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UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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No. 23-726-cv

UNITED STATES of America, et al.,
EX REL. Adam HART,
Plaintiffs-Appellants,
v.

MCKESSON CORPORATION, et al.,
Defendants-Appellees.*

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Appeal from the United States District Court for the Southern District of New York (Ronnie Abrams, *J.*)

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Argued: November 28, 2023

Decided: March 12, 2024

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Before: Lynch and Park, Circuit Judges, and Williams, District Judge.**

Gerard E. Lynch, Circuit Judge:

In this *qui tam* action, Adam Hart sued McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (together, "McKesson") under the federal False Claims

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* The Clerk of Court is respectfully directed to amend the official caption in this case to conform with the caption above.

** Judge Omar A. Williams of the United States District Court for the District of Connecticut, sitting by designation.

Act (the "FCA"), 31 U.S.C. § 3729 *et seq.*, and the FCA analogues of 27 states and the District of Columbia. Hart, a former McKesson Business Development Executive, alleges that McKesson, a pharmaceutical wholesaler, offered its customers free access to two valuable business management tools to induce those customers to purchase drugs from McKesson. He argues that McKesson's use of the tools operated as a kickback under the federal Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b, and similar anti-kickback laws of various states and the District of Columbia.

The United States District Court for the Southern District of New York (Ronnie Abrams, *J.*) dismissed Hart's federal claim, concluding that Hart had failed to allege that McKesson acted with the requisite scienter under the AKS. It dismissed his remaining claims on the ground that they were all premised on a violation of the federal AKS.

As explained below, we agree with the district court that to violate the federal AKS, a defendant must act knowing that its conduct is, in some way, unlawful, and that Hart failed to allege facts sufficient to satisfy that standard. We disagree, however, with the district court's conclusion that Hart's claims under the FCA analogues of several states and the District of Columbia were premised solely on a violation of the federal AKS. Accordingly, we AFFIRM the district court's dismissal of Hart's federal claim, VACATE the dismissal of Hart's remaining claims, and REMAND for further proceedings consistent with this opinion.

## BACKGROUND

### I. Factual Background[1]

McKesson is a large wholesale pharmaceutical distributor that sells products across the United States. It provides drugs and other medical supplies to various health care providers, including oncology providers. McKesson includes two divisions that serve oncology customers – the U.S. Oncology Network ("USON"), which offers tools and services to member health care practices in exchange for management fees, and the Open Market Division, which operates as a traditional drug wholesaler that purchases drugs from manufacturers and sells them at a markup to health care practices.

Oncology practices often obtain specialty drugs from wholesalers like McKesson. When an oncology practice buys a specialty drug from a wholesaler, it bills its patient's insurer for the cost of the drug. Medicare and Medicaid are federally funded health insurance programs that are major payors for oncology drugs procured in that fashion. Those programs reimburse health care providers for such drugs at standardized rates set by Medicare. Because the reimbursement rates do not change based on what a given provider paid for the drugs, each provider bears the risk that the reimbursement rate for a given drug will fall below its costs. If the reimbursement rate exceeds a provider's costs, however, the provider can profit from the difference.

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[1] When reviewing the district court's grant of a motion to dismiss, we – like the district court – take the plaintiff's well-pleaded allegations as true and draw all reasonable inferences in his favor. *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 104 (2d Cir. 2021).

McKesson offers two tools (the "Business Management Tools") to help providers maximize their profits and mitigate the risk that the reimbursement rate will fall below the actual cost they paid for drugs. The first tool, the Margin Analyzer, evaluates sets of "therapeutically interchangeable" drugs by comparing McKesson's price for each drug to publicly available Medicare reimbursement rates for that drug. App'x 277-78, ¶¶ 63, 65. Using the Margin Analyzer, a medical provider can thus compare drugs that McKesson categorizes as interchangeable to determine which treatment option provides the highest profit margin based on how each drug's reimbursement rate measures up to McKesson's prices. The Margin Analyzer does not evaluate the comparative medical benefits of the drugs that it analyzes, nor does it evaluate which drug would provide the least expensive option for a given patient. Instead, according to Hart, the tool's "sole function is to identify which among several purportedly equivalent drugs will earn a physician practice – and, not coincidentally, McKesson – the most money." *Id.* at 279, ¶ 67. The second tool, the Regimen Profiler, is similar to the Margin Analyzer, but it provides profit-margin information for an entire course of treatment, as opposed to information only for specific drugs. Several of McKesson's Open Market Division customers who had received the Business Management Tools submitted millions of dollars in Medicare reimbursement claims from 2012 to late 2017.

But according to Hart, while the Business Management Tools led to increased costs for insurers, they were hugely valuable tools for McKesson and for health care providers, and McKesson understood as much. Hart alleges, for example, that multiple

internal and external analyses determined that the Margin Analyzer and Regimen Profiler possessed significant value. Further, the Business Management Tools formed a central component of McKesson's national marketing and sales strategy, and McKesson often won new business by touting the benefits of the tools to health care providers.

Hart's objection to the Business Management Tools is that McKesson's Open Market Division offered them for free to induce providers to buy drugs from McKesson.[2] The Open Market Division offered providers two basic purchase arrangements. Under one arrangement, providers could purchase individual drugs without making any additional commitments to McKesson, leaving those providers free to purchase other drugs from McKesson competitors. Under the other arrangement, providers promised to use McKesson as their primary wholesale supplier of branded and generic drugs. In exchange for that promise, McKesson granted providers free access to the Business Management Tools. Only providers enrolled in the second type of purchase arrangement could access those tools; McKesson refused to offer them on a standalone basis, even when providers expressly requested as much and offered to pay. Thus, according to Hart, McKesson provided the valuable Business Management Tools as an unlawful kickback to induce customers to buy from McKesson.

Hart further contends that McKesson acted willfully. He points out that sales executives and other customer-facing employees at McKesson received regular training on the AKS and that those training

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[2] Unlike McKesson's Open Market Division, USON provides customers with the Business Management Tools, along with other tools and services, in exchange for a management fee.

sessions emphasized that providing anything of value to induce a sale of pharmaceuticals violates federal law. Hart also alleges that he and other McKesson employees often discussed concerns that McKesson's sales practices (including its use of the Business Management Tools) were improper. He further alleges that McKesson destroyed several documents after this litigation began to conceal its wrongful conduct.

**II. Procedural History**

Hart filed his complaint on February 6, 2015. Because Hart asserted a *qui tam* action under the FCA,[3] the United States was given an opportunity to intervene in the case. *See* 31 U.S.C. § 3730(b)(2), (b)(4). After the government declined to intervene, Hart filed his first amended complaint (the "FAC") on June 3, 2020. The defendants moved to dismiss the FAC, and the district court granted that motion on May 5, 2022. The district court reasoned that the plaintiff failed to plausibly plead that the defendants acted with the requisite scienter under the AKS. Nonetheless, the court gave the plaintiff leave to amend his complaint a second time to add more allegations regarding McKesson's scienter, and Hart filed his second amended complaint (the "SAC") roughly one month later. McKesson moved to dismiss the SAC, and on March 28, 2023, the district court again granted the motion. *United States ex rel. Hart v.*

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[3] A private individual may bring a *qui tam* action under the FCA for violations of the AKS. The FCA prohibits, as relevant here, "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). The AKS, in turn, provides that "a claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g).

*McKesson Corp.*, No. 15-CV-0903 (RA), 2023 WL 2663528, at *13 (S.D.N.Y. Mar. 28, 2023).

In its opinion on the motion to dismiss the SAC, the district court concluded that to act "willfully," as required for liability under the AKS, a defendant must act knowing that its conduct was unlawful. *Id.* at *7. The court then concluded that Hart's allegations, including the new allegations that he added to the SAC, did not plausibly plead that McKesson acted willfully under that standard. *Id.* at *8-12. The district court also dismissed Hart's claims under the FCA analogues of several states and the District of Columbia, reasoning that those claims were premised only on "a violation of the *federal AKS*," which Hart had not plausibly alleged. *Id.* at *8 (emphasis in original). The court again granted Hart leave to amend his complaint because it was "conceivable" that Hart could state a claim under the anti-kickback laws of one or more states, which may have a lower scienter requirement than the federal AKS. *Id.* at *13.[4]

On April 7, 2023, Hart filed a notice of intent not to amend his complaint and requested that the court enter a final judgment. The district court did so on April 17. This appeal followed.

## DISCUSSION

Hart argues on appeal that the district court erred in dismissing his federal FCA claim because he alleged sufficient facts to show that McKesson acted with the requisite scienter under the federal AKS. He also argues that the district court erred in dismissing his remaining claims because, contrary to the district

[4] The court noted, however, that it was "skeptical that it would retain jurisdiction" over a third amended complaint that raised exclusively state-law claims. *Id.*

court's conclusion, they were not premised solely on a violation of the federal AKS. As explained below, we agree with the district court's dismissal of Hart's federal FCA claim but disagree with its dismissal of the remaining claims.

## I. Standard of Review

We review *de novo* a district court's grant of a motion to dismiss. *Meyer v. Seidel*, 89 F.4th 117, 128 (2d Cir. 2023). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

"Claims under the FCA are subject to the particularity requirement of Federal Rule of Civil Procedure 9(b)." *United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020). Accordingly, a plaintiff bringing an FCA claim "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To do so, plaintiffs must "plead the factual basis which gives rise to a strong inference of fraudulent intent." *Strock*, 982 F.3d at 66 (internal quotation marks omitted), quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991).

## II. The Federal AKS Claim

### *A. Willfulness*

The primary issue on appeal is whether the SAC plausibly alleges that McKesson acted with the *mens rea* applicable under the federal AKS. That statute provides, in pertinent part, that

> [w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly,

> in cash or in kind to any person to induce such person . . . to purchase . . . 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)(B). A defendant convicted under the AKS may be subject to significant penalties, including ten years' imprisonment and fines of up to $100,000. *See id.*

When interpreting a statute, "[w]e begin with the text." *Facebook, Inc. v. Duguid*, 592 U.S. 395, 402, 141 S.Ct. 1163, 209 L.Ed.2d 272 (2021). The statute here requires, *inter alia*, that a defendant act "willfully" to be liable, but it does not define that term.

Interpreting the term "willfully" has long "bedeviled" courts, *United States v. George*, 386 F.3d 383, 389 (2d Cir. 2004), because it is "'a word of many meanings' whose construction is often dependent on the context," *Bryan v. United States*, 524 U.S. 184, 191, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998), quoting *Spies v. United States*, 317 U.S. 492, 497, 63 S.Ct. 364, 87 L.Ed. 418 (1943). "Most obviously it differentiates between deliberate and unwitting conduct, but in the criminal law it also typically refers to a culpable state of mind." *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. Thus, "[a]s a general matter, when used in the criminal context, a willful act is one undertaken with a bad purpose." *United States v. Kosinski*, 976 F.3d 135, 154 (2d Cir. 2020) (alterations in original) (internal quotation marks omitted), quoting *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. "In other words, in order to establish a willful violation of a [criminal] statute, the Government must prove that the defendant acted with knowledge that his conduct was unlawful." *United States v. Kukushkin*, 61 F.4th 327, 332 (2d Cir. 2023) (internal

quotation marks omitted), quoting *Bryan*, 524 U.S. at 191-92, 118 S.Ct. 1939.

At the same time, it is well settled that "ignorance of the law or a mistake of law is no defense to criminal prosecution." *Cheek v. United States*, 498 U.S. 192, 199, 111 S.Ct. 604, 112 L.Ed.2d 617 (1991). Accordingly, with few exceptions, "a person who acts willfully need not be aware of the *specific* law that his conduct may be violating." *United States v. Henry*, 888 F.3d 589, 599 (2d Cir. 2018) (emphasis added). "Rather, 'knowledge that the conduct is unlawful is all that is required.'" *Id.*, quoting *Bryan*, 524 U.S. at 196, 118 S.Ct. 1939.[5]

Drawing on that background understanding of willfulness, our only opinion to address the AKS's *mens rea* requirement suggested that to violate the AKS, a defendant must act knowing that his conduct is unlawful, even if the defendant is not aware that his conduct is unlawful under the AKS specifically. *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022). In that case, we explained that the "bad purpose" required for willful violations of criminal statutes is best "understood as 'a voluntary, intentional violation of a known legal duty.'" *Id.*, quoting *United States v. Bishop*, 412 U.S. 346, 360, 93

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[5] The Supreme Court has applied a heightened standard of willfulness to certain "highly technical statutes," requiring not only that a defendant understand that her conduct is unlawful but also that she "have knowledge of the law" that she is alleged to have violated. *Bryan*, 524 U.S. at 194-95, 118 S.Ct. 1939, citing *Cheek*, 498 U.S. at 201, 111 S.Ct. 604, and *Ratzlaf v. United States*, 510 U.S. 135, 138, 149, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994). McKesson does not argue for such a standard here. Nor could it. The AKS expressly provides that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]" to be criminally liable. 42 U.S.C. § 1320a-7b(h).

S.Ct. 2008, 36 L.Ed.2d 941 (1973). Thus, we reasoned that an individual who "accidentally violate[s] the statute" because he is "unaware" that a given payment arrangement is prohibited by law cannot be held criminally liable under the AKS. *Id.* But a person can "willfully" violate a criminal statute like the AKS, "as long as he knows that his conduct is illegal, even if he is not aware of the exact statutory provision that his conduct violates." *Id.* at 77 n.8.

Although *Pfizer* addressed a slightly different issue than the one we now face, its discussion of the term "willfully" in the AKS is evidence that we have understood that term as it is typically interpreted in federal criminal law. Moreover, the interpretation suggested in *Pfizer* aligns with the approach to the AKS taken by several of our sister circuits, which have held or implied that to be liable under the AKS, defendants must know that their particular conduct was wrongful. *See*, *e.g.*, *United States v. Montgomery*, No. 20-5891, 2022 WL 2284387, at *12 (6th Cir. June 23, 2022); *United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021); *United States v. Hill*, 745 F. App'x 806, 815-16 (11th Cir. 2018); *United States v. Nagelvoort*, 856 F.3d 1117, 1126 (7th Cir. 2017); *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015); *United States v. Yielding*, 657 F.3d 688, 708 (8th Cir. 2011).

*Pfizer*'s interpretation also makes sense given the text and structure of the statute. The AKS forbids "offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" to make certain purchases. 42 U.S.C. § 1320a-7b(b)(2)(B). Thus, the statute's plain language is expansive. To cabin the statute's broad reach, Congress defined twelve exceptions to the AKS's criminal penalties, some of which are themselves quite broad. *See*, *e.g.*, *id.* § 1320a-

7b(b)(3)(A) (criminal penalties shall not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program"). Moreover, Congress created a robust regime through which the Department of Health and Human Services ("HHS") can establish safe harbors that exempt certain arrangements from the AKS and issue advisory opinions explaining whether the AKS reaches particular arrangements. *Id.* §§ 1320a-7c(a)(1)(D), 1320a-7d.

All of that suggests that Congress understood that the precise contours of the AKS would evolve over time. Thus, interpreting "willfully" to require that a defendant act understanding that his conduct is unlawful (if not necessarily under the AKS) accords with the general goal of criminal law to punish only those who act with a "vicious will." *Ruan v. United States*, 597 U.S. 450, 457, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022) (internal quotation marks omitted), quoting *Morissette v. United States*, 342 U.S. 246, 251, 72 S.Ct. 240, 96 L.Ed. 288 (1952). A more expansive interpretation would risk creating a trap for the unwary and deter socially beneficial conduct. *See id.* at 459, 142 S.Ct. 2370; *United States v. Pineda*, 847 F.2d 64, 65 (2d Cir. 1988) (rejecting challenge to sentencing enhancement "because the statute requires proof that a defendant knowingly and intentionally possessed a controlled substance").

The legal landscape that has emerged through HHS's safe harbors and advisory opinions only strengthens that conclusion. HHS has codified over 35 safe harbor provisions and continues to add new safe harbors and modify existing ones. *See* 42 C.F.R.

§ 1001.952(a)-(kk). Thus, the reach of the AKS is far from settled. In addition, HHS has acknowledged that the existence of its safe harbor provisions may not resolve whether a particular arrangement is permissible under the AKS. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991). Specifically, it has explained that a business arrangement that does not satisfy a safe harbor could be (1) outside the ambit of the AKS altogether, (2) a clear violation of the AKS that also fails to satisfy a safe harbor, or (3) an arrangement that "violate[s] the statute in a less serious manner" but that is also not "in compliance with a safe harbor provision," in which case "there is no way to predict the degree of risk" of prosecution. *Id.* As a result, even a well-counseled defendant who has taken every effort to comply with the AKS and all other relevant laws could still find herself accidentally in violation of the statute. The same is true for HHS's advisory opinions. A defendant could innocently rely on a published advisory opinion to conclude that her conduct is lawful, even if she is ultimately incorrect. Again, defining "willfully" to require that a defendant act knowing that her conduct is in some way unlawful avoids sweeping in such innocent conduct.[6]

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[6] We do not suggest that the defendants in this case relied on an advisory opinion or safe harbor to conclude that their conduct was lawful. Rather, our discussion of the legal landscape that has arisen from HHS's advisory opinions and safe harbors merely illustrates that understanding the reach of the AKS is a difficult endeavor. A defendant could innocently conclude in light of a safe harbor provision or advisory opinion that its conduct is lawful under the AKS and all other applicable laws. The possibility that such a defendant would draw that conclusion and turn out to be incorrect supports interpreting willfulness to require knowledge of wrongdoing.

The historical evolution of the AKS also supports that interpretation. Congress amended the AKS to add the term "knowingly and willfully" in 1980. Medicare and Medicaid Amendments of 1980, Pub L. No. 96-499, tit. IX, § 917, 94 Stat. 2599, 2625 (1980). The drafters of the amendment added the term "knowingly and willfully" out of a "concern[] that criminal penalties may be imposed under current law to an individual *whose conduct, while improper, was inadvertent*." H.R. Rep. No. 96-1167, at 59 (1980), *as reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (emphasis added).

Several years later, the Ninth Circuit held that "knowingly and willfully" required not only that a defendant act knowing that her conduct was unlawful in general, but also that she act with specific knowledge of the AKS. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995). Other circuits rejected that interpretation, concluding that "ignorance of the law is no excuse" and that "knowledge that conduct is unlawful is all that is required." *E.g.*, *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (internal quotation mark omitted), quoting *Bryan*, 524 U.S. at 196, 118 S.Ct. 1939.

In 2010, Congress resolved the conflict. It amended the statute to provide that, to violate the AKS, "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(h)). Thus, Congress rejected the Ninth Circuit's heightened standard of willfulness, but it left intact the AKS's willfulness requirement, even as other circuits interpreted that term to require a defendant to know that her conduct was in some way unlawful. *See also* 155 Cong. Rec.

S10,852, S10,853 (2009) (statement of Sen. Edward Kaufman) (explaining that "the Ninth Circuit Court of Appeals has read the term to require proof that the defendant not only intended to engage in unlawful conduct, but also knew of the particular law in question and intended to violate that particular law"). The retention of the willfulness requirement in that context suggests that Congress still intended the term to protect against criminal liability for unwitting defendants by requiring that a defendant act with knowledge that her conduct is *somehow* unlawful, even though it eschewed any requirement that a defendant know about the AKS specifically.[7]

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[7] Our determination is also consistent with the scienter requirement for health care fraud. In developing the 2010 amendment, Congress addressed the AKS and the health care fraud statute concurrently. *See* 155 Cong. Rec. at S10,853 (statement of Sen. Edward Kaufman) ("Both the anti-kickback statute and the health care fraud statute include the term 'willfully.' The heightened mental state [required by the Ninth Circuit] . . . is inappropriate for these crimes."). Thus, logically, both statutes now require that a defendant act "knowingly and willfully" to be criminally liable. *Compare* 42 U.S.C. § 1320a-7b(b)(2)(B) *with* 18 U.S.C. § 1347(a). At least one of our sister circuits has explained that a defendant acts "knowingly and willfully" under the health care fraud statute "when he acts with 'knowledge that his conduct was unlawful.'" *United States v. Clay*, 832 F.3d 1259, 1301 (11th Cir. 2016), quoting *United States v. Dominguez*, 661 F.3d 1051, 1068 (11th Cir. 2011). Similarly, in *United States v. Jafari*, 663 F. App'x 18 (2d Cir. 2016), we determined that the *mens rea* requirement of the health care fraud statute was satisfied where the government established that the defendant knew she was committing fraud. *Id.* at 20. In other words, we found that the scienter requirement was satisfied when evidence established that the defendant knew she was committing an unlawful act. The inquiry in *Jafari* stopped before determining whether the defendant knew that she was violating the health care fraud statute specifically.

Finally, a comparison between the criminal provision at issue in this case and its civil counterpart lends further support to our interpretation. The AKS is abutted by a provision that imposes civil liability against, *inter alia*, those who "knowingly" make false representations in certain health care contexts. *See*, *e.g.*, 42 U.S.C. § 1320a-7a(a)(3). The material difference between the term "knowingly" in § 1320a-7a and the phrase "knowingly and willfully" in the AKS suggests that Congress intended to require knowledge of illegality for liability under the latter. *See Bishop*, 412 U.S. at 360, 93 S.Ct. 2008; *see also Rehaif v. United States*, 588 U.S. ——, 139 S. Ct. 2191, 2205, 204 L.Ed.2d 594 (2019) (Alito, *J.*, dissenting).

Accordingly, we hold that the term "willfully" in the AKS means what it typically means in federal criminal law. To act willfully under the AKS, a defendant must act with a "bad purpose," *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. In other words, the defendant must act "with knowledge that his conduct was unlawful." *Kukushkin*, 61 F.4th at 332 (internal quotation mark omitted), quoting *Bryan*, 524 U.S. at 191-92, 118 S.Ct. 1939.

None of this is to say, however, that a defendant must know of the AKS specifically or intend to violate that statute. Such a requirement would conflict with the plain language of the 2010 amendment. A person may be criminally liable under the AKS without knowing of that statute or having a specific intent to violate it, provided that the person acts with knowledge that her conduct is, in some way, unlawful. Our interpretation of the AKS's willfulness requirement thus protects those (and only those) who innocently and inadvertently engage in prohibited conduct.

Hart asks us to adopt either of two alternative interpretations of the term willfully, but neither interpretation is satisfactory. First, seizing on the portion of our opinion in *Pfizer* explaining that a "bad purpose" means a voluntary and intentional violation of a known legal duty, *Pfizer*, 42 F.4th at 77, Hart asks us to adopt a two-factor interpretation of willfulness. He argues that the willfulness requirement may be satisfied through evidence that the defendant "(1) intentionally provid[ed] something of value in connection with a medical purchase reimbursed by the government, (2) while knowing that it is illegal to provide things of value in connection with such purchases." Appellant's Br. at 31.

We disagree. At the outset, Hart's proposal is based on a misreading of our opinion in *Pfizer*. Although that opinion explained that a "bad purpose" is "accurately understood as 'a voluntary, intentional violation of a known legal duty,'" *Pfizer*, 42 F.4th at 77, quoting *Bishop*, 412 U.S. at 360, 93 S.Ct. 2008, it also made clear that "a person can 'willfully' violate a statute as long as he knows that *his conduct* is illegal, even if he is not aware of the exact statutory provision that his conduct violates," *id.* at 77 n.8 (emphasis added). The full context of the opinion thus indicates that the relevant knowledge that a defendant must possess is knowledge that "his conduct" is illegal; according to *Pfizer*, a defendant's knowledge of his general legal obligations is not enough if he does not also know that his actions violate those obligations.

Second, Hart's two-factor definition would criminalize too much innocent conduct. Suppose that a pharmaceutical company creates a free 24/7 customer support hotline to allow providers to ask questions about the company's products. Even if the company is generally aware of the AKS's prohibition on

kickbacks, the company still could create the hotline out of a good-faith desire to help doctors treat their patients more effectively, without knowing that the hotline violated the AKS or any other law. In such circumstances, one could hardly say that the company acted with the "vicious will" that "our criminal law seeks to punish," *Ruan*, 597 U.S. at 457, 142 S.Ct. 2370 (internal quotation marks omitted), quoting *Morissette*, 342 U.S. at 251, 72 S.Ct. 240. But under Hart's proposed definition, the company could suffer criminal penalties anyway if the hotline was deemed prohibited remuneration.

Third, although Hart cites a handful of out-of-circuit opinions to support his two-factor test, those opinions do not help him. In the first, *United States v. Sosa*, 777 F.3d 1279 (11th Cir. 2015), the defendant engaged in conduct that was plainly illegal – writing checks to a "recruiter" who, in exchange, paid patients in cash to encourage them to visit a certain medical clinic for treatment. *Id.* at 1287-88, 1293-94. Indeed, the defendant in *Sosa* admitted to law enforcement that "he knew that [the recruiter] was in charge of bringing patients to the clinic," that the checks the defendant wrote the recruiter were "payment for bringing those patients to the clinic," "that the patients were being paid," and "that it was illegal to pay the patients." *Id.* at 1288. *Sosa* therefore had no occasion to consider whether a defendant whose actions are closer to the perimeter of the AKS's proscriptions must understand that his specific conduct was unlawful. Although, as Hart points out, *Sosa* stated in passing that a "defendant need not have known that a specific referral arrangement violated the law" to be liable under the AKS, that statement paraphrased another Eleventh Circuit opinion. *Id.* at 1293, citing *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013). That

opinion stated more precisely that a defendant does not need to know "that a specific 'referral arrangement violated *the Anti-Kickback statute* in order to be convicted'" because the Eleventh Circuit correctly rejected the argument that a defendant needs to be *specifically aware of the AKS* to be criminally liable. *Vernon*, 723 F.3d at 1256 (emphasis added), quoting *United States v. Starks*, 157 F.3d 833, 837 (11th Cir. 1998). Thus, the law in the Eleventh Circuit is consistent with our holding here – to act willfully, a defendant need not be aware of the AKS or have a specific intent to violate that statute, but she must act knowing that her conduct is in some way unlawful. Indeed, *Sosa* itself explained that willfulness under the AKS requires that the defendant "acted 'voluntarily and purposely, with the *specific intent to do something the law forbids*, that is with a bad purpose, *either to disobey or disregard the law*.'" *Sosa*, 777 F.3d at 1293 (emphases added), quoting *Vernon*, 723 F.3d at 1256.

Hart's other primary authorities are likewise inapplicable. As with *Sosa*, those cases all involved kickback schemes that were plainly illegal. *See United States v. Goodwin*, 974 F.3d 872, 873 (8th Cir. 2020) (defendant shared profits of medical testing company in exchange for referring patients to the company); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (defendant was aware that his teaching contract with a hospital was a sham designed to disguise kickbacks for patient referrals); *United States v. Nowlin*, 640 F. App'x 337, 340, 344 (5th Cir. 2016) (defendant received commissions from medical equipment company in exchange for referring clients to the company). And, as with *Sosa*, those cases all come from circuits that have elsewhere held or implied that willfulness under the AKS requires knowledge that the defendant's specific conduct is wrongful. *See*, *e.g.*, *Yielding*,

657 F.3d at 708; *Nagelvoort*, 856 F.3d at 1126; *Nora*, 988 F.3d at 830. Thus, we decline to adopt Hart's two-factor approach to defining willfulness.

Hart's second proposed definition derives from an outlier opinion from the Fifth Circuit, *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013). We reject that definition, too. In *St. Junius*, the court stated that to show a criminal violation of the AKS, the government "must prove that the defendant willfully committed an act that violated" that statute. *Id.* at 210. It rejected the argument that the government must prove that the defendant acted knowing that her conduct was unlawful. *Id.* at 210 n.19. In other words, the Fifth Circuit ruled that as long as a defendant intentionally performed an act, and that act in fact violated the AKS, the defendant violated the law even if she had no idea that her conduct was unlawful in any way. In so ruling, the court relied exclusively on the portion of the AKS that provides that to violate the AKS, "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]," 42 U.S.C. § 1320a-7b(b). *St. Junius*, 739 F.3d at 210 n.19.

*St. Junius*'s reasoning is unpersuasive. As we have established above, there is a distinction between knowledge of unlawfulness in general and knowledge of a particular statute. The provision of the AKS relied on by *St. Junius* addresses the latter, not the former.[8]

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[8] Hart briefly argues that the AKS is the only federal statute that prohibits offering remuneration in connection with medical purchases that are reimbursed by the federal government. So, he continues, when Congress clarified that a defendant need not have knowledge of the AKS to be criminally liable, it also removed any requirement that a defendant have *general* knowledge of illegality. That argument fails out of the gate. Contrary to Hart's suggestion, conduct underlying an AKS conviction can easily

*St. Junius*'s use of that provision to conclude that defendants need not have *any* knowledge of unlawfulness to act willfully under the AKS is therefore not well supported. Perhaps for that reason, the Fifth Circuit has failed to follow the reasoning of *St. Junius* in several subsequent published opinions. *See*, *e.g.*, *United States v. Shah*, 84 F.4th 190, 239-40 (5th Cir. 2023) ("Willfulness, under the AKS, means acting with specific intent to do something the law forbids."); *Nora*, 988 F.3d at 830 (similar); *United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (similar). We therefore decline to apply *St. Junius* here.

Accordingly, neither of Hart's proposed definitions has merit. Instead, to act "willfully" under the AKS's criminal provisions, a defendant must act knowing that his conduct is unlawful, even if he is not aware of the AKS specifically.

*B. Sufficiency of Hart's Allegations*

Having established the proper definition of willfulness, we now turn to whether Hart has alleged sufficient facts pertinent to that definition to survive a motion to dismiss. Hart points to three categories of allegations that he contends give rise to a plausible inference of willfulness as we have defined it – allegations that McKesson destroyed certain documents after receiving notice that its conduct may be unlawful, that Hart himself suggested to certain McKesson employees that McKesson's use of the Business Management Tools violated the company's compliance policies or was otherwise inappropriate, and that one

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implicate other crimes including, among others, wire fraud, health care fraud, and bribery. Thus, the statutory language providing that a defendant need not know about the AKS to act willfully does not mean that a defendant need not have any knowledge of unlawfulness.

McKesson executive sent an email to another executive that attached a document that included a reference to the Business Management Tools and stated, "You didn't get this from me . . . . ok?". We hold that none of those allegations alone or together gives rise to a plausible inference that McKesson acted willfully.[9]

First, Hart points to McKesson's alleged destruction of certain documents. Hart alleges, for example, that after the Department of Justice sent McKesson a Civil Investigative Demand seeking documents related to Hart's *qui tam* action, McKesson asked Hart to return the laptop he used when he worked there. He further alleges that, although the laptop contained "a trove of relevant documents," App'x 321, ¶ 168, McKesson scrubbed the laptop of its contents after Hart returned it. According to Hart, that allegation plausibly suggests that McKesson attempted to conceal its alleged prior misconduct, which in turn suggests that McKesson acted willfully.

Under the circumstances, we disagree. At most, the allegation suggests that at some point during

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[9] Hart spends much of this section of his brief arguing that he plausibly alleged willfulness by alleging that McKesson was aware of the AKS's prohibitions and still offered the Business Management Tools for free, even though McKesson knew that those tools were valuable. That argument fails, as it is nothing more than an attempt to resuscitate his proposed two-factor definition of willfulness, which we have already rejected. Hart also suggests that the district court erred by imposing a "heightened pleading standard," Appellant's Br. 42, by listing certain kinds of allegations that could plausibly suggest willfulness under the AKS. But by including an illustrative list of potentially relevant allegations, the district court did not hold Hart to a more stringent pleading standard. Rather, the district court considered Hart's allegations on their own terms and concluded, as we do, that they failed to create a plausible inference of willfulness under the typical federal pleading standards.

this litigation, McKesson determined that its use of the Business Management Tools may have been improper. But courts that have found concealment probative of wrongful intent have typically done so when the concealment happened *concurrently* with the violation. *See*, *e.g.*, *Vernon*, 723 F.3d at 1269 (defendant concealed kickback payments through "a sham job title" given to the kickback recipient while the payments were ongoing); *Ricard*, 922 F.3d at 648-49 (defendant concealed her monthly income while receiving unlawful kickbacks); *see also United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 752, 143 S.Ct. 1391, 216 L.Ed.2d 1 (2023) (whether, under the FCA, a defendant acted "knowingly" in submitting a false claim turns on "what the defendant thought when submitting the false claim – not what the defendant may have thought *after* submitting it"). Hart does not allege that McKesson took any efforts to conceal its alleged wrongdoing before the litigation began.[10]

Hart also alleges that McKesson removed a customer testimonial video about the Margin Analyzer from its website and claims to have lost or destroyed the video and the footage used to make that video. But there is nothing to suggest that McKesson attempted to conceal the testimonial video other than the fact that McKesson currently does not possess that video or the footage used to make it. Hart does not allege that McKesson had an obligation to preserve those materials or that McKesson would have normally

[10] We note, moreover, that Hart does not allege that it was not standard practice for McKesson to reclaim, scrub, and recycle company-owned laptops previously used by former employees. Nor does Hart suggest that laptops of his colleagues were scrubbed, even though he alleges that McKesson was engaged in a "nationwide" scheme. App'x 298, ¶ 120.

retained the materials under other circumstances. Accordingly, the document destruction allegations are insufficient.

Second, Hart relies on a handful of allegations that, while he was still employed at McKesson, he discussed his concerns about the propriety of McKesson's use of the Business Management Tools. He relies, for example, on a message that he sent to his supervisor while both of them attended a training session on McKesson's compliance policies that included a presentation on the AKS. During the session, Hart told his supervisor that he felt that McKesson's current sales practices violated the policies discussed at the session. Even interpreting that allegation in the light most favorable to Hart, it suggests only that *Hart* believed that McKesson's use of the Business Management Tools violated the AKS.[11] Hart does not allege that his supervisor agreed with him or even expressed any concern that Hart may have been right. Hart's own belief that McKesson's use of the Business Management Tools was unlawful does not help show that *McKesson* believed the same.

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[11] Even that is a generous interpretation of Hart's allegations, which are peculiarly indirect. Hart, who can presumably recall his own concerns with the Business Management Tools, does not allege outright that he told his supervisor that he thought McKesson's use of the Business Management Tools violated the law. Instead, he says that he told his supervisor that he thought McKesson's "sales practices" violated "the compliance policies that were presented in the training session." App'x 320, ¶ 164. He suggests that because McKesson's sales practices included the use of the Business Management Tools to secure purchase agreements and the training session included a presentation on the AKS, we should infer that the supervisor would have concluded that Hart meant that making the Business Management Tools available to certain Open Market Division customers was illegal. We assume for purposes of this discussion, without deciding, that such an inference in Hart's favor is reasonable.

Hart similarly alleges that he had "frequent conversations" with the creator of the Margin Analyzer, during which the two employees "discussed concerns that McKesson was inappropriately exploiting the value-added business tool . . . by giving the tool for free to open market customers." App'x 320, ¶ 166. Again, Hart does not allege that the tool's creator *shared* Hart's concerns. Even assuming that he did, however, Hart does not allege that the belief was shared by others on McKesson's sales team or that the views of the tool's creator can be imputed to McKesson as a whole.

Finally, Hart points to his allegation that one of McKesson's senior sales executives sent another McKesson executive an email that stated, "You didn't get this from me . . . ok?" and attached three documents. The attached documents total 170 pages and cover a host of topics, including valuations of over 150 services provided by McKesson.[12] The documents mention the Business Management Tools only five times, buried in discussions and analyses of numerous other topics that have nothing to do with Hart's case. To whatever extent that the email suggests that the sender acted surreptitiously in providing the documents to the recipient, there is nothing to connect

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[12] The SAC does not attach the three documents, but the district court concluded that it could consider the documents in deciding the motion to dismiss because they were incorporated by reference in the complaint and the complaint relied heavily on their terms and effect. *See Hart*, 2023 WL 2663528, at *9; *see also*, *e.g.*, *Clark v. Hanley*, 89 F.4th 78, 93 (2d Cir. 2023) (courts reviewing a motion to dismiss pursuant to Rule 12(b)(6) may review, *inter alia*, documents that are incorporated in the complaint by reference or are integral to the complaint). Hart does not argue on appeal that the district court erred in considering those documents.

that sentiment to the references to the Business Management Tools, or even to suggest that the reason for secrecy involved revelations of corporate misconduct. Thus, Hart has not plausibly alleged that the sender of the email intended to convey any information about the Business Management Tools – still less, that the email's sender or recipient believed that McKesson's use of the Business Management Tools was unlawful or that McKesson as a whole shared such a view.

The district court noted that the SAC lacked allegations similar to those that other courts have found support an inference of willfulness. For example, Hart did not allege that McKesson took steps to conceal its behavior, had notice that its sales practices might be unlawful, stopped offering the Business Management Tools for no charge out of a concern that doing so might be unlawful, or believed that the Business Management Tools were shams. Although no such allegations are necessary to plead willfulness, Hart's inability to raise any similar allegations underscores that it is implausible to infer that McKesson believed that offering the Business Management Tools was unlawful.

Accordingly, none of Hart's allegations, alone or in combination with each other, plausibly suggests that when McKesson offered its Business Management Tools to encourage customers to commit to purchasing from McKesson, it believed that its conduct was unlawful under the AKS or any other law. As a result, the district court did not err in dismissing Hart's federal FCA claim for failure to state a claim.[13]

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[13] Hart's federal FCA claim is based solely on McKesson's alleged violation of the federal AKS; he does not argue that he has a claim under the federal FCA that is premised on a violation of one or more state anti-kickback laws. Instead, the only state-

### III. The State-Law Claims

Finally, we turn to Hart's remaining claims under the laws of 27 states and the District of Columbia (the "State-Law Claims").[14] The district court dismissed those claims on the ground that Hart brought his claims under the state FCA analogues only "by way of a violation of the *federal AKS*." *Hart*, 2023 WL 2663528, at *8 (emphasis in original). That conclusion was erroneous.

To be sure, the focus of the SAC is Hart's contention that McKesson's conduct violated the federal AKS. But he alleges that "[t]he States also have enacted statutes prohibiting kickbacks in connection with State Medicaid services," App'x 265, ¶ 37, and that "McKesson's conduct violates the federal AKS *and similar State laws*," *id.* at 270, ¶ 53 (emphasis added). Indeed, Hart even listed the various state anti-kickback statutes that he contends McKesson violated.[15]

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law theories that he has articulated arise under various state false claims acts. Accordingly, to the extent that a *federal* FCA claim could exist based on a violation of a *state* anti-kickback statute, Hart has abandoned such a claim.

[14] McKesson contends that we should not address Hart's argument that the State-Law Claims survived the motion to dismiss because he forfeited that argument by not raising it below. But McKesson's memorandum supporting its motion to dismiss below discussed only the federal AKS. Thus, in his responsive memorandum, Hart addressed McKesson's arguments about the federal claim, while also pointing out that McKesson "ha[d] not moved to dismiss any of [his] state law claims." App'x 876. McKesson contends that Hart's response on the State-Law Claims is too cursory to preserve his argument that those claims should survive. But we conclude that Hart's failure to develop an opposition to an argument that *McKesson* did not make does not amount to a forfeiture by Hart.

[15] In general, the "[f]ederal pleading rules . . . do not countenance dismissal of a complaint for imperfect statement of the

Thus, the district court erred in dismissing Hart's State-Law Claims on the basis that they were premised solely on violations of the federal AKS.

Importantly, Hart argues that many of the state anti-kickback laws have no scienter requirement or a lesser requirement than willfulness. Thus, even though his complaint is insufficient to state a federal FCA claim based on the federal AKS, it may be sufficient to state a state-law claim under one or more of the state anti-kickback laws cited in his complaint.[16] Accordingly, we vacate the district court's dismissal of the State-Law Claims and remand the case for further proceedings.[17]

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legal theory supporting the claim asserted." *Johnson v. City of Shelby*, 574 U.S. 10, 11, 135 S.Ct. 346, 190 L.Ed.2d 309 (2014). McKesson argues, however, that Hart's state *qui tam* claims are subject to Rule 9(b), Fed. R. Civ. P., and therefore he must plead with particularity "the circumstances constituting fraud." According to McKesson, that requires specifying what law McKesson allegedly violated and how it violated that law. Hart argues that the rule that McKesson argues for applies only in cases implicating the Private Securities Litigation Reform Act. We need not resolve the dispute, however, because even assuming that McKesson is correct, Hart's allegations are adequate. Hart expressly listed the state laws that he contends McKesson violated and explained at length how McKesson allegedly violated those laws – by using the Business Management Tools to induce customers to make purchase commitments with McKesson.

[16] McKesson briefly argues that Hart fails to state a claim under two of the state anti-kickback statutes cited in the SAC. We decline to address that argument, as McKesson did not move to dismiss Hart's claims on that basis below, nor was it the reason for the district court's decision. We thus express no opinion on whether Hart's SAC adequately alleges a claim under any of the relevant FCA or AKS analogues.

[17] We in no way intimate that the district court should retain jurisdiction over the State-Law Claims; that matter is left to the

## CONCLUSION

For the reasons stated above, we hold that to act willfully under the AKS, a defendant must act knowing that its conduct is unlawful under either the AKS or other law. Because Hart's allegations do not plausibly suggest that McKesson acted with such knowledge of illegality, his federal FCA claim based on the federal AKS must be dismissed. But since he also brought state-law claims under other false claims and anti-kickback statutes that may not have the same *mens rea* requirements, the district court should not have dismissed those claims on the ground that they were premised only on the federal AKS. Accordingly, we AFFIRM the district court's dismissal of Hart's federal FCA claim, VACATE the dismissal of the State-Law Claims, and REMAND for further proceedings consistent with this opinion.

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district court's sound discretion. The point is merely that the dismissal of the state FCA claims *on the merits*, based on an incorrect understanding of the nature of those claims, was error.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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No. 15-CV-0903 (RA)

UNITED STATES of America, et al.,
EX REL. Adam HART,
Plaintiff,

v.

MCKESSON CORPORATION, et al.,
Defendants.

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[Filed March 28, 2023]

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OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

Plaintiff-Relator Adam Hart brought this *qui tam* action against McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (collectively "McKesson") on behalf of the United States of America and twenty-eight states. In the main, Hart alleges that McKesson offered "something of value" to oncology practices that joined programs requiring them to purchase a substantial proportion of their drugs from McKesson —namely, two business-management tools, the Margin Analyzer and the Regimen Profiler, which allowed the practices to increase their profit margins for prescribed medications—and that doing so violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq*. ("AKS"). Claims for reimbursement

submitted by these practices, Hart asserts, were tainted by the kickback scheme and thus in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), and its state analogues.

The Court previously dismissed the First Amended Complaint filed in this action, finding that, although Hart had plausibly alleged that the business-management tools at issue constituted remuneration under the AKS, he failed to plausibly allege that McKesson acted with the requisite scienter and failed to plead the fraudulent scheme with particularity as required by Federal Rule of Civil Procedure 9(b). *See United States ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575 (S.D.N.Y. 2022) (the "Prior Opinion"). The Court granted leave to amend, and Hart has since filed a Second Amended Complaint (the "Complaint"), adding new allegations which, he claims, plausibly allege that McKesson had knowledge of the unlawfulness of the scheme. McKesson has again moved to dismiss. For the reasons that follow, the motion is granted, albeit again without prejudice.[1]

## BACKGROUND

The facts giving rise to this action, most of which were also detailed in the Court's Prior Opinion, are by now familiar to counsel and the parties. New allegations, as relevant here, are described in Section VI, *see infra* [App. 42a-43a]. All facts are taken from the Complaint and are assumed to be true for purposes of

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[1] As described *infra* [App. 47a-48a, 61a-62a], the Court concludes that amendment to salvage the claims brought under the False Claims Act analogues of the twenty-eight states and the District of Columbia would not necessarily be futile. Accordingly, it determines that dismissal without prejudice is once again warranted, although skeptical that federal jurisdiction would be proper with further amendment to exclusively bring those state law claims. *See* 28 U.S.C. § 1367(c)(3).

the present motion. *See Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).

**I. The Parties**

McKesson Corporation is a Delaware corporation headquartered in Irving, Texas. Compl. ¶¶ 16, 17. McKesson sells pharmaceuticals, medical supplies, and related services to health care providers. *Id.* ¶¶ 2, 42. McKesson Corporation is the parent company of the other McKesson Defendants, "which are all wholly-owned direct or indirect subsidiaries of McKesson Corporation." *Id.* ¶ 16. McKesson Specialty Distribution LLC is a Delaware limited liability company and a wholly owned subsidiary of McKesson Corporation. *Id.* ¶ 17. McKesson Specialty Care Distribution Corporation is a Delaware corporation and also a wholly owned subsidiary of McKesson Corporation. *Id.*[2] Hart alleges, upon information and belief, that during the relevant time period, McKesson Specialty Health ("MSH") was a business unit of McKesson Corporation, McKesson Specialty Care Distribution Corporation, and McKesson Specialty Distribution LLC. *Id.* Through MSH, McKesson operated as a wholesale distributor, buying specialty drugs and reselling them to customers across the country. *Id.* ¶¶ 2, 17-18, 42.

Plaintiff-Relator Hart was employed by McKesson from August 2011 until September 2014 as a Business Development Executive ("BDE") in its Specialty Health business unit. *Id.* ¶ 15. His responsibilities included generating new business opportunities among community-based oncology practices in the southeastern United States. *Id.* Once a customer was recruited, Hart would provide services for the first year, after

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[2] In or around May 2013, McKesson Specialty Care Distribution JV LLC merged with McKesson Specialty Care Distribution Corporation, which became the surviving company. Compl. ¶ 17.

which a "McKesson Account Executive" was assigned. *Id.* The McKesson Account Executive was responsible for maintaining and increasing sales, but Hart remained in touch with practices through "sales meetings, sales calls, requests for assistance from other personnel, and communications with coworkers." *Id.*

## II. McKesson's Oncology Business

As relevant here, MSH provided "specialty pharmaceuticals and services to community oncology practices." *Id.* ¶ 49.[3] The specialty drugs used in cancer treatment are complex to manufacture, require special handling, and, as a result, are more expensive than other drugs. *Id.* ¶ 41. Some oncology practices obtain the drugs from a specialty pharmacy, which then bills patients' insurers. *Id.* ¶ 43. Others opt to purchase drugs from wholesalers like McKesson, provide those drugs to their patients, and then bill the patients' insurers themselves. *Id.*

In 2014, the oncology business was MSH's largest line of business by revenue, generating $7 billion of MSH's $9 billion in annual revenue. *Id.* ¶ 49. There were two divisions of the oncology business, and Hart worked in the "open market" division, which operated as a traditional drug wholesaler and distributor. *Id.* ¶¶ 49-50. The allegations in the complaint are limited to the practices of the open market division. *Id.* ¶¶ 50-51.

## III. The Business-Management Tools

Hart's claims are based on McKesson's usage of two business-management tools—the Margin Analyzer and the Regimen Profiler—which were offered almost exclusively to practices that committed to purchasing

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[3] Community oncology practices provide oncology care in an "office setting," as opposed to providers who operate in a hospital setting. Compl. ¶ 43.

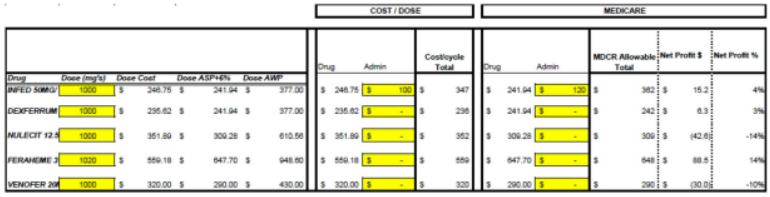
a significant portion of their drugs from McKesson. *Id.* ¶ 75.

**A. The Margin Analyzer**

Beginning in approximately 2011, McKesson offered its customers "complimentary access" to the Margin Analyzer. *Id.* ¶ 54. With the benefit of further amendment, the Complaint now specifies a "non-exhaustive" list of 113 practices from locations throughout the country which were provided the Margin Analyzer free of charge. *Id.* ¶ 55. Among other things, the tool allowed oncology practices like these to compare the reimbursement rates of interchangeable drugs. *Id.* ¶¶ 58-59. McKesson had identified "therapeutically interchangeable" choices for ten categories of drugs commonly used by oncology practices. *Id.* ¶ 64. For any given category, the Margin Analyzer relied on pricing and reimbursement data to determine which of the similar drugs would yield the highest profit for the practice. *Id.* ¶¶ 65, 67. McKesson employees input reimbursement data from Medicare and private insurers, allowing the tool to analyze the profitability of different drugs based on a patient's insurer. *Id.* ¶¶ 61-63, 65-67.

By way of illustration, the Complaint includes the following illustration of the tool's utility. The Margin Analyzer listed five "therapeutically interchangeable" options for parenteral irons. *Id.* ¶ 86. In Q1 2012, McKesson's data showed that, for Medicare-insured patients, the difference between acquisition cost and reimbursement price was significantly greater for one brand of parenteral irons, Feraheme, than other brands. *Id.* ¶¶ 86-87. For Summit Cancer Care in Savannah, Georgia, specifically, a switch from prescribing only Infed parenteral irons (margin of $15.19 per dose), to a mix of 80% Feraheme (margin of $88.52

per dose) and 20% Infed would increase annualized net profits by $10,560. *Id.* The Margin Analyzer excerpt below shows the type of data comparisons available to McKesson representatives and the practices with whom they shared them:



| | | | | | COST / DOSE | | | MEDICARE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Drug | Dose (mg's) | Dose Cost | Dose ASP+6% | Dose AWP | Drug | Admin | Cost/cycle Total | Drug | Admin | MDCR Allowable Total | Net Profit $ | Net Profit % |
| INFED 50MG/ | 1000 | $ 246.75 | $ 241.94 | $ 377.00 | $ 246.75 | $ 100 | $ 347 | $ 241.94 | $ 120 | $ 362 | $ 15.2 | 4% |
| DEXFERRUM | 1000 | $ 235.62 | $ 241.94 | $ 377.00 | $ 235.62 | $ - | $ 236 | $ 241.94 | $ - | $ 242 | $ 6.3 | 3% |
| NULECIT 12.5 | 1000 | $ 351.89 | $ 309.28 | $ 610.56 | $ 351.89 | $ - | $ 352 | $ 309.28 | $ - | $ 309 | $ (42.6) | -14% |
| FERAHEME 3 | 1020 | $ 559.18 | $ 647.70 | $ 948.60 | $ 559.18 | $ - | $ 559 | $ 647.70 | $ - | $ 648 | $ 88.5 | 14% |
| VENOFER 20 | 1000 | $ 320.00 | $ 290.00 | $ 490.00 | $ 320.00 | $ - | $ 320 | $ 290.00 | $ - | $ 290 | $ (30.0) | -10% |

Compl., Ex. 4 at 7 (Q2 2012 SCC Margin Analyzer).

The Margin Analyzer was used not only to compare the cost and profit margin on a per drug, per insurer basis, but also to give forward-looking recommendations based on that data. BDEs or Account Executives were thus able to forecast various scenarios by inputting different drug mixes or potential payors, and then used those findings to aid the practices in choosing a drug distribution that was most profitable for the practice. *See* Compl. ¶¶ 82-87. Because the Margin Analyzer allowed practices to instantly compare the profit margin of one drug versus others in the same category, a BDE or Account Executive could identify areas with large profit opportunities. *See id.* McKesson personnel met with their customers at "Quarterly Business Reviews" to review the Margin Analyzer and to provide "a detailed analysis of the practice's finances and business operation." *Id.* ¶ 71.

In order to generate these results, the Margin Analyzer required data, including: the fee schedules published quarterly by the Centers for Medicare and Medicaid Services ("CMS"); the customer's quarterly purchase records; the prices at which McKesson sold its drugs; and the fee schedules of relevant private

insurers. *Id.* ¶¶ 60-62. McKesson employees would gather and input this data into spreadsheets for each practice, and update them on a quarterly basis as the data changed. *Id.*

Because different insurers reimbursed different drugs at different rates, a drug most profitable for a Medicare patient may not be as profitable for a patient with a given private insurer. The Margin Analyzer not only accounted for the different reimbursement amounts offered by different insurers, but synthesized the data into a "cheat sheet" page that recommended the most profitable drug in each category by payor. *See id.* ¶¶ 90-91; *id.*, Ex. 3, Q4 2012 SCC Margin Analyzer. The "cheat sheet" generated for the Summit Cancer Care in Q4 of 2012, for example, recommended one of three different antiemetic drugs, *see* Compl. at ¶ 91, depending on whether the patient was covered by BlueCross BlueShield, Cigna, or Medicare, as seen below:


*Id.*, Ex. 3 at 3 (Q4 2012 SCC Margin Analyzer). As with all of the data in the Margin Analyzer, McKesson would update these sheets every quarter as reimbursement rates changed. Compl. ¶¶ 93-94. The most cost-effective drugs were subject to change each quarter. *Compare id.*, Ex. 3, Q4 2012 SCC Margin Analyzer, *with id.*, Ex. 5, Q1 2013 SCC Margin Analyzer.

McKesson used the Margin Analyzer in three contexts: to acquire new customers and/or retain existing customers, *id.* ¶ 70; to provide consultation

and financial advice to existing customers at in-person "Quarterly Business Reviews," *id.* ¶ 71; and to encourage the purchase of new drugs (or drugs with new pricing), *id.* ¶ 72.

**B. The Regimen Profiler**

The Regimen Profiler worked in much the same way as the Margin Analyzer, but rather than calculate the margins for an individual drug, it calculated costs for the whole treatment regimen. *Id.* ¶¶ 6, 106. Oncology practices typically incur significant non-drug related costs in the administration of cancer therapy, including the cost of preparing or administering the treatments, such that the price of the drug itself is only one component of the overall cost. *Id.* ¶¶ 107, 109. The Regimen Profiler filled this gap—calculating profit margins for the course of treatment, including non-drug costs. *Id.* Insurers reimbursed these non-drug costs as well, and so the Regimen Profiler, like the Margin Analyzer, calculated the profitability of each treatment regimen on a provider-by-provider basis. *Id.* ¶ 109. The tool was designed to be used in conjunction with the Margin Analyzer to understand a practice's overall profitability and/or potential profitability. *See id.*, Ex. 1 (Margin Analyzer Sales Sheet). McKesson employed the Regimen Profiler in the same manner as the Margin Analyzer—to pitch new customers and retain existing ones. Compl. ¶ 112. Moreover, as with the Margin Analyzer, McKesson made an "explicit contractual promise" only to commitment program customers to provide the Regimen Profiler free of charge. *Id.*

**C. McKesson's Offer of the Business Management Tools to Commitment Program Customers**

Hart alleges that these tools were provided, for free, on a quarterly basis, to a number of oncology practices

throughout the country. They were not, however, distributed to all of McKesson's customers. Instead, the Margin Analyzer and Regimen Profiler were offered, "with few (or no) exceptions . . . *only* to physician practices that contracted to join the Onmark Select, Prime, or MVP programs." *Id.* ¶ 75 (emphasis in original). The Onmark Select, Prime Membership, and McKesson Value Program ("MVP") (collectively the "commitment programs"), required practices to purchase a certain volume of their drugs from McKesson. *Id.* ¶ 74. The Onmark Select program required use of McKesson as the "primary wholesale supplier" for branded and generic drugs, while the Prime and MVP programs required a commitment to purchase approximately 90% to 95% of the practice's branded and generic drugs from McKesson. *Id.*

If they did not join one of the commitment programs, oncology practices were still able to purchase drugs from McKesson. But MSH did not allow non-commitment program customers to access the business-management tools. *Id.* ¶¶ 76, 112. One practice, for instance—Hematology Oncology of the Treasure Coast—sought to end its purchase commitment with McKesson, and was explicitly told that, if it did so, it would lose access to the Margin Analyzer. *Id.* ¶ 76.

Although his First Amended Complaint named twelve practices that were allegedly offered these tools for free and signed commitment programs with McKesson, Hart's Second Amended Complaint now alleges a far larger number of practices which fit into this category—including such diverse practices as Commonwealth Hematology Oncology in Quincy, Massachusetts; Rocky Mounty Oncology Center PLLC in Casper, Wyoming; Katmai Oncology Group in Anchorage, Alaska; and Oncare Hawaii, Inc. in

Honolulu, Hawaii. *Id.* ¶ 55. In all, Hart's Complaint now lists 113 practices from across some thirty states and the District of Columbia, *see id.*, which were allegedly "offered the Margin Analyzer and/or the Regimen Profiler for free as an inducement to make a purchase commitment from McKesson." *Id.* ¶ 79. The Complaint further claims that

> During the sales pitch to practices like those identified in Paragraph 55, McKesson would populate the Margin Analyzer with the practices' specific drug utilization information to demonstrate the utility of the Margin Analyzer. The physician practices then signed purchase commitments with McKesson and informed McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their decision to commit to buying specialty drugs from McKesson.

*Id.* ¶ 80. Hart further alleges that, in addition to the practices named in the Complaint, this conduct occurred nationwide. *Id.* ¶ 134.

Hart's complaint also contains allegations that suggest McKesson knew that the Margin Analyzer and Regimen Profiler were valued by its customers. Sales training materials attached to the complaint emphasized the importance of the Margin Analyzer to retaining customers. And McKesson purportedly believed that the tools were important to both enhancing its profitability and creating "stickiness" among its customers. *Id.* ¶ 78; *id.* Ex. 9 at 8-9 (2014 South Region Meeting Presentation) (describing the importance of "creat[ing] stickiness" through "value-added services"). Hart also references internal communications in which McKesson concluded at least some customers stayed with McKesson, over lower cost providers, in order to retain access to the Margin Analyzer. *Id.* ¶ 70

("McKesson acknowledged in internal communications that it has practice group customers who refuse to leave MSH for lower cost providers of specialty drugs because those practices would lose access to the Margin Analyzer in the event they did so."). The company even allegedly prepared a "customer testimonial video" dedicated to the business-management tools, touting their potential value to community oncology practices. *Id.* ¶ 130.

McKesson's view that the tools were important to customer acquisition and retention was purportedly further emphasized at its in-person sales conferences. At those events, executives from McKesson made clear that the Margin Analyzer and Regimen Profiler should be at the center of sales pitches to new customers. *Id.* ¶¶ 76, 123-26, 146. Indeed, according to Hart, the Margin Analyzer and Regimen Profiler were "so central to McKesson's business that McKesson fired one BDE because he was not sufficiently emphasizing the Margin Analyzer and the Regimen Profiler in his sales pitches." *Id.* ¶ 125.

## IV. The Anti-Kickback Statute and False Claims Act

The AKS and FCA work in conjunction to create a private right of action for violation of the federal criminal anti-kickback statute. The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; 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)-(B). Claims are defined as "any request or demand for money from an officer, agent, employee, or contractor of the United States." 31 U.S.C. § 3729(b)(2)(A).

The AKS prohibits any individual or entity from "knowingly and willfully offer[ing] or pay[ing] any

remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or arrange for 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." 42 U.S.C. § 1320a-7b(b)(2)(B). Claims resulting from an AKS violation constitute "a false or fraudulent claim" for the purposes of the FCA. 42 U.S.C. § 1320a-7b(g); *see also United States v. Novartis Pharms. Corp.*, 2020 WL 1436706, at *1 (S.D.N.Y. Mar. 24, 2020).

**V. Procedural History**

Plaintiff filed his initial complaint on February 6, 2015. Because the action was brought under the False Claims Act, the complaint was placed under seal to afford the government an opportunity to intervene. *See* 31 U.S.C. § 3730(b)(2). The government ultimately declined to intervene, and the complaint was unsealed as of May 29, 2020. Plaintiff then filed the First Amended Complaint, which stated claims against McKesson under the FCA, as well as under the False Claims Act analogues of twenty-eight states and the District of Columbia, based on the same alleged conduct.

On May 5, 2022, the Court granted McKesson's motion to dismiss the First Amended Complaint, finding that although the First Amended Complaint plausibly alleged that the Margin Analyzer and Regimen Profiler constituted "remuneration" under the AKS, and that they "have substantial value apart from the products offered by McKesson," Prior Opinion, 602 F. Supp. 3d at 586-87, Hart had not adequately pleaded McKesson acted with the scienter required under the AKS, *id.* at 592. *See also id.* at 594 (noting that the AKS requires allegations which "give

rise to a plausible inference that McKesson knew its conduct was unlawful"). The Court reserved judgment on whether Hart had pleaded a nationwide scheme. *See id.* at 598.

Hart was granted leave to amend to correct the pleading issues identified in the Court's dismissal order. *See id.* at 598-99. He filed a Second Amended Complaint on June 7, 2022, *see* Dkt. 159, and McKesson once again moved to dismiss. The Court heard oral argument on the motion on March 15, 2023.

## VI. The Second Amended Complaint's New Allegations of Scienter

Following the Court's prior dismissal—in addition to naming additional practices which were given the Margin Analyzer and Regimen Profiler free of charge, and further allegations regarding McKesson employees' general awareness of the AKS—Hart added two new sections to the Complaint. The first, entitled "Additional Allegations of Scienter," includes allegations about previously undescribed conversations between Hart and other McKesson employees about the possibility that the company's provision of the tools may violate the AKS. Compl. ¶¶ 163-66. In key part, this section alleges that an Ernst & Young analysis valuing the Margin Analyzer and Regimen Profiler at $125,000 and $25,000 per year, respectively, was sent to several McKesson executives. *Id.* ¶ 160. According to Hart, McKesson's Senior Vice President of Open Market Sales then emailed a presentation containing those valuations to the Vice President of Payer and Revenue Cycle Services, with a note in the body of the email stating: "You didn't get this from me . . . ok?" *Id.* (ellipses in original). The section further alleges that, while at a live web-based training on the AKS, Hart sent an instant message to his supervisor

"stating that McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session," and that his concerns were "dismissed." *Id.* ¶ 164. Finally, the section alleges that Hart had "frequent conversations" with the creator of the Margin Analyzer while the two were traveling for sales pitches, and that they discussed concerns that McKesson was "inappropriately exploiting the value-added business tool." *Id.* ¶ 166.

The second additional section, "McKesson Has Destroyed Documents Evidencing Its Conduct," boldly alleges that McKesson purposefully destroyed evidence relevant to the present action. *Id.* § VII(G). It asserts that "McKesson has shown knowledge of guilt" by "taking steps to conceal evidence of its prior activity." *Id.* ¶ 167. "For example, although [McKesson] previously touted the Margin Analyzer on its website, including through a customer testimonial video," the Complaint alleges, it "has since taken down the video and claimed to have lost or destroyed [it]." *Id.* So too, the section details the "destr[uction] [of] critical documents relating to the allegations in this case, even after it had a duty to preserve such documents." *Id.* ¶ 168.

**LEGAL STANDARD**

When considering a motion to dismiss under 12(b)(6), a court must "accept all allegations in the complaint as true and draw all inferences in the nonmoving party's favor." *LaFaro v. New York Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009) (cleaned up). The complaint must "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face,'" *Ashcroft v. Iqbal*, 556 U.S. 662,

678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)), and must be dismissed if it fails to state a claim upon which relief can be granted, *see* Fed R. Civ. P. 12(b)(6). A complaint that offers only "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action, will not do.'" *Id.* (quoting *Twombly*, 550 U.S. at 555). Nor will a complaint suffice if it contains only "'naked assertion[s]' devoid of further 'factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Because FCA claims "fall within the express scope of Rule 9(b)," *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam), a relator must "state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b). While the circumstances of the fraud must be pled with particularity, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" under Rule 9(b). Fed. R. Civ. P. 9(b). Where an FCA claim is predicated on a violation of the AKS, both the FCA and AKS violations must be pled in compliance with Rule 9(b). *United States v. Novartis Pharms. Corp.*, 2020 WL 1436706, at *3 (S.D.N.Y. Mar. 24, 2020) (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617-18 (2d Cir. 2016) and *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513-14 (S.D.N.Y. 2014)). Claims under the FCA state analogues must also satisfy Rule 9(b). *Novartis*, 2020 WL 1436706, at *3 (citing *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) ("*Arnstein*")). To satisfy Rule 9(b)'s heightened pleading requirement, a complaint must "adduce specific facts supporting a strong inference of fraud." *United States ex rel. Chorches for Bakr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 82 (2d Cir. 2017).

## DISCUSSION

In its motion to dismiss, McKesson contends that the Second Amended Complaint remains unable to state a claim as a matter of law, as it still: (1) fails to plausibly allege that Defendants acted with the required scienter under the AKS; and (2) fails to plead the fraudulent scheme with particularity. For the reasons that follow, the Court finds that, even with the benefit of specific instruction on the failings of the First Amended Complaint in the Court's Prior Opinion, a year of discovery, and another chance to amend his pleadings, Hart has failed to include sufficient factual allegations to support a plausible interference that McKesson acted with knowledge that its conduct was unlawful, as required under the federal AKS.[4] The Court therefore grants McKesson's motion, and dismisses the Second Amended Complaint.

### I. Hart Fails to Plausibly Allege that McKesson Acted with the Requisite Scienter

The AKS prohibits a person from "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Hart is not only required to plead that McKesson offered these tools to its customers, but that it did so with a culpable—*i.e.*, "knowing[] and willful[]," *id.*—mental state.

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[4] Because the Court finds that the requisite scienter was not alleged to state a claim under the AKS, it need not consider McKesson's arguments in the alternative that Hart has failed to plead the alleged fraud with sufficient specificity under Federal Rule of Civil Procedure 9(b).

**A. The Scienter Requirement of the AKS**

Where an FCA claim is based on a violation of the AKS, the AKS scienter requirement must also be satisfied. As this Court previously held, "to satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful." Prior Opinion, 602 F. Supp. 3d at 595; *see also id.* at 593-94 (collecting cases and considering the legislative history). In the time since that opinion, the Second Circuit has confirmed this reading of the AKS. *See Pfizer, Inc. v. United States Dept. of Health and Human Servs.*, 42 F.4th 67, 77 (2d Cir. 2022). In *Pfizer*, the Circuit explained that, while a plaintiff need not establish a defendant acted with a "bad purpose" or "corrupt intent" to state a claim under the AKS, the statute's use of "willful" means that it requires "a voluntary, intentional violation of a known legal duty"—for the defendant to "know[] that [its] conduct is illegal." *Id.* (quoting *United States v. Bishop*, 412 U.S. 346, 360 (1973)); *see also id.* (observing that "Congress added the willfulness element to the AKS to avoid punishing 'an individual whose conduct, while improper, was inadvertent'") (quoting H.R. Rep. 96-1167, at 59 (1980)). Put differently, because the "AKS does not apply to those who are unaware that [(conduct constituting kickbacks)] [is] prohibited by law and accidentally violate the statute," the statute requires proof of an "intentional violation of a known legal duty." *Id.*

Perhaps in light of the Circuit's statutory interpretation in *Pfizer*, Hart has declined to once again press his challenge as to the required mental state under the AKS, and now acknowledges that his Complaint must plausibly allege that McKesson acted with knowledge that its conduct was illegal. Opp. at 5. Nevertheless, Hart continues to argue that such

knowledge can be shown via a two-step set of allegations. Specifically, he asserts that, where pleadings allege that a defendant "(1) knows that the AKS prohibits the provision of anything of value as an inducement, yet (2) engages in intentional conduct to provide things of value as inducements anyway," such allegations state a claim under the AKS. Opp. at 5.

Such a two-step approach, however, was specifically rejected by this Court before. *See* Prior Opinion, 602 F. Supp. 3d at 595-96 (observing that "awareness of the requirements of the AKS and the general unlawfulness of inducements" coupled with "facts to support the conclusion that the tools may constitute 'remuneration'" were not enough to "support a finding that McKesson knew this particular course of conduct was unlawful"). The same argument from Hart now merits the same conclusion. Hart's Complaint must contain factual allegations from which the Court can plausibly infer that McKesson acted with the knowledge that its conduct—offering the Margin Analyzer and Regimen Profiler free of charge to oncology practices that contracted to join the programs requiring them to purchase a certain volume of McKesson drugs—was unlawful. *See United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *13-*14 (N.D. Ill. Sept. 30, 2019) ("*Suarez I*"); *see also United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568, at *4-5 (E.D. Pa. June 19, 2017).

Hart's argument in the alternative that the Complaint's state law claims should survive, even failing plausible allegations of scienter under the federal AKS, also fails. To be sure, Hart does bring claims under the False Claims Act analogues of twenty-eight states and the District of Columbia. *See* Compl. ¶ 13 (citing each of the state FCAs, such as the California

False Claims Act, Cal. Gov't Code § 12650 *et seq.*). And, as Hart argues, some of those state law regimes have anti-kickback statutes of their own which do not incorporate a "willfulness" scienter requirement as does the federal AKS. *See* Opp. at 4 n.1 (citing Tex. Hum. Res. Code §§ 36.0011(a), 36.002(12)). But Hart's complaint here does not allege a violation of the states' FCA analogues by way of kickbacks under each of those state law regimes. Rather, it alleges that "Defendants' actions . . . also violate the laws of the States, each of which has enacted a false claims act analogous to the federal FCA, each of which requires compliance *with* ***the AKS*** as a condition of payment of Medicaid reimbursement. . . ." Compl. ¶ 13 (emphasis added). Put differently: his Complaint brings claims under both the federal FCA and the states' FCAs by way of a violation of the *federal AKS*.

Accordingly, as in its Prior Opinion, the Court treats the state law claims together with the federal claims, as each here ultimately require—but are missing—plausible allegations of the requisite scienter under the federal AKS.

**B. Hart's Amended Allegations of Scienter**

Hart's Complaint now includes allegations of conversations he shared with other McKesson employees about the purportedly "inappropriate" nature of the company's use of the business tools in sales, allegations related to an email containing valuations of the tools shared by a company executive, and additional allegations regarding McKesson's general trainings on the AKS. For the reasons that follow, none of these allegations suffice to plausibly allege that McKesson acted with knowledge that providing the Margin Analyzer and Regimen Profiler free of charge to certain oncology practices was unlawful.

First, Hart now claims that he sent an instant message to his direct supervisor, Bennett Holtzman, during a live web-training presentation on McKesson's compliance policies that they were both attending. Hart alleges that the message stated:

> that McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session. Holtzman dismissed [Hart's] concerns and responded by instructing [him] to continue his sales work and not to worry about the compliance policies that prohibited the sales practices that [Hart] . . . had been instructed by McKesson executives to use.

Compl. ¶ 164. This message and response, however, falls short of alleging that McKesson knew that its conduct was unlawful. As the court in *United States ex rel. Fitzer v. Allergan, Inc.* ("*Fitzer I*"), held, "the fact that Relator told Allergan that *he* believed the physician locator violated the AKS . . . [does not] indicate[] that *Allergan* was acting with malintent." 2021 WL 4133713, at *7 (D. Md. Sept. 10, 2021) (emphasis added); *see also United States ex rel. Fitzer v. Allergan, Inc.*, 2021 WL 5840874, at *4 (D. Md. Dec. 9, 2021) ("*Fitzer II*") (noting the allegation "that Relator told Allergan it was violating the AKS provides no facts that relate to Allergan's state of mind"). If anything, the allegations here are even weaker than those at issue in *Fitzer I*. There, the relator specifically indicated that the conduct at issue, Allergan's provision of a "physical locator," violated the AKS. Here, by comparison, the Complaint only goes so far as alleging that Hart indicated that McKesson's general "sales practices" (which, through artful pleading, he alleges

"included using the Margin Analyzer and Regimen Profiler") violated the company's compliance policies. Compl. ¶ 164.

Hart's attempt, moreover, to liken his allegations of these instant messages to the later-filed amended complaint in *Fitzer II*, which ultimately survived a motion to dismiss, is unavailing. The *Fitzer II* court specifically noted that it was the third amended complaint's allegation that the vice president of sales "debate[d]" the legality of the scheme, and said that he would raise it with the CEO, which finally sufficed to allege the requisite scienter. *Fitzer II*, 2021 WL 5840874, at *3-4. At most, Hart here alleges that he raised generalized compliance concerns to his immediate sales supervisor via instant messenger during a training. That conversation is unlike the final iteration of the pleadings in *Fitzer II*, wherein unlawful conduct was raised to the highest levels of the defendant company, and those complaints were considered and nevertheless disregarded. *See* 2021 WL 5840874, at *4. Instead, just like the dismissed second amended complaint in *Fitzer I*, *see* 2021 WL 4133713, at *7, a general statement made to a regional manager that "current sales practices" violated "compliance policies," Compl. ¶ 164, will not do to allege that McKesson was knowingly violating the law.

Similarly, Hart's allegations of newly recalled conversations with fellow McKesson sales employees about how the use of the Margin Analyzer and Regimen Profiler was "unethical" and "wrongful," *id.* ¶¶ 165-66, are insufficient to plausibly allege that the company had the requisite scienter. Specifically, Hart asserts that he shared his concerns about the tools given that they purportedly encouraged customers to

purchase "the highest margin drugs," therefore leading to higher costs for patients and payors. *Id.*[5] He also describes a conversation he shared with another employee about how it was "inappropriate" for McKesson to provide the Margin Analyzer to Open Market customers because it had been "created originally" for customers of U.S. Oncology ("USON"). *Id.* ¶ 166. As in *Fitzer I*, allegations about things that *Hart* said to other sales employees within the company, without more, does not establish what *McKesson* believed about offering the business tools to oncology practices. *See Fitzer I,* 2021 WL 4133713, at *7. But even if the Court were to credit Hart's allegations as somehow speaking to the company's knowledge, beliefs about the "inappropriate" or "unethical" nature of providing the business tools is, without more, insufficient to adequately plead purported knowledge of *unlawfulness*—let alone an "intentional violation of a known legal duty," *Pfizer*, 42 F.4th at 77.

Second, Hart attempts to allege McKesson knew of the illegality of providing the Margin Analyzer and Regimen Profiler based on an email from Kirk Kaminsky, then the Senior Vice President of Open Market Sales, forwarding certain USON documents to Dianna Verrilli, Senior Vice President of Payer Solutions, with a cover message reading: "You didn't get this from me . . . ok?" Compl. ¶ 160. The Court is unpersuaded that the Complaint's reliance upon this

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[5] The allegation that the tools would lead to practices necessarily prescribing the highest-cost drugs is inconsistent with other allegations in the Complaint. In the Complaint's attached Exhibit 3, for instance, the highest margin drug recommended to Summit Cancer Care was often a less-expensive option. *See*, *e.g.*, Compl., Ex. 3 (comparing ARANSESP, $1626.32 with a profit of -$454.04, with PROCRIP $1327.39 with a profit of $222.35).

email and its attachments plausibly alleges knowledge of unlawfulness.

As an initial matter, although the Complaint did not specifically attach the email or its attachments, the Court may consider these documents because they were incorporated by reference. *See In re Cocoa Servs., LLC*, 2018 WL 1801240 (Bankr. S.D.N.Y. Apr. 13, 2018) (quoting *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007) ("The materials that may be considered on a motion to dismiss are those 'asserted within the four corners of the complaint . . . and any documents incorporated in the complaint by reference.'")). Indeed, even if Hart had not incorporated the email and its attachments into the Complaint, given his extensive and specific reliance upon them to allege scienter, the Court "may nevertheless consider" them, as "the [C]omplaint relies heavily upon [their] terms and effect, which renders the document[s] 'integral' to the [C]omplaint." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (cleaned up).

With the benefit of the email and its attachments, it is not clear that the cover message relates to the Margin Analyzer or Regimen Profiler at all, or that information about the valuation of those programs, specifically, is what Kaminsky was referring to. The email attached three separate documents totaling 170 pages, each covering a range of materials—everything from physician compensation, *see* Pastan Decl., Ex. 1(b) at 8, to rates of return on invested capital, *see id.* at 14, to McKesson's vision insurance and retirement plans for employees, *see id.*, Ex. 1(c) at 27-28. Indeed, the Margin Analyzer was only referenced three times, and the Regimen Profiler twice, across all of those pages—and even then, only in passing within descriptive cells of a 61-sheet table valuing a range

of services, *see id.*, Ex. 1(b) at 27, 32, 37, and 53, or buried in the body of text on page 82 of an 84-page summary document, *see id.*, Ex. 1(c) at 82.

In any event, even if the Court were to accept that Kaminsky's cover email was in reference to the tools, his message does not plausibly allege that he had any belief that McKesson's provision of the Margin Analyzer or Regimen Profiler free of charge was in any way unlawful. His message could have been included for any number of reasons: perhaps because Verrilli should not have been receiving materials from the Open Market business unit, for instance, or because Ernst & Young had only provided certain executives of the company with a draft assessment. These suppositions are not for the Court to make, as it is a plaintiff who must make the allegations required to plausibly support his claims. In short: the documents attached do not lead to a plausible inference that the cover email was in reference to the business tools at issue—let alone that McKesson had knowledge of the purported illegality of offering them free of charge to select practices. *Contra* Compl. ¶ 160 (alleging the email "indicat[ed] [Kaminsky's] knowledge that McKesson's provision of these value-added business tools for free . . . was wrongful and unlawful").

Beyond the newly described conversations with fellow McKesson sales employees and the Kaminsky email, Hart's Complaint merely reiterates (albeit in more extended form) allegations that McKesson had general knowledge of the requirements of the AKS and the unlawfulness of inducements in violation of the statute. He alleges that internal company policies, for instance, prohibited providing of "things of value" to induce purchases of items that would ultimately be reimbursed by government sponsored health care providers, and that employees received trainings on

the AKS's demands. *See*, *e.g.*, *id.* ¶¶ 143-45. But as the Court specifically observed in its Prior Opinion, allegations like these, even coupled with those that McKesson knew that the Margin Analyzer and Regimen Profiler were business tools with independent value, do not support an inference of scienter as required by the AKS. *See* 602 F.3d at 596 ("Allegations that McKesson knew remuneration to induce purchases was prohibited in general, however, cannot alone support a finding that McKesson knew this particular course of conduct was unlawful.").

The Complaint continues to lack specific allegations of the type that other courts have found to support a plausible inference of knowledge that the conduct was unlawful, such as actions taken to conceal the fraudulent scheme, *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); notice from counsel that the program may be unlawful, *United States v. Teva Pharms.*, 2021 WL 4132592, at *6; *United States v. Millennium Radiology, Inc.*, 2014 WL 4908275, at *8 (S.D. Ohio Sept. 30, 2014); *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *3 (D. Mass. Aug. 23, 2016) (internal document characterizing relationship as a "quid pro quo" was sufficient to establish dispute as to scienter at summary judgment stage); cancellation of the program due to concerns over its lawfulness, *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 829 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018); or a service without legitimate value that was a pretext to provide remuneration, *Arnstein*, 2016 WL 750720, at *17 (describing relator's allegation that company-sponsored speaker programs were "shams").

To the contrary, the conduct complained of here was, based on the Complaint's own allegations and attached exhibits, openly advertised and even widely discussed. Such allegations undermine any claim that McKesson was intentionally violating a known legal duty. *See*, *e.g.*, *United States v. Novartis AG*, 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011) ("Plaintiffs do not allege any facts, circumstantial or otherwise, that Novartis believed, or acted in a way suggesting it believed, that its marketing . . . was illegal. Rather, and in contrast to other cases where the courts have found sufficiently pleaded AKS claims, Plaintiffs' amended complaint suggests Novartis allegedly paid kickbacks to physicians quite openly."). In *United States v. Valley Campus Pharmacy, Inc.*, for instance, the court observed that "Relator's allegations seem to indicate that Defendants thought their offering of PA services was lawful, as they advertised these services openly on their website and in a presentation in Las Vegas." 2021 WL 5406148, at *3 (C.D. Cal. Oct. 12, 2021), *aff'd* 2023 WL 195514 (9th Cir. Jan. 17, 2023). Allegations of open, public behavior "coincides more with merely the intent to use [the services at issue] as a 'sales and marketing tool,' and not a knowingly unlawful means of obtaining referrals." *Id.* As such, they "do not support a plausible inference of scienter" under the AKS. *Id.*

Hart's allegations that McKesson purportedly destroyed documents do not alter the Court's conclusion.[6] Taken as true for purposes of the

[6] While the Court does not rely on this for purposes of the present motion, and accepts each of the Complaint's allegations as true, it is worth noting that, during the course of discovery prior to the filing of the present Complaint, Magistrate Judge Cott considered at least some of Hart's accusations that

present motion, these allegations do not give rise to the plausible inference that McKesson destroyed documents in order to conceal conduct it knew was unlawful. Rather, Hart alleges that McKesson removed references to the Margin Analyzer from it's public-facing website, *see* Compl. ¶ 167; that it no longer has the consumer testimonial video regarding those tools (which is nevertheless already described in substance by the Complaint), *see id.*, and that it "does not appear to have maintained and/or preserved" records of either its employees' emails related to the business tools, or records of their AKS compliance training, *see id.* at 168-70. Apart from conclusory allegations that the ostensible destruction of these materials is evidence of "guilt" or that McKesson "knew its conduct was wrongful," however, the Complaint does not provide specific allegations to support the plausible inference that McKesson engaged in document destruction in order to conceal evidence which would demonstrate scienter under the AKS. *Contra*, *e.g.*, *Burciaga v. GEO Grp., Inc.*, 2017 WL 10605270 (S.D. Cal. Feb. 28, 2017) (finding that the evidence that "Defendant destroy[ed]

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McKesson had destroyed evidence—namely, those related to the destruction of materials on Hart's laptop, *see* Compl. ¶¶ 168, 170—and found them to be entirely unsupported. *See* Dkt. 138 (letter motion from Hart to Judge Cott raising the same allegations); Dkt. 144, Tr. (Jan. 12, 2022), at 5:17-20 ("I don't think there is enough in the record . . . to suggest that there was some improper destruction of these documents"); *id.* at 21:22-22:4 ("As presented [any document destruction] seems to have occurred in the normal course . . . companies like McKesson rightfully engage in appropriate destruction in the regular course."). It is true, however, as Plaintiff emphasized at oral argument before this Court, that Judge Cott did not consider specific allegations related to the destruction of a customer testimonial video, *see* Compl. ¶ 167, nor those related to the failure to preserve records of McKesson employees' AKS compliance training, *see id.* ¶ 169.

records to keep them from ACA auditors" was sufficient to meet the FCA scienter standard); *SEC v. Suterwalla*, 2008 WL 9371764 (S.D. Cal. Feb. 4, 2008) (alleging the plaintiff destroyed documents protected by an injunction in order to conceal fraud).

Moreover, the cases that Hart cites to argue that his new allegations plausibly allege knowledge of illegality do not salvage his claims, as each are distinguishable. A first set of those cases included specific allegations that defendants were provided with (and reviewed) detailed information—at the highest levels of the business—about how the conduct complained of violated the AKS, and that such concerns were specifically considered. In *United States v. Teva Pharmaceuticals USA, Inc.*, 560 F. Supp. 3d 412 (D. Mass. 2021), for instance, the government highlighted the fact that Teva employees circulated a law firm's advice to the company "warning of the risks associated with donations to copay assistance charities" under the AKS, the specific conduct complained of in that action. *Id.* at 421-22. So too, in *United States v. Genesis Glob. Healthcare*, 2021 WL 4268279 (S.D. Ga. Sept. 20, 2021), the district court highlighted investment documents given to executives of the defendant company which "informed [them] about the AKS's prohibition against" the specific conduct complained of, and "warned that [the] investments . . . were suspect." *Id.* at *12. The *Genesis* court further described that, when defendant's executives specifically discussed the practice at an investor meeting, an "initial investor raised concerns about the scheme's legality under the AKS with [the executives] and subsequently backed out of the investment." *Id.* Allegations like these—evincing specific consideration regarding the legality of a given scheme under the AKS—suffice to allege that the

defendant acted with knowledge that the scheme was unlawful. *See also*, *e.g.*, *Strunck*, 2020 WL 362717, at *4 (citing allegations that company's VP received articles discussing the illegality of the at-issue conduct and knew similar conduct was unlawful). But the Complaint here—unlike in *Teva*, *Genesis*, or *Strunck*—contains no allegations that McKesson executives either received or considered advice regarding the legality of providing the Margin Analyzer and Regimen Profiler to select oncology practices.

Other cases relied upon by Hart involved distinct allegations that defendants were engaging in conduct that either violated internal policies prohibiting the specific conduct as unlawful under the AKS, or which was widely recognized within the industry as illegal. In *United States v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019), internal company guidance prohibited the specific conduct at issue in the action, based on the company's stated belief that such conduct may run afoul of the AKS. *See id.* at *9-12. Similarly, *United States ex rel. Bilotta v. Novartis Pharmaceuticals Co.* involved allegations that defendants had repeatedly violated internal policies and industry guidance related to speaker programs. *See* 50 F. Supp. 3d 497, 518-21 (S.D.N.Y. 2014). There, the pleadings alleged that Novartis ethics and compliance policies specifically required that speaker programs be held at venues "conducive to an exchange of medical information," and that food and beverages should be "ancillary to meaningful discussion" and "modest in quantity and cost." *Id.* at 519. The district court emphasized that "Novartis's conduct—as alleged in the pleadings—violates each of these policies, raising a strong inference that Novartis acted knowingly and willfully in using the speaker

events to induce prescription-writing in violation of the anti-kickback laws." *Id.* Finally, *United States ex rel. Pasqua v. Kan-Di-Ki*, 2012 WL 12895229 (C.D. Cal. June 18, 2012), involved allegations that the conduct which was the subject of the action was "known throughout the health care industry" to violate the AKS "at the time Defendants engaged in such conduct." *Id.* at *5.

Here, by contrast, while Hart alleges that McKesson had general internal policies regarding the AKS, *see*, *e.g.*, Compl. ¶¶ 8, 157-59, he does not allege that it had specific policies warning that provision of the Margin Analyzer or Regimen Profiler to practices free of charge may have been unlawful. Similarly, Hart does not allege that providing business management tools like the Margin Analyzer and Regimen Profiler were widely recognized "throughout the health care industry" at the time, *Pasqua*, 2012 WL 12895229, at *5, to raise AKS-related concerns. Quite to the contrary, the Complaint itself highlights that McKesson *openly advertised* the Margin Analyzer and Regimen Profiler tools, *see* Compl. ¶¶ 130, 167, and further attaches documents referencing similar business management tools provided by other healthcare companies at the time, *see* Dkt. 176-5 at 17 (McKesson analysis of competitor business tools). And, as the Court noted in the Prior Opinion dismissing the First Amended Complaint, at least some OIG guidance appears to have recognized that the provision of certain types of tools and support do not run afoul of the AKS. *See* 602 F. Supp. 3d at 589-90. The 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003), for instance, acknowledges that companies may provide certain support services which do not implicate the AKS.

OIG Advisory Opinions further indicated—at the time of McKesson's alleged conduct here—that simply because a product or service has value does not necessarily mean that it violates the AKS. *See*, *e.g.*, OIG Adv. Op. No. 12-20 (concluding software products did not violate the AKS); OIG Adv. Op. No. 00-10 (concluding that providing information regarding insurance coverage and reimbursement did not violate the AKS).

Lastly, Hart relies on several cases in which there was no question that the defendant knew that direct payments to induce referrals violated the AKS—a situation plainly inapposite to the allegations here. *See*, *e.g.*, *United States v. Mittal*, 36 F. App'x 20 (2d Cir. 2006) (defendant received cash payments for referrals); *United States v. Nowlin*, 640 F. App'x 337 (5th Cir. 2016) (defendant agreed to refer clients in exchange for commissions); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (defendant admitted that "his relationship with the Hospital had turned into receiving payment for patient referrals").

As before, while Hart's Complaint plausibly identifies conduct that could constitute unlawful inducement under the AKS, and that McKesson had general awareness of the AKS's requirements, it fails to plausibly allege that McKesson provided the Margin Analyzer and Regimen Profiler to practices free of charge with the requisite scienter. *See*, *e.g.*, *Forney*, 2017 WL 2653568, at *4-*5 ("[Relator alleged] that the effect of the scheme was to induce physicians to refer Medtronic's products to their patients, [but had] not alleged that its subjective purpose was to do so."). Congress could have adopted a different scienter requirement when it passed the AKS, but specifically chose to impose the willfulness element that it did, and this Court is bound by that choice, as interpreted

by the Second Circuit. *See Pfizer*, 42 F.4th at 77. Having failed to plausibly allege this scienter under the statute, Hart thus fails to state a claim as a matter of law, and McKesson's motion to dismiss is granted.

**II. Leave to Amend**

Whether to grant leave to further amend a complaint is committed to the "sound discretion of the district court." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). "Ordinarily, a plaintiff should be granted leave to amend at least once after having the benefit of a court's reasoning in dismissing the complaint." *Obra Pia Ltd. v. Seagrape Inv'rs LLC*, 2021 WL 1978545, at *3 (S.D.N.Y. May 18, 2021). This is especially true on the Court's first ruling on a motion to dismiss. *Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Secs. LLC*, 797 F.3d 160, 190 (2d Cir. 2015) ("Without the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies."); *see also Cresci v. Mohawk Valley Cmty. Coll.*, 693 F. App'x 21, 25 (2d Cir. 2017) ("The proper time for a plaintiff to move to amend the complaint is when the plaintiff learns from the District Court in what respect the complaint is deficient. Before learning from the court what are its deficiencies, the plaintiff cannot know whether he is capable of amending the complaint efficaciously."). "Granting leave to amend is futile," however, "if it appears that plaintiff cannot address the deficiencies identified by the court and allege facts sufficient to support the claim." *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 347 F. App'x 617, 622 (2d Cir. 2009).

Here, Hart has already had the benefit of multiple rounds of amendment—the latest of which came after the Court granted leave to amend in a thirty-five-page

opinion clearly delineating remaining deficiencies in the pleadings. *See* Prior Opinion, 602 F. Supp. 3d at 595 ("[T]o satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful . . ."). Even with the benefit of the Court's instruction, however, Hart has proven unable to plausibly allege that McKesson acted with the requisite scienter under the federal AKS.

Nevertheless, Hart's Complaint does bring claims under the FCA analogues of twenty-eight states, as well as the District of Columbia. Because "many of [those state law regimes] have their own analogous anti-kickback statutes," Compl. ¶ 13, it is conceivable that Hart could amend the pleadings to specifically allege that McKesson had the requisite scienter to violate the AKS counterparts of those states which do not incorporate the same "willfulness" standard, and thereby bring claims under those states' FCAs. To be sure, the Court is skeptical that it would retain jurisdiction over a possible Third Amended Complaint exclusively raising these state claims. *See, Kolari v. New York-Presbyterian Hosp.*, 455 F.3d 118, 122 (2d Cir. 2006) (the doctrine of pendent jurisdiction over state-law claims is traditionally "a doctrine of discretion, not of plaintiff's right"); *see also* 28 U.S.C. § 1367(c)(3) (clarifying a district court "may decline to exercise supplemental jurisdiction" if it has "dismissed all claims over which it has original jurisdiction"). But, in the exercise of its discretion, it nevertheless grants Hart leave for further amendment, should he have a good faith basis for doing so.

## CONCLUSION

For the foregoing reasons, the motion to dismiss is granted without prejudice. The Clerk of Court is respectfully directed to terminate the motions pending at docket entries 171 and 174.[7]

SO ORDERED.

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[7] The Court grants in part and denies in part McKesson's motion to seal Exhibits 1(b)-1(d), 2, 4, and 5 to the Declaration of Nicholas Pastan, filed in conjunction with McKesson's motion to dismiss the Second Amended Complaint. See Dkt. 174.

While McKesson has established that portions of these documents relate to internal business and sales discussions, and that they include information from executive presentations and confidential business modeling, any sealing request must be narrowly tailored under *Lugosch v. Pyramic Co. of Onondaga*, 435 F.3d 110 (2d Cir. 2006), and related cases, to protect only "highly proprietary" commercial information from public disclosure, *GoSMiLE, Inc. v. Dr. Jonathan Levine, D.M.D. P.C.*, 769 F. Supp. 2d 630, 649-50 (S.D.N.Y. 2011) (allowing sealing of documents attached as exhibits where they "contain[ed] highly proprietary material concerning the defendants' marketing strategies, product development, costs and budgeting"). Accordingly, no later than April 28, 2023, McKesson is ordered to file proposed redacted versions of Exhibits 1(b)-1(d), 2, 4, and 5, specifically redacting only those portions of the documents that reflect such "highly proprietary" confidential business information.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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No. 15-CV-0903 (RA)

UNITED STATES of America, et al.,
EX REL. Adam HART,
Plaintiff,

v.

MCKESSON CORPORATION, et al.,
Defendants.

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[Filed May 5, 2022]

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OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

Plaintiff-Relator Adam Hart has filed this *qui tam* action against McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (collectively "McKesson") on behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia (collectively "the States"). Hart alleges that McKesson offered business-management tools to specialty oncology practices that joined programs requiring them to purchase a substantial proportion of their drugs from McKesson, and that doing so violated

the Anti-Kickback Statute ("AKS"). 42 U.S.C. § 1320a-7b(b). Any claims for reimbursement submitted by these practices to the United States or the States, he asserts, were tainted by the kickback scheme and thus in violation of the federal False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA"), and the corresponding state laws, *see* Am. Compl. ¶¶ 1, 3.

McKesson has moved to dismiss, arguing that: (1) Hart fails to plausibly allege that the business-management tools constituted remuneration under the AKS; (2) Hart fails to plausibly allege that Defendants acted with the requisite scienter; and (3) Hart fails to plead the fraudulent scheme with the particularity required by Federal Rule of Civil Procedure 9(b). For the reasons that follow, Defendants' motion to dismiss is granted, though Plaintiff is granted leave to amend.

## BACKGROUND[1]

### I. The Parties

McKesson Corporation is a Delaware corporation headquartered in Irving, Texas. Am. Compl. ¶ 15. McKesson sells pharmaceuticals, medical supplies, and related services to health care providers. *Id.* ¶¶ 2, 40. McKesson Corporation is the parent company of the other McKesson Defendants, "which are wholly-owned direct or indirect subsidiaries of McKesson Corporation." *Id.* ¶ 15. McKesson Specialty Distribution LLC is a Delaware limited liability company and a wholly-owned subsidiary of McKesson Corporation. *Id.* ¶ 16. McKesson Specialty Care Distribution Corporation is a Delaware corporation and also a wholly-

[1] The facts in this section and throughout are taken from Plaintiff's amended complaint (the "complaint") and are assumed to be true for purposes of this motion. *See Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).

owned subsidiary of McKesson Corporation. *Id.*[2] Hart alleges, upon information and belief, that during the relevant time period, McKesson Specialty Health ("MSH") was a business unit of McKesson Corporation, McKesson Specialty Care Distribution Corporation, and McKesson Specialty Distribution LLC. *Id.* Through MSH, McKesson operated as a wholesale distributor, buying specialty drugs and reselling them to customers across the country. *Id.* ¶¶ 2, 16-17, 40.

Plaintiff-Relator Hart was employed by McKesson from August 2011 until September 2014 as a Business Development Executive ("BDE") in its Specialty Health business unit. *Id.* ¶ 14. His responsibilities included generating new business opportunities among community-based oncology practices in the southeastern United States. *Id.* Once a customer was recruited, Hart would provide services for the first year, after which a "McKesson Account Executive" was assigned. *Id.* The McKesson Account Executive was responsible for maintaining and increasing sales, but Hart remained in touch with practices through "sales meetings, sales calls, requests for assistance from other personnel, and communications with coworkers." *Id.*

**II. McKesson's Oncology Business**

As relevant here, MSH provided "specialty pharmaceuticals and services to community oncology practices." *Id.* ¶ 47.[3] The specialty drugs used in cancer

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[2] In or around May 2013, McKesson Specialty Care Distribution JV LLC merged with McKesson Specialty Care Distribution Corporation, which became the surviving company. Am. Compl. ¶ 16.

[3] Community oncology practices provide oncology care in an "office setting," as opposed to providers who operate in a hospital setting. Am. Compl. ¶ 41.

treatment are complex to manufacture, require special handling, and, as a result, are more expensive than other drugs. *Id.* ¶ 39. Some oncology practices obtain the drugs from a specialty pharmacy, which then bills patients' insurers. *Id.* ¶ 41. Others opt to purchase drugs from wholesalers like McKesson, provide those drugs to their patients, and then bill the patients' insurers themselves. *Id.*

In 2014, the oncology business was MSH's largest line of business by revenue, generating $7 billion of MSH's $9 billion in annual revenue. *Id.* ¶ 47. There were two divisions of the oncology business, and Hart worked in the "open market" division, which operated as a traditional drug wholesaler and distributor. *Id.* ¶¶ 47-48. The allegations in the complaint are limited to the practices of the open market division. *Id.* ¶¶ 48-49.

## III. The Business-Management Tools

Hart's claims are based primarily on McKesson's usage of two business-management tools—the Margin Analyzer and the Regimen Profiler—which were offered almost exclusively to practices that committed to purchasing a significant portion of their drugs from McKesson. *Id.* ¶ 69.

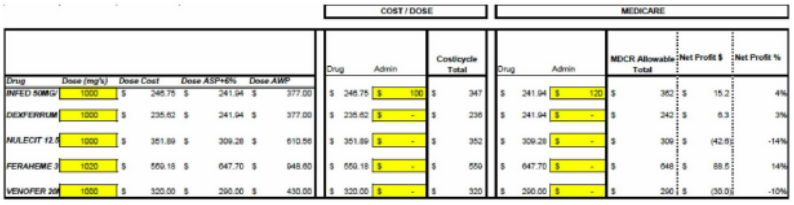
### A. The Margin Analyzer

Beginning in approximately 2011, McKesson offered its customers "complimentary access" to the Margin Analyzer. *Id.* ¶ 52.[4] Among other things, the tool allowed oncology practices to compare the

[4] The complaint also alleges that Brian Larson, who developed the Margin Analyzer, continued to maintain it until at least June 2015, Am. Compl. ¶ 52, and that between 2012 and November 30, 2017, McKesson's customers submitted "hundreds of millions of dollars" in false claims to Medicare after having received either the Margin Analyzer or Regimen Profiler, *id.* ¶ 121.

reimbursement rates of interchangeable drugs. *Id.* ¶¶ 54-55. McKesson had identified "therapeutically interchangeable" choices for ten categories of drugs commonly used by oncology practices. *Id.* ¶ 60. For any given category, the Margin Analyzer relied on pricing and reimbursement data to determine which of the similar drugs would yield the highest profit for the practice. *Id.* ¶¶ 61, 63. McKesson employees input reimbursement data from Medicare and private insurers, allowing the tool to analyze the profitability of different drugs based on a patient's insurer. *Id.* ¶¶ 57-59, 61-63.

Hart's complaint includes the following illustration of the tool's utility. The Margin Analyzer listed five "therapeutically interchangeable options" for parenteral irons. *Id.* ¶ 77. In Q2 2012, McKesson's data showed that, for Medicare-insured patients, the difference between acquisition cost and reimbursement price was significantly greater for one brand of parenteral irons, Feraheme, than other brands. *Id.* For Summit Cancer Care in Savannah, Georgia, specifically, a switch from prescribing only Infed parenteral irons (margin of $15.20 per dose), to a mix of 80% Feraheme (margin of $88.50 per dose) and 20% Infed would increase annualized net profits by $10,560. *Id.* ¶ 78. The Margin Analyzer excerpt below shows the type of data comparisons available to McKesson representatives and the practices:



| | | | | | COST / DOSE | | | MEDICARE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Drug | Dose (mg's) | Dose Cost | Dose ASP+6% | Dose AWP | Drug | Admin | Costcycle Total | Drug | Admin | MDCR Allowable Total | Net Profit $ | Net Profit % |
| INFED 50MG/ | 1000 | $ 246.75 | $ 241.94 | $ 377.00 | $ 246.75 | $ 100 | $ 347 | $ 241.94 | $ 120 | $ 362 | $ 15.2 | 4% |
| DEXFERRUM | 1000 | $ 235.62 | $ 241.94 | $ 377.00 | $ 235.62 | $ - | $ 236 | $ 241.94 | $ - | $ 242 | $ 6.3 | 3% |
| NULECIT 12.5 | 1000 | $ 351.89 | $ 309.28 | $ 610.56 | $ 351.89 | $ - | $ 352 | $ 309.28 | $ - | $ 309 | $ (42.6) | -14% |
| FERAHEME 1 | 1020 | $ 559.18 | $ 647.70 | $ 948.60 | $ 559.18 | $ - | $ 559 | $ 647.70 | $ - | $ 648 | $ 88.5 | 14% |
| VENOFER 20 | 1000 | $ 320.00 | $ 290.00 | $ 430.00 | $ 320.00 | $ - | $ 320 | $ 290.00 | $ - | $ 290 | $ (30.0) | -10% |

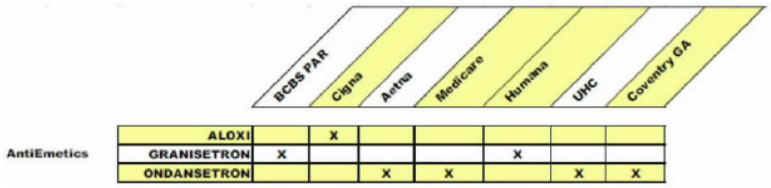
*See* Am. Compl. Ex. 4 (Q2 2012 SCC Margin Analyzer).

The Margin Analyzer was used not only to compare the cost and profit margin on a per drug, per insurer basis, but also to give forward-looking recommendations based on that data. BDEs or Account Executives were able to forecast various scenarios by inputting different drug mixes or potential payors, and then used those findings to aid the practices in choosing a drug distribution that was most profitable. *See* Am. Compl. ¶¶ 73-78. Because the Margin Analyzer allowed practices to instantly compare the profit margin of one drug versus others in the same category, a BDE or Account Executive could identify areas with large profit opportunities. *See id.* McKesson personnel met with their customers at "Quarterly Business Reviews" to review the Margin Analyzer and to provide "a detailed analysis of the practice's finances and business operation." *Id.* ¶ 65.

In order to generate these results, the Margin Analyzer required data, including: the fee schedules published quarterly by the Centers for Medicare and Medicaid Services ("CMS"); the customer's quarterly purchase records; the prices at which McKesson sold its drugs; and the fee schedules of relevant private insurers. *Id.* ¶¶ 56-58. McKesson employees would gather and input this data into spreadsheets for each practice, and update them on a quarterly basis as the data changed. *Id.*

Because different insurers reimbursed different drugs at different rates, a drug most profitable for a Medicare patient may not be as profitable for a patient with a given private insurer. The Margin Analyzer not only accounted for the different reimbursement amounts offered by different insurers, but synthesized the data into a "cheat sheet" page that recommended the most profitable drug in each category, by payor. *See id.* ¶¶ 81-82; *id.* Ex. 1 Q4 2012 SCC Margin

Analyzer; *id.* Ex. 5 Q1 2013 SCC Margin Analyzer. The "cheat sheet" generated for the Summit Cancer Care in Q4 of 2012, for example, recommended one of three different antiemetic drugs depending on whether the patient was covered by BlueCross BlueShield, Cigna, or Medicare. *See* Am. Compl. at ¶ 82; Q4 2012 SCC Margin Analyzer.




As with all the data in the Margin Analyzer, McKesson would update these sheets every quarter as reimbursement rates changed. Am. Compl. ¶¶ 84-85. The most cost-effective drugs were subject to change each quarter. Compare Q4 2012 SCC Margin Analyzer with Q1 2013 SCC Margin Analyzer.

McKesson used the Margin Analyzer in three contexts: to acquire new customers and/or retain existing customers, *id.* ¶ 64; to provide consultation and financial advice to existing customers at in-person "Quarterly Business Reviews," *id.* ¶ 65; and to encourage the purchase of new drugs (or drugs with new pricing), *id.* ¶ 66.

**B. The Regimen Profiler**

The Regimen Profiler worked in much the same way as the Margin Analyzer, but rather than calculate the margins for an individual drug, it calculated costs for the whole treatment regimen. *Id.* ¶¶ 5, 96. Oncology practices typically incur significant non-drug related costs in the administration of cancer therapy, such as the cost of preparing or administering the treatments, so the price of the drug itself is only one component of

the overall cost. *Id.* ¶¶ 97, 99. The Regimen Profiler filled this gap—calculating profit margins for the course of treatment, including non-drug costs. *Id.* Insurers reimbursed these non-drug costs as well, and so the Regimen Profiler, like the Margin Analyzer, calculated the profitability of each treatment regimen on a provider-by-provider basis. *Id.* ¶ 99. The tool was designed to be used in conjunction with the Margin Analyzer to understand a practice's overall profitability and/or potential profitability. *See id.* Ex. 3 (Margin Analyzer Sales Sheet). McKesson employed the Regimen Profiler in the same manner as the Margin Analyzer—to pitch new customers and retain existing ones. Am. Compl. ¶ 101. Moreover, as with the Margin Analyzer, McKesson made an "explicit contractual promise" only to commitment program customers to provide the Regimen Profiler free of charge. *Id.*

**C. McKesson's Offer of the Business Management Tools to Commitment Program Customers**

Hart alleges that these tools were provided, for free, on a quarterly basis, to a number of oncology practices in the Southeast. They were not, however, distributed to all of McKesson's customers. Instead, the Margin Analyzer and Regimen Profiler were offered, "with few (or no) exceptions . . . *only* to physician practices that contracted to join the Onmark Select, Prime, or MVP programs." *Id.* ¶ 69 (emphasis in original). The Onmark Select, Prime Membership, and McKesson Value Program ("MVP") (collectively the "commitment programs"), required practices to purchase a certain volume of their drugs from McKesson. *Id.* ¶ 68. The Onmark Select program required use of McKesson as the "primary wholesale supplier" for branded and generic drugs, while the Prime and MVP programs required a commitment to purchase approximately

90% to 95% of the practice's branded and generic drugs from McKesson. *Id.*

If they did not join one of the commitment programs, oncology practices were still able to purchase drugs from McKesson. But MSH did not allow non-commitment program customers to access the business-management tools. *Id.* ¶¶ 70, 101. One practice—Hematology Oncology of the Treasure Coast—that sought to end its purchase commitment with McKesson was explicitly told that if it did so, it would lose access to the Margin Analyzer. *Id.* ¶ 70.

Hart names twelve practices that were offered the tools for free and signed commitment programs with McKesson: Summit Cancer Care (Savannah, GA) Premier Oncology Center (Naples, FL), Spalding Oncology (Griffin, GA), Florida Medical Clinic (Land O' Lakes, FL), Noor Merchant, MD (Sebastian, FL), Suncoast Medical Clinic (St. Petersburg, FL), Oncology Hematology Associates of West Broward (Tamarac, FL), ICON Oncology (Jacksonville, FL), Emerald Coast Cancer Center (Ft. Walton Beach, FL), Citrus Hematology and Oncology (Inverness, FL), Central Florida Cancer Institute (Davenport, FL), and Alabama Cancer Care (Gadsden, AL). *Id.* ¶ 53. Each of these practices were, allegedly,

> offered the Margin Analyzer and/or the Regimen Profiler for free as an inducement to make a purchase commitment from McKesson. During the sales pitch to these practices, McKesson populated the Margin Analyzer with the practices' specific drug utilization information to demonstrate the utility of the Margin Analyzer. Each of these physician practices signed purchase commitments with McKesson and informed McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their

> decision to commit to buying specialty drugs from McKesson.

*Id.* ¶ 71. With respect to the Regimen Profiler, Hart states that Summit Cancer Care, Premier Oncology Center, Florida Medical Clinic, Emerald Coast Cancer Center, and Southern Hematology and Oncology were also "offered the Regimen Profiler as an inducement to make a purchase commitment from McKesson, subsequently signed purchase commitments, and used the Regimen Profiler." *Id.* ¶ 101.

Without specifying any particular oncology practices outside of Florida, Georgia, or Alabama, Hart further alleges that this conduct occurred nationwide. *Id.* ¶¶ 71, 122. Because he knew McKesson's general policies, and had experience with other BDEs from national sales conferences, Hart alleges "scores of other providers across the country" were provided the Margin Analyzer and Regimen Profiler for free as an inducement to join the commitment programs. *Id.* ¶¶ 71, 114, 121-122.

Hart's complaint also contains allegations that suggest McKesson knew that the Margin Analyzer and Regimen Profiler were valued by its customers. Sales training materials attached to the complaint emphasized the importance of the Margin Analyzer to retaining customers. *See id.* Ex. 2 (Margin Analyzer Flyer); Margin Analyzer Sales Sheet. And McKesson purportedly believed that the tools were important to both enhancing its profitability and creating "stickiness" among its customers. Am. Compl. ¶ 70; *id.* Ex. 8 at 8-9 (2014 South Region Meeting Presentation). Hart also references internal communications in which McKesson concluded at least some customers stayed with McKesson, over lower cost providers, in order to retain access to the Margin Analyzer. Am. Compl.

¶ 64. The company prepared a customer testimonial video dedicated to the business-management tools, touting their potential value to community oncology practices. *Id.* ¶ 109.

McKesson's view that the tools were important to customer acquisition and retention was purportedly emphasized at its in-person sales conferences. At those events, executives from McKesson made clear that the Margin Analyzer should be at the center of sales pitches to new customers. *Id.* ¶¶ 70, 107, 114. Indeed, according to Hart, the Margin Analyzer and Regimen Profiler were so central to the company's sales direction that one BDE was fired for failing to sufficiently highlight the tools. *Id.* ¶ 107.

## IV. The Anti-Kickback Statute and False Claims Act

The AKS and FCA work in conjunction to create a private right of action for violation of the federal criminal anti-kickback statute. The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; 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)-(B). Claims are defined as "any request or demand for money from an officer, agent, employee, or contractor of the United States." 31 U.S.C. § 3729(b)(2)(A).

The AKS prohibits any individual or entity from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or arrange for 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." 42

U.S.C. § 1320a-7b(b)(2)(B). Claims resulting from an AKS violation constitute "a false or fraudulent claim" for the purposes of the FCA. 42 U.S.C. § 1320a-7b(g); *see also United States v. Novartis Pharms. Corp.*, No. 13-CV-3700 (KMW), 2020 WL 1436706, at *1 (S.D.N.Y. Mar. 24, 2020).

**V. Procedural History**

Plaintiff filed his initial complaint on February 6, 2015. Because the action was brought under the False Claims Act, the complaint was placed under seal to afford the Government an opportunity to intervene. *See* 31 U.S.C. § 3730(b)(2). The Government ultimately declined to intervene, and the complaint was unsealed as of May 29, 2020. Plaintiff then amended his complaint (the "complaint"). In it, Hart alleges that McKesson's practice of offering the business-management tools exclusively to customers who joined its commitment programs resulted in the submission of false claims to the government. Am. Compl. ¶¶ 120-122. Because this policy constitutes an AKS violation, he asserts, claims submitted for reimbursement to government health care programs in connection with the violation are "false" under the FCA. *Id.* ¶¶ 8, 123. Hart also alleges that McKesson knew that providing any valuable services to induce purchases was unlawful and that it also knew the customers to whom it offered the Margin Analyzer and Regimen Profiler were submitting claims to federal and state health care programs. Am. Compl. ¶¶ 7, 117.

The complaint includes one claim based on Defendants' purported FCA violation (Count 1), *id.* ¶¶ 124-131; 31 U.S.C. § 3729(a)(1)(A)-(B), as well as causes of action under the False Claims Act analogs of 28 States and the District of Columbia (Counts II-XXIX, "the state analogs"), based on the same conduct.

Defendants now move to dismiss the complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). For the reasons that follow, the motion is granted.

**LEGAL STANDARD**

When considering a motion to dismiss under 12(b)(6), a court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." *LaFaro v. New York Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009).[5] A complaint must be dismissed if it fails to state a claim upon which relief can be granted. Fed R. Civ. P. 12(b)(6). The complaint must "contain sufficient factual matter ... to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). A complaint that offers only "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action, will not do.'" *Id.* (quoting *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955). Nor will a complaint suffice if it contains only "'naked assertion[s]' devoid of further 'factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557, 127 S.Ct. 1955).

Because FCA claims "fall within the express scope of Rule 9(b)," *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam), a relator must "state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b). While the circumstances of the fraud must be pled with particularity, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" under

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[5] Unless otherwise indicated, case quotations omit all internal citations, quotations, footnotes, and alterations.

Rule 9(b). Fed. R. Civ. P. 9(b). Rule 9(b) demands specificity, but "it does not elevate the standard of certainty that a pleading must attain beyond the ordinary level of plausibility." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 88 (2d Cir. 2017). Where an FCA claim is predicated on a violation of the AKS, both the FCA and AKS violations must be pled in compliance with Rule 9(b). *United States v. Novartis Pharms. Corp.*, No. 13-CV-3700 (KMW), 2020 WL 1436706, at *3 (S.D.N.Y. Mar. 24, 2020) (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617-18 (2d Cir. 2016) and *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513-14 (S.D.N.Y. 2014)). Claims under the FCA state analogs must also satisfy Rule 9(b). *Novartis*, 2020 WL 1436706, at *3 (citing *United States ex rel. Arnstein v. TEVA Pharms. USA, Inc.*, No. 13-CV-3702, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) ("*Arnstein*")).

**DISCUSSION**

In its motion to dismiss, McKesson contends that Hart's complaint fails in three respects: (1) it fails to plausibly allege that the business-management tools constituted remuneration; (2) it fails to plausibly allege that Defendants acted with the required scienter; and (3) it fails to plead the fraudulent scheme with particularity. For the reasons that follow, the Court finds that the tools, as described, plausibly constitute remuneration, but agrees with Defendants that Hart has failed to include sufficient allegations to support an interference that McKesson acted with knowledge that its conduct was unlawful. The claims must therefore be dismissed.

## I. Hart has Plausibly Alleged that the Margin Analyzer and Regimen Profiler Constitute Remuneration

The AKS proscribes the knowing and willful offer or payment of "any remuneration (including any kick-back, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind," in order to induce the purchase of drugs or services that will ultimately be reimbursed by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Where a purchase has been tainted by illegal remuneration, the claim is a false or fraudulent claim within the meaning of the FCA. 42 U.S.C. § 1320a-7b(g); *see also Novartis*, 2020 WL 1436706, at *1.

### A. The Scope of "Remuneration"

Remuneration is required to establish a violation of the AKS, but the term is not defined by the statute. Nonetheless, courts have consistently found that the term has an "expansive scope," and can encompass anything of value. *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 552 (S.D.N.Y. 2018) (collecting cases); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 805-06 (S.D.N.Y. 2017) *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018); *United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 756 (S.D.N.Y. 2015); *U.S. v. Matthew Blair*, No. CR ELH-19-00410, 2021 WL 4339132, at *15-*16 (D. Md. Sept. 23, 2021). This interpretation accords with the plain meaning of remuneration, and with the purpose of the 1977 amendment that altered the scope of the AKS by adding "remuneration." *Pfizer Inc. v. United States Dep't of Health & Hum. Servs.*, No. 20-CV-4920 (MKV), 2021 WL 4523676, at *11 (S.D.N.Y. Sept. 30, 2021) *appeal filed*, No. 21-2764 (October 29, 2021) (discussing the definition of "remuneration"); *Blair*, 2021 WL 4339132,

at *15-*16 (same); *see also OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35958, 1991 WL 304395 (July 29, 1991) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever."). Before the 1977 amendment, the AKS only applied to "bribes, kickbacks, and rebates." *See* 56 Fed. Reg. 35952, 35958; *see also* Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977) (codified as amended at 42 U.S.C. §§ 1320a-7b(b)(1)(A)-(B)). The term "any remuneration" was added to ensure that, regardless of the particular type of value exchanged, the substance of an arrangement or service would be controlling rather than merely the form. *See* H.R. REP. 95-393, pt. 2, at 53, 1977 WL 16075 (1977); *see also* 56 Fed. Reg. 35952, 35958 ("The statute's legislative history . . . makes clear that the fundamental analysis required of a trier of fact is 'to recognize that the substance rather than simply the form' of a transaction should be controlling." (internal quotation omitted)); 123 Cong. Rec. 30,280 (1977) (statement of Rep. Rostenkowski, Chairman of the House Committee on Ways and Means and principal author of the 1977 amendments) ("In broadening these criminal provisions, your committee sought to make clear that kickbacks are wrong no matter how a transaction might be constructed to obscure the true purpose of a payment.").[6]

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[6] Courts have also relied on the definition of remuneration in the civil health care fraud statute to determine the scope of the term in the criminal statute. *See United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 757 n.4 (S.D.N.Y. 2015) (discussing the differences between the civil and criminal statutes and collecting cases in which courts have relied on the definition in § 1320a-7a(i)(6) in interpreting § 1320a-7b(b)). In the civil statute,

Drawing on the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers and subsequent OIG advisory opinions, McKesson argues that Hart must plead that the Margin Analyzer and Regimen Profiler had "substantial and independent value" in order to constitute remuneration under the AKS. Plaintiff counters that, even assuming without deciding that application of the higher "substantial and independent value" standard is proper here, the tools as alleged in the complaint nonetheless constitute things of "substantial and independent value."

**B. Whether the Tools Constitute Remuneration**

Accepting as true the facts in the complaint, and drawing all inferences in Plaintiff's favor, as required at this stage, *Doe v. Columbia Univ.*, 831 F.3d 46, 48 (2d Cir. 2016), Plaintiff has plausibly alleged that the Margin Analyzer and Regimen Profiler have substantial value apart from the products offered by McKesson. The "30-second Elevator Pitch" from McKesson's sales materials on the Margin Analyzer, for example, reads as follows:

> McKesson Specialty Health's Margin Analyzer is a spreadsheet-based tool that provides oncology practices with a detailed view of their current drug purchasing and reimbursement trends, serving as an important tool for successful financial

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remuneration is defined as "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6); *see also U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05-CV-5393 (RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011), *aff'd*, 734 F.3d 154 (2d Cir. 2013) ("The AKS defines remuneration as including 'transfers of items or services for free or for other than fair market value.' 42 U.S.C. § 1320a-7a(i)(6)."). Remuneration as used in the criminal statute, moreover, has a more expansive scope than the civil analog. *See Narco Freedom, Inc.*, 95 F. Supp. 3d at 756-57.

> management. The analysis provides insight to specific cost, reimbursement and utilization by drug code, as well as trending by quarter to aid in budget forecasting — all of which helps provide a better understanding of which drug choices make the most financial sense for a practice. The Account Executive, in collaboration with a Clinical Specialist when requested, reviews the customized data with practices on a quarterly basis, allowing for regular touch-points with decision makers and an opportunity to introduce additional products and services that can help further enhance a practice's vitality.

Margin Analyzer Sales Sheet at 1. Hart has alleged that these tools were central to McKesson's sales pitches to new customers, and that at least a dozen oncology practices "signed purchase commitments with McKesson and informed McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their decision to commit to buying specialty drugs from McKesson." Am. Compl. ¶ 71.

In response, McKesson makes several arguments: that the tools lacked substantial value because the underlying data was available for free; that the tools did not have value because they provided only potential cost-savings; and that the tools were not independent of McKesson's product offerings, and thus had no value to non-McKesson customers. These arguments are unavailing at this stage.

First, McKesson contends that the underlying information was available for free, and therefore, the tools did not have "value" under the AKS. This is too narrow a view of what McKesson claims to have offered to the oncology practices. The complaint does not merely

allege that McKesson provided raw data to oncology practices so that those practices could perform their own financial analyses. Rather, McKesson purportedly created the Margin Analyzer and Regimen Profiler in order to integrate data from multiple sources—McKesson's prices, reimbursement rates from multiple insurers, including Medicare, and the practices' drug usage by dose—and synthesized that data in a manner useful to its customers. In addition to creating the tools, McKesson also updated them on a quarterly basis. Perhaps the practices could have undertaken this process on their own by creating their own spreadsheets and formulas, downloading the public data on a quarterly basis, and compiling it into a readable format. But due to lack of time, resources, or expertise, customers chose to have McKesson perform these services for them. Some purportedly chose McKesson over other lower cost providers because of these services. *See id.* ¶ 64. That practices saw value in these tools is underscored by McKesson's internal assessment of the Margin Analyzer as the "the single most important, and most valuable, tool for McKesson to win new business and maintain its existing customers." *Id.* ¶ 107.

Moreover, McKesson offered more than the data itself; it allegedly instructed its employees to identify key areas of improvement for the practices, and its employees met with practices on a quarterly basis to discuss their findings. It is no accident that McKesson wanted practices to view McKesson as a "'consultant' that can help them increase profit," *id.* ¶ 64, because Hart alleges the BDEs and Account Executives were, in essence, performing consulting work "for which a physician practice might otherwise pay a practice-management consultant," *id.* ¶ 101. In sum, the overall

value of the tools and consultations was greater than the value of the underlying data itself.

Second, the Margin Analyzer, Regimen Profiler, and connected services offered more than speculative cost-savings; as alleged, the tools themselves had value. One division of McKesson provided the Margin Analyzer and Regimen Profiler in a package of business-management tools in exchange for a percentage of a practice's overall revenue. *Id.* ¶ 105. That those same tools were offered for free to commitment program customers gives rise to a plausible inference that the tools had value. Furthermore, McKesson is alleged to have stated, in internal communications, that there were customers who stayed with McKesson, over lower cost providers, because if they left they would lose access to the Margin Analyzer. *Id.* ¶ 64.[7] McKesson purportedly created a promotional video using testimonials by customers who emphasized that the tools enhanced the financial success of their practices. *Id.* ¶ 109. Although the Court agrees that the monetary value of the tools cannot be measured by the amount of cost-savings they offered customers, the complaint contains sufficient allegations to support an inference that the tools themselves had inherent value.

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[7] At oral argument, Defendants argued that the Court should not conflate McKesson's "internal exhortations," of the tools' value with their actual value, but that distinction is unavailing. Oral Argument Tr. at 11-12. The "value" ascribed to the tools by McKesson internally is of course not dispositive of whether a tool has "value" under the AKS. But, the allegation that employees were required to emphasize these tools to potential customers may nonetheless support a plausible inference that the tools had value, as it does here. At the pleading stage, where the Court must draw all inferences in Plaintiff's favor, these allegations provide support for Plaintiff's overall contention that the tools were "something of value."

Finally, although a somewhat closer question, Plaintiff has plausibly alleged that the tools were "independent" of the products sold by McKesson. McKesson contends that where the use of a service is "'tied to the product purchased," there is no independent value. Defs.' Mem. at 19 (quoting *U.S. ex rel. Forney v. Medtronic, Inc.*, No. CV 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) ("*Forney*")). The critical distinction, however, is not whether the service is merely connected with, or "tied to," the product, but rather whether the service is "part of" the product itself, such that it cannot be considered to be something of value in its own right. In an advisory opinion, OIG explained this distinction as follows:

> Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. Therefore, standing alone, these services have no substantial independent value and do not implicate the Federal anti-kickback statute.

OIG Advisory Opinion No. No. 00-10, 2000 WL 35747420, at *4. In that opinion, OIG went on to explain that even services that are integral to the products, such as pre-qualification of patients for coverage and reimbursement, can still implicate the AKS if combined with other services that "conferred an independent benefit." *Id.* ("For example, coupling a reimbursement support service with a program either requiring payment for ordered products only if the referring provider is paid or guaranteeing a minimum

'spread' between the purchase price and third-party reimbursement levels would implicate the anti-kickback statute."). Under this framework, a computer that can only print lab results would not constitute remuneration because it is "part of" the product itself, whereas an ordinary personal computer could constitute remuneration. *See* 56 Fed. Reg. 35952, 35978; *see also* OIG Advisory Opinion No. No. 10-04, 2010 WL 1937992, at *3.

Although it is true that the tools enhanced customers' experiences in purchasing drugs from McKesson and McKesson used these tools as part of its business relationship with its customers, it is not the case that these tools would have been "virtually meaningless" to customers who did not purchase drugs from McKesson. In fact, that contention is contradicted by the allegation in the complaint, which the Court accepts as true, that at least one practice requested continued access to the tools after ending its commitment program. *See* Am. Compl. at 70. While the tools may have had more utility to customers who were part of the commitment programs and were able to benefit from McKesson's quarterly updates and consultations, it is plausible that these tools had value to oncology practices regardless of whether they were active McKesson customers.

The business-management tools and quarterly consultations are also distinguishable from the types of typical product support services OIG describes in its 2003 Guidance. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735, 2003 WL 2010428 (May 5, 2003) (describing product support services as "billing assistance tailored to the purchased products, reimbursement consultation, and other programs

specifically tied to support of the purchased product") ("2003 OIG Guidance"). These tools are not analogous to, for example, software that aids physicians in reordering and accessing records of their patients' prescription medication, *see* OIG Adv. Op. No. 12-19, 2012 WL 7148095, at *6-*8, or general product support, *see United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 724 (N.D. Ill. 2020) ("*Suarez II*") (discussing scope of permissible product support). Instead, they are data-driven tools that customers used, with the help of McKesson representatives, to make financially optimal purchasing choices. If the tools in question had an intrinsic connection to the drug purchases, or would be of no use to oncology practices that did not buy drugs from McKesson, that might dictate a different result. As pled, however, these additional services are not so related to McKesson's drug offerings that they can be said to be integral to the products themselves or without "independent value."

An examination of the facts in the *Forney v. Medtronic* case, on which Defendants rely, is instructive. *See* 2017 WL 2653568. There, the products at issue were heart implants, and Medtronic offered services such as "free surgical support, implant device follow-up" and "free staff [at] clinics" to check the status of the implanted devices. *Id.* at 2. According to the complaint in that case, Medtronic even sought to hire staff that could "scrub in on surgical procedures," in order to "represent Medtronic during surgeries" and provide technical assistance. *Id.* Free staff who check the status of heart implants is of no value to a physician who has not purchased any heart implants. A spreadsheet that helps oncology practices track which drugs will generate the greatest profits, on the

other hand, is not so integral to the product itself and thus not akin to the various support services at issue in *Forney*.

For these reasons, even using the "substantial and independent value" standard urged by Defendants, the complaint still contains sufficient facts to establish that the Margin Analyzer and Regimen Profiler constitute remuneration.

### C. Judicial Notice of the Purportedly Similar Tools

Finally, McKesson's attempt to call into question the value of the tools by comparison to similar tools published by other entities, is, at this stage, inappropriate. McKesson seeks to have the Court take judicial notice of tools offered by national associations such as the American Society of Clinical Oncology, other pharmaceutical distributors like Cardinal Health, and online health care entities such as NantHealth or Via Oncology. McKesson alleges that each of these entities offered tools that provided the same services as the Margin Analyzer and Regimen Profiler. According to McKesson, "if the physician office can get the business analytical tools for free off the Internet, or easily from other distributors, then [the business-management tools] cannot provide substantial value." Defs.' Mem. At 18; *see also* Oral Argument Tr. at 10.

Federal Rule of Evidence 201 permits a court to take judicial notice of a fact that "is generally known within the trial court's territorial jurisdiction; or can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). "Because the effect of judicial notice is to deprive a party of the opportunity to use rebuttal evidence, cross-examination, and argument to attack contrary evidence, caution must be used in

determining that a fact is beyond controversy under Rule 201(b)." *Finn v. Barney*, 471 F. App'x 30, 32 (2d Cir. 2012) (quoting *Int'l Star Class Yacht Racing Ass'n v. Tommy Hilfiger U.S.A., Inc.*, 146 F.3d 66, 70 (2d Cir. 1998)).

Courts may take notice of public information in adjudicating a motion to dismiss without converting that motion to a summary judgment motion. *See Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 426 (2d Cir. 2008). McKesson, however, is not seeking for the Court to take notice of an incontrovertible fact, but rather, for it to evaluate a plethora of other "business analytical tools" and determine that those tools are substantially the same as the tools offered by McKesson. That is well beyond the sort of straightforward information of which courts routinely take judicial notice. *See*, *e.g.*, *United States v. Michael*, 664 F. App'x 32, 36 (2d Cir. 2016) (holding that the district court did not abuse its discretion in taking judicial notice of the relationship between Eastern Standard Time and Coordinated Universal Time); *Finn*, 471 F. App'x at 32; *United States v. Kelly*, 368 F. App'x 194, 199 (2d Cir. 2010) (taking judicial notice of a guilty plea); *see also* Advisory Committee Notes to 1972 Proposed Rules, Fed. R. Evid. 201(b) ("With respect to judicial notice of adjudicative facts, the tradition has been one of caution in requiring that the matter be beyond reasonable controversy."). While McKesson cites several cases in support of its argument, those cases, involving straightforward factual information, stand in stark contrast to the judicial notice it seeks here. *See Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1092 (2d Cir. 1995) (taking judicial notice of guilty pleas); *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 179 (S.D.N.Y. 2006) (taking judicial notice of statements made on Plaintiff's website);

*Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015) (taking judicial notice of documents sourced from government websites, electronic databases, and information on the company's website that was "capable of accurate and ready determination"). McKesson's remaining cases are distinguishable because they involve notice of the mere fact that public information existed, without relying on the substance of the underlying information. *See New Jersey Carpenters Health Fund v. Royal Bank of Scotland Grp., PLC*, 709 F.3d 109, 127 n.11 (2d Cir. 2013) (stating that courts may take judicial notice of "the *fact* that press coverage contained . . . certain information so long as they do not rely on the truth of that information"); *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (The court did "not take judicial notice of the documents for the truth of the matters asserted in them, but rather to establish that the matters [had] been publicly asserted.").

Here, McKesson is not merely asking for the Court to take judicial notice that other tools existed. Rather, McKesson's request that the Court take notice of these "obvious comparators," requires a fact-based comparison of those tools to the Margin Analyzer and Regimen Profiler. Such an inquiry is not within the Court's purview, especially not on a motion to dismiss. *See Kelly-Brown v. Winfrey*, 717 F.3d 295, 313 (2d Cir. 2013) ("Our role in considering a motion to dismiss is not to resolve these sorts of factual disputes.").

The Second Circuit has cautioned that "the more critical an issue is to the ultimate disposition of the case, the less appropriate judicial notice becomes." *Pina v. Henderson*, 752 F.2d 47, 50 (2d Cir. 1985). That warning is apt here, where McKesson seeks a determination that the offering of similar tools for free

demonstrates that McKesson's tools did not have any value. McKesson may ultimately prevail by using these comparator tools to demonstrate that equivalent tools were offered for free, but the Court declines to conclude as much now by taking judicial notice of a disputed fact—that the comparators are not only similar but obviously so—on a motion to dismiss.

Accordingly, Hart's complaint adequately alleges that the tools constituted remuneration.

## II. Hart Has Failed to Plausibly Allege that McKesson Acted with the Requisite Scienter

The AKS prohibits a person from "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Hart is not only required to plead that McKesson offered these tools to its customers, but that it did so with a culpable mental state.

### A. The Scienter Requirement of the AKS

There is no dispute that any violation of the FCA must be done knowingly, but where an FCA claim is based on a violation of the AKS, the AKS scienter requirement must also be satisfied. The parties disagree as to what mental state is required to allege a "willful" violation. Plaintiff argues he must plead only "that the defendant willfully committed an act that violated the Anti-Kickback Statute." Pl.'s Mem at 18 (quoting *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013)). McKesson, however, asserts that willfulness requires McKesson to have acted "with an intent to do something unlawful." Defs.' Reply at 9.

Willful is a "word of many meanings," and its construction is influenced by the context in which it is used. *Ratzlaf v. United States*, 510 U.S. 135, 141, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994). The Supreme Court has distinguished, for example, a "willful violation of the tax laws," which requires a finding that the defendant was aware of a specific provision of the tax code he was charged with violating, from the "traditional rule" that willfulness requires only "knowledge that the conduct is unlawful." *See Bryan v. United States*, 524 U.S. 184, 194-96, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998). In the context of the AKS, "courts have observed that 'interpreting the mens rea requirement of the Anti-Kickback Statute has yielded different results.'" *Bilotta*, 50 F. Supp. 3d 497, 514 n.6 (S.D.N.Y. 2014) (quoting *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 678 n.18 (W.D. Pa. Aug. 21, 2014)). The Second Circuit was presented with an opportunity to evaluate the meaning of willfulness in the AKS in 2002, when a defendant questioned on appeal whether in a "prosecution for a violation of the Medicare anti-kickback statute, the Government is required to prove that the defendant knew of and intended to violate that specific statute." *United States v. Mittal*, 36 F. App'x 20, 21 (2d Cir. 2002). In *Mittal*, the district court had instructed the jury that

> 'Willfully' means to act with knowledge that one's conduct is unlawful and with the intent to do something that the law forbids, that is to say with the bad purpose to disobey or to disregard the law. To find that the defendant acted willfully, you must find that he knew what he was doing was illegal, although he need not have known the specific statute he may have been violating. The defendant's conduct was not willful if it was due to negligence, inadvertence, or mistake.

*Id.* at 21. Rather than resolve the "lack of unanimity among the other Circuits" on whether the district court's instruction was proper, or whether willfulness in this context required a specific intent to violate the AKS, the Second Circuit found that any error in the instruction was harmless because the defendant's actual knowledge of the AKS had been established at trial. *Id.* at 21-22.

The circuit split referenced by the court in *Mittal* was resolved in 2010 by the Patient Protection and Affordable Care Act (PPACA), which added the following language to the AKS:

> Actual knowledge or specific intent not required: with respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

42 U.S.C. § 1320a-7b(h). Following this amendment, most courts have understood the term willfully, as used in the AKS, as following the "traditional rule" that "knowledge that the conduct is unlawful is all that is required." *See Bryan*, 524 U.S. at 196, 118 S.Ct. 1939. Although neither party has cited Second Circuit authority squarely addressing the scope of the willfulness requirement after the 2010 amendment, at least one court in the Eastern District has expressly adopted this definition. *United States v. Novartis AG*, No. 04-CV-4265 (NGG) (RLM), 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011) (holding that in order to "meet the AKS's 'willfulness' requirement" the defendant must have "act[ed] with the intent to do something that the law forbids."). Application of the so-called "traditional rule" also accords with *Mittal*. *See* 36 F. App'x at 21. The majority of circuit courts to have addressed this issue, both before and after the 2010 amendment, have similarly recognized that the

term "willfully" requires knowledge that the relevant conduct is unlawful. *See United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989); *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015); *United States v. Nagelvoort*, 856 F.3d 1117, 1126 (7th Cir. 2017) *cert. denied* —— U.S. ——, 138 S.Ct. 556, 199 L.Ed.2d 436 ("[Defendants] contend that the evidence presented at trial was insufficient to prove that they knowingly or willfully violated the Anti-Kickback Statute when they entered into the arrangements at issue. Again, however, there was sufficient evidence from which the jury could have concluded that both appellants knew the contracts were illegal."); *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996) ("In the Medicare anti-kickback statute, the word "willfully" modifies a series of prohibited acts. Both the plain language of that statute, and respect for the traditional principle that ignorance of the law is no defense, suggest that a heightened *mens rea* standard should only require proof that Dr. Jain knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"); *United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015) ("In order to find that a person acted willfully in violation of § 1320a-7b, the person must have acted voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law. However, the defendant need not have known that a specific referral arrangement violated the law."). While these decisions are not binding, the Court is persuaded that willfulness in the AKS requires a defendant to have acted with knowledge that its conduct was unlawful.

This holding is further supported by the legislative history of the 2010 amendment, which indicates that

its purpose was to clarify that actual knowledge of the statute was *not* required, and that willfulness in this context only required the defendant to know its conduct was unlawful. *See* 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (statement of Rep. Kaufman discussing predecessor bill to PPACA, the Health Care Enforcement Act of 2009) ("The Ninth Circuit Court of Appeals has read the term to require proof that the defendant not only intended to engage in unlawful conduct, but also knew of the particular law in question and intended to violate that particular law. This heightened mental state requirement may be appropriate for criminal violations of hyper-technical regulations, but it is inappropriate for these crimes, which punish simple fraud."); *see also United States v. Shvets*, 631 F. App'x 91, 95-96 (3d Cir. 2015) *cert. denied* 578 U.S. 911, 136 S. Ct. 1526, 194 L.Ed.2d 613 (2016) (discussing legislative history in the context of the health care fraud statute). In sum, the complaint must at least give rise to a plausible inference that McKesson knew its conduct was unlawful, but Hart need not allege actual knowledge of the AKS or specific intent to violate it.

Hart argues for an even lower standard, based on the Fifth Circuit's holding in *United States v. St. Junius*—that "willfulness" requires only that the conduct was not negligent or accidental. 739 F.3d at 210; Pl.'s Opp at 18 ("[T]he statute's intent element distinguishes negligent or accidental conduct, which is innocent, from willful conduct, which is culpable."). In *St. Junius*, the Fifth Circuit held that the "the Government must prove that the defendant willfully committed an act that violated the Anti-Kickback Statute." *St. Junius*, 739 F.3d at 210. In so doing, it distinguished its holding from the heightened

standard articulated by the Ninth Circuit in *United States v. Dearing*, 504 F.3d 897 (9th Cir. 2007):

> *Dearing* holds that the willfulness component of 18 U.S.C. § 1347 (which is not the Anti-Kickback Statute, but rather, a general health care fraud statute) requires that the government prove that the defendant acted with knowledge that her conduct was unlawful. *Dearing*, however, was decided prior to a statutory amendment that clarified Congress' intent with respect to the willfulness element of § 1347. Section 1347 was amended in 2010 as was 42 U.S.C. § 1320a-7b, the Anti-Kickback Statute. The § 1347 amendment adds language that mirrors the 2010 amendment to the Anti-Kickback Statute found in § 1320a-7b(h). Section 1320a-7b(h) made clear that the government need not prove that the defendant had "actual knowledge of the statute or a specific intent to violate the statute." In light of the amendment, *Dearing* is unpersuasive on this issue.

*St. Junius*, 739 F.3d at 210 n.19. Subsequent Fifth Circuit cases, however, have applied the traditional rule in the AKS context, which calls into question how *St. Junius* fits into the Fifth Circuit's "willfulness" jurisprudence. *See United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021) ("Although the precise meaning of the term "willfully" can vary depending on the context . . . this court has held that the general understanding of the term applies to its use in the general health care fraud statute and the health care anti-kickback statute."); *see also United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) ("Under this definition of willfulness, 'knowledge that the conduct is unlawful is all that is required.'"). And, at least one court has drawn the distinction proposed by Plaintiff's

counsel at oral argument, that the level of intent required depends on whether the charge is a criminal AKS violation or a civil FCA violation based on an AKS as violation. *See* Oral Argument Tr. at 28, *see United States v. Marlin Med. Sols. LLC*, No. SA-5:21-CV-00160 (OLG), 579 F.Supp.3d 876, 884-85, 885 n.2 (W.D. Tex. Jan. 12, 2022). There is some support in the Fifth Circuit for Plaintiff's reading of *St. Junius*, *see United States v. Waller*, No. CR H-14-171-11, 2017 WL 2559092, at *6 (S.D. Tex. June 13, 2017), *aff'd*, 741 F. App'x 267 (5th Cir. 2018), but at least one court has cited *St. Junius* while still applying the traditional rule in the AKS context, *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 656 (N.D. Tex. 2020) ("To act 'willfully' is to act 'with the specific intent to do something the law forbids' . . . However, 'a person need not have actual knowledge of' the AKS 'or specific intent to commit a violation of' the AKS." (first quoting *United States v. Gibson*, 875 F.3d 179, 188 (5th Cir. 2017) and then quoting 42 U.S.C. § 1320a-7b(h) and citing *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013))).

Even if the Court accepts Plaintiff's reading of *St. Junius*, the decision is not binding here, and the Court is not persuaded the holding is mandated by the 2010 amendment. Indeed, the more persuasive view is that of the numerous circuit courts which have continued to follow the traditional rule after the 2010 amendment. *See supra* pp. 24-25. Moreover, several courts have applied the traditional definition after the 2010 amendment in civil cases where an AKS violation is a predicate for an FCA claim. *United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1113 (N.D. Ill. 2018) ("Defendants also insist that relator has not pled the scienter required for an AKS violation. The statute's willfulness requirement

indeed means that relator must allege that defendants had at least some 'bad purpose . . . to do something that the law forbids.'" (alteration in original)); *see also United States v. Teva Pharms. USA, Inc.*, 560 F.Supp.3d 412, 421-22 (D. Mass. 2021); *United States ex rel. Ani Gharibian et al. v. Valley Campus Pharmacy, Inc.*, No. 2:16-CV-4777 (MCS) (PLA), 2021 WL 4816648, at *13 (C.D. Cal. June 23, 2021) ("[T]o establish willfulness, the [relator] must prove that defendants knew their conduct was unlawful." (alteration in original)); *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. CV 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); *United States ex rel. Scarlett Lutz et al. v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498, 510-11 (D.S.C. 2016); *see also United States v. Mathur*, No. 2:11-CR-00312 (MMD), 2012 WL 4742833, at *5 (D. Nev. Sept. 13, 2012), report and recommendation adopted, 2012 WL 4711960 (D. Nev. Oct. 3, 2012) (discussing effect of 2010 amendment on circuit split).

Accordingly, to satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful, although he need not allege it acted with specific knowledge of the AKS.

**B. Hart's Allegations Regarding McKesson's Scienter**

As noted above, unlike the "circumstances constituting fraud," which must be pled with particularity, Rule 9(b) only requires that intent or knowledge be "alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, the complaint must contain some factual allegations from which the Court can infer Defendants acted with the knowledge that their conduct was unlawful. *See United States ex rel. Suarez v. AbbVie Inc.*, No. 15-CV-

8928, 2019 WL 4749967, at *13-*14 (N.D. Ill. Sept. 30, 2019) ("*Suarez I*"); *see also Forney*, 2017 WL 2653568, at *4-*5. Any such allegations are lacking here.

Hart has alleged that McKesson's contracts, code of conduct, and SEC filings indicated an awareness of the requirements of the AKS and the general unlawfulness of inducements. Am. Compl. ¶¶ 111-12. McKesson's internal policies, for example, prohibited employees from providing of "things of value" to induce purchases of items that would ultimately be reimbursed by government sponsored health care providers. *Id.* Hart has also alleged facts to support the conclusion that the tools may constitute "remuneration" under the broad language of the AKS. *See supra* Section I.B. Allegations that McKesson knew remuneration to induce purchases was prohibited in general, however, cannot alone support a finding that McKesson knew this particular course of conduct was unlawful. In other words, absent from his complaint are any allegations from which the Court can plausibly infer that McKesson knew providing these tools to commitment program customers was unlawful. Without such allegations, Hart fails to state a claim.

The complaint here lacks allegations of the type that courts have found to support an inference of scienter, such as actions taken to conceal the fraudulent scheme, *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. CV 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); notice from counsel that the program may be unlawful, *United States v. Teva Pharms.*, 560 F.Supp.3d at 421-22; *United States v. Millennium Radiology, Inc.*, No. 1:11-CV-825, 2014 WL 4908275, at *8 (S.D. Ohio Sept. 30, 2014); *United States ex rel. Banigan v. Organon USA Inc.*, No. CV 07-12153 (RWZ), 2016 WL 10704126, at *3 (D. Mass. Aug. 23,

2016) (internal document characterizing relationship as a "quid pro quo" was sufficient to establish dispute as to scienter at summary judgment stage); cancellation of the program due to concerns over its lawfulness, *Wood*, 246 F. Supp. 3d at 829; or a service without legitimate value that was a pretext to provide remuneration, *United States v. TEVA Pharms. USA, Inc.*, No. 13-CV-3702 (CM), 2016 WL 750720, at *28 (S.D.N.Y. Feb. 22, 2016) (describing company-sponsored speaker programs as "shams"). According to Plaintiff's own allegations, it appears the program was openly advertised and widely discussed both within the company and among its customers. *See Novartis*, 2011 WL 13234720, at *9 ("Plaintiffs do not allege any facts, circumstantial or otherwise, that Novartis believed, or acted in a way suggesting it believed, that its marketing . . . was illegal. Rather, and in contrast to other cases where the courts have found sufficiently pleaded AKS claims, Plaintiffs' amended complaint suggests Novartis allegedly paid kickbacks to physicians quite openly."). Hart's complaint is lacking even general allegations which suggest that McKesson knew that offering the tools to commitment program customers was unlawful—indeed, his description of McKesson's conduct arguably suggests the opposite. *United States v. Valley Campus Pharmacy, Inc.*, No. 2:16-CV-04777 (MCS) (PLA), 2021 WL 5406148, at *3 (C.D. Cal. Oct. 12, 2021) *appeal filed* No. 21-56253 (Nov 16, 2021) ("Relator never alleges, even generally, that Defendants knew that their offer of free PA services was unlawful. In fact, Relator's allegations seem to indicate that Defendants thought their offering of PA services was lawful, as they advertised these services openly on their website and in a presentation in Las Vegas.").

In sum, identifying a policy that plausibly violates the AKS and alleging that a defendant had a general

awareness of the laws regulating the pharmaceutical industry is not enough to establish scienter. There must be facts from which the Court can infer that Defendants knew the conduct was unlawful and proceeded with the business practice regardless. *See Forney*, 2017 WL 2653568, at *4-*5 ("[Relator alleged] that the effect of the scheme was to induce physicians to refer Medtronic's products to their patients, [but had] not alleged that its subjective purpose was to do so."). Hart's complaint lacks any such non-conclusory allegations as to scienter, and accordingly, his claims must be dismissed.

## III. Had Hart Alleged Scienter, His Complaint Would Have Sufficed to Allege the Submission of False Claims

The Second Circuit has held that alleging "fraud under the FCA [requires] two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." *Chorches*, 865 F.3d at 83 (quoting *Hagerty ex rel. U.S. v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016)). McKesson argues that the complaint is deficient because it neither "identif[ies] a single false claim, nor does it allege facts that allow the court to 'adduce specific facts supporting a strong inference of fraud.'" Defs.' Mem. at 22 (quoting *Chorches*, 865 F.3d at 82). Due to the absence of facts supporting an inference of scienter, Hart has failed to plausibly allege a fraud, although his complaint does contain allegations sufficient to support an inference that claims were ultimately submitted to the government.

To allege that claims were submitted to the government, a plaintiff does not need to possess "specific identified false invoices." *Chorches*, 865 F.3d at 86. Instead, "a complaint can satisfy Rule 9(b)'s

particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Id.* at 86; *see also United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 248 (2d Cir. 2019).

Although the bills and invoices here were not "peculiarly within the knowledge" of the Defendants, as they were in *Chorches*, they were outside of Hart's purview nonetheless. In his capacity as a BDE, Hart cannot be expected to have had access to the oncology practices' bills or other evidence related to the actual submission of claims. Hart instead relies on the records available to him—in particular, the Margin Analyzer reports provided to Summit Cancer Care over several quarters (Q2 2012, Q4 2012, Q1 2013)—and his allegations support a plausible inference that McKesson knew its customers were routinely submitting claims to Medicare and other federal health care programs. The data reported in Summer Cancer Care's Margin Analyzer spreadsheets demonstrates that many of the submissions for reimbursement were made to Medicare. *See* Q4 2012 SCC Margin Analyzer; Q1 2013 SCC Margin Analyzer. That its employees regularly updated the tools with the newest CMS schedules also supports an inference that McKesson knew its customers were likely to submit claims to Medicare, as those schedules are primarily relevant to Medicare beneficiaries. Moreover, the primary utility of the Margin Analyzer and Regimen Profiler was the ability to highlight cost-savings based on comparison of acquisition costs to reimbursement rates of various insurers, including Medicare. These allegations support a "strong inference" that the practices named

in the complaint which were provided the Margin Analyzer and Regimen Profiler actually submitted claims for reimbursement to federal health care programs.

Defendants argue that Hart's complaint contains less substantive allegations as to the submission of these claims than a complaint the Second Circuit recently held was insufficient in *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244 (2d Cir. 2019). In *Gelbman*, the Second Circuit found that the plaintiff in an FCA case had failed to plausibly allege any invoices were uniquely in the defendants' control, and also failed to plead facts that gave rise to a strong inference of fraud. *Id.* at 248. While that case is instructive, the facts are distinguishable. The relator in *Gelbman* was an "Information Specialist," who purportedly learned of the fraud when performing work on "Medicaid management and fraud detection." *Id.* at 246. Given that role, the Circuit concluded that he would have had access to more detailed records than those referenced in the complaint. Here, by contrast, Hart would not be expected to have access to any purchase records in his role as BDE. Moreover, the complaint in *Gelbman* left the court to "speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government of more than $14 billion over the course of six years." *Id.* at 249. In particular, the Circuit criticized the lack of detail around how the fraud was carried out:

> Gelbman alleges in a conclusory fashion that his superiors at NYSDOH "conspired" with an unknown number of unidentified "HRA representatives" to "manipulate and rig" eMedNY. Gelbman does not detail how eMedNY was rigged (*e.g.*, by altering eMedNY's computer algorithms, or by making post-hoc adjustments to eMedNY payment

> determinations), or who carried out the rigging (*e.g.*, NYSDOH employees, City employees, or some unknown third party).

*Id.* at 248-49. While Hart has failed to allege McKesson acted willfully, his complaint does not leave doubt as to the nature or scope of the conduct at issue. In sum, Hart's complaint is adequate to support an inference that claims were submitted by the practices in the Southeast which Hart identified as having received the Margin Analyzer and Regimen Profiler.

Finally, McKesson argues that even if the detailed allegations regarding Summit Cancer Care support a claim as to that practice, Hart has not adequately alleged that claims were submitted by practices nationwide. Defs.' Reply at 7 ("From that one assertion, and from that one customer, Relator asks the Court to fill in the details on not only the claims submitted by Summit, none of which is identified, but for all other unidentified customers around the country."). In light of the Court's dismissal of this action, and grant of leave to amend, *see infra* Section IV, as well as the representations by Plaintiff's counsel that Hart now has additional information regarding McKesson's conduct nationwide, *see* Oral Argument Tr. at 25-26, the Court will refrain from evaluating the sufficiency of the allegations as to the nationwide scheme at this time.

**IV. Hart is Granted Leave to Amend**

Although Plaintiff has not explicitly sought leave to amend, the Court nonetheless grants Plaintiff leave to file a second amended complaint to address the inadequacies discussed here, provided he has a good faith basis to do so. *See Khodeir v. Sayyed*, 323 F.R.D. 193, 197 (S.D.N.Y. 2017). Rule 15 states that "the court should freely give leave [to amend a complaint]

when justice so requires." Fed. R. Civ. P. 15(a)(2). The Second Circuit has emphasized that this is a "permissive" standard, and that leave to amend should be liberally granted, consistent with the Circuit's "strong preference for resolving disputes on the merits." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015). "Ordinarily, a plaintiff should be granted leave to amend at least once after having the benefit of a court's reasoning in dismissing the complaint." *Obra Pia Ltd. v. Seagrape Inv'rs LLC*, 19-CV-7840 (RA), 2021 WL 1978545, at *3 (S.D.N.Y. May 18, 2021). This is especially true on the Court's first ruling on a motion to dismiss. *Loreley*, 797 F.3d at 190 ("Without the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies."); *see also Cresci v. Mohawk Valley Cmty. Coll.*, 693 F. App'x 21, 25 (2d Cir. 2017) ("The proper time for a plaintiff to move to amend the complaint is when the plaintiff learns from the District Court in what respect the complaint is deficient. Before learning from the court what are its deficiencies, the plaintiff cannot know whether he is capable of amending the complaint efficaciously."). With the benefit of the Court's reasoning, as well as the numerous arguments raised by Defendants' motion to dismiss, Plaintiff may be able to cure the deficiencies in his complaint.[8]

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[8] Defendants included a footnote in their memorandum of law in support of the motion to dismiss stating that Hart's allegations "raise significant commercial speech defenses." Defs.' Mem. at 1 n.1. "Because the arguments appear only in footnotes, they are not properly raised, and the Court is under no obligation to consider them." *See Weslowski v. Zugibe*, 96 F. Supp. 3d 308, 314 (S.D.N.Y. 2015), *aff'd*, 626 F. App'x 20 (2d Cir. 2015) (collecting cases). If Plaintiff amends his complaint, Defendants may raise this issue in full in a subsequent motion if they choose to do so.

## CONCLUSION

For the reasons stated above, the motion to dismiss is granted, albeit with leave to amend. If he chooses to do so, Plaintiff may file a second amended complaint no later than June 7, 2022.

SO ORDERED.

## STATUTORY PROVISIONS INVOLVED

1. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), provides:

### § 1320a-7b. Criminal penalties for acts involving Federal health care programs

* * *

**(b) Illegal remunerations**

**(1)** Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

**(A)** in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

**(B)** in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering 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 and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

**(2)** 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—

**(A)** to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

**(B)** to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering 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 and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

**(3)** Paragraphs (1) and (2) shall not apply to—

**(A)** a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

**(B)** any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

**(C)** any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

**(i)** the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

**(ii)** in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount

received from each such vendor with respect to purchases made by or on behalf of the entity;

**(D)** a waiver of any coinsurance under part B of subchapter XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. 201 et seq.];

**(E)** any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) of this title;

**(F)** any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

**(G)** the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII, if the conditions described in clauses (i) through (iii) of section 1320a-7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114(a)(3) of this title), section 1320a-7a(i)(6)(A) of this title shall

be applied without regard to clauses (ii) and (iii) of that section);

**(H)** any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23(a)(4) of this title;

**(I)** any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(*l*)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity;

**(J)** a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title;

**(K)** an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1395jjj of this title, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish; and

**(L)** a bona fide mental health or behavioral health improvement or maintenance program, if—

**(i)** such program—

**(I)** consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

**(II)** is made available to a physician or other clinician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician or other clinician;

**(III)** is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial changes to the operation of such program), that includes—

**(aa)** a description of the content and duration of the program;

**(bb)** a description of the evidence-based support for the design of the program;

**(cc)** the estimated cost of the program;

**(dd)** the personnel (including the qualifications of such personnel) implementing the program; and

**(ee)** the method by which such entity will evaluate the use and success of the program;

**(IV)** is offered by an entity described in clause (ii) with a formal medical staff to all physicians and other clinicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

**(V)** is offered to all such physicians and clinicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician or clinician for such entity;

**(VI)** is evidence-based and conducted by a qualified health professional; and

**(VII)** meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

**(ii)** such entity is—

**(I)** a hospital;

**(II)** an ambulatory surgical center;

**(III)** a community health center;

**(IV)** a rural emergency hospital;

**(V)** a skilled nursing facility; or

**(VI)** any similar entity, as determined by the Secretary; and

**(iii)** neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician or other clinician to such entity or the amount or value of other business generated by such physician for the entity.

**(4)** Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

* * *

2. The False Claims Act, 31 U.S.C. § 3729, provides:

**§ 3729. False claims**

**(a) Liability for Certain Acts.—**

**(1) In general.**—Subject to paragraph (2), any person who—

**(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

**(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

**(C)** conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

**(D)** has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

**(E)** is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

**(F)** knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

**(G)** knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an

obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

**(2) Reduced damages.**—If the court finds that—

**(A)** the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

**(B)** such person fully cooperated with any Government investigation of such violation; and

**(C)** at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

**(3) Costs of civil actions.**—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

**(b) Definitions.**—For purposes of this section—

**(1)** the terms "knowing" and "knowingly"—

**(A)** mean that a person, with respect to information—

**(i)** has actual knowledge of the information;

**(ii)** acts in deliberate ignorance of the truth or falsity of the information; or

**(iii)** acts in reckless disregard of the truth or falsity of the information; and

**(B)** require no proof of specific intent to defraud;

**(2)** the term "claim"—

**(A)** means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

**(i)** is presented to an officer, employee, or agent of the United States; or

**(ii)** is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

**(I)** provides or has provided any portion of the money or property requested or demanded; or

**(II)** will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

**(B)** does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no

restrictions on that individual's use of the money or property;

**(3)** the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

**(4)** the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

**(c) Exemption From Disclosure.**—Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

**(d) Exclusion.**—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

* * *

3. The False Claims Act, 31 U.S.C. § 3730, provides:

**§ 3730. Civil actions for false claims**

**(a) Responsibilities of the Attorney General.**—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

**(b) Actions by Private Persons.**—**(1)** A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

**(2)** A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

**(3)** The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

**(4)** Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

**(A)** proceed with the action, in which case the action shall be conducted by the Government; or

**(B)** notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

**(5)** When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

**(c) Rights of the Parties to Qui Tam Actions.—** **(1)** If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

**(2)(A)** The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

**(B)** The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

**(C)** Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

**(i)** limiting the number of witnesses the person may call;

**(ii)** limiting the length of the testimony of such witnesses;

**(iii)** limiting the person's cross-examination of witnesses; or

**(iv)** otherwise limiting the participation by the person in the litigation.

**(D)** Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

**(3)** If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

**(4)** Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed

discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

**(5)** Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

**(d) Award to Qui Tam Plaintiff.—(1)** If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or

from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

**(2)** If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

**(3)** Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances

pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

**(4)** If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

**(e) Certain Actions Barred.—(1)** No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

**(2)(A)** No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

**(B)** For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 13103(f) of title 5.

**(3)** In no event may a person bring an action under subsection (b) which is based upon allegations or

transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

**(4)(A)** The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

**(i)** in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

**(ii)** in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

**(iii)** from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

**(B)** For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has 3 knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

**(f) Government Not Liable for Certain Expenses.** —The Government is not liable for expenses which a person incurs in bringing an action under this section.

**(g) Fees and Expenses to Prevailing Defendant.**—In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

**(h) Relief From Retaliatory Actions.—**

**(1) In general.**—Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

**(2) Relief.**—Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

**(3) Limitation on bringing civil action.—** A civil action under this subsection may not be brought more than 3 years after the date when the retaliation occurred.