). (*Id.* ¶ 122). That was relator's job during her employment at Janssen. (*Id.* ¶ 16). ABSs helped Janssen's top customers "maximize profits on their [IOI] businesses." (*Id.* ¶ 122). According to the SAC, Janssen "typically sought out and hired former practice managers, hospital administrators, and individuals with prior managed care employment experience for ABS positions." (*Id.* ¶ 124). Their primary job was "advising health care providers regarding the establishment and operation of infusion suites." (*Id.* ¶ 125). According to the SAC, they discussed the clinical aspects of Remicade and Simponi ARIA only "occasionally," and Janssen employed a separate team of sales representatives to provide clinical information about the medications to physicians. (*Id.*).

Second, Janssen "arranged and paid for outside business consultants who had expertise in medical practice and infusion business management to provide business advisory services to top accounts." (*Id.* ¶ 123). The SAC alleges that the "hourly market rate for these business consultants can be hundreds of dollars," and that by hiring them to provide services to its customers, Janssen "negated the need for many physicians to hire and pay for" those consultants themselves. (*Id.* ¶¶ 134, 138).

The SAC includes nearly fifty pages of allegations detailing the services provided by Janssen to its customers that allegedly violated state and federal law. (*See generally id.* ¶¶ 139-88). The Court will not detail those allegations, many of which are irrelevant to the present claims, but will provide a brief summary.

The SAC generally alleges that ABSs and outside consultants helped rheumatology and gastroenterology practices design and set up IOI suites. (*Id.* ¶ 139). It alleges that ABSs and outside consultants provided those practices with a variety of services, including presentations on topics such as the economic benefits of an IOI business and how to lay out an IOI suite and schedule infusions in order to maximize profitability, (*id.* ¶¶ 140(a), 140(b)); advice on how to furnish and decorate IOI suites, (*id.* ¶ 140(b)); and consultations with ABSs to review an "efficiency checklist" of "various operational and practice management issues," (*id.* ¶¶ 141-42)).

The SAC further alleges that ABSs and outside consultants provided ongoing support to rheumatology and gastroenterology practices once they opened IOI businesses. (*Id.* ¶ 166). It alleges that Janssen provided them with a variety of services to "help them maintain and grow their infusion businesses," such as:

1. presentations on topics that included optimizing infusion schedules and increasing service volume in order to increase profitability, (*id.* ¶ 166(a)); "manag[ing] their operational issues more proactively," (*id.* ¶ 166(c)); implementing efficient procedures regarding drug eligibility and benefits verification, coding, and billing for infusion services, (*id.* ¶ 166(e)); increasing patient satisfaction by refurbishing or relocating IOI suites, (*id.* ¶ 166(g)); expanding their infusion businesses by adding other treatments, such as "oncology treatments and treatments for blood and lymph conditions," (*id.* ¶ 166(h)); maximizing discounts for Remicade and Simponi ARIA

purchased through Janssen's bulk discounting program, (*id.* ¶¶ 59, 166(j)); and adopting Electronic Health Record ("EHR") technology in order to earn incentive payments available through the Medicare EHR Incentive Program, (*id.* ¶ 166(i));

2. customized analysis, including the use of software programs, about increasing their practices' profitability by prescribing Remicade or Simponi ARIA instead of other medications and optimizing their infusion schedules in order to decrease operating costs, (*id.* ¶ 166(a));
3. customized advice on how practices could "maximize their reimbursement amounts and profits for Remicade and Simponi ARIA and the related infusion services as well as other frequently billed services and drugs," (*id.* ¶ 166(d)), and temporarily reclassify areas of their practice to use them to provide infusion services, (*id.* ¶ 166(m));
4. assistance with surveying patients to learn about their infusion experience in order to improve patient satisfaction and thus obtain higher reimbursement rates, (*id.* ¶ 166(d)); tracking and managing accounts receivable in order to increase payment collections from patients and insurers, (*id.* ¶ 166(f)); facilitating referral arrangements with physicians who do not provide IOI services, including maintaining an online IOI locator, (*id.* ¶ 166(l)); and switching from Remicade to Simponi ARIA because it would increase both the number of infusions the practices could perform daily and the reimbursement they could receive for each one, thus increasing their total revenues, (*id.* ¶ 166(o)); and
5. recruitment of practice managers, infusion nurses, and office staff, (*id.* ¶ 166(p)).

According to the SAC, ABSs typically provided these various business services "during

consultative sessions with practice managers, practice stakeholders, and office staff that typically lasted approximately three hours." (*Id.* ¶ 171). Allegedly, ABSs "spent more time implementing strategies than presenting them," and took a hands-on approach to improving the "operations, efficiency, and profitability" of infusion businesses. (*Id.* ¶ 172).

The SAC further alleges that during relator's career as an ABS, she "met with many of her top physician practice accounts on a weekly basis" and provided the described business advisory services. (*Id.* ¶ 175). It provides several examples of how relator provided those services to various rheumatology and gastroenterology practices, which are each identified by a pseudonym (*e.g.*, "Account A"):

1. she helped Account A address a variety of "operational problems," such as how it allocated staff and billed for infusions, which "return[ed] its infusion suite to profitability," (*id.* ¶176(a));
2. she trained the new office manager at Account B "on how to maximize the practice's infusion suite's efficiency and profitability" by performing more Remicade infusions, and she arranged for outside consultants to advise the office manager and a physician on how to negotiate higher reimbursement rates, (*id.* ¶ 176(b));
3. she helped Account C optimize its infusion suite, negotiate higher reimbursement rates, adopt EHR that satisfied Medicare requirements, and design a new infusion center, (*id.* ¶ 176(c));
4. she, "along with an outside consultant[,] . . . instructed [Account D] on negotiating payer contracts and ultimately helped it to obtain more favorable reimbursement rates," (*id.* ¶ 176(d));
5. she persuaded Account E to perform more infusions of Remicade and Simponi ARIA

at a preexisting infusion suite and advised it on how to operate and grow its IOI business, (*id.* ¶ 176(e));

6. she helped Account F establish an IOI business, train its employees, and secure referrals for infusion services from a nearby hospital, (*id.* ¶ 176(f));
7. "[she] helped Account G open an infusion suite at a centralized location, train its employees on the operation of the infusion business, hire an infusion nurse director, and improve its reimbursement rates from commercial insurers," (*id.* ¶ 176(g)); and
8. she helped Account H, which had opened an IOI business with help from another ABS, with "specific operational issues," (*id.* ¶ 176(h)).

According to the SAC, rheumatology and gastroenterology practices with IOI businesses "derived significant value from Janssen's free business advisory services and support." (*Id.* ¶ 177). It alleges that they "repeatedly accepted, and indeed requested, Janssen's assistance" and that their physicians and practice managers "regularly created time in their full schedules" to consult with ABSs and outside consultants. (*Id.* ¶¶ 178(a), 178(b)). It further alleges that "Janssen paid significant sums to provide [them] with ABS services" and paid outside consultants as much as $1,200 per session to provide business advisory services. (*Id.* ¶¶ 180, 182). Allegedly, those services "not only helped the accounts earn enormous profits on Remicade and Simponi ARIA, but also had a spillover effect and helped the accounts increase the profits they earned on many other drugs and services," including several other infusible medications that "nearly all" of them prescribed and administered. (*Id.* ¶ 183; *see also id.* ¶ 173 (alleging that "much of the business operations and practice management information and advice that Janssen provided applied equally to other infusible drugs and services")).

5. <u>Claims for Reimbursement from Medicare and Medicaid</u>

The SAC alleges that several physicians who received "free business advisory services

and support from Janssen" submitted claims for reimbursement to Medicare and Medicaid for Remicade, Simponi ARIA, and related infusion services. (*Id.* ¶ 189). For example, it alleges that between 2015 and 2017, Account B submitted claims for reimbursement to Medicare Part B for Remicade approximately every eight weeks. (*Id.* ¶ 191). It also alleges that during that same time period, Account B "regularly" received "many of the free business advisory services" set forth above. (*Id.*). Similarly, it alleges that physicians from several other practices "billed Medicare for a significant volume" of Remicade or Simponi ARIA infusions while receiving "free business advisory services and support from Janssen." (*Id.* ¶¶ 192-93). For several of those practices, the SAC sets forth in a table how many Remicade infusions they allegedly administered and billed to Medicare annually between 2012 and 2017. (*Id.* ¶ 192). And for one practice, the SAC alleges how many Simponi ARIA infusions it administered and billed to Medicare in 2015, 2016, and 2017. (*Id.* ¶ 193).

B. Procedural Background

On October 28, 2016, relator filed the initial complaint in this case. The complaint was amended twice, first on May 10, 2017, and again on February 11, 2020. The SAC asserts claims for treble damages and civil penalties for violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A) (Count 1); treble damages and civil penalties for violations of the FCA, 31 U.S.C. § 3729(a)(1)(B) (Count 2); and damages and penalties for violations of various state analogues to the FCA (Counts 3-29). The SAC alleges that it is brought on behalf of the United States and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington, and the District of Columbia ("the plaintiff states").

On August 9, 2019, the United States and the plaintiff states declined to intervene in the

case. On December 13, 2019, the Court ordered the unsealing of the matter.

On March 18, 2020, Janssen moved to dismiss the SAC.

II. Standard of Review

On a motion to dismiss made pursuant to Rule 12(b)(6), 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). In other words, the "[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 Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

Under Fed. R. Civ. P. 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

Defendant contends that the SAC should be dismissed because it does not allege a violation of the Anti-Kickback Statute—specifically, because (1) the services that defendant allegedly gave physicians lack substantial independent value, and (2) it fails to allege that any

violation of the statute was knowing and willful. (Def. Mot. at 2). Defendant also contends that it should be dismissed because it fails to plead with the particularity required by Rule 9(b) that physicians who received the services submitted false claims to the government. (*Id.*).

A. Whether the SAC Alleges a Violation of the Anti-Kickback Statute

The FCA claims are based on a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). The Anti-Kickback Statute itself "does not provide for a private right of action." *United States ex rel. Kalec v. NuWave Monitoring, LLC*, 84 F. Supp. 3d 793, 806 (N.D. Ill. 2015). However, "a claim that includes items or services resulting from a violation of [it] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Therefore, "liability under the [FCA] can be predicated on a violation of the Anti-Kickback Statute." *See United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 137 (1st Cir. 2020) (internal quotations omitted).

As set forth above, the Anti-Kickback Statute prohibits "knowingly and willfully" soliciting, receiving, offering, or paying "any remuneration . . . to induce" a person to refer a patient for goods or services that are reimbursed by a federal health care program. 42 U.S.C. § 1320a-7b(b). Thus, to state a claim for a violation of the statute, a complaint must allege, among other things, that the defendant (1) solicited, received, offered, or paid "remuneration" and (2) did so "knowingly and willfully." *See id.*

It is well-settled that the heightened pleading requirements of Rule 9(b) apply to claims brought under the FCA. *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 38 (1st Cir. 2017). Specifically, a relator "must provide details that identify particular false claims for payment that were submitted to the government." *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013) (internal quotations omitted). However, it is less clear whether a relator must also allege predicate violations of the Anti-Kickback Statute with

the specificity required by Rule 9(b). *Compare United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *5 (N.D. Ill. Sept. 30, 2019) (finding that an alleged Anti-Kickback Statute violation must be pleaded with the specificity required by Rule 9(b)), *with Cooper v. Pottstown Hosp. Co.*, 2015 WL 1137664, at *3-4 (E.D. Pa. Mar. 13, 2015) (evaluating the alleged predicate Anti-Kickback Statute violation of a FCA claim under the Rule 12(b)(6) pleading standard). In any event, defendant does not contend so here. It contends that the SAC should be dismissed under Rule 9(b), but only because it does not identify particular false claims that were submitted to the government. (*See* Def. Mem. at 19; Def. Reply at 3). Accordingly, the Court will analyze whether the SAC adequately alleges a violation of the Anti-Kickback Statute under the Rule 12(b)(6) standard.

1. Whether the SAC Alleges Illegal Remuneration

a. What Qualifies as Illegal Remuneration

The Anti-Kickback Statute itself does not define "remuneration." *See* 42 U.S.C. §§ 1301, 1320a-7b(b). It does, however, provide that the term "includ[es] any kickback, bribe, or rebate." *Id.* § 1320a-7b(b). The HHS Office of the Inspector General ("OIG") has issued guidance documents providing an interpretation of the statute.[2] Those documents are not binding, but are entitled to judicial consideration to the extent that they have the "power to persuade." *See Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Moreover, both parties rely on them extensively here. (Def. Mem. at 5-6; Pl. Mem. at 5-7); *cf. Suarez*, 2019 WL 4749967, at *6 (interpreting litigants' reliance on the same OIG guidance "as a concession that it is authoritative for purposes of this motion, even

[2] HHS has also published safe-harbor regulations providing that under certain conditions, particular payment practices are not subject to prosecution or sanctions under the Anti-Kickback Statute. 42 C.F.R. § 1001.952. Defendant does not contend that any of the alleged practices at issue are covered by those regulations.

though administrative guidance is not binding law").

In a 2003 guidance document, the OIG discussed what the parties refer to here as "product support services." Those are services offered by drug companies "in connection with the sale of their products," such as "billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003). The OIG stated that "[s]tanding alone, services that have no substantial independent value to the purchaser may not implicate the [A]nti-[K]ickback [S]tatute." *Id.* However, it cautioned that "if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns." *Id.* And it advised that a service may "have independent value to the physician" if it "eliminate[s] an expense that the physician would have otherwise incurred." *Id.* at 23737.

In 2013, the OIG issued another statement indicating that goods or services without independent value do not qualify as illegal remuneration. In its response to a comment on a proposed rule, it stated that it had "long distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not." Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013). It illustrated the difference with an example:

> For instance, we have stated that a free computer provided to a physician by a laboratory company would have no independent value to the physician if the

> computer could be used only, for example, to print out test results produced by the laboratory company. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement.

Id. And it again advised that goods or services with "no independent value to the recipient apart from the services the donor provides" do "not implicate the [A]nti-[K]ickback [S]tatute." *Id.*

Relying on that guidance from the OIG, at least two federal district courts have held that services lacking substantial independent value are not illegal remuneration under the Anti-Kickback Statute. In *United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568 (E.D. Pa. June 19, 2017), the relator alleged that Medtronic had provided a variety of free services to customers who bought its surgically-implanted heart devices. *Id.* at *1-2. Those services "included free surgical support, implant device follow-up that it continued to offer long after device implantation, and free staff to clinics at which Medtronic employees would spend four to eight hours conducting interrogations and other services." *Id.* at *1. The complaint broadly alleged that those services "benefitted physician practices," but did not explain which ones would otherwise have been performed by the physicians' staff. *Id.* at *4. The court held that the complaint had "failed to allege with particularity how the free services Medtronic provided to physicians constituted illegal remuneration." *Id.* First, it concluded that the complaint had not adequately explained how the free services had "independent" value; rather, the allegations showed only that Medtronic "provided technical product support in connection with the purchase of its products." *Id.* Second, the court found that the complaint had failed to "demonstrate that any independent value . . . was *substantial*." *Id.* It found the allegations "that the services generally benefitted Medtronic's customers' bottom lines or that physicians used Medtronic's services in lieu of having to pay for their own employees" to be insufficient under Rule 9(b). *Id.* (internal quotations omitted).

In *Suarez*, the court reached a similar result. 2019 WL 4749967. There, the relator alleged that AbbVie ran an "Ambassador Program" for its prescription drug Humira in which registered nurses visited patients and "train[ed] [them] on obtaining insurance payment for the drug, self-injecting the drug, and disposing of injection equipment." *Id.* at *1-2. They also visited physicians' offices "to respond to specific questions about specific patients." *Id.* at *2. The court held that these allegations amounted "only [to] the provision of Humira-related services." *Id.* at *7. It observed that all of the services offered by AbbVie's Ambassadors were about how to use and receive reimbursement specifically for that medication, and that while the relator had alleged "that these services were not limited solely to the use of Humira," the only allegations in the complaint "undisputedly concern[ed] Humira." *Id.* (internal quotations omitted). Moreover, the court said, the relator had "plead[ed] no factual content" to support his allegation that the services had "independent value" by "eliminat[ing] an expense that the physician would have otherwise incurred." *Id.* at *8 (quoting OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23737).[3]

Relator contends that the services alleged here are distinguishable from the ones described in those cases because they are "business advisory services" rather than "product support services." (Pl. Mem. at 9). Citing OIG guidance that identifies "free training . . . in such

[3] Notably, a different court has concluded that a different complaint sufficiently alleged that AbbVie's Ambassador Program "plausibly provided independent value to physicians who prescribed Humira by eliminating expenses that physicians would have otherwise incurred," at least to the extent necessary to survive a motion to dismiss as it related to allegations of a violation of § 10(b) of the Securities and Exchange Act. *Holwill v. AbbVie, Inc.*, 2020 WL 5235005, at *2-3 (N.D. Ill. Sept. 1, 2020). The product support services that the court determined provided independent value to physicians included "assistance with pharmacy and insurance authorization and coverage, providing open enrollment resources, helping with paperwork, instruction on self-injection, answering questions, and conducting follow-ups," because those were services that "ordinarily would have been provided by the prescribing physician's office." *Id.* at *3. Thus, the court found that the complaint adequately alleged services that "confer[ed] a benefit on a referring provider." *Id.* at *2 (quoting OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735). Because the court's inquiry focused on the alleged federal securities law violations, the discussion of the allegedly illegal product support services is limited. *See id.* at *2-3.

areas as management techniques" as a "suspect incentive arrangement," she suggests that the "substantial independent value" requirement does not apply here. (*Id.* at 6-7, 12 (quoting OIG Special Fraud Alerts, 59 Fed. Reg. 65372, 65375-76 (Dec. 19. 1994))). But the guidance document that she cites to concerns "incentive arrangements" untethered to the provision of any product or service, which is not the situation here. *See* OIG Special Fraud Alerts, 59 Fed. Reg. at 65375-76. And when it comes to services offered by drug companies in connection with the sale of their products, the OIG has made no distinction between "business advisory services" and "product support services." *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.

Similarly, relator contends that the services at issue are subject to a different test because they constitute "payments in kind or gifts." (Pl. Mem. at 7); *see* OIG Special Fraud Alerts, 59 Fed. Reg. at 65376. But the OIG's guidance on such payments or gifts discusses prizes, bonuses, grants, or other items of obvious cash value. *See* OIG Special Fraud Alerts, 59 Fed. Reg. at 65376. "There is little question" that such benefits as "free supplies, meals, and trips [] constitute remuneration." *United States ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 271 (D. Mass. 2016). By contrast, services offered in connection with and in support of lawful product sales are not always so clearly problematic. *See, e.g.*, *id.* at 270-71 (concluding that training patients on how to use insulin pumps might constitute illegal remuneration only because the provider allegedly paid trainers above-market rates).

Instead, the question seems to be whether such services, regardless of how they are characterized, have "substantial independent value" to the persons to whom they are provided. *See Forney*, 2017 WL 2653568, at *4. Alternatively, the *Suarez* court described the inquiry as whether a drug maker "offered services 'integrally related' to [its product] '*in tandem with*

another service or program that confers a benefit on a referring provider,'" or "'eliminate[d] an expense that the physician would have otherwise incurred.'" 2019 WL 4749967, at *7 (quoting OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735, 23737).

b. Whether the Services Had Independent Value

Defendant contends that the services alleged here are nothing more than "permissible product support" tied to the sale of Remicade and Simponi ARIA. (Def. Mem. at 14-16); *see Forney*, 2017 WL 2653568, at *4. Accordingly, it says, they have no independent value.

It is true that some of the alleged services appear to be specific to Remicade and Simponi ARIA. For example, the SAC alleges that ABSs and outside consultants presented information to physicians on how to maximize discounts for those drugs when purchasing through defendant's own bulk discounting program. (SAC ¶¶ 59, 166(j)). It is hard to see how such presentations could have value to physicians beyond assisting them with those particular medications.

However, the SAC alleges that other services provided by defendant had independent value because they also applied to infusible medications other than Remicade and Simponi ARIA. For example, it alleges that ABSs and outside consultants gave presentations and customized advice to physicians on how to optimize their infusion schedules to increase volume and thus their profitability. (*Id.* ¶ 166(a); *see also id.* ¶¶ 166(d), 166(e), 166(g), 166(h), 166(m)). It alleges that the value of such services "applied equally to other infusible drugs and services," including several specific medications that "nearly all" of defendant's customers prescribed. (*Id.* ¶¶ 173, 183).[4]

[4] The SAC alleges that if the infusion businesses were not profitable then physicians would revert to older, non-infusible therapies. (*See* SAC ¶ 146). Defendant contends that this means the business advisory services that

Defendant contends that the SAC "cites no example . . . in which any physician used [its] . . . services for any other infusible or non-infusible medication" other than Remicade and Simponi ARIA. (Def. Reply at 5). But even if such examples are necessary for the complaint to state a claim, the SAC provides them. It alleges that at least one of the medical practices served by relator "applied the free information and strategies [it] learned" from defendant to other infusible drugs by negotiating higher reimbursement rates on Remicade *and* other infusion drugs it administers. (*See* SAC ¶ 176(b)). It further alleges how she assisted another practice optimize its infusion schedules for both Remicade and a competing medication. (*See id.* ¶ 176(d)). Those allegations are sufficiently specific to show that defendant's infusion-related services had at least some value for administering medications other than Remicade and Simponi ARIA.

Moreover, other services that defendant allegedly provided appear to have value entirely separate from their infusible medications. For example, the SAC alleges that ABSs (including relator) and outside consultants gave presentations and customized advice to physicians on how to adopt EHR technology that would qualify them for incentive payments available through the Medicare EHR Incentive Program. (*Id.* ¶¶ 166(i), 176(c)). It further alleges that those services helped physicians "earn the maximum incentive payments from Medicare," which could exceed $44,000, and "avoid paying penalties" of up to 5% of their Medicare reimbursements. (*Id.* ¶ 166(i)). Similarly, the SAC alleges that ABSs helped physicians negotiate better reimbursement rates not only for Remicade and Simponi ARIA, but also for "other top revenue-generating services (usually the top 20-30 services and drugs billed by a practice)." (*Id.* ¶ 166(d)). It alleges that "[t]his helped [physicians] maximize their reimbursement amounts and profits for

enabled practices to be profitable were tied to defendant's infusible medications in particular. (Def. Mem. at 3). However, because the SAC alleges that the value of those services applied to other prescribed infusible medications, defendant's conclusion does not necessarily follow.

Remicade and Simponi ARIA and the related infusion services as well as other frequently billed services and drugs." (*Id.*). It further alleges that ABSs assisted physicians add other infusion service lines and treatments that do not involve Remicade or Simponi ARIA, such as oncological treatments and treatments for blood and lymph conditions. (*Id.* ¶ 166(h)). Thus, the SAC alleges that the provision of those services had value to physicians apart from the physicians' use of defendant's products, and therefore plausibly alleges that they had independent value.

In short, taking the allegations in the SAC as true, at least some of the services that defendant allegedly offered plausibly had value independent of Remicade and Simponi ARIA. The question becomes whether that value was substantial enough to implicate the Anti-Kickback Statute.

c. Whether the Independent Value of the Services Was Substantial

Defendant contends that the services at issue did not have substantial value because they consisted of publicly available information. By way of example, it cites several presentations referred to in the SAC, which it says drew from public sources. (Def. Mem. at 13-14). It contends that because the OIG has said in an advisory opinion that services have only nominal value if "[s]imilar information content is available on the Internet and from other public sources without charge," those presentations cannot have substantial value. (*Id.* at 14); *see* OIG Adv. Op. No. 07-16, 2007 WL 6400843, at *3 (Dec. 5, 2007).

The presence of some publicly available information in some of the presentations allegedly offered by defendant does not, by itself, prove that none of that information had substantial value. As an initial matter, defendant cannot introduce the OIG advisory opinion that it cites as evidence that it did not violate the Anti-Kickback Statute because it did not request that opinion. 42 C.F.R. § 1008.55 ("An advisory opinion may not be introduced into evidence by a

person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate . . . any . . . law."); *see, e.g., United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *4 (D. Mass. Aug. 23, 2016). However, even if the Court considered the OIG advisory opinion to, at the very least, inform its analysis, it is inapposite here. The public sources cited by defendant are not yet part of the record. They are neither incorporated by reference in the complaint nor central to its claims. *See Freeman v. Town of Hudson*, 714 F.3d 29, 36-37 (1st Cir. 2013). Defendant contends that the Court may nonetheless take judicial notice of them. *See Martin v. Mead Johnson Nutrition Co.*, 2010 WL 3928710, at *2 (D. Mass. Sept. 13, 2010), *report and recommendation adopted in part, rejected in part*, 2010 WL 3928707 (D. Mass. Sept. 30, 2010) (taking judicial notice of a website's contents "for the limited purpose of showing that the information contained therein was publicly available"). But even if that is true, and some portions of some presentations were publicly available, the SAC alleges that the presentations still had substantial value, as shown by the fact that physicians and practice staff regularly created time in their schedules to meet with the ABSs and outside consultants in order to listen to them. (Pl. Mem. at 13-14; SAC ¶ 178(b)). Moreover, relator contends that even if some of the presentations lacked substantial value because they contained public information, defendant has not shown that was true for all the presentations used by its ABSs and outside consultants. (Pl. Mem. at 14).

In any event, even if every one of the presentations made by the ABSs and outside consultants lacked substantial value, the SAC alleges that other services provided had such value. Indeed, it alleges that "ABSs spent more time implementing strategies than presenting them." (SAC ¶ 172). For example, ABSs allegedly provided physicians with customized analysis, including the use of software programs, on how to improve the profitability of their

infusion practices by optimizing their infusion schedules. (*Id.* ¶ 166(a)). They also allegedly advised physicians that "the information and assistance that they provided was applicable to other infusion service lines or treatments and the [physicians'] infusion businesses as a whole." (*Id.* ¶ 184). Similarly, they allegedly advised physicians directly on how to "maximize their reimbursement amounts and profits" for medications and services other than Remicade and Simponi ARIA. (*Id.* ¶ 166(d)).

Taking those allegations as true, those services plausibly had value to physicians that was both independent of defendant's products and substantial. Defendant nonetheless contends that the SAC "contains the same type of conclusory allegations" of substantial value that were found deficient in *Suarez* and *Forney*. (Def. Mem. at 12). Those courts held that under Rule 9(b) the complaint must allege "*how* those services substantially benefited [physicians'] bottom lines." *See Forney*, 2017 WL 2653568, at *4; *see also Suarez*, 2019 WL 4749967, at *9 (noting that the realtor "allege[ed] only in a conclusory manner that the [defendant's] services eliminated costs that doctors would otherwise have had to cover"). Here, the SAC does specifically allege how the services at issue benefited physicians' "bottom lines."[5] For example, it alleges that by advising physicians on how to adopt new EHR technology, ABSs and outside consultants helped physicians "earn the maximum incentive payments from Medicare," which could exceed $44,000, and "avoid paying penalties" of up to 5% of their Medicare reimbursements. (SAC ¶ 166(i)). Similarly, it alleges that by analyzing the infusion schedules of physicians' practices, ABSs and consultants helped the practices administer more infusions and thereby increase their profits. (*Id.* ¶ 166(a)). It specifically alleges that optimizing their infusion schedules enabled

[5] Because the allegations adequately satisfy this part of the test for pleading a violation of the Anti-Kickback Statute under the heightened pleading requirements of Rule 9(b), they necessarily adequately satisfy this test under the pleading requirements of Rule 12(b)(6).

practices to minimize their overhead costs by reducing the amount of necessary nurse coverage, and thus the hourly fees they would have paid a nurse to administer the infusions. (*Id.*). Moreover, it alleges instances in which relator provided those particular services to particular practices. (*See id.* ¶¶ 176(b)-(d)).

In summary, the SAC plausibly alleges that at least some of the services provided by defendant had substantial independent value to physicians. And although some of the other services alleged may have had "no independent value," some of the services allegedly provided plausibly "raise kickback concerns" because they were provided "in tandem with" those services that did "confer[] a benefit" on physicians. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735. Accordingly, taking the allegations in the SAC as true, they are sufficient to allege that defendant paid illegal remuneration to physicians. Whether those allegations are true is, of course, a question for another day.

2. Whether the SAC Alleges That Defendant Knowingly and Willfully Offered or Paid Illegal Remuneration

As set forth above, the Anti-Kickback Statute prohibits offering or paying remuneration, but only if a person does so "knowingly and willfully." 42 U.S.C. § 1320a-7b(b). "To act knowingly, a defendant must 'do something voluntarily . . . not [] by mistake or accident or even negligently,' and to act willfully, a defendant must 'do something purposely, with the intent to violate the law.'" *Banigan*, 2016 WL 10704126, at *3 (quoting *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989)).[6]

It is doubtful that the SAC's conclusory allegations that defendant "intentionally used

[6] The state analogues to the federal statute also have scienter requirements, although some may vary slightly from the federal requirement. *See, e.g.*, Mass. Gen. Laws ch. 12, § 5B(a) (requiring that a defendant acted "knowingly").

free business services" to "induce" physicians to prescribe its products would be sufficient, without more, to satisfy the scienter requirements. (SAC ¶¶ 126, 186). The *Forney* court rejected similar allegations that a defendant "induced physicians and others with purchasing power to select [its] devices" as insufficient to satisfy that requirement. 2017 WL 2653568, at *5. Notably, however, the complaint there alleged that "the *effect* of the scheme was to induce physicians to refer [defendant's] products to their patients" without alleging that "[defendant's] subjective purpose was to do so." *Id.* (emphasis added). Here, by contrast, the SAC alleges that defendant's "*objective* was for the ABSs' services to influence physicians and induce sales of Remicade and Simponi Aria through business support." (SAC ¶ 126 (emphasis added)).

Furthermore, and in any event, other allegations in the SAC indicate that at least some of defendant's employees knew those services violated the Anti-Kickback Statute. Specifically, it alleges that a 2014 internal document prepared by defendant's compliance department warned employees that the statute "[m]akes it illegal for pharmaceutical manufacturers to give [health care providers] anything of value to induce them to prescribe or purchase products that are reimbursed in whole or part by a federal health care program." (*Id.* ¶ 204 (alterations in original)). And it further alleges that certain passages in that document "openly admitted . . . that the very services that [ABSs] regularly provided to rheumatology and gastroenterology practices constituted kickbacks," such as:

> [E]mployees may not offer consulting services that relate to the management of customers' business practices because the customer is ultimately responsible for seeking that advice and in many cases paying for the service.
>
> If a company were to provide advice, it could be considered a kickback because it could offset the normal overhead expenses for the practice as well as expose our company to potential legal liability.

(*Id.* ¶ 206; *see also id.* ¶ 207). Of course, the mere existence of that compliance document does not conclusively establish the requisite degree of knowledge and intent. But at the motion to

dismiss stage, the Court must accept those allegations as true. *Cf. Banigan*, 2016 WL 10704126, at *3 (finding that the defendants were aware of the Anti-Kickback Statute and related OIG guidance to be sufficient evidence to put the question of scienter under the Anti-Kickback Statute before a jury).

The SAC does not clearly allege that the ABSs themselves knew their conduct was unlawful. It alleges that defendant "led ABSs to believe" that the services they provided were legal. (SAC ¶ 170). It suggests that, at most, some ABSs may have suspected otherwise, but alleges that they "continued to provide the free business advisory services to accounts because that was their job, and they trusted (wrongly) that [defendant] believed it was legal to provide the services." (*Id.* ¶ 208).

However, the SAC plausibly alleges that the managers of those ABSs knew that the services provided violated the Anti-Kickback Statute. Specifically, it alleges that "they went to great lengths to conceal the nature of the services ABSs provided to accounts." (*Id.* ¶ 170). Those efforts allegedly included "repeatedly warn[ing] ABSs not to leave a paper trail" and "repeatedly instruct[ing] ABSs not to send them account updates, questions from customers, or anything business[-]related via text message or email because 'we do not want to leave a paper trail.'" (*Id.*). Those allegations, taken as a whole, are sufficient to suggest that at least some of defendant's employees knew the services provided by ABSs were unlawful and nevertheless supervised and intentionally aided ABSs as they provided them.[7] Accordingly, the SAC

[7] Defendant contends that the Court should not infer that it knew the services offered by ABSs were unlawful based on "allegations that [it] took pains to paper over [their] true nature." (Def. Mem. at 18 n.13); *see Suarez*, 2019 WL 4749967, at *14 (concluding that the court could not draw an inference that defendant knew its actions were unlawful from allegations that defendant sought to downplay Ambassadors' role as healthcare providers or sales representatives; warned Ambassadors not to document the time they spent with doctors; instructed them not to mention Humira in write-ups after patient visits; and instructed them to call their supervisors about questions concerning admissible behavior with patients rather than put the questions in writing). But the *Suarez* court arrived at that conclusion for two reasons that do not apply here. First, it did so "because it [was] unclear whether the alleged cover-up efforts ha[d] any relation to the services alleged to constitute illegal remunerations in

plausibly alleges an inference that defendant knowingly and willfully paid remuneration in violation of the Anti-Kickback Statute.

B. Whether the SAC Pleads with Particularity that False Claims Were Submitted to the Government

Defendant also contends that the SAC should be dismissed because it does not satisfy the pleading requirements of Fed. R. Civ. P. 9(b). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." That heightened pleading requirement applies to claims brought under the FCA, at least to the extent that a relator "must provide details that identify particular false claims for payment that were submitted to the government." *See Ge*, 737 F.3d at 123. Thus, "[r]elators are required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." *Id.* (quoting *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000)).

As the First Circuit explained in *Ge*:

> A relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, 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 are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, we believe that some of this information for at least some of the claims must be pleaded in order to satisfy

[that] case." *Suarez*, 2019 WL 4749967, at *14. By contrast, here the SAC alleges that the managers tried to cover up the very same services that allegedly constitute illegal remuneration. (*See* SAC ¶ 170 (alleging that defendant's employees "instructed ABSs to avoid putting their profitability and practice management discussions with accounts in writing and to never leave the . . . individualized business analyses behind with accounts")). Second, the *Suarez* court found that the fact that the defendant's website "openly advertise[d]" the services at issue "dispel[led] any inference that [the defendant] was trying to conceal [those] services." *Suarez*, 2019 WL 4749967, at *14. Here, there is no allegation that defendant publicly advertised the services offered by ABSs.

Rule 9(b).

737 F.3d at 123 (internal quotation marks and alterations omitted) (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir. 2004)).

The First Circuit has, "[i]n applying this general rule over time, . . . nevertheless recognized at least one exception." *Nargol*, 865 F.3d at 39. It has "recognized a difference between *qui tam* actions alleging that the defendant made false claims to the government and those alleging that the defendant induced third-parties to file false claims with the government." *Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 130 (1st Cir. 2016). Courts are to "apply a 'more flexible' standard in actions of the latter, indirect type: where the defendant allegedly 'induced *third parties* to file false claims with the government . . . a relator [can] satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.'" *Nargol*, 865 F.3d at 39 (quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)) (some internal quotations omitted). "Such evidence must pair the details of the scheme with 'reliable indicia that lead to a strong inference that claims were actually submitted.'" *Nargol*, 865 F.3d at 39 (quoting *Duxbury*, 579 F.3d at 29).

Here, the SAC alleges that defendant induced third parties—specifically, physicians at rheumatology and gastroenterology practices—to file false claims with the government. But it does not allege the submission of any specific false claims with the level of detail set forth in *Ge*. *See* 737 F.3d at 123. Accordingly, relator must establish the necessary degree of particularity through "factual or statistical evidence [that] strengthen[s] the inference of fraud beyond possibility." *Duxbury*, 579 F.3d at 29. Three First Circuit cases offer some guidance on when such allegations are sufficient to satisfy the requirements of Rule 9(b).

In *Ge*, the complaint alleged that the defendant pharmaceutical company had failed to file

accurate and timely adverse event reports with the FDA, and that if it had done so, numerous claims for its pharmaceuticals would not have been submitted to the federal government. 737 F.3d at 119-21. The FCA claim was dismissed because the relator "made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of [defendant's] alleged misconduct." *Id.* at 124. "What [was] missing [were] any supporting allegations upon which her conclusion rest[ed] and any particulars." *Id.*

In contrast, in *Duxbury*, the court found that the complaint alleged facts sufficient to sustain an inference of fraud. 579 F.3d at 30. The relator alleged that kickbacks provided by the defendant resulted in the submission of false claims by eight named healthcare providers in the state of Washington. *Id.* As to those eight providers, the complaint provided allegations of dollar amounts and (in at least one instance) the number of claims. *Id.* The court found that those eight specific sets of allegations provided sufficient factual support to satisfy the requirements of Rule 9(b): "[i]n particular, [the relator] has identified, as to each of the eight medical providers (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." *Id.* It described the question, however, as "a close call." *Id.*; *see Ge*, 737 F.3d at 124 (referring to the allegations in *Duxbury* as "barely adequate").

More recently, the court again found a complaint sufficient under Rule 9(b) in *Nargol*. 863 F.3d at 41. There, the relators alleged that a medical device manufacturer "knowingly palmed off . . . devices that materially deviated from the approved specifications." *Id.* at 40. The complaint identified only a "single exemplar false claim" filed in New York. *Id.* at 37. It did "nothing to allege that [the] devices were advertised to and implanted by physicians in . . . any

other state or municipality except for the state of New York." *Id.* at 42. But it also alleged that "several thousand Medicare and Medicaid recipients received" devices made by the defendant, more than half of those devices fell outside FDA-approved specifications, and "the latency of the defect was such that doctors would have had no reason not to submit claims for reimbursement." *Id.* at 41.

The *Nargol* court found that those allegations "lead to a strong inference that claims were actually submitted" for government reimbursement. *Id.* It distinguished the type of fraud alleged—claims for medical devices that deviated from approved specifications—from past "cases alleging unlawful marketing for off-label uses or off-label dosages." *Id.* at 39-40. Unlike in those cases, where patients or physicians might pay out-of-pocket instead of submitting claims to Medicare or Medicaid, "doctors would have had no reason not to submit claims for reimbursement for noncompliant devices." *Id.* at 41. Thus, because the complaint alleged that thousands of Medicare and Medicaid recipients received defendant's devices and that more than half of those devices were defective, it was "statistically certain" that the defendant had induced physicians to file false claims for government reimbursement. *Id.* The court did "not decide" whether "the one pleaded example offered [from New York] [was] necessary." *Id.* at 41 n.8.

However, the *Nargol* court found the complaint's allegations sufficient only to show that false claims were submitted to the United States and the state of New York. *Id.* That was because the complaint alleged that several thousand Medicare and Medicaid patients, including several hundred in New York, had likely received defective devices. *See id.* at 37, 41-42. The court held those allegations sufficient to sustain the relators' claims under the FCA for reimbursement submitted to the United States and under New York state law for reimbursements submitted to New York. *Id.* at 41-42. But because the complaint did "nothing to allege that

[defendant's] devices were advertised to and implanted by physicians in . . . any other state or municipality," the relators' allegations were insufficient to sustain their claims under any other state-law analogues to the FCA. *Id.* at 42.

Here, the SAC alleges that several medical practices submitted false claims to Medicare. Specifically, it alleges that "from approximately August 2015 to mid-2017," at least one and possibly two physicians at one practice (Account B) submitted claims to Medicare for Remicade infusions that they gave "approximately every eight weeks" to a patient with psoriatic arthritis. (SAC ¶ 191).[8] It further alleges that during that time period, Account B "regularly accepted [defendant's] offer to provide many of the free business advisory services" at issue. (*Id.*). Similarly, the SAC alleges that between 2012 and 2017, nine different physicians at six different practices billed Medicare for thousands of Remicade infusions each year while defendant "regularly provided them with valuable business advisory services and support for no charge." (*Id.* ¶ 192). And it further alleges that from 2015 to 2017, one physician billed Medicare for thousands of Simponi ARIA infusions each year while "regularly receiving free business advisory services and support from" defendant. (*Id.* ¶ 193). Notably, however, the SAC does not allege where any of these physicians or practices were located, nor does it allege specific dates of false claims or specific dollar amounts. (*See id.* ¶¶ 191-93).

The SAC also alleges statistics about the number of total claims for Remicade and Simponi ARIA submitted to Medicare and Medicaid each year. It alleges that from 2013 to 2017, an annual average of 58,641 Medicare beneficiaries received Remicade, costing Medicare

[8] The SAC alleges that "Physician B-2 and/or Physician B-3" at Account B submitted claims for reimbursement to Medicare during this time period. (SAC ¶ 191).

Part B more than $1 billion annually. (*Id.* ¶ 49).[9] It further alleges that from 2008 to 2016, the Medicaid programs of the plaintiff states paid out a total of more than $1 billion in reimbursements for Remicade. (*Id.* ¶ 50). It makes similar allegations about Simponi ARIA. (*See id.* ¶¶ 57-58).

The SAC's allegations about specific false claims are less detailed than the ones held sufficient in *Duxbury*. As there, relator has identified the "who" (at least nine physicians at nine different practices), the "what" (acceptance of business advisory services that supposedly violated the Anti-Kickback Statute), the "when" (from 2012 to 2017), and the filing of the false claims themselves.[10] *See Duxbury*, 579 F.3d at 30.[11] But unlike in *Duxbury*, it is not clear exactly where those claims originated—the SAC does not say where any of the physicians or practices were located. *See Duxbury*, 579 F.3d at 30 (alleging the submission of false claims by eight healthcare providers in the state of Washington). Thus, the SAC contains fewer details about the actual false claims than the complaint did in *Duxbury*, which the First Circuit said was "barely adequate" and where dismissal was considered a "close call." *Duxbury*, 579 F.3d at 30; *Ge*, 737 F.3d at 124.

Nevertheless, the sum of the SAC's allegations creates a sufficiently plausible inference

[9] The SAC alleges that relator "is unaware of Medicare Part C plans' combined spending on" Remicade and Simponi ARIA, but that "it is reasonable to assume that adding the Part C plans' expenditures on [both drugs] would cause these figures to climb substantially." (*Id.* ¶¶ 49, 57).

[10] The SAC identifies the number of Remicade and Simponi ARIA infusions administered to Medicare beneficiaries and billed to Medicare by nine specific physicians. (*Id.* ¶ 192-93). The SAC further alleges that an additional physician, "Physician B-3," may have also submitted claims for reimbursement for Remicade during the relevant period. (*Id.* ¶ 191). Further, although the SAC only identifies the specific number of Remicade infusions billed to Medicare for six practices, it alleges that physicians from three additional practices that she worked with also submitted claims for reimbursement for Remicade and Simponi ARIA during the relevant period. (*Id.*).

[11] Although it is not clear from the opinion in *Duxbury*, the complaint there also alleged that some healthcare providers had submitted false claims over a period of several years. *See, e.g.*, First Am. Compl. ¶ 211(a), *United States ex rel. Duxbury v. Ortho Biotech Prods, L.P.*, 2006 WL 3427218 (alleging the submission of false claims by a hospital from "approximately 1993 through 1997").

that false claims were actually submitted to the United States. It alleges that over several years, Medicare paid billions of dollars in reimbursements for Remicade and Simponi ARIA. (*Id.* ¶¶ 49-50, 57-58). To be sure, it does not allege that all—or even most—of those reimbursement claims were false. *See Nargol*, 865 F.3d at 41 (noting that "more than half" of defendant's devices allegedly fell outside FDA-approved specifications). But it does allege that most infusions of Remicade and Simponi ARIA were administered by rheumatology and gastroenterology practices with infusion services and that Medicare and Medicaid beneficiaries made up a "large percentage" of those patient populations. (*See* SAC ¶¶ 118, 201). And it alleges that defendant paid such practices "across the country" unlawful remuneration in the form of business advisory services. (*Id.* ¶¶ 124, 143). Finally, and importantly, the SAC alleges with some particularity that several physicians and practices did indeed submit false claims to Medicare after receiving business advisory services from defendant. (*Id.* ¶¶ 191-93). Those specific allegations, combined with the factual and statistical evidence described above, supply "reliable indicia that lead to a strong inference that" false claims were "actually submitted" to the United States. *See Duxbury*, 579 F.3d at 29.

Defendant contends that the Court should limit relator's FCA claims to only the nine practices specifically described in the SAC. (Def. Reply at 10-11). In support of that argument, it cites *United States ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App'x 162 (3d Cir. 2015). In *Judd*, the Third Circuit affirmed the dismissal of a physician's FCA claims as to all healthcare providers other than one where he worked. *See id.* at 168-69. It did so because his complaint contained only a "brief, conclusory assertion" that his "discussions with other providers . . . demonstrate that [the defendant's] practices . . . extend to other medical practices." *Id.* at 169 (quotations omitted).

However, the allegations here relating to practices other than the nine specifically described in the SAC are more detailed than those in *Judd*. The SAC alleges that defendant employed "over 40 [] ABSs nationwide" who gave illegal remuneration to healthcare providers "across the country" in the form of free business advisory services, just as relator did to the nine specified accounts. (SAC ¶¶ 124, 166). And it alleges statistical data showing that Medicare paid billions of dollars in Remicade and Simponi ARIA reimbursements to providers nationwide. (*Id.* ¶¶ 49, 57). Unlike in *Judd*, those allegations amount to more than a "mere opportunity for fraud" by providers other than the nine specified practices. *See Judd*, 638 F. App'x at 169. And while the SAC does not specifically allege that any of those other providers submitted false claims, that is not required under First Circuit law. *See Nargol*, 865 F.3d at 37, 41-42 (permitting a relator to pursue FCA claims for *all* claims submitted to the United States even though the complaint only alleged a "single exemplar false claim" originating in New York). Thus, the SAC's allegations are sufficient to sustain relator's FCA claims for false claims submitted to the United States, either by the nine specified practices or by other ones.[12]

However, it is much less clear that false claims were submitted to the Medicaid programs of the plaintiff states. The SAC alleges that those programs paid out more than $1 billion in reimbursements for Remicade and Simponi ARIA over several years. (SAC ¶¶ 50, 58). And it also alleges that during that same time period, defendant gave unlawful remuneration in the form

[12] Defendant also contends, in the alternative, that the Court should limit the scope of discovery to those nine practices specified in the SAC. (Def. Reply at 11 n.8). In cases where relators have alleged the submission of particular false claims only in some parts of the country, courts in this district have indeed limited discovery to those regions in order "to probe the validity of the kickback allegations before considering whether to authorize nationwide discovery." *See, e.g.*, *United States ex rel. Carpenter v. Abbott Lab'ys., Inc.*, 723 F. Supp. 2d 395, 409-10 (D. Mass. 2010); *U.S. ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008). The First Circuit has upheld such limits after reviewing them for an abuse of discretion. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 719 F.3d 31, 39-40 (1st Cir. 2013). The Court will address that issue, as appropriate, in the Rule 16 scheduling conference.

of business advisory services to rheumatology and gastroenterology practices in states "across the country." (*Id.* ¶ 143). But unlike in *Nargol*, the SAC does not allege that any particular state paid some number of false claims. *See Nargol*, 865 F.3d at 42 (describing how the complaint estimated that "nearly 425 [false claims] would have been paid for by New York State Medicaid"). Nor does it combine its statistical evidence with any allegations that particular physicians submitted false claims to any state's Medicaid program. *See id.* at 37 (noting that the complaint described how a physician in New York submitted an allegedly false claim for reimbursement for defendant's products to New York State Medicaid). While it alleges that several practices submitted false claims to Medicare, it does not allege that they did so to any state Medicaid program. (*See* SAC ¶¶ 192-93). It does not even state the names or locations of those practices. (*See id.*).[13]

In short, the only evidence in the SAC that false claims were submitted to the Medicaid programs of the various plaintiff states is that (1) those programs paid $1 billion in reimbursements for Remicade and Simponi ARIA; and (2) defendant gave unlawful remuneration to several healthcare providers "across the country" in the "largest" market for those drugs. (*Id.* ¶¶ 50, 58, 118, 143). Even accepting those allegations as true, that is not enough to "strengthen the inference" that false claims were submitted to any plaintiff state's Medicaid program "beyond possibility." *See Duxbury*, 579 F.3d at 29. Thus, even under the "more flexible standard" applicable here, those allegations are insufficient to sustain relator's

[13] Relator represents that, "[i]f necessary," she could amend her complaint to identify the names of those physicians and practices as well as identify other practices "in other parts of the country." (Pl. Mem. at 19). But she has made no attempt to do so, and it is inappropriate for her to wait for an adverse ruling before doing so. *See Hamilton v. Partners Healthcare Sys., Inc.*, 879 F.3d 407, 414-15 (1st Cir. 2018) (finding that a district court did not abuse its discretion in denying plaintiffs' request for leave to amend their complaint when the plaintiffs were aware of its defects, acknowledged that it would have been "very easy" for them to eliminate those defects, waited to broach the subject directly with the court, and did not provide an adequate reason as to why they did not amend earlier because the plaintiffs were thereby treating the complaint as a "risk-free trial balloon").

claims under any of the state-law analogues to the FCA. *See Nargol*, 865 F.3d at 41-42.

Accordingly, defendant's motion to dismiss the SAC under Rule 12(b)(6) and Rule 9(b) will be denied as to the FCA claims (Counts 1 and 2) but will be granted with respect to the claims brought under the various state-law analogues to the FCA (Counts 3-29).

IV. Conclusion

For the foregoing reasons, defendant's motion to dismiss is GRANTED as to Counts 3-29 and is otherwise DENIED.

So Ordered.

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

Dated: October 21, 2020