United States of America ex rel. v. Janssen Biotech, Inc. Doc. 670

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER ON
CROSS-MOTIONS FOR SUMMARY JUDGMENT

SAYLOR, J.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free business consulting services to physicians in order to induce them to prescribe its infusible medications. According to relator, the free services amounted to illegal kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, ("AKS"), which in turn led to the submission of false claims for payment in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA").

Defendant Janssen Biotech, Inc., is a pharmaceutical company that manufactures and sells Remicade and Simponi ARIA, two infusible medications used to treat a variety of diseases. Relator Julie Long is a former Janssen employee.

While at Janssen, relator was an Area Business Specialist ("ABS"). Her position involved, among other things, promoting the sale of the two medications. That included providing advice or assistance concerning the establishment and operation of in-office infusion ("IOI") suites in the offices of physicians. Her territory was central Pennsylvania.

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Relator's theory of the case is not that Janssen paid rebates or other forms of financial compensation, or supplied free or discounted products, or gave free trips or meals to physicians. Rather, it is that the services provided by Janssen to physician practices concerning infusion suites effectively constituted free business consulting advice. According to relator, those services crossed the line from lawful marketing and product support to unlawful "remuneration" in violation of the AKS.

Janssen has moved for summary judgment as to multiple issues, including (1) whether there was, in fact, unlawful "remuneration" within the meaning of the AKS; (2) whether it acted "knowingly" and "willfully" within the meaning of the AKS; and (3) whether there is sufficient evidence of an FCA violation. As to the first issue, it contends, among other things, that the evidence is insufficient to establish a violation of the AKS and that the services provided were protected speech under the First Amendment. Relator has cross-moved for summary judgment as to the issue of scienter under both the AKS and the FCA.

In assessing whether the provision of services violates the AKS, courts have looked to whether those services had "substantial independent value." Here, there is no dispute that Janssen provided services to physician practices concerning the establishment and operation of infusion suites, and that those services had substantial value; rather, the central question is whether they had "independent" value—that is, whether they had value in their own right, independent of the products.

Relator spends little time attempting to demonstrate that the services had independent value because the infusion suites could be used by rheumatologists or gastroenterologists for other infusible medications. Rather, her principal contention is that the information concerning

the establishment and operation of the suites was unlawful because it constituted free business consulting advice, not medical or clinical advice in support of the products.

Relator also argues that the services constituted unlawful "remuneration" under the AKS because Janssen provided the services solely in order to boost sales of the two medications. Janssen contends that the establishment of such suites removed barriers to infusion and substantially improved patient access, which in turn substantially reduced patient attrition (individuals who receive prescriptions for infusible medications but who do not take the necessary steps to receive their infusions). It is certainly a fair inference that Janssen did not provide information to physician practices as a public service, but to increase sales. But the central question here as to the issue of "remuneration" is not whether Janssen had a profit motive—it surely did—but whether the evidence demonstrates that the services had value that was "independent" of the medications.

There are two unusual aspects to this case, which in tandem create substantial evidentiary problems for relator. The first is that relator—unlike the typical situation in a *qui tam* suit—did not herself participate in any allegedly unlawful activity, and apparently did not witness any such activity by others. Indeed, she submitted no affidavit in opposition to the motion for summary judgment. Furthermore, she submitted no affidavit from any other ABS; no other ABS was deposed; and she has submitted no affidavits or deposition testimony from any physician or practice manager. As a result, relator offers almost no direct evidence as to the events at the center of this lawsuit—the actual interactions between Janssen representatives and physician practices.

The second concerns the precise nature of the services provided by Janssen that are in dispute. The issue arises because of a significant concession made by relator in the course of the

litigation. Janssen supplied ABSs, including relator, with slide decks and other written materials to show to physicians as part of their presentations. The materials covered a variety of topics, including such topics as "Considerations for Proactive Practice Management" and "Billing and Coding for Infusion." All such written materials were approved by an internal multidisciplinary review committee at Janssen. ABSs were instructed to limit their discussions to company-approved topics when meeting with physicians.

Relator has expressly conceded—first in the course of a discovery dispute, and then again at summary judgment—that the content of those written materials, and the fact that they were presented to physician practices, did *not* constitute the provision of unlawful consulting services in violation of the AKS. In relator's view, if the ABSs had simply read those materials aloud to physicians, no AKS violation would have occurred. Rather, she contends that ABSs provided unlawful "live" services and presentations—in other words, that the ABSs said or did things when meeting with physician practices that went beyond the content of the written materials, and that violated the AKS. That raises two immediate questions: what were those "live" services, and did they materially vary from the written materials?

It is of course a reasonable inference that ABSs did not simply read the contents of the slide decks verbatim when they met with physician practices, and that at a minimum they engaged in conversations and answered questions. But, again, there is no direct evidence as to what actually was said or done in any of those meetings. In the absence of such evidence, relator instead relies on circumstantial evidence, as she is entitled to do, and reasonable inferences from that evidence. But that evidence is sparse at best, and falls far short of proving an AKS violation based on those communications.

In short, there is a large evidentiary hole at the heart of this case. And while the Court

has no trouble concluding, as an abstract matter, that the provision of free business consulting services to physicians for the purposes of inducing them to prescribe medications would violate the AKS, it is relator's responsibility at this stage to muster evidence sufficient to prove that a violation occurred. For the reasons set forth below, she has failed to do so.

The closest relator comes to establishing an AKS violation concerns a program called the Infusion Optimization Modeler, or "IOM" (and a related program called iBiz). The IOM was used to assist physician practices that were already infusing patients with Remicade and Simponi ARIA to help determine whether they could provide more infusions to more patients given their capacity constraints. One of the (concededly lawful) written presentations approved by Janssen for ABSs was called "Managing Biologics in the Physician Office." It included, among other things, general advice for physician practices concerning improving the efficiency of infusion suites and increasing the ability of the practice to perform patient infusions. The IOM went a step further, and used actual data from a practice (such as staffing and equipment) to provide advice as to whether the practice's capacity to infuse the two medications could be increased through more efficient use of resources. But relator failed to provide sufficient evidence to show that those services had "independent" value—again, value that existed independently of the two medications.

In any event, even assuming that there is sufficient evidence to find that Janssen provided at least some services to physician practices that had substantial independent value, and even assuming that it did so in order to induce physicians to purchase its products, there is a further problem with relator's case: she has not put forth sufficient evidence to show that Janssen "knowingly and willfully" violated the statute.

The AKS is both a civil and a criminal statute, and therefore the standard for a violation (although not the burden of proof) is the same in both contexts. To act "knowingly" is "to do something voluntarily, to do it deliberately, not to do something by mistake or accident or even negligently." *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989). To act "willfully" is "to do something purposely with the intent to violate the law," or "to do something the law forbids." *Id.*

There is no dispute that Janssen was very much aware of the existence of the AKS; that it had compliance policies that prohibited the offering of "consulting services that relate to the management of customers' business practices"; and that it employed individuals who were charged, among other things, with the task of ensuring compliance with the AKS and with Janssen's corporate policies. And there is likewise no dispute that the programming at issue was not the product of a rogue employee, or a single office acting without authorization, but was instead a corporate initiative that was reviewed and approved at a fairly high management level.

Relator, however, has submitted no evidence that any individual employee at the company knew or believed that the challenged services violated the law, and insufficient evidence that the corporation as a whole was flagrantly indifferent to its legal obligations.

Again, relator herself does not contend that she herself participated in any wrongdoing, and she does not contend that she personally witnessed any deliberate and intentional misconduct. And while she attempts to piece together scraps of evidence in an effort to demonstrate acts of concealment or consciousness of guilt, in fact that evidence falls far short of proof of the necessary intent.

Instead, at the end of the day, relator's argument as to willfulness largely amounts to this: (1) Janssen's compliance policies prohibited the provision of business consulting services; (2)

Janssen representatives provided business consulting services; and therefore (3) Janssen knowingly and willfully violated the law. In this context, at least, that is not enough. The AKS does not provide for strict liability, or liability based on negligence or mistake. It is certainly true that Janssen was aware that there was a line—albeit an ill-defined line—that it could not cross without violating the law. But without evidence that Janssen actually intended to cross it, or was flagrantly indifferent to that possibility, relator cannot prove that Janssen knowingly and willfully violated the AKS. And that is particularly true when relator has conceded that the written materials used by ABSs, and that are central to this case, were entirely lawful.

As a final note, the resolution of the factual and legal issues in this matter is greatly complicated by relator's approach to the evidentiary record. Rather than simply pointing to evidence that supports her position, or that contradicts or casts doubt on that of her opponent, relator has elected to bury the Court in an avalanche of exhibits that frequently do not support her contentions or are simply irrelevant. On top of that, she uses multiple cross-references to citations that are themselves irrelevant or misleading, or that involve another layer of cross-references; uses misleading quotations from a key exhibit; and substitutes conclusory or argumentative assertions for statements of fact. The Court has endeavored to sort through that record as best as it can under the circumstances, while bearing in mind that it is the duty of the parties to cite to the evidence, not the duty of the Court to ferret it out from a voluminous record. "Judges are not like pigs, hunting for truffles buried in briefs." *United States v. Dunkel*, 927 F.2d 955 (7th Cir. 1991).

Accordingly, and for the following reasons, the motion of defendant for summary judgment will be granted, and the cross-motion of relator for summary judgment will be denied.

I. Background

A. Factual Background

The following facts are undisputed unless otherwise noted.

1. The Infusible Medications

Janssen Biotech, Inc., is a pharmaceutical company that manufactures and sells Remicade and Simponi ARIA. Both are infusible biologic therapies for treatment of patients with immune-mediated inflammatory conditions. (Def.'s Statement of Undisputed Material Facts, Dkt. No. 539, ¶ 2) ("Def.'s SMF").

Remicade (the brand name for infliximab) received its initial marketing approval from the Food and Drug Administration in 1998. (*Id.* ¶ 4). It is currently approved for the treatment of moderately to severely active Crohn's disease; fistulizing Crohn's disease; rheumatoid arthritis; ankylosing spondylitis; psoriatic arthritis; moderately to severely active ulcerative colitis; and pediatric patients with moderately to severely active Crohn's disease or ulcerative colitis. (*Id.* ¶¶ 4-6).

Simponi ARIA (the brand name for golimumab) was first approved in 2013 for the treatment of moderately to severely active rheumatoid arthritis, and is now approved to treat active ankylosing spondylitis and psoriatic arthritis. (*Id.* ¶¶ 7-8).

Both Remicade and Simponi ARIA are infusible products, meaning that they are administered to patients through an intravenous infusion that takes roughly two hours (for Remicade) or 30 minutes (for Simponi ARIA) to complete. (*Id.* ¶ 9). Both products are normally prescribed by gastroenterologists or rheumatologists. Infusions may take place at a hospital; at a medical office; at a stand-alone infusion center; or at home, with appropriate medical personnel and equipment.

According to Janssen, a recurring issue with the administration of infusible medications

arises from the attrition of patients—that is, patients who have received a prescription but do not follow through as required. That includes both "pre-needle attrition" (a patient who does not receive the first infusion) and "post-needle attrition" (a patient who begins treatment but discontinues infusions or does so irregularly). (*Id.* ¶¶ 21-25; Long Dep., Ex. 17, Dkt. No. 539-17, at 150-54). As noted, Janssen contends that the establishment of infusion suites in physician offices increases patient access to infusible medications by giving them a wider and more convenient range of options.

2. The Role of the Area Business Specialists

Janssen had two separate teams of employees that focused on marketing Remicade and Simponi ARIA. (Def.'s SMF ¶ 11). One focused on prescriptions and one on issues concerning infusions. (*Id.* ¶¶ 11-13).

The first was called "Immunology Specialists" or "ISs." ISs focused on traditional detailing or marketing of the clinical benefits of the products at what Janssen called the "Site of Demand" or "SOD," the location at which a patient received a prescription. (*Id.* ¶ 12).

The second was called "Area Business Specialists," or "ABSs." ABSs focused on marketing at what Janssen called the "Site of Care" or "SOC," the location at which a patient actually received the infusion. (*Id.* ¶ 14).[1] For a given patient, the Site of Demand and Site of Care could differ—for example, if a physician would prescribe Remicade to patients but did not have the capacity to infuse patients in his or her office and would therefore refer them to another provider. (*Id.* ¶ 15).

Janssen created the ABS role in 2002. (*Id.* ¶ 18). ABSs used call plans created by

[1] Janssen categorized Sites of Care into different groups, including in-office infusion suites ("IOIs"), hospital out-patient departments ("HOPDs"), and stand-alone infusion centers. (Def.'s SMF ¶ 14). Relator does not assert any claims based on services that Janssen provided to hospitals. (2nd Am. Compl. ¶ 166(r) n.14).

Janssen to determine which accounts to call on and the frequency with which they would do so. (*Id.* ¶ 44).

3. Julie Long

Relator Julie Long worked at Janssen as an ABS from 2003 through early 2016. (*Id.* ¶ 65). She was assigned to a territory in central Pennsylvania that included 11 practices that she called on during her time as an ABS. (*Id.* ¶¶ 65, 97).[2]

4. The Promotional Review Committee

Janssen created a multi-disciplinary Promotional Review Committee ("PRC") that approved programming for ABSs to use at a Site of Care. (*Id.* ¶¶ 29, Def.'s Supp. Objections and Responses to Interrogatories, Ex. 122, Dkt. No. 599-33, at 15). Membership on the PRC rotated on a frequent basis. (Def.'s Supp. Objections and Responses to Interrogatories, Ex. 122, Dkt. No. 599-33, at 16).[3] The PRC approved all of the written programming at issue in this proceeding.

5. SOC Programming

The SOC programming approved by the PRC covered a variety of topics that generally addressed the establishment and operation of in-office infusion suites.

An example of the type of programming is set forth in a document entitled "Site of Care

[2] The eleven practices are the Altoona Arthritis & Osteoporosis Center; Arthritis & Osteoporosis Center; Berks Center for Digestive Health (a/k/a Berks Center for Digestive Disease; Digestive Disease Associates; Digestive Disease of West Reading (DDWR)); Capital Arthritis and Rheumatology Associates (f/k/a George Kunkel, M.D.); Cumberland Valley Rheumatology (f/k/a Schlansky & Clawson); Ellen M. Field-Rubbo, M.D.; Emkey Arthritis & Osteoporosis Clinic; Jackson Siegelbaum Gastroenterology (f/k/a West Shore Endoscopy Center); Pottstown Medical Specialists (a/k/a PMSI); Sanford, Roumm, and Acharya Rheumatology (f/k/a Sanford and Roumm Rheumatology); and U.S. Digestive Health (f/k/a Lancaster Gastroenterology (LGI), Regional Gastroenterology Associates of Lancaster (RGAL)). (Def.'s SMF ¶ 97).

[3] The PRC included various in-house attorneys who served for different periods of time. (Def.'s Supp. Objections and Responses to Interrogatories, Ex. 122, Dkt. No. 599-33, at 16). Janssen does not assert an advice-of-counsel defense, and has not waived the attorney-client privilege as to any communications with the lawyers on the PRC. (Def.'s SMF, n.1).

Solutions 2010 at-a-glance guide." (Ex. 98, Dkt. No. 598-48, at 2). It describes "support tools and resources," and states that its purpose is for ABSs to "[a]ssist your customers in addressing the clinical and operational aspects of delivery of therapy with REMICADE to help ensure access and enhance the quality of patient care." *(Id.*). The document lists a number of "program/description" items along with the intended "audience" for the program, such as a physician, nurse, office manager, billing staff, or administrative staff. (*Id.* at 3-5).

Thus, for example, under "Nurse Training Programs," the guides lists six programs: "Clinical Considerations When Administering REMICADE (UPDATED)"; "Introduction to Infusing REMICADE – Part 1 and Part II"; "Establishing a Clinical Pathway for REMICADE"; "Operation Considerations for the Infusion Clinician Administering REMICADE"; "Infusion Therapy Education for REMICADE–Observational Visit"; and "Considerations for the Administration of REMICADE in Pediatric Crohn's Disease." (*Id.* at 3). Within those listings of programs are various descriptions, including such matters as "patient screening and assessment," "managing infusion reactions," "practical information necessary for the delivery of therapy with REMICADE," "enhancing efficiency . . . while providing quality care for your patients," "suggestions for improving communication, coordination, and continuity of care," "ensur[ing] appropriate patient management and proper administration of infusion therapy," and "age-specific assessment considerations for school-age and adolescent patients." (*Id.*).

Another section of the document, captioned "Operational Support Programs," lists 15 programs, including such matters as "Successful Management of Patients Receiving REMICADE" (covering "patient counseling, insurance, scheduling, and obtaining REMICADE"); "Reimbursement and Billing Process" (covering "coding and billing, understand[ing] updated Medicare rules . . . and appeals procedures"); and "Enhancing Patient

Care and Access" (covering "how proper management of infusion resources and administrative procedures can improve on-site delivery of infusion therapy with REMICADE"). (*Id.* at 4).

Three of the programs are described as follows:

Checkpoints for Infusion Center Optimization

> Provides an overview of current infusible therapies, and outlines guidelines and resources that can improve processes within the infusion center.

Considerations for Proactive Practice Management (UPDATED)

> Provides assistance with understanding operational issues currently facing practices, including practice costs and the reimbursement landscape, technology advances and emerging trends, and benchmarking and identification of potential areas for improvement.

Setting Up In-Office Infusions of REMICADE: Information Resources (UPDATED)

> Provides an overview of setting up new in-office infusion sites for therapy with REMICADE and benefits of physician-controlled infusions in facilitating quality patient management.

(*Id.*)

6. <u>The Slide Decks</u>

As part of the programming, the PRC approved slide decks for ABSs to present to medical providers. Accompanying the slide decks were scripts and written instructions for the ABSs to follow when making presentations. (Def.'s SMF ¶¶ 16, 29, 75, 78-79).

The precise number and content of those slide decks is unclear, but at least ten are part of the evidentiary record, as follows.[4]

[4] In addition to those ten, the record includes evidence of the existence of other SOC programming—for example, "Prior Authorizations and Benefit Investigation Workflow Optimization," "Navigating Affordability in Commercial Plans and Medicare," "In-Office Infusion Drug Procurement Models," "Quality of Care in the Infusion Suite," "Inventory and Supply Management," "Considerations for Standard Operating Procedures in the Infusion Suite," "ICD-10," "EHR and MU-2," and "Payer Relationship Management." (Dkt. No. 539-49).

a. "Billing and Coding for Infusions" (Ex. 42) (Dkt. No. 539-42)

This is a 25-page document that describes the complex process of billing and coding for infusion treatments, including methods to maximize the accuracy of claims and possible problems leading to denial or underpayment of claims. It ends with an instruction to the ABSs to "engage your audience in discussion."

b. "Considerations for Proactive Practice Management" (Ex. 29) (Dkt. No. 597-38)

This is a 40-page document that covers a variety of topics for an infusion practice, including potential staffing issues; Medicare reimbursement; private payer reimbursement; establishing "operational SOPs" (standard operating procedures) that focused on matters such as billing and reimbursement issues, including verifying insurance coverage and collecting co-pays; establishing a financial management plan; undertaking quality assurance measures; evaluating technology advances and emerging trends; determining benchmarks and areas of improvement for the practice; and inventory management for ordering drugs and supplies.

c. "Considerations for Working with a Specialty Pharmacy" (Ex. 41) (Dkt. No. 539-41)

This is a 41-page document that addresses issues arising with specialty pharmacies, who contract directly with payers "to provide patient-specific injectable, infusible, and other specialty drugs," and who "[w]ork in lieu of traditional distributors/wholesalers to provide drugs to sites of care." Among other things, such specialty pharmacies have different billing and payment arrangements. The presentation ends with a description of the indications and usage of Remicade and a list of safety considerations, such as possible side effects and contraindications.

d. "Exceptions and Appeals Process" (Ex. 68) (Dkt. No. 598-17)

This is a 32-page document that addresses the process for exceptions to payer policies in

order to provide coverage for a treatment and how to appeal a denial of coverage.

e. "Infusion Referrals: Improving the Continuity of Care" (Ex. 44) (Dkt. No. 539-44)

This is a 24-page document that focuses on issues to prevent "referral gaps" between the consultation of a patient with a prescribing physician and infusion of the product, which interferes with "continuity of care" for the patient. It focuses, among other things, on ensuring patient satisfaction to avoid attrition.

f. "Infusion Services and Ambulatory Surgical Centers" (Ex. 76) (Dkt. No. 598-25)

This is a 26-page document that explains the distinction between a certified Ambulatory Surgical Center ("ASC") space and physician office space under applicable Medicare regulations, and provides guidance as to how to adapt ASC space to provide infusion services.[5]

g. "Medicare Quality Payment Program" (Ex. 104) (Dkt. No. 599-3)

This is a 34-page document that discusses the Medicare Quality Payment Program, a performance-based system that rewards Medicare Part B providers "who deliver high-quality patient care."

h. "Successful Implementation of a New Infusion Suite for Gastroenterology Practices" (Ex. 108) (Dkt. No. 599-7)

This is a 53-page document that "highlight[s] some key steps in the process of setting up infusion suites in gastroenterology (GI) practices." (Ex. 108, Dkt. No. 599-7, at 3). It includes a section on "Considerations in Setting Up an Infusion Suite," including such issues as space, staff, chairs, supplies, and scheduling. (*Id.* at 7-16). Other sections address "Methods to Acquire

[5] Among other distinctions, ASCs are paid a facility fee by Medicare and are paid separately for covered ancillary services, including payment for drugs and biologicals.

REMICADE," which includes information on private payers generally and specialty pharmacies (*id.* at 19-21); "Coding and Billing for REMICADE and Infusion Services" (*id.* at 22-25); "Support Services for REMICADE," which is essentially a description of a separate Janssen operation called "AccessOne" (*id.* at 30-36); and "Important Safety Information for REMICADE," which provides general medical information concerning the product (*id.* at 39-53).

i. "Successful Infusion Suite Management for Gastroenterology" (Ex. 109) (Dkt. No. 599-8)

This is a 25-page document that includes a presentation whose "goal . . . is to inform and educate gastroenterology (GI) practices about what is involved in providing in-office infusions (IOI)." (Ex. 109, Dkt. No. 599-8 at 4). It includes a section called "Considerations for In-Office Infusions" that addresses topics such as the increased use of biologic therapies and the future of such therapies; a section called "Considerations for Stakeholders Involved" that addresses topics such as "How IOIs Can Improve Patient Care and Interaction," "Considerations for Patients and Payers," and "Challenges and Considerations Associated with IOI"; and a section called "Preparing to Provide In-Office Infusions" that addresses topics such as "Understanding What is Required for Setting Up IOIs," staffing and equipment requirements, "Overhead Costs Considerations," "Practice Workflow Considerations," and "Considerations for Managing Costs and Resources." (*Id.* at 6-26).

j. "Managing Biologics in the Physician Office" (Ex. 43) (Dkt. No. 539-43)

This is a 75-page document that addresses a variety of issues arising out of the administration of Remicade and other biological therapies. Approximately one-third of the document (24 pages) consists of "overview" of Remicade and safety information concerning the

product. It includes a "business update" that discusses reimbursement issues, including Medicare coverage. It includes a four-page section entitled "In-Office Infusion Efficiency" that addresses, in broad terms, how scheduling issues, resource utilization, and capacity constraints may affect patient infusion. And it includes a discussion of the "payer/reimbursement landscape" that addresses various matters involving coverage and payment by Medicare, Medicaid, and commercial payers.

Among other things, the document describes the variables that could impact the efficiency of an IOI, including "[s]pace and [s]taffing," "[d]efined [r]oles and [r]esponsibilites," and "[s]cheduling," among others. (Ex. 43, Dkt. No. 539-43, at 48). It also includes some slides on which ABSs could apparently insert data provided by the practice, including the numbers of Remicade vials the practice had been purchasing, new patients, patients who completed treatment, and total infusions provided. (*Id.* at 40-46).

The final five pages of the slide deck consist of four forms in which certain types of data could be inserted. The first is a form of checklist, called an "Infusion Workflow Sheet," that lists various steps in the infusion process along with blank spaces to enter the "Date Completed" and "Initiated." (*Id.* at 71-72). It includes the following statement: "This form provides information regarding the roles, responsibilities, and goals of each individual involved in the infusion process. It will ease communication across departments and offer an efficient and effective way to provide infusion services." (*Id.*). The second is a "Reimbursement Tracking Log for REMICADE (infliximab)" with blank spaces to enter "patient name," "insurance company," "date treated," and other billing-related information. (*Id.* at 73). The third is a "Suggested SPP Inventory Control Sheet" with blank spaces to enter various dates and other information concerning the ordering and inventory management of the product. (*Id.* at 74). The fourth is an

"Infusion Tracking Log for REMICADE Induction and Maintenance Dosing," for "Patients Starting Therapy with REMICADE (infliximab)," with blank spaces to enter patient names and places and dates of infusion. (*Id.* at 75).

7. The "Hot Buttons" Program

One of the programs available to the ABSs to use to present information to practices was called "Hot Buttons." This program took the form of an iPad app that "interactively allow[ed] customers to indicate which areas in the operation of their practice could use improvement." The ABS could then "present the slide deck that corresponds with their issue," which was referred to internally as a "Practice Pearl." (Ex. 50, Dkt. No. 539-50, at 2; Ex. 49, Dkt. No. 539-49, at 3). All of the slide decks included in the "Hot Buttons" program were approved by the PRC. (Dkt. Ex. No. 50, No. 539-50 at 2).

8. The IOM and Related Materials

Another form of programming was called the "Infusion Optimization Modeler," or "IOM." (Def.'s SMF ¶ 36). The aim of the IOM was to "provide[] practices with information on their infusion capacity and the potential increase to Remicade infusion capacity if the practice decided to remove a capacity constraint." (*Id.*).[6] It used as inputs certain information provided by a practice: "the practice's existing Remicade patient population, number of infusion chairs, and infusion staff hours." (*Id.*). The inputs also included the amount of time that the practice budgeted for a Remicade infusion from beginning to end, as well as an estimate of the

[6] Some of the language in the IOM printouts appears to have changed over time to emphasize its focus specifically on Remicade infusions. For example, the "output" section of a 2004 IOM printout uses the terms "full-load infusions potential," "current infusions scheduled," and "available additional infusions in practice," while a 2013 IOM printout uses the terms "full-load REMICADE infusions potential," "current REMICADE infusions scheduled," and "potential REMICADE scheduling improvement." (Dkt. No. 539-45 at 3; Dkt. No. 539-46 at 4). The 2013 version also includes lines for "full-load other infusions potential" and "current other infusions scheduled," which are both zero in the version provided. (Dkt. No. 539-46 at 4). Neither party discusses the import, if any, of the reference to "other infusions."

distribution of how long Remicade infusions actually took in practice. (Ex. 45; Dkt. No. 539-45; Ex. 46, Dkt. No. 539-46).

Based on that information, the IOM could create an output showing the difference between the practice's "full-load infusions potential"—that is, the number of infusions the practice could administer per week if it were using its resources as efficiency as possible—and its "current infusions scheduled." (*Id.*). It also provided a section on "capacity sensitivity," which included the time until a practice was "resource constrained," and what the constraint was; the two examples provided list "chairs" and "staff" as the relevant constraints. (*Id.*). It then provided an estimate of how many additional infusions the practice could provide per week if the resource constraints were removed. (*Id.*).

Another presentation, "iBiz," was a result of the combination of the IOM and another presentation called "Infusion Services Review." (Relator's Statement of Disputed Material Facts, Dkt. No. 597, ¶ 130) ("Rel. SDMF"). The record does not include the full text of this presentation, although a Janssen employee described it as "[b]asically a new, combined version of the MBPO [the slide deck entitled "Managing Biologics in the Physician Office"] and IOM." (Ex. 61, Dkt. No. 598-10, at 2).

9. Xcenda

At some point, Janssen engaged a subcontractor named Xcenda to provide services in connection with its ABS programming. According to Janssen, Xcenda personnel supplemented its ABSs in the field, and received the same training, performed the same role, and presented the same materials as an ABS. (Def.'s SMF ¶¶ 51, 58-59). Janssen paid Xcenda approximately $3,000 per session when Xcenda personnel delivered the SOC presentations rather than Janssen's ABSs. (Ex. 59, Dkt. No. 539-59, at 3)

According to relator, Xcenda was a consulting company that was hired by Janssen to provide business consulting services to physician practices. (Rel. SDMF ¶¶ 50-59). Relator further contends that the payment of $3,000 per session to Xcenda is evidence that the presentations of the ABSs had substantial value. (*Id.*).

10. Janssen Compliance Policies

Janssen had compliance policies intended to ensure that its employees complied with relevant law, including the AKS. (Def.'s SMF ¶ 70; Ex. 71, Dkt. No. 539-71, at 16; Ex. 72, Dkt. No. 539-72, at 5).[7] These included guidance documents and other compliance policies that explicitly regulated what ABSs could and could not do when presenting to practices. (Def.'s SMF ¶¶ 70-85). ABSs, including relator, received training on those policies. (Def.'s SMF ¶ 76).

The compliance policies included instruction about the AKS. Among other things, ABSs were advised that they "[could not] exchange anything of value in return for business" and that they could not "give [healthcare providers] anything of value to induce them to prescribe or purchase products that are reimbursed in whole or part by a federal healthcare program." (Ex. 71, Dkt. No. 539-71, at 16; Ex. 72, Dkt. No. 539-72, at 5).

ABSs were also instructed, on multiple occasions, that they could only use company-approved materials when making presentations to practices, and could not even "[h]ighlight[]" or "[c]hange the order of the pages" in approved promotional materials. (Def.'s SMF ¶¶ 77-78; Ex. 71, Dkt. No. 539-71, at 69). They were specifically instructed that they were "not business advisors" and could not offer "business consulting" or "consulting services that relate to the management of customers' business practices." (Def.'s SMF ¶ 80). This meant, among other

[7] Relator disputes whether those policies were actually "followed in practice," but she does not present a genuine dispute as to the existence *vel non* of the policies. (Rel. SDMF ¶¶ 70-71).

things, that they could not provide "consulting services to a physician's office that are part of the physician's general overhead," nor could they "calculate, discuss, or promote profitability with health care providers." (Def.'s SMF ¶¶ 81-82).

B. Procedural Background

Relator filed this suit on October 28, 2016, on behalf of the United States, 28 states, and the District of Columbia. (Dkt. No. 1). On August 9, 2019, the United States and the various states declined to intervene. (Dkt. No. 40). On December 13, 2019, the Court ordered the unsealing of the matter. (Dkt. No. 46).

Janssen moved to dismiss the second amended complaint on March 18, 2020. (Dkt. No. 58). On October 21, 2020, the Court granted Janssen's motion to dismiss as to the state-law FCA analogues but denied it as to the federal FCA claims. (Dkt. No. 75).

Later, following a voluntary stipulation by relator and the government that the FCA claims should be governed by the six-year statute of limitations under 31 U.S.C. § 3731(b)(1), Janssen moved for judgment on the pleadings as to any claims that predated October 28, 2010. (Dkt. No. 315). The Court granted that motion on January 27, 2023. (Dkt. No. 372).

Janssen later moved for judgment on the pleadings based on the FCA's public-disclosure bar, 31 U.S.C. § 3730(e)(4)(A). (Dkt. No. 377). The Court denied that motion on February 15, 2024. (Dkt. No. 432).

Because relator was based in Harrisburg, Pennsylvania, and was assigned to a territory that was limited to central Pennsylvania, the Court initially limited discovery to that geographic area as well as any national or regional policies or practices that were applicable to her work. The Court also directed that it would provide Janssen an opportunity to test the allegations of the complaint by summary judgment based on that initial phase of discovery.

Both relator and Janssen have now moved for summary judgment. Janssen seeks summary judgment as to the entirety of relator's claims. (Dkt. No. 537). Relator seeks summary judgment on the issue of defendant's scienter under both the AKS and the FCA. (Dkt. No. 542). Janssen also moved to "deem admitted or strike portions of" relator's statement of disputed material facts, which the Court will address in a separate order. (Dkt. No. 590).

II. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Burt v. Board of Trs. of Univ. of R.I.*, 84 F.4th 42, 59 (1st Cir. 2023) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant, would permit a rational factfinder to resolve the issue in favor of either party." *M.L. ex rel. D.L. v. Concord Sch. Dist.*, 86 F.4th 501, 510 (1st Cir. 2023) (quoting *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990)) (citation modified). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (citation modified). The nonmoving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256-57.

III. Analysis

A. Defendant's Motion for Summary Judgment

Janssen has moved for summary judgment, arguing that relator has failed to establish the required elements to show a violation of the AKS or the FCA.[8] As to the AKS, Janssen contends that relator has failed to establish a genuine dispute of material fact that the SOC programs constituted prohibited remuneration under the AKS, or that it acted with the requisite willfulness. It also contends that its promotional services constitute protected speech under the First Amendment.

1. The Anti-Kickback Statute

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits, in relevant part, "knowingly and willfully offer[ing] or pay[ing] 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 . . . 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). Relator must therefore prove three elements to establish a violation of the AKS: (1) that by providing the SOC programs, Janssen offered or paid "remuneration" to practices; (2) that the remuneration was provided with the intent to induce those practices to purchase Remicade or Simponi ARIA; and (3) that Janssen acted with the requisite scienter—that is, "knowingly and willfully."

2. "Remuneration" Generally

The AKS, in relevant part, prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly,

[8] Janssen has also moved for summary judgment on the grounds that the *qui tam* statute violates the Appointments Clause, U.S. Const. Art. II, § 2, and Vesting and Take Care Clauses, U.S. Const. Art. II, § 3. For the reasons set forth below, the Court will not reach either issue, as relator has failed to put forth sufficient evidence to establish a violation of the AKS.

in cash or in kind to any person to induce such person . . . to purchase . . . any . . . item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). The statute does not specifically define what constitutes "remuneration," other than providing the three examples of a "kickback," "bribe," and a "rebate." *See id.*

"Where Congress fails to specify the meaning of a statutory term, courts typically read statutory terms to covey their ordinary meaning, including as reflected in dictionary definitions." *Soto-Hernandez v. Holder*, 729 F.3d 1, 4 (1st Cir. 2013) (citation modified); *see Vertex Pharms. Inc. v. U.S. Dep't of Health & Hum. Servs.*, 774 F. Supp. 3d 211, 231 (D.D.C. 2025) (interpreting "remuneration" according to its ordinary meaning to cover "any reward; recompense; or salary" (citation modified)); *Pharmaceutical Coal. for Patient Access v. United States*, 126 F.4th 947, 961 (4th Cir. 2025) ("We therefore determine that 'remuneration' here has its ordinary meaning of payment or compensation, not a specialized meaning of a corrupt payment that distorts the medical decision-making process.").

Nonetheless, the term "remuneration" under the AKS has not been broadly interpreted to cover every service provided in connection with the sale of a pharmaceutical or medical device. Every act of assistance, explanation, or advice by a pharmaceutical representative to a physician—even the most basic advice concerning a product—has at least some value. A literal interpretation of "remuneration" would make virtually all pharmaceutical detailing or marketing a crime. *See Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 557, 580 (2011) (describing the common practice of pharmaceutical detailing, which "often involves a scheduled visit to a doctor's office to persuade the doctor to prescribe a particular pharmaceutical," and holding that detailing is a form of protected speech). And it would likewise prohibit the provision of support or technical assistance even as to complex medical devices or products, in situations where (as a practical

matter) only the manufacturer is in a position to provide the necessary assistance.

To avoid such results, courts have generally applied a framework that defines unlawful "remuneration" under the AKS to consist of the provision of services that have "substantial independent value" to the recipient—that is, value independent of the provider's product.

The "substantial independent value" framework originated in guidance from the Office of Inspector General of the Department of Health and Human Services.[9] A 2000 OIG advisory opinion described the concept of "substantial independent value" 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. 00-10, 2000 WL 35747420, at *4.

Later OIG guidance further expanded on that discussion of "substantial independent value" and its implications for AKS compliance:

> Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement

[9] To be clear, the interpretation of the AKS is properly a role for the court, not the OIG/HHS. And while the court may look to the agency for assistance in interpreting the statute, the agency's views are not entitled to deference. *See Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 396 (2024).

> support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

It appears that every court to have considered the issue has applied the OIG framework to determine whether particular services constituted "remuneration" under the AKS. *See, e.g., United States ex rel. Witkin v. Medtronic, Inc.*, 2024 WL 1892405, at *17 (D. Mass. Mar. 31, 2024); *United States ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575, 589 (S.D.N.Y. 2022), *aff'd in relevant part*, 96 F.4th 145 (2d Cir. 2024); *United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *6-7 (N.D. Ill. Sep. 30, 2019); *United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017).

In *Hart*, the court found that a relator had plausibly alleged that a "Margin Analyzer" tool offered by McKesson constituted "remuneration" because "it [was] plausible that these tools had value to oncology practices regardless of whether they were active McKesson customers" and because they were "distinguishable from the types of typical product support services OIG describes in its 2003 Guidance." *Hart*, 602 F. Supp. 3d at 589-90. The court concluded that the question of "substantial independent value" under the OIG framework "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." *Id.* at 589.

Similarly, in *Witkin*, the court found a genuine dispute of material fact precluding summary judgment on the issue of "remuneration" where there was some evidence that the defendant's "conduct in running . . . clinics" for its products "crossed the line from mere product support to effectively running the . . . clinics on behalf of the physicians." *Witkin*, 2024 WL

1892405, at *17. However, in *Forney*, the court found that allegations concerning "free surgical support" for an implantable product—including representatives who would "'scrub in' on surgical procedures" and providing "implant device follow-up"—did not constitute "remuneration" because the relator did not allege how those services were independent of the products themselves. *Forney*, 2017 WL 2653568, at *1, 4.

Relator first contends that the "substantial independent value" framework should not apply at all, and that any form of remuneration is unlawful, whether or not it has independent value. (Plaintiff-Relator's Memorandum in Opposition to Janssen's Motion for Summary Judgment, Dkt. No. 596, at 8) ("Rel. Mem."). While that argument is perhaps not frivolous, relator does nothing to develop it. Among other things, she does not attempt to explain why every court to have considered the issue has reached an incorrect conclusion. Indeed, her argument is completely tautological: she contends that "[t]he 'substantial independent value' concept arises only in OIG guidance addressing product-integral support services without independent value," and that the SOC programs were independent of defendant's products, and therefore were not "product-integral services." (*See id.* at 8-9). The Court is reluctant, to say the least, to blaze a new trail in this area in the absence of any significant legal briefing or any discussion of the practical consequences of such an interpretation. That caution is particularly warranted in light of the fact that the AKS is a felony criminal statute embedded in a complex regulatory framework, and that any interpretation of its terms applies equally in the civil and criminal setting. *See United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1050 (6th Cir. 2023).

The Court will therefore apply the "substantial independent value" standard. The application of that standard, however, can be somewhat difficult, and the line between

permissible medical, clinical, technical, product support, billing, and reimbursement advice on the one hand, and impermissible business or management advice on the other, is far from precise.

It seems clear as a general matter that a pharmaceutical or medical device company representative may provide medical, clinical, and technical support concerning the administration or use of a product. Thus, for example, a pharmaceutical representative can educate a physician and staff about the uses of medication, its contraindications, and its risk factors. A representative of a medical device company can provide clinical support (including providing assistance during surgery) to ensure that a device is being used appropriately and to assist with any complications. Such advice would not constitute remuneration, because it would be "specifically tied to support of the purchased product." *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.

It seems equally clear, as a general matter, that a company representative cannot provide business or management advice as to the overall practice of a physician. Nor can a representative perform tasks that fall within the ordinary course of that practice, such as scheduling patient appointments, that would otherwise be part of a physician's overhead. But advice concerning billing or reimbursement for the product is permissible, even though it represents a form of business, rather than medical or clinical, advice.

Between those guideposts, the landscape is unclear, particularly at the intersection between medical/clinical and management/business issues. Such issues cannot be resolved in the abstract, or based on conclusory labels, but only by focusing on the actual evidence.

3. Whether the Claims are Barred by the First Amendment

Defendant contends that the term "remuneration" must be construed narrowly to avoid potential First Amendment concerns that would result from "[h]olding that truthful promotional speech can be illegal remuneration." (Def.'s Memorandum in Support of Motion for Summary

Judgment, Dkt. No. 538, at 12) ("Def.'s Mem."). Relator contends in response that "[t]he First Amendment does not shield a pharmaceutical company from the consequences of providing illegal inducements to prescribers, even when those inducements incidentally involve communication of information." (Rel. Mem. at 6).

As a starting point, the Supreme Court has recognized that pharmaceutical marketing is a form of commercial speech that is entitled to a measure of First Amendment protection. *See Sorrell*, 564 U.S. at 567. It would thus raise First Amendment concerns if federal law entirely barred pharmaceutical companies from providing certain kinds of information to medical practices.

The AKS, however, does not regulate pharmaceutical marketing as such. It does not prohibit pharmaceutical companies, or anyone else, from offering information to physician practices in the abstract. Instead, it prohibits them from offering things of value with the intent to induce the recipient to purchase something in exchange. There is a meaningful distinction between a regulation of speech as speech—that is, a restriction on what a person may or may not say—and regulating speech where the speech itself is offered as part of an illegal arrangement.

A hypothetical may help to illustrate the point. Some professional services, including talk therapy and legal advice, are considered speech subject to protection under the First Amendment. *See Chiles v. Salazar*, 607 U.S. 627, 644 (2026) (talk therapy); *Upsolve, Inc. v. James*, 155 F.4th 133, 141-42 (2d Cir. 2025) (legal advice). Suppose a medical-device company wants to sell products to a particular hospital. The company makes the following offer to the hospital: if you commit to purchasing our products, rather than those of our competitors, we will offer your employees free talk therapy to help combat the stresses of working in a hospital, and we will offer your hospital the ability to consult with our in-house legal team as often as you

would like. Such an arrangement would clearly violate the AKS (assuming, of course, the scienter and other requirements were met): the company would be offering remuneration (free therapy and legal services) with the intent to induce the purchase of its products. And even though the only thing the company would be offering would be speech, it is difficult to see how barring that kind of arrangement would raise First Amendment concerns.

In short, where valuable speech is offered as the *quid* in a *quid pro quo* arrangement, prohibiting such arrangements would clearly survive First Amendment scrutiny. *Cf. National Republican Senatorial Comm. v. Federal Election Comm'n*, 146 S. Ct. 2404, 2418 (2026) (recognizing the prevention of *quid pro quo* "corruption or the appearance of [*quid pro quo*] corruption" as a "legitimate governmental interest for restricting campaign finances," a form of speech); *Citizens United v. Federal Election Comm'n*, 558 U.S. 310, 359 (2010) (same). And, again, defendant does not argue that the AKS is in fact unconstitutional as applied to it in these circumstances; instead, it argues that constitutional considerations should influence how the Court interprets whether the SOC programs constituted remuneration as defined in the AKS.

This Court considered, and rejected, a related argument in *United States v. Regeneron Pharmaceuticals, Inc.*, 2020 WL 7130004 (D. Mass. Dec. 4, 2020). That case involved allegations that certain donations the defendant made to a nonprofit that helped patients cover Medicare copays for prescription drugs violated the AKS. *Id.* at *2, *10. The defendant argued that because part of the government's theory rested on communications between the defendant and the nonprofit about the nonprofit's funding needs, the government was "essentially penalizing speech" by interpreting the AKS to bar such arrangements. *Id.* at *16. The Court noted, however, that the case was "about restrictions on conduct . . . not restrictions on speech." *Id.* The AKS prohibits certain conduct—offering remuneration with the intent to induce

purchases—not speech. The mere fact that, in some circumstances, speech may itself constitute valuable remuneration does not mean that a restriction on the act of offering valuable speech to induce purchases raises First Amendment concerns.

Accordingly, summary judgment will not be granted to defendant on the ground that the services at issue are protected by the First Amendment.

4. What Services Relator Contends Were Unlawful

The next question is identifying the services provided by defendant that relator contends constituted unlawful remuneration.

As noted, relator has expressly disclaimed any argument that the slide decks and other written programming or presentations that were approved by the PRC for use by ABSs constituted unlawful remuneration. That issue was litigated earlier in the case, when Janssen sought to compel relator to amend an interrogatory response concerning what services she alleged violated the AKS. (Dkt. No. 398). In response to Janssen's motion, relator stated, in no uncertain terms, that it was a "false impression that the alleged remuneration/kickbacks underlying Relator's [AKS and FCA] claims are written materials." (Relator's Memorandum in Opposition to Def.'s Motion to Compel, Dkt. No. 400, at 1). Instead, she contended that "the free live consultative services and support that Janssen had its [ABSs] and outside consultants regularly provide to targeted physician practices" constituted the prohibited remuneration. (*Id.*).[10]

In one of her responses to Janssen's Statement of Undisputed Material Facts under Local Rule 56.1, relator repeated that position—although in a somewhat odd and backhanded fashion:

[10] Relying on that representation, the Court recognized that her "interrogatory response does not identify the slideshow presentations themselves as violating the [AKS and FCA]. Rather, it was the provision of those 'live consultative services and support' by ABSs and outside consultants without charge that constituted unlawful remuneration and kickbacks." (Order Concerning Motion to Compel, Dkt. No. 433, at 2).

> Janssen Statement of Fact No. 27: Relator does "not assert that the slideshow presentations [used during the SOC Programs] themselves constituted unlawful remuneration or kickbacks." Nor does Relator allege that Janssen's provision of "'written presentations' or any other written materials" constituted unlawful remuneration or kickbacks. Rather, Relator alleges that "the alleged remuneration upon which [her] AKS and FCA claims are based is the free live Services and consultative presentations and programs through which the ABSs and outside consultants provided the Services."
>
> Response: Disputed. Relator's "interrogatory response clearly identifies a range of services that relator alleges Janssen unlawfully provided to selected practices, including 'consultive meetings,' also called 'programs and presentations,' which may have included the use of the identified slideshow presentations 'as visual aids.'" Relator does "not assert that the slideshow presentations themselves constituted unlawful remuneration or kickbacks, but that Janssen provided free services that made use of those presentations."

(Appendix A, Dkt. No. 591-1, at 4) (citations omitted).

The consequences of that position are significant. The slide decks alone cover a wide variety of topics, including ones entitled "Considerations for Proactive Practice Management" and "Managing Biologics in the Physician Office." (Ex. 29, Dkt. No. 597-38; Ex. 43, Dkt. No. 539-43). If the content of the written materials is concededly lawful—and if the content of the live presentations by ABSs was not materially or substantially different—then the live presentations must be lawful as well. Put another way, if an ABS simply read the contents of the slide decks aloud, under relator's view, no AKS violation would have occurred. The same would be true if an ABS delivered that content orally with no material variation.[11]

Two central questions in this lawsuit thus appear to be the following: what, exactly, did

[11] ABSs were generally instructed by Janssen to limit their discussions with providers to company-approved topics, whether orally or in writing. Thus, for example, a training slide deck (Health Care Compliance Site of Care ABS Speaker Training, Ex. 72, 539-72, at 16, 37), provides that speakers can address questions that are not within the scope of the slide deck if they are within the speaker's personal knowledge as long as the speaker states that the response does not reflect the company's position and is objective and non-promotional. The deck also provides that the presentations are "[n]ot an [o]pportunity to: [s]ell off-label or have discussions that are not company-approved; [m]odify, add or delete slides; [or] [p]rovide supplementary information or materials not approve for use by the company." (*Id.* at 14).

the ABSs say or do in their live presentations? And did those live presentations materially vary from the written presentation materials?

Somewhat surprisingly, given the importance of those questions, there is very little evidence on point. There is no direct evidence at all of the content of any oral communication between any ABS and any physician practice. As noted, relator herself did not submit any affidavit in opposition to Janssen's motion for summary judgment.[12] There are no affidavits or deposition testimony from any other ABS. And there are no affidavits or deposition testimony from any physician, nurse, or other healthcare provider, or any office manager or other administrative staff of a physician practice.

Unhelpfully, relator relies to a substantial extent on conclusory or argumentative assertions that have little or no record support. Thus, for example, she alleges that the slide decks were used as "discussion starters" or "foundational tools," not as "scripts." (Rel. Mem., Dkt. No. 596, at 2). But those quotations are from the characterization of the evidence from her own experts, not from any actual witness or Janssen document.[13] Although a court "may consider expert testimony at the summary judgment stage, 'expert testimony without a factual foundation cannot defeat a motion for summary judgment.'" *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 248 (D. Mass. 2014) (quoting *Virgin Atl. Airways Ltd. v.*

[12] Relator testified in her deposition that while she was an ABS, she did not believe that any of her work violated the law or Janssen's internal compliance policies. (Long Dep., Ex. 17, Dkt. No. 539-17, at 289).

[13] Plaintiff's expert Ian Larkin stated that the written presentations "were used as a discussion starter. . . . They conveyed valuable information on benchmarks and on industry standards and other matters like that, but they also helped facilitate conversations through Q&As, through identifying needs that were most important for a given client, . . . and thereby help their clients focus on what they needed to do to make their operations more efficient." (Ex. 48, Dkt. No. 597-58, at 243-44 (citation modified)). Her expert Adriene Fugh-Berman stated that "the slide presentations [were] not just being handed to physicians. They're a tool that is being used by the ABS, who has a whole relationship with the physician and the office and is providing curated, tailored services to that office. . . . [T]he slide sets themselves are just foundational tools that are being used." (Ex. 58, Dkt. No. 598-7, at 276).

British Airways PLC, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999)) (citation modified).

Of course, the content of live communications between ABSs and providers can be proved through circumstantial evidence. Furthermore, any reasonable inferences from the evidence must be drawn in relator's favor on summary judgment. *See Quintana-Dieppa v. Department of the Army*, 130 F.4th 1, 7 (1st Cir. 2025). But that circumstantial evidence is limited at best, and is based almost entirely on a very narrow set of documents. In substance, the relevant documents cited by relator are the following:

a. The Trahan Email

First, relator relies on an email dated November 16, 2012, from Karen Trahan, a Regional Business Director at Janssen, to Marti Heckman, a National Sales Director and her supervisor. (Ex. 66, Dkt. No. 598-15). In response to a request from Heckman to "outline . . . the specifics of what the ABS team can do, that our clinical reps can't," Trahan responded: "It is the depth of knowledge and understanding in the SOC 360 programs that the ABSs know and can diagnose situations when needed since they know the depth of the content." (*Id.* at 2-3). She continued:

> It is not the content, it is the depth of the conversations, the dialogue to engage the customers and the efficiencies and optimization discussions that differentiates. It is their process orientation and the attention to detail to diagnose issues when an issue or barrier arises . . . the ability to do a differential diagnosis through appropriate questioning to get to the root cause of some issues.

(*Id.* at 2).

That description certainly suggests that some of the value imparted by the ABSs was not in the information contained in the written presentations, but instead came from the "depth" of conversations ABSs had with practices and their ability to "diagnose situations." (*Id.*). At a broad level, that supports relator's contention that the conversations between the ABSs and practices may have gone beyond what was in the written materials. But the email does not indicate what the content of any of those conversations actually was, beyond describing them

with a few generalized adjectives. And it is therefore of little value in determining whether any ABS actually provided information that violated the AKS.

b. The ZS Associates Document

Next, relator relies on a statement in a document that described the ABS role, in part, as "[p]rovid[ing] legally approved consultative services" to in-office infusion practices "to assist with optimization of infusion capabilities and overall practice management." (Ex. 1, Dkt. No. 597-1, at 4).[14]

The exhibit in question consists of an email dated February 27, 2013, from Marti Heckman to Karen Trahan and another Janssen manager asking them to provide comments on an attached document. (*Id.* at 1). The document has footers on each page indicating that it was prepared by a company called "ZS Associates" and that it was the "output" of the "Immunology Optimization Workshop." (*Id.* at 5-13).[15] It is divided into sections labeled "Engagement Objectives > IOI," "Allocation of Effort > IOI," "Competitors/Third Parties > IOI," "Impact on [Janssen] Success > IOI," and "Engagement Objectives > Hospital." (*Id.*). The first section lists five "Engagement Objectives": "Promote clinical benefits," "Promote patient affordability programs," "Ensure product access and reimbursement within site of care," "Ensure product administration and infusion process," and "Provide IV sustainability support." (*Id.* at 1-4). Under the last of those categories, under "Services," it states: "Provide legally approved

[14] On multiple occasions, relator cites to that phrase from the ZS Associates document, but selectively quotes it by omitting the phrase "legally approved." *See, e.g.*, (Rel. Mem. at 5); *(id*. at 15); (Rel. SDMF ¶¶ 11, 20, 71.

[15] The precise genesis of the document is not clear. According to Karen Trahan, ZS Associates was a "data analytics company that helped us realign our territories." (Trahan Dep., Ex. 6, Dkt. No. 343-4, at 171). The document was prepared after Trahan attended a meeting at Janssen in Pennsylvania. (Ex. 1, Dkt. No. 597-1, at 1). Because the email asked for comments on the document, it is unclear whether the document was intended to be a draft, although it is not marked as such.

consultative services to assist with optimization of infusion capabilities and overall practice management" and "Conduct SoC 360 programming." (*Id.* at 4).[16]

Relator focuses on that entry—which, again, was produced by an outside vendor—as evidence that Janssen ABSs in fact provided "consultative services" to assist physicians with "overall practice management." (Rel. Mem. at 2, 5). There is no other evidence cited by relator in support of the contention that ABSs actually provided services as to "overall practice management" to any physician practice. Janssen has not waived the attorney-client privilege, and there is thus no evidence as to what services were "legally approved."

In any event, the ZS Associates document is couched in general terms, and does not provide any detail as to what was actually presented "live" by ABSs to physician practice groups. The references to the MBPO and the IOM modeler are addressed below.

c. <u>The MBPO</u>

Next, relator relies on the slide deck entitled "Managing Biologics in the Physician Office," or "MBPO." (Ex. 43, Dkt. No. 539-43).[17]

As noted, the MBPO was a slide deck presentation that covered several different topics, including past and future trends in biologic therapies; information concerning payment and reimbursement for Remicade; and the variables that impact the efficiency of an IOI, including "[s]pace and [s]taffing," "[d]efined [r]oles and [r]esponsibilites" and "[s]cheduling," among

[16] The same phrase occurs later in the document under "Impact on [Janssen] Success" and "Engagement Objectives" for hospitals. (*Id.* at 8, 12). In the former reference, it is followed by a parenthetical "(i.e., IOM scheduling modeler, MBPO's business reviews)" (*id.* at 8); in the latter reference, the parenthetical is "(i.e., MBHOPD)" (*id.* at 12).

[17] The presentations delivered by ABSs were either "branded" or "unbranded." A "branded" presentation was one that "specifically referenced Remicade or Simponi ARIA and thus required the ABS to provide safety and efficacy information about the product." (Def.'s SMF ¶ 30). The MBPO was "branded." (Ex. 40, Dkt. No. 539-40, at 14).

others. (*Id.* at 48). It also included some slides on which data from the practice could be inserted, including the number of Remicade vials the practice had been purchasing, its numbers of new patients, patients who completed treatment, and total number of infusions provided. (*Id.* at 43-46). That portion of the document is essentially a template for a log for various data items, with no analysis of that data.

Again, relator has conceded that the MBPO slide deck itself is not unlawful remuneration. The slide deck clearly contemplates that data from the physician's office would be inserted in the blank spaces. But there is no record evidence as to whether any such data, on any occasion, was filled in by physician practice managers, by ABSs, or both.

d. <u>The IOM and iBiz</u>

Finally, relator cites to the "Infusion Optimization Modeler," or "IOM" (Ex. 45, Dkt. No. 539-45; Ex. 46, Dkt. No 539-46); and the "Infusion Business Review," or "iBiz," (Def.'s SMF ¶ 28 n.15).

The IOM was a program that would "generate[] a standardized print-out for the practice populated with the practice's existing Remicade patient population, number of infusion chairs, and infusion staff hours, as reported by the practice." (*Id.* ¶ 36). Based on that information, the IOM would tell a practice how it was "[r]esource [c]onstrained" (e.g., by "[s]taff," "[c]hairs," etc.), and calculate how many more infusions per week the practice could conduct if that constraint were removed. (Ex. 45, Dkt. No. 539-45; Ex. 46, Dkt. No. 539-46). The IOM is discussed in more substantial detail below.

iBiz was a later-developed presentation that combined the IOM with another presentation called the "Infusion Services Review." (Rel. SDMF ¶ 130). It similarly involved taking data from a practice concerning Remicade prescriptions, number of chairs, staff, and other variables, and showing how a lack of capacity might be constraining a practice's resources. (*See*

Ex. 61, Dkt. No. 598-10; Ex. 62, Dkt. No. 598-11).[18]

5. Whether Those Services Constituted Unlawful Remuneration

The Court now turns to whether there is sufficient evidence to show that the services provided live by ABSs constituted unlawful "remuneration" in violation of the AKS.

There is no real question that the services provided by defendant had "value," and that the value was "substantial," in the sense that it was not immaterial or *de minimis*.[19] And it is self-evident that the ultimate purpose of the SOC programming was to increase sales of the two medications. Again, the issue is whether those services had substantial "independent" value—that is, value that would not exist if the products did not exist.[20]

a. Suitability of Infusion Suites for Other Products

Relator contends that the infusion suites had independent value because once they were created, they could be used by rheumatologists and gastroenterologists for other infusible medications. If true, that would arguably demonstrate that the services provided to assist in the establishment and operation of those suites had "independent" value. Indeed, one might have expected that such evidence would be an important aspect of relator's case, and that relator would have submitted evidence as to the existence of other infusible medications; the use of such

[18] As opposed to the IOM, none of the actual printouts generated by iBiz appear to be in the summary judgment record.

[19] There is substantial evidence in the record as to how valuable some physician practices found the SOC programs. One email, for example, recounts that the office manager at a practice that had recently opened an IOI "could not thank Janssen enough," and "said that [the practice] could not have opened this IOI without us." (Ex. 27, Dkt. No. 597-36, at 2). Relator also points to the deposition testimony of Thao Marzullo, a Janssen Product Manager for SOC Marketing, who testified that "IOIs would close if site of care marketing"—essentially, the ABSs—"did not provide" the SOC programs. (Rel. SDMF ¶ 38; Ex. 28, Dkt. No. 597-37, at 194). The full quote from Marzullo, however, was that IOIs would close if "site of care marketing did not provide the *educational approved materials*"—that is, the materials that had been approved by the PRC. (*Id.* (emphasis added)).

[20] Several of the SOC programs—or, at least the written presentations that were delivered as part of the programs—appear to fall squarely within the existing OIG guidance as to what constitutes "independent' value. *See, e.g.*, "Billing and Coding for Infusions." (Ex. 42, Dkt. No. 539-42). *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

medications by rheumatologists and gastroenterologists; and the suitability of IOI suites to infuse those other medications.

Instead, relator's opposition memorandum contains only two sentences directly addressing the subject:

> Janssen's corporate representative confirmed that SOC programs 'would be of interest' to any physician operating an IOI, regardless of whether they used Janssen's drugs.

(Rel. Mem. at 9).

> The consultative services addressed general business challenges facing infusion practices, not the administration of any specific drug, and would be valuable even to practices not using or planning to use Remicade or Simponi ARIA.

(*Id.* at 10 (citation omitted)). In support of those assertions, relator cites to eleven paragraphs of her Response to Defendant's Statement of Undisputed Material Facts, each of which in turn cites to multiple exhibits. (*See* Rel. SDMF ¶¶ 11, 30, 32-34, 36, 72, 82, 163, 185, 186).

Nearly all of those citations, however, are to evidence concerning other topics or to the approved written materials that relator concedes do not violate the AKS. Thus, for example, three of the citations are to the contents of slide decks. Relator argues that the slide deck labeled "Billing and Coding for Infusions" was "unbranded," meaning that it did not mention Remicade or Simponi ARIA, and that therefore "[t]he information and advice provided during this SOC program was applicable to all drugs that physicians could administer via infusions in their infusion suite, not just Remicade and Simponi ARIA." (Rel. SDMF ¶ 32).[21] The basic problem with that argument, of course, is that relator has conceded that the slide decks did not have substantial independent value. *See also id.* ¶ 33 (making a similar argument as to the slide deck

[21] Again, Janssen contends that certain slide decks are unbranded because any specific reference to Remicade or Simponi ARIA would require a full disclosure of product-specific instructions and warnings. (*See* Wood Dep., Dkt. No. 543-1, at 258).

entitled "Considerations for Working with a Specialty Pharmacy"); *id.* ¶ 34 (same, for the slide deck "Managing Biologics in the Physician's Office"); *id.* ¶ 36 (same, for the IOM).

As for expert testimony, relator cites to two opinions, neither of which directly addresses the topic of the suitability of the suites for other medications. *See id.* ¶ 82 (citing opinion of Ian Larkin that the services provided by ABSs "constituted, at least in part, advice on operations and business issues faced by physicians operating IOIs that were applicable to management of the overall infusion suite business"); *id.* ¶ 186 (citing opinion of Kevin McAnaney that the "job [of ABSs] was to provide physician practices with valuable actionable intelligence on how to set up and operate their infusion centers more efficiently and more profitably . . . "). There is thus no expert testimony as to the existence of other infusible products that are commonly used by rheumatologists or gastroenterologists, or the adaptability of the IOI suites to the use of such products. If there is such expert testimony in the evidentiary record, relator has not cited it.

Relator also cites to the deposition testimony of Angela Wood, a Janssen compliance officer. She testified at her deposition that "a few" of the SOC programs, which she said were "educational in nature," were "applicable to oncology." (Wood Dep., Dkt. No. 543-1, at 394-98).[22] The fact that some of the materials might also have been presented to oncology practices by Janssen representatives is of limited relevance, however, to the question of whether rheumatologists and gastroenterologists could use the suites to infuse other products.

Finally, Brian Smith, a Rule 30(b)(6) witness produced by Janssen, was asked at his deposition: "Would you agree that some of those programs would be of interest or have value to doctors even if those doctors were not going to use Remicade or Simponi ARIA?" (Smith Dep.,

[22] Wood also testified that Janssen's portfolio of oncology medications included infusibles, and that oncology practices could administer Remicade as an alternative site of care. (*Id.* at 396-97).

Dkt. No. 543-3, at 249). He answered: "They would have interest if the provider—the physician wanted to infuse products in their office regardless of Simponi ARIA or Remicade." *Id.*

In summary, the relevant evidence cited by relator in support of the proposition that IOI suites could be used by rheumatologists or gastroenterologists to infuse other products consists, in substance, of a single sentence by a single witness. But a mere acknowledgment that the SOC programming—which, again, involved written materials that relator concedes were lawful—would be "of interest" to providers who "wanted to infuse [other] products" falls well short of proof of an AKS violation.

b. Business Consulting Services Provided by "Live Presentations"

Again, the applicability of the services provided to other infusible products is not the focus of relator's arguments. Instead, her case centers on what she calls "hands-on, practice-specific business consulting services" provided by ABSs to infusion practices. (Rel. Mem. at 2). Relator asserts multiple arguments that those services had independent value, several of which may be addressed summarily.

First, relator appears to contend that the sheer magnitude of the services provided necessarily demonstrates that unlawful remuneration was provided in violation of the AKS. *See* (Rel. Mem. at 10) ("The Magnitude of the Benefits Demonstrates Substantial Independent Value"). But it is unclear how the size of the programming, or the amount of resources devoted to it, without more, relates to "independent" value. For example, the traditional product detailing work performed by Janssen ISs is unquestionably large in scale and resource-intensive, yet relator does not contend that the work constitutes unlawful remuneration. The magnitude of the services provided by ABSs may have other evidentiary purposes—for example, it demonstrates the importance of the programming to Janssen, which tends to support the conclusion that

Janssen intended that the programming would lead to higher sales. But it proves nothing concerning the "independence" of any value provided.

Second, relator argues that the services provided went beyond the establishment and operation of infusion suites to management consulting for the benefit of a physician's entire practice, not just the infusion component. The only evidence relator offers to establish that proposition is the ZS Associates presentation, which, as noted, stated that the role of the ABSs was to provide "legally approved consultative services to assist with optimization of infusion capabilities and overall practice management." (Ex. 1, Dkt. No. 597-1, at 4). But there is no record evidence that any ABS, anywhere, actually provided any "overall practice management" services to physicians, much less any services that were not "legally approved."

Third, relator argues that the fact that Janssen paid Xcenda $3,000 per session when its personnel delivered SOC presentations to physician practices proves that the services had value. (Rel. Mem at 10). Relator claims that as a result, "Janssen cannot plausibly contend that identical services became valueless when provided free to physician practices." (*Id.*). But the fact that the services had value is not in serious dispute; the question is whether they had "independent" value.[23] And she has offered no evidence in opposition to Janssen's contention that Xcenda provided the same services that were provided by the ABSs, and no evidence as to what was specifically said or done by any Xcenda representative.

The heart of relator's case is the contention that ABS provided business consulting services that were individually "tailored" or "customized" for physician practices, which

[23] Again, the difference between "value" and "independent value" is significant. For example, if Janssen decided to have outside consultants deliver presentations that consisted solely of safety information about Remicade, it would obviously have to pay them to do so—even though that information would not have independent value to the practice receiving it.

demonstrates that those services had independent value. Relator focuses in particular on the MBPO and the IOM and iBiz programs, which relator contends were designed to provide consulting advice that would improve the "efficiency" of the IOI suites, and therefore increase physician profits. *See* (Rel. Mem. at 2) (arguing that the IOM "exemplifies these [unlawful] business advisory services," and that "ABSs collected and analyzed practice-specific operational data, including patient volumes, staffing levels, chair capacity, reimbursement timing, and practice costs, to evaluate operational constraints and recommend changes to increase infusion capacity").

As a threshold matter, the fact that advice was tailored or customized to the needs of a particular physician practice is certainly relevant, but it is not controlling. For example, a company representative who assists a surgeon in the operating room in the use of a medical device is providing highly individualized and tailored advice, but it is not independent of the product. On the other hand, the provision of business advice to a practice that is entirely independent of the product is likely problematic whether it is tailored or not.

In any event, the MBPO is an approved slide deck that relator concedes was lawful. As noted, one section of the MBPO presentation is titled "In-Office Infusion Efficiency." (Ex. 43, Dkt. No. 539-43, at 49). It describes the variables that could impact IOI efficiency, including space and staffing and scheduling. (*Id.* at 50). A slide titled "Scheduling" lists ten suggestions for maximizing efficiency, including among others, such things as "Consider a nurse-to-patient ratio of 1-to-3 or 1-to-4" and "Stagger infusion start times to maximize resource utilization." (*Id.* at 51). A slide titled "Resource Utilization and Capacity Constraints" lists three "[c]auses of inefficient resource utilization": "Sufficient staff resources but insufficient chair resources," "Sufficient chair resources but inefficient staff resources," and "Sufficient chair and staff

resources but scheduling the infusions in a sub-optimal way." (*Id.* at 52). A slide titled "Available 3-Hour Treatment Appointments" lists things such as "Number of infusion chairs" and "Number of hours per day" with blank spaces for entry of data. (*Id.* at 53). Similarly, a slide titled "Actual Time Slots Utilized vs. Available REMICADE 3-Hour Treatment Appointments" appears to have a blank space where data might be entered, with no actual data. (*Id.* at 54). To the extent that ABS went beyond the MBPO program to provide further information to physician practices in the form of live presentations, it appears that the only evidence of such presentations concerns the IOM and the iBiz programs.

The IOM was part of the SOC programming approved by the PRC. (*See* Long Dep., Ex. 17, Dkt. No. 539-17, at 169-70).[24] It does not appear to involve a written slide presentation, but rather a (relatively simple) computer program.[25] Although the record is silent, it is a reasonable inference that it was downloaded onto a device to which an ABS had access.

The input data, such as the number of patients and chairs, was necessarily provided by the physician practice. It appears that ABSs entered that data into the IOM and ran the program, which produced a short printout. (Ex. 45-46, Dkt. Nos. 539-45, 539-46). In relator's words:

> If an office verbalized to us that they could not get a patient in for an infusion within the amount of time necessary according to the order, we could do an optimization modeler on their infusion center to see if they were at capacity, and we could actually measure out the point at which they would have to add more resources to ensure that would happen. . . .
>
> In doing that, we would work with them to find the number of patients that they're seeing, what their chairs look like, what the time looks like, what hours are they open, so we look at their variables in their infusion center.
>
> . . .

[24] Because the IBiz program appears to be based on the IOM and MBPO programs, and because the evidence as to the program is limited, the Court will confine its discussion to the IOM programs.

[25] Because the IOM apparently did not involve a slide deck or other written presentation, the Court will assume that it was not within the scope of relator's concession as to the lawfulness of such materials.

> And then in that, we can run a model to show them what the most efficient way was to run their infusion center.

(Long Dep., Ex. 17, Dkt. No. 539-17, at 170-72). There is nothing in the record about how the program manipulated the data to arrive at its conclusions, but it appears to have been premised on fairly basic arithmetical calculations.

The advice provided was limited to information; ABSs did not take any actual steps to assist practices to increase capacity. Again, as relator described it:

> [W]e could give them the information, but for them to actually make the changes, they had to take the bull by the horns and do that themselves.

(*Id.* at 24).

Thus, and in simple terms, the IOM is a program that built on the general advice of the MBPO program concerning IOI suite efficiency—which relator has conceded is lawful—and provided specific advice as to a particular physician practice. The question, then, is whether that additional step crossed the line from lawful support to an unlawful kickback.

Based on the record evidence cited by relator, the answer to that question is no. By definition, the IOM was employed with physician practices that were already infusing Remicade and/or Simponi ARIA. The IOM is entirely related to those two infusible medications; there is no evidence that it had any application to any other infusible medications that might be prescribed by rheumatologists or gastroenterologists—if, in fact, such medications exist.[26]

Among other things, Remicade requires a two-hour infusion, and Simponi ARIA requires 30 minutes. The "efficiency" of the infusion suites—that is, the ability of the suites to handle additional patients—is clearly dependent on the length of time it takes to set up and perform

[26] As noted, relator's strongest evidence in that regard is the statement by Brian Smith that the SOC programming would "have interest" to physicians who "wanted to infuse products in their office regardless of Simponi ARIA or Remicade." (Smith Dep., Dkt. No. 543-3, at 249).

those infusions, and the staff and equipment necessary to accomplish those tasks. At a minimum, without any evidence as to the existence of other infusible products, the length of time required to infuse those products, or the support required to administer them safely, there is no basis to conclude that the IOM had any independent value to physician practices. Put another way, if Remicade and Simponi ARIA did not exist, the IOM would have no value. It is not sufficient simply to characterize the services as involving management or business consulting advice; the same might be said about billing or reimbursement advice, which is plainly lawful, or the advice described in the written materials—including the discussion in the MBPO slide deck about improving infusion efficiency—that relator concedes is lawful.

Finally, the services provided through the IOM are distinguishable from business advice that courts have found to constitute unlawful remuneration in other AKS cases. *United States ex. rel. Hart v. McKesson Corp.* is instructive. 602 F. Supp. 3d 575 (S.D.N.Y. 2022), *aff'd in relevant part*, 96 F.4th 145 (2d Cir. 2024). That case involved, among other things, McKesson's provision of a tool called the "Margin Analyzer" to oncology practices. *Id.* at 581. That tool (and related tools) allowed practices "to compare the reimbursement rates of interchangeable drugs," thereby allowing practices to determine "which of the similar drugs would yield the highest profit for the practice." *Id.* The court found, in ruling on McKesson's motion to dismiss, that the realtor had "plausibly alleged that the Margin Analyzer . . . ha[d] substantial value apart from the products offered by McKesson," and therefore constituted remuneration. *Id.* at 587.

The allegations in *Hart* went well beyond mere provision of those tools. McKesson also "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." *Id.* at 588. In addition, while business-management tools, including the Margin Analyzer, were offered for free

to practices that committed to purchase a given quantity of McKesson's products, another division of McKesson sold the same tools to practices "in exchange for a percentage of a practice's overall revenue." *Id.* As the *Hart* court noted, the fact that the same tools that were offered to some customers for free were sold to others "gives rise to a plausible inference that the tools had value." *Id.*

Here, by contrast, there is no evidence that the IOM was used to measure the profitability of different medications; that Janssen employees were instructed to identify overall "key areas of improvement" for physician practices, and to provide that information quarterly; or that the IOM was offered for a price by another of Janssen's divisions. Nor is there any other case law cited by relator in which similar or analogous facts have been found to constitute an AKS violation.

Thus, according to the record evidence, the IOM presentations constituted product support for the two infusible medications that did not have substantial independent value to the physician practices.

6. Conclusion

In summary, viewing the evidence in the light most favorable to her, and drawing all reasonable inferences from the evidence in her favor, relator has failed to come forward with evidence sufficient to establish that defendant provided services having "substantial independent value" in order to induce physician practices to purchase Remicade or Simponi ARIA. The Court accordingly concludes that the evidence does not support a finding of a violation of the AKS.

Rather than stop at that point, the Court will also take up the issue of whether the evidence supports a finding of a knowing and willful violation.

7. Knowing and Willful Violation

To prove an AKS violation, relator must show that defendant not only provided unlawful remuneration to induce the purchase of its medications, but that it did so "knowingly and willfully."

a. Legal Standard Generally

To act "knowingly and willfully" for purposes of the AKS, a defendant must act with knowledge that its conduct is unlawful and intent to violate the law. To act "willfully" for purposes of the AKS means "to do something purposely, with the intent to violate the law," or "to do something purposely that [the] law forbids," and that to act "knowingly" is "to do something voluntarily, to do it deliberately, not to do something by mistake or by accident or even negligently." *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989). It is not necessary to prove that the defendant intended to violate the AKS in particular. The AKS explicitly provides that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]" to satisfy the scienter requirement. 42 U.S.C. § 1320a-7b(h). Thus, the AKS requires that the defendant act with knowledge that its conduct is unlawful and with the intent to violate the law, but does not require that the defendant intend to violate the AKS in particular. *See United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 157 (2d Cir. 2024); *United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015); *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015).

b. The Collective Knowledge Doctrine

As a general matter, the knowledge of a corporation may be established in one of two ways. First, a plaintiff can show that an employee, acting (1) within the scope of his or her employment and (2) in a situation where it is fair to impute the employee's mental state to the corporation, possesses the relevant knowledge. *See Platten v. HG Bermuda Exempted Ltd.*, 437

F.3d 118, 130 (1st Cir. 2006); *United States v. Josleyn*, 206 F.3d 144, 159 (1st Cir. 2000). Alternatively, in some situations, the "collective knowledge" doctrine applies, such that the corporation's knowledge consists of all the knowledge held collectively by its employees. *See United States v. Bank of New England, N.A.*, 821 F.2d 844, 856 (1st Cir. 1987).

In *Bank of New England*, the First Circuit approved a jury instruction that the jury could find that the defendant acted willfully if the government proved either that "[1] an employee within the scope of his employment willfully failed to file a required report [under the Currency Transaction Reporting Act ("CTRA")] or [2] that the bank was flagrantly indifferent to its obligations." *Bank of New England*, 821 F.2d at 855. The First Circuit had noted that the use of the word "willfully" in the CTRA required the government to prove both "the defendant's knowledge of the reporting requirements and his specific intent to commit the crime." *Id.* at 854 (quoting *United States v. Hernando Ospina*, 798 F.2d 1570, 1580 (11th Cir. 1986)); *see Hartzel v. United States*, 322 U.S. 680, 686 (1944) ("T[he] requirement of a specific intent springs from the statutory use of the world 'willfully.'").[27]

The Court will follow the standard articulated in *Bank of New England*, as modified in light of the statutory language of the AKS. As to the requirement that the relator prove that defendant "knowingly" violated the AKS, it will apply the collective knowledge doctrine, recognizing that it is not necessary that relator prove "actual knowledge" of the AKS. *See* 42 U.S.C. § 1320a-7b(h). As to the requirement that relator proved that defendant "willfully" violated the statute, it will require evidence either (1) that one or more employees, acting within

[27] The District of Columbia Circuit has held that under the False Claims Act, "'collective knowledge' provides an inappropriate basis for proof of scienter." *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010). The First Circuit has not addressed the issue. Because the present issue involves the AKS, and because the statutory language of the FCA is not identical, the Court will apply the collective knowledge doctrine.

the scope of their employment, had the intent to violate the law or (2) that the corporation was "flagrantly indifferent" to its legal obligations, recognizing that it is not necessary that relator prove "a specific intent to commit a violation" of the AKS. *See id.*

c. Interaction Between Criminal and Civil Standards

The AKS is a criminal statute, although it may be used, as here, as the predicate to establish civil liability. The same interpretation of the statute applies in both the civil and criminal contexts. *See, e.g.*, *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1050 (6th Cir. 2023) ("Recall that the same language [in the AKS] creates civil *and* criminal liability. In the context of dual-application statutes like this one, we give the same interpretation to the same words, whether applied in a civil or criminal setting."). The standard of proof in the civil context, of course, is preponderance of the evidence, not proof beyond a reasonable doubt.

d. Relator's Evidence of Knowledge and Willfulness

The Court turns next to a review of the evidence submitted by relator in support of her contention that defendants knowingly and willfully violated the AKS. Relator essentially relies on four categories of evidence in support of that claims.

(1) Evidence of Alleged Concealment

Relator first contends that "Janssen took steps to obscure the true nature of the SOC programs." (Rel. Mem. at 15) (citation modified). Evidence that a defendant attempted to hide potential violations of law is certainly probative of willfulness. *See, e.g.*, *United States ex rel. Aharon v. Nuvance Health, Inc.*, 2025 WL 968583, at *10 (S.D.N.Y. Mar. 31, 2025) (noting, in context of FCA scienter, that "courts have held that actions taken to hide a defendant's potential non-compliance with a regulatory requirement suggest scienter").[28]

[28] Janssen contends that it openly disclosed its SOC programs to federal authorities and that therefore it could not have had any intent to conceal what it was doing. (*See* Def.'s Mem. at 22; Def.'s SMF ¶¶ 114-24). Such

It is of course true that the alteration of documents can be a means by which unlawful activities can be concealed. But it is also true that a routine feature of any organization is the circulation of documents for review and comment, and the subsequent editing of those documents. Editing, to make documents clearer and more accurate and to ensure legal compliance, is generally a desirable activity. And there is a vast difference between editing for the purpose of concealment and editing for the purpose of accuracy.

Here, relator points to four instances of documents that were allegedly edited as an act of concealment to disguise unlawful violations of the AKS.[29]

First, relator points to an email exchange from June 2013 in which Angela Wood, a Janssen compliance officer, was asked by an individual named James Knepp to provide comments on "a few slides" to be presented to ABSs at an upcoming sales team meeting. (Ex. 117, Dkt. No. 599-28). Wood responded that such presentations typically include a slide "up front" with "compliance-related disclaimers" and provides an example, which (among other things) states that ABSs should not discuss profits or reimbursements for competing products. (*Id.*). She also suggests changing the term "Operational Efficiency" to "something like Access Support for our IV Therapies" and changing a title reading "IOI Sustainability" to "IOI Support for Our Products." (*Id.*).

Second, relator points to email exchange from December 2013 in which Wood is asked to provide "feedback/approval" on a slide deck that was to be used for training for Regional

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evidence, while relevant, is of limited value, as there are many reasons why the government may not realize the impact of such a disclosure or may not have the resources to follow up with an investigation.

[29] Relator also points to a fifth instance: a "pocket resource" that she contends was edited to add certain phrases and remove others. The citation she provides, however, is not to the document itself, but to an expert report that purports to quote from the document. (Ex. 72, Dkt. No. 598-21, at 34). The document is not attached to the report. Under the circumstances, the Court will not consider the expert's characterization of a document that is not in the record.

Business Managers (and, eventually, ABSs). (Ex. 118, Dkt. No. 599-29). Wood again requested that "standard compliance disclaimers slides" be included "up front," including adding cautions that only PRC-approved materials could be used during sales calls and that ABSs could not discuss "profit margins." (*Id.*). She also suggested, as to "Slide 11," that the phrase "Engage all account stakeholders (HOPD and IOI) to increase IV utilization" be changed to "Engage all account stakeholders (HOPD and IOI) on clinical benefits of our IV products and challenge them to identify appropriate patients for IV." (*Id.*).

Third, relator sites to an email exchange from January 2011 in which an individual named Larry Box reported that certain materials (identified as "MBOs") had been presented to "HCC and Comp" and "received approval with only a minor change." (Ex. 119, Dkt. No. 599-30). (Presumably, "HCC" refers to "Health Care Compliance" and "Comp" refers to "compliance"). The "minor change" was in "the section that listed strategy examples, we replaced 'Increase Market Share' with 'Improve Site of Care access to enhance product growth.'" (*Id.*).

Fourth, relator cites to an email dated September 12, 2014, from Louis Zambelli to eight other individuals. (Ex. 120, Dkt. No. 599-31). The email attaches a document (which is not provided) that "should help answer most if not all of your questions" about "the MBO document for H2" (which is not identified). (*Id.*). The email includes the following statement: "PLEASE NOTE: Do not talk about growth using vial information . . . . NO to % Growth in vials either. All we can use is patient growth. Remember we are all about access and patients. I suggest making sure you and your IAM teams are aligned with new patient growth since other RBDs may see some of this work????" (*Id.*).

Those documents, however, cannot begin to support the weight relator seeks to place on them. The first two instances involved requests to a compliance officer for comment on training

materials before they were presented. She provided those comments, all of which were minor, and all of which were apparently adopted. The third involved a document that included a change that had been suggested earlier by a compliance officer, which was also adopted. And the fourth involved a direction to staff that certain topics should not be discussed, and did not involve any act of editing at all. Broadly speaking, all four instances involved cautions or reminders that ABSs should steer clear of business discussions and focus instead on patient care.

Of course, the mere fact that defendant can offer innocent explanations for the edits, without more, is not sufficient. But only reasonable inferences may be drawn in relator's favor. *See Bickerstaff v. Vassar Coll.*, 196 F.3d 435, 448 (2d Cir. 1999) ("An inference is not a suspicion or a guess. It is a reasoned, logical decision to conclude that a disputed fact exists on the basis of another fact that is known to exist." (citation modified)); *GeoMetWatch Corp. v. Behunin*, 38 F.4th 1183, 1200 (10th Cir. 2022) ("While [courts] draw all reasonable inferences in favor of the non-moving party [at summary judgment], an inference is unreasonable if it requires a degree of speculation and conjecture that renders the factfinder's findings a guess or mere possibility." (citation modified)).

In the absence of any countervailing evidence, it is unreasonable to infer that the three instances where a document was sent to a compliance officer for review, and the officer suggested changes, represented an attempt by a compliance officer to "conceal" the true nature of the SOC programs. That is particularly true where there is no evidence or suggestion that the recommendations of compliance officers were ignored. Nor is it reasonable to infer that the caution to "talk about" growth in patients rather than "vials" is a deliberate act of concealment.

The cases relator cites for the proposition that "[c]oncealment supports an inference of consciousness of guilt" are readily distinguishable. In *United States v. Vernon*, the defendant

concealed the true nature of his relationship with an individual who was offered kickbacks to refer patients to the defendant's specialty pharmacy business by hiring the individual as a "sales representative," despite the fact that the individual did "very little work" for the defendant's company, was paid at a rate "significantly higher" than the company's other "sales representatives," and that the defendant, before hiring the individual, "insisted that he receive a list" of the patients the individual could refer. 723 F.3d 1234, 1268-69 (11th Cir. 2013). *United States ex rel. Strunck v. Mallinckrodt Ard LLC* involved allegations that the defendant intentionally structured its donations to a copay assistance fund to ensure that only its drugs would be covered, and that an employee emailed articles "regarding the illegality of copay subsidies for Medicare Part D patients" to another employee. 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020). And *United States v. Ricard* included evidence that the defendant, who had referred patients to a home health agency in exchange for kickbacks, "misrepresented her monthly income in a loan application and, during the entirety of her employment at [the agency] did not file income tax returns," purportedly at least in part to disguise the fact that she was being paid based on how many patients she referred to the agency. 922 F.3d 639, 648 (5th Cir. 2019). Nothing in the record here remotely approaches such forms of concealment of unlawful activity.

(2) Evidence of Internal Warnings

Relator next contends that "internal warnings flagged the SOC programs as potential kickbacks." (Rel. Opp. at 16 (citation modified)). Such "internal warnings" may be probative of intent where an employee warns that the specific conduct in which the company has undertaken, or is about to undertake, is illegal. *See United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 421-22 (D. Mass. 2021); *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *3 (D. Mass. Aug. 23, 2016). Here, relator cites to evidence that two of

defendant's employees responsible for compliance voiced concerns or cautions about the SOC programming.

First, in 2010, Chris Firriolo, a Janssen director of regulatory affairs, wrote to Angela Wood and another compliance officer about Janssen's plan to engage Xcenda to help provide the SOC programs. (Rel. SDMF ¶ 203). In his email, Firriolo cautioned that "there [was] the potential risk that" the SOC programs "could be presented as a means to generate revenue for the practice" to which they were provided, rather than "improving access and care to patients prescribed treatment with REMICADE." (Ex. 79, Dkt. No. 598-28, at 3). He also wrote that there was "the risk that inappropriate involvement by us (or an agent of ours) could be viewed as offsetting costs that the practice would otherwise need to incur to set up their in-office infusion capacity." (*Id.*).[30]

Second, in 2011, Roger Kung, a Janssen compliance officer, initiated a review of the SOC programs to ensure their "alignment" with defendant's "compliance frameworks." (Rel. SDMF ¶ 212; Ex. 81, Dkt. No. 598-30, at 3). That review noted several "compliance sensitivities" with the programs, including the (accurate) contention that defendant could not "provide a resource or service that is not related to the use of our product or may benefit the customer with value that they would otherwise need to pay for themselves," or that would "offset[] other overhead expenditure[s]." (Ex. 81, Dkt. No. 598-30, at 8 (citation modified)). Firriolo later prepared a summary of Kung's review that repeated the same "compliance sensitivities." (Ex. 82, Dkt. No. 598-31).

That evidence, however, shows nothing more than the fact that Janssen employed

[30] Later emails included in the same exhibit show that the plan was reviewed and approved by Janssen's compliance department. (*Id.* at 2).

compliance officers who did their jobs: reminding others of the company's relevant legal obligations and cautioning as to potential risks and sensitivities. There is no suggestion that any employee believed the programs, as implemented, violated the AKS or any other law. If a mere discussion of "potential risk[s]" or "sensitivities" is sufficient evidence to show that defendant willfully violated the law, defendant would effectively be punished for having a compliance department at all—or at least one that actually pointed out areas of risk or concern.

The cases that relator cites involved circumstances where defendant had specifically identified a particular arrangement as a "*quid pro quo*," or that one of a defendant's employees "circulated a law firm presentation warning of the risks associated with donations to copay assistance charities" while the defendant was doing precisely that. *Organon*, 2016 WL 10704216, at *3 ("quid pro quo"); *Teva Pharms.*, 560 F. Supp. 3d at 421-22 (copay assistance presentation). Again, there is nothing approaching such a situation here.

(3) Evidence of Past Institutional Issues

Relator further contends that "Janssen's institutional history demonstrates awareness of AKS risk." (Rel. Mem. at 17) (citation modified). She notes that defendant and other units of Johnson & Johnson had previously settled several FCA cases and entered into a Corporate Integrity Agreement with HHS-OIG. (Rel. SDMF ¶ 246).

The mere fact that Janssen settled other cases, however, has little, if any, relevance to this case. At most, the evidence to which relator points shows institutional knowledge of the existence and requirements of the AKS—facts that are not, at least as a general matter, in dispute. But that alone is not enough to show that defendant acted knowingly and willfully here.

(4) Evidence of Compliance Programs

Finally, relator contends that "Jannsen's own compliance policies prohibited the SOC programs." (Rel. Mem. at 14) (citation modified). Evidence of widespread disregard of

established compliance policies is certainly evidence of willfulness, as it suggests that such policies may amount to nothing more than a sham. *See United States v. Teva Pharms. USA, Inc.*, 2019 WL 1245656, at *11 (S.D.N.Y. Feb. 27, 2019) (noting that compliance policies "are only as good as their implementation; the very nature of a sham is that it pretends to be compliant when it is not") (quoting *United States ex rel. Booker v. Pfizer, Inc.*, 188 F. Supp. 3d 122, 134 (D. Mass. 2016)); *United States ex rel. Bilotta v. Novartis Pharms. Corp.*, 50 F. Supp. 3d 497, 519 (S.D.N.Y. 2014) (noting that, where a defendant's conduct violates several provisions of its compliance policies, it "rais[es] a strong inference that [defendant] acted knowingly and willfully" in offering prohibited remuneration).

Relator's argument on this point proceeds essentially as follows. First, relator notes (correctly) that defendant's compliance policies prohibited its employees from engaging in "consulting" or offering "consulting services" to practices. (Ex. 72, Dkt. No. 539-72, at 12-14; Ex. 76, Dkt. No. 539-76, at 50; Ex. 77, Dkt. No. 539-77, at 16). Second, she contends that the SOC programs in fact constituted unlawful consulting services. (Rel. Mem. at 15). Therefore, she contends, the fact that defendant's employees continued to offer the SOC programs shows widespread noncompliance with defendant's policies.

That argument does not withstand scrutiny. All of the SOC programming at issue in this case was approved by individuals at Janssen with compliance responsibilities. There is no evidence that employees were ignoring the guidance or warnings of the compliance officers. And the relevant question is whether any of defendant's employees *knew* that they constituted unlawful services and intentionally provided them anyway, or otherwise deliberately or recklessly disregarded the requirements of the law. On that point, the evidence is essentially silent. The parts of the record to which relator cites, both in opposing defendant's motion for

summary judgment and in support of her own motion, simply do not show, or even suggest, that any of defendant's employees believed that the SOC programs constituted unlawful "consulting" in violation of the AKS.

Relator points to the deposition testimony of Brian Smith, who testified as a Rule 30(b)(6) deponent for Janssen. (Rel. SDMF ¶ 224). Smith testified that the SOC programs included information about "how to start an IOI, how to manage an IOI, how to make an IOI more efficient." (Smith Dep., Dkt. No. 543-3, at 115-16). Relator contrasts that with Angela Wood's testimony that defendant's employees "were not permitted to" engage in "consulting." (Wood Dep., Dkt. No. 543-1, at 193).

But when Smith was asked immediately after he gave that response if he "believe[d] that the ABS site of care programming was providing information as a consultant to the medical practices," he answered that "[he] d[id] not." (Smith Dep., Dkt. No. 543-3, at 116). And when asked whether providing information about "how to start an IOI" constituted education about "administering" Remicade or Simponi ARIA, Smith testified that "[i]f a physician has decided they want to administer Remicade to a patient and they want to administer it in their office, they are going to need to know how to procure the drug, how to mix it, how to administer, what kind of nurse support you are going to have to have. What kind of supplies you may need." (*Id.* at 118-20). And Wood herself testified that "consulting" was "very different" from "what our ABSs were doing." (Wood Dep., Dkt. No. 543-1, at 191).[31]

[31] Relator also points to evidence that defendant's "own representative testified" that an "independent-value analysis . . . was required for 'good faith' AKS compliance." (Rel. Mem. at 15). Relator contends that the fact that defendant conducted a fair-market value analysis for its arrangement with Xcenda to deliver the SOC programming, but not for its provision of the SOC programs to physician practices, shows that it was not following its own policies. (*Id.*; Rel. SDMF ¶¶ 55-57, 165-70, 225-30). However, the only relevant evidence, from Angela Wood's deposition, indicates that the reason why defendant conducted a fair-market value assessment of the Xcenda arrangement was that Xcenda was a subsidiary of AmerisourceBergen, a company that also purchased defendant's drugs. (Wood Dep., Dkt. No. 543-1, at 236). As a result, a fair-market value assessment was required to ensure that defendant was not overpaying Xcenda for the services it was providing in order to induce AmerisourceBergen to

Furthermore, and as noted, relator herself provides no real evidence of willfulness. She submitted no affidavit in opposition to the motion for summary judgment. There are no affidavits or deposition testimony from any of her fellow ABS employees describing how they provided unauthorized or unlawful consulting services. And there are no affidavits or deposition testimony from any physician, health care professional, or office manager detailing the provision of such services. And she does not contend that she personally participated in any AKS violation. Indeed, in her deposition, she testified as follows:

> Q. When you were working as an ABS, you didn't believe that you yourself were violating [Janssen's] HCC [Health Care Compliance] policy? . . .
>
> A. That is correct, yes.
>
> . . .
>
> Q. You didn't believe you were providing a kickback?
>
> A. Not at the time.

(Long Dep., Ex. 17, Dkt. No. 539-17, at 145-46).

Finally, as evidence of Janssen's willfulness, relator points to an internal training document that stated: "Bottom line: none of our job activities can violate the false claims act or the anti-kickback statute. Easier said than done. There is a lot of gray in [healthcare compliance]." (Ex. 83, Dkt. No. 598-32, at 8). The document in question is a 46-page slide deck from February 2014 that is titled "ABS Site of Care Speaker Program Training." (*Id.* at 5). It was reviewed and approved by multiple individuals at Janssen, including compliance officer Angela Wood. The slides provide an overview of the "Compliance Landscape," focused largely

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purchase more of defendant's products. (*Id.* at 236-37). The physician practices, by contrast, were differently situated, because defendant was not paying them for providing some service to defendant. For that reason, as Wood explained, a fair-market value analysis would not have looked at "the value back to the physician," and was therefore not required by defendant's policies. (*Id.* at 244).

on the AKS and the FCA, followed by a series of slides providing specific instructions and advice as to what ABSs and others could and could not say and do (for example, instructing that they could not "[p]rovide supplementary information or materials not approved for use by the company"). (*Id.* at 18). The legal overview includes the statement quoted by relator that health care compliance includes "a lot of gray." (*Id.* at 8).

The statement is, of course, perfectly accurate: there is, in fact, "a lot of gray" in health care compliance, particularly as to the application of the AKS. The statement might be evidence of willfulness if a reasonable person would have interpreted it as an invitation or encouragement to ABSs to violate the statute, or that the law could be violated without consequence. But no reasonable person—in the context in which it was presented, which was a training session that discussed the requirements of the AKS and the adverse consequences of violations—would interpret it that way.

(5) Conclusion

In summary, viewing the evidence in the light most favorable to her, and drawing all reasonable inferences from the evidence in her favor, relator has failed to produce evidence sufficient to establish a knowing and willful violation of the AKS. She has produced no evidence that any individual employee of Janssen had the necessary intent to violate the law, and the evidence falls well short of establishing that the corporation as a whole was flagrantly indifferent to its legal obligations. Accordingly, relator cannot make out an AKS claim, and defendant is therefore entitled to summary judgment in its favor.

8. False Claims Act

Because relator has not established that there is a genuine issue of material fact as to a violation of the Anti-Kickback Statute, it is not necessary to reach defendant's arguments as to the False Claims Act.

B. Relator's Motion for Summary Judgment

Relator cross-moved for summary judgment on the issue of defendant's scienter. For the reasons set forth above, because there is no genuine dispute of material fact that defendant did not act with the requisite scienter, the motion will be denied.

IV. Conclusion

For the foregoing reasons, defendant's motion for summary judgment is GRANTED and relator's motion for summary judgment is DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
United States District Judge

Dated: September 30, 2026