226 F.Supp.3d 1032 (2016)

UNITED STATES of America, et al., ex rel. Brown v. CELGENE CORPORATION.

United States District Court, C.D. California.

Signed December 28, 2016.

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Presiding: The Honorable **GEORGE H. KING**, *U.S. DISTRICT JUDGE*.

Proceedings: (In Chambers) Order re: Defendant's Motion for Summary Judgment (Doc. 325)

Defendant Celgene Corp. ("Celgene") moves for summary judgment on all claims asserted by Plaintiff-Relator Beverly Brown ("Brown") in her Third Amended Complaint. We have considered the parties' joint brief (Doc. 325), the authorities and record citations referenced therein, the joint statement of uncontroverted facts (Doc. 326), the United States' Statement of Interest ("SOI") and the response thereto [1035] (Docs. 328, 338), the State of Texas's SOI and the response and reply thereto (Docs. 340, 345 361), and the notices of supplemental authority filed by the parties (Docs. 342, 364-368). We deem this matter appropriate for resolution without oral argument. L.R. 7-15. We grant the motion in part and deny it in part.

I. BACKGROUND

Celgene is a pharmaceutical company. Two of its drugs are at issue in this case: Thalomid and Revlimid. Thalomid first received FDA approval in July 1998 for treatment of erythema nodosum leprosum ("ENL"), a complication associated with leprosy. Doc. 329-58. In May 2006, Thalomid received a second approval for use (in combination with dexamethasone) in patients with newly-diagnosed multiple myeloma ("MM").

Doc. 329-60.[1] Revlimid first received FDA approval in December 2005 for "the treatment of patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes ["MDS"] associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities." Doc. 329-59.[2] In June 2006, the FDA approved Revlimid, in combination with dexamethasone, for MM patients who had received at least one prior therapy. Doc. 329-61. In June 2013, the FDA approved Revlimid in mantle cell lymphoma patients "whose disease has relapsed or progressed after two prior therapies, one of which included bortzezombid." Doc. 329-62.

Brown is a former Celgene employee. She was hired in April 2001 as an "Immunology Specialist," although she actually performed sales work. Doc. 333-48, ¶¶ 1, 15. In late 2007, Brown became concerned when her manager instructed her to call physicians' offices to ask them to change billing codes associated with prescriptions of Celgene's drugs. ¶¶ 49-57. Brown sent a letter to management to complain about this practice, which she believed was illegal. ¶ 58. Brown later contacted the FDA and legal counsel. ¶¶ 63-64. As a result of these contacts, Brown came to believe that many of the things she had been required to do at Celgene were unlawful. *Id.*

On April 27, 2010, Brown initiated this *qui tam* action against Celgene, on behalf of the United States, twenty-four states, the District of Columbia, and the City of Chicago. Doc. 1. These governmental entities declined to intervene. Doc. 54. The case was unsealed, and the complaint was served on Celgene on October 1, 2013. Doc. 58. Brown filed her Third Amended Complaint ("TAC") on February 5, 2014. Doc. 72. The TAC asserts two claims under the False Claims Act ("FCA"), 31 U.S.C. § 3729, and dozens of other claims under analogous state laws. On July 10, 2014, we denied Celgene's motion to dismiss the TAC, except with respect to three state-law claims, which we dismissed. Doc. 147. On August 29, 2016, Celgene filed this motion for summary judgment. Doc. 325. [1036] The parties' positions are briefly summarized as follows: Brown's claims are predicated on the theory that Celgene engaged in an unlawful campaign to promote Thalomid and Revlimid, which included off-label promotion and payment of illegal kickbacks to physicians. According to Brown, Celgene's off-label promotion mostly involved direct contact with physicians and was centered on cancer. Although Celgene's drugs were not approved for any cancer use until 2005 and were approved for a narrow subset of cancers thereafter, the company began promoting Thalomid and Revlimid for a wide variety of cancers as soon as these drugs hit the market. Celgene paid kickbacks — in the form of speaker fees, paid clinical trials, advisory board positions, and authorship of ghost-written articles — to physicians in exchange for prescriptions of its drugs. Celgene's efforts were successful in causing physicians to prescribe Thalomid and Revlimid, and that some of the resulting prescriptions were submitted to, and paid by, Medicare, various state Medicaid programs, TRICARE, and the Department of Veterans Affairs ("VA"). Brown argues that Celgene is liable under the FCA and its state

equivalents for these claims because claims for off-label prescriptions or prescriptions tainted by kickbacks are not reimbursable under the relevant programs.

Celgene argues that it did nothing wrong. In its view, off-label promotion is not illegal; in fact, truthful off-label promotion may be protected by the First Amendment. In any case, Brown cannot show that Celgene's promotional activities caused doctors to prescribe Thalomid and Revlimid; physicians exercise independent judgment in deciding what drug to prescribe, and there were legitimate medical reasons for a physician to prescribe these drugs off-label. Celgene disputes Brown's contention that the relevant government programs are required to reject claims for off-label prescriptions; it argues that the programs actually have discretion to reimburse off-label uses that are in a patient's best interest. Even if off-label claims are not reimbursable, Brown has not shown that this prohibition was material to the government or that Celgene knowingly violated the law. As to Brown's kickback claim, Celgene argues that all of the payments it made to physicians were for legitimate services.

II. LEGAL STANDARD

We may grant summary judgment only "if the movant shows that 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). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). On a motion for summary judgment, the district court's "function is not ... to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* at 249, 106 S.Ct. 2505.

The moving party bears the initial responsibility to point to the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Where the nonmoving party has the burden of proof at trial, the moving party can carry its initial burden either by submitting affirmative evidence that there is not a triable, factual dispute or by demonstrating that the nonmoving party "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case." *Id.* at 322, 106 S.Ct. 2548. The burden then shifts to the nonmoving party "to designate specific facts demonstrating the existence of genuine issues for trial." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, [1037] 387 (9th Cir. 2010) (citing *Celotex Corp.*, 477 U.S. at 324, 106 S.Ct. 2548). This means that the evidence is such that "a jury could reasonably render a verdict in the non-moving party's favor." *Id.* (citing *Anderson*, 477 U.S. at 252, 106 S.Ct. 2505). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255, 106 S.Ct. 2505.

III. OFF-LABEL PROMOTION

The FCA imposes liability where a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To prevail under § 3729(a)(1)(A), a relator must prove: "(1) a false or fraudulent claim (2) that was material to the decision-making process (3) which defendant presented, or caused to be presented, to the United States for payment or approval (4) with knowledge that the claim was false or fraudulent." *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047 (9th Cir. 2012).

Brown argues that Celgene is liable under the FCA because it engaged in a systematic campaign to encourage doctors to write off-label prescriptions of Thalomid and Revlimid when it knew these prescriptions were not reimbursable under the relevant government programs but would nonetheless be submitted for reimbursement. Celgene argues that Brown cannot prove causation, falsity, materiality, or scienter, in that order.

A. Causation

Brown can establish causation by showing that (1) Celgene's promotional activities caused doctors to write off-label prescriptions, and (2) these prescriptions were subsequently presented to Medicare and other government programs for reimbursement. *See, e.g., U.S. ex rel. Colquitt v. Abbott Labs.*, 2016 WL 80000, at *6 (N.D. Tex. Jan. 7, 2016). In analyzing these causation questions, we apply the "substantial factor" test, and ask whether presentment of Medicare claims was a foreseeable and natural consequence of Celgene's conduct. *See id.* We begin by considering the evidence on causation, before considering two legal arguments advanced by Celgene.

1. Causation Evidence

i. Celgene's Factual Showing

Celgene points to declarations from physicians stating that (1) they exercise independent judgment in deciding what drugs to prescribe; (2) they exercised independent judgment in prescribing Thalomid and Revlimid for off-label uses; and (3) their prescribing decisions were not influenced by their interactions with sales representatives. *See, e.g.*, Docs. 333-14 at 7; 329-31 at 3, ¶ 9; 329-33 at 7-8, ¶¶ 16-17. It also cites evidence showing that there were legitimate medical reasons for physicians to prescribe its drugs for certain off-label uses. *See* Doc. 326 at 6-12, 21-22 ¶¶ D8-D17, D36-D38 (describing clinical research showing potential effectiveness of Thalomid and Revlimid for certain off-label uses); *see also* Doc. 333-14 at 8 (Brown's expert Charles L. Bennett, M.D., acknowledging that Thalomid was a "breakthrough" for "patients stricken by certain forms of cancer"). This evidence is sufficient to shift the burden to Brown to "designate specific facts demonstrating the existence of genuine issues for trial." *In re Oracle Corp.*, 627 F.3d at 387.

ii. Brown's Evidence

Brown's evidence shows the following: On July 16, 1998, the FDA approved Thalomid for treatment of ENL, a complication associated with leprosy. This was a very small market; there are only a few hundred new leprosy cases diagnosed each year, and ENL only occurs in about a quarter of these cases. Doc. 334-4 at 22, n.32. Thalomid was not approved to treat [1038] any form of cancer until May 2006, when the FDA approved it, in combination with another drug, to treat newly diagnosed MM. Celgene's other drug — Revlimid — was not approved at all until December 2005, when the FDA approved it for a narrow subset of MDS cases; it gained an additional MM indication in 2006, which was similarly narrow in scope. Thus, Celgene arguably should not have promoted its drugs to treat cancer before December 2005; even after this point, its promotion arguably should have been limited to the narrow subset of cases for which it had received approval.[3]

Nonetheless, Celgene began to promote Thalomid for off-label cancer uses almost immediately after obtaining FDA approval for use in ENL cases. In 1999, for example, Celgene produced a document entitled "Thalomid Marketing Plan." Doc. 329-106. The document set forth plans to market Thalomid for off-label uses by, among other things, preparing "sales materials" for oncologists and hematologists, displaying exhibits at conventions of the American Society of Clinical Oncology and the American Society of Hematology, and publishing advertisements in journals targeting these specialists. *Id.* at 18-27. Hematologists and oncologists, of course, treat cancer, not leprosy. Marketing documents from later years tell a similar story. The 2000 Thalomid Marketing Plan stated that the company should strive to "legitimize Thalomid as a treatment option for a variety of tumor types ... while supporting the focused activity of our field force in MM." Doc. 329-107 at 4. The 2004 Business Plan for the West Region set specific sales goals for off-label uses of Thalomid, and urged representatives to discuss off-label cancer uses "on every call." Doc. 329-109 at 3, 9-10.

Celgene employed a large and growing sales force to implement the strategies described in its marketing documents. When Celgene launched Thalomid, it already had a sales force of about 20 people. Doc. 326 at 57, ¶ P45. By 2002, Celgene employed over 100 sales representatives, and by 2006, it had over 230 employees in this position. *Id.* ¶¶ P46-P47. Brown, the relator in this case, was hired to serve as one of these representatives in 2001. Doc. 333-48, ¶ 1. Brown was required to read extensively about oncology and the effects that Thalomid had on specific types of cancer, and was trained to discuss cancer uses of Thalomid with doctors. ¶¶ 20-22. After this training, Brown was required to take an oncology test; once she passed, she was told to start calling doctors to discuss literature regarding the use of Thalomid to treat ovarian, MDS, brain, and prostate cancers. ¶ 24. Brown avers that from the beginning of her time at Celgene, her primary responsibility was to [1039] interact with oncologists and hematologists. ¶ 18. Eventually, "conversations were geared towards getting doctors to prescribe" off-label uses for specific patients. ¶ 31.

Brown's account is supported by other evidence showing that Celgene's sales representatives were regularly discussing off-label cancer uses with physicians around this time. *See, e.g.*, Doc. 330-4 (email chain from 2004, praising sales representative for taking physicians out to dinner to discuss off-label cancer uses of Thalomid).

Celgene's campaign was successful in encouraging physicians to prescribe off-label. Brown's expert, Joel W. Hay, Ph.D., analyzed data for sales contacts made by Celgene's sales representatives between August 2004 and May 2006. Doc. 334-4 at 21-22, ¶ 45. Hay found that Celgene's sales representatives made between 4,000 and 5,000 physician contacts per month, with nearly 80% of these contacts involving hematology-oncology or oncology specialists. *Id.* at 22, ¶ 46. During this period, Celgene sold between 800,000 and 1,000,000 Thalomid capsules per month, almost exclusively for off-label uses. Docs. 334-3 at 31; 334-4 at 22, ¶ 45 (99.75% of sales between 2001 and 2005 were for off-label uses). Physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts. Doc. 334-4 at 26-28, ¶¶ 53-54.

Celgene understood that its promotional efforts were successful in causing physicians to write prescriptions. For example, Celgene evaluated sale representatives based on their success in convincing physicians to prescribe Thalomid and Revlimid[4] and compensated representatives based on their sales volume.[5] This specific evidence that Celgene's marketing efforts were successful is reinforced by general evidence that pharmaceutical marketing is effective in influencing doctors' prescribing decisions.[6]

Hundreds of thousands of claims for off-label uses of Thalomid and Revlimid were submitted to Medicare and other government programs during the time when Celgene [1040] was promoting these drugs off-label. Based on data provided by the Center for Medicare and Medicaid Services ("CMS"), Dr. Hay estimated that 43,092 claims for off-label use of Thalomid were presented to Medicare between 1999 and 2005. Doc. 334-3 at 44, ¶ 87. Another 133,854 claims for off-label uses of Thalomid and 152,060 claims for off-label uses of Revlimid were submitted after 2005. *Id.* at 10. Claims for off-label uses of these drugs were also presented to TRICARE and the Florida Medicaid program. *Id.* at 45, 50-51, 53.

Celgene knew many of the prescriptions for its drugs, including those for off-label cancer uses, would be submitted to Medicare. *See* Doc. 331-93 at 6-7 (testimony of Celgene's 30(b)(6) deponent). Moreover, Celgene sometimes played an active role in facilitating the submission of claims. The 1999 Thalomid Marketing Plan listed "assist[ing] with drug reimbursement" as one of the strategies Celgene would employ to achieve its "brand objectives," one of which was for "oncology sales to be greater than 70% of the use." Doc. 329-106 at 12. Celgene's 30(b)(6) deponent acknowledged that the company would facilitate

conversations between doctors' offices, pharmacies, and patients to help resolve billing issues. Doc. 331-93 at 7.

iii. Conclusion

Brown's evidence shows that Celgene engaged in a systematic campaign to promote off-label uses of Thalomid and Revlimid, that physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts, that Celgene knew its promotional activities were delivering results, and that marketing to doctors is generally effective. In addition, Brown presents evidence that hundreds of thousands of claims for off-label uses of Thalomid and Revlimid were presented to government healthcare programs during the years when Celgene was engaged in off-label promotion of these drugs, that Celgene knew Medicare would be called upon to pay for many of these prescriptions, and that Celgene played an active role in facilitating the submission of certain claims. From this evidence, a reasonable jury could find that Celgene's off-label promotion was a substantial factor in causing physicians to prescribe Thalomid and Revlimid for off-label uses, and that submission of claims for these prescriptions occurred as a foreseeable and natural consequence of Celgene's conduct.

Celgene's evidence would not foreclose a reasonable jury from making this finding. A reasonable jury could choose to reject the physicians' testimony that Celgene's marketing efforts did not influence their prescribing decisions, based on evidence (such as that set forth in the Campbell Declaration) showing that physicians are often influenced subconsciously by pharmaceutical marketing. A reasonable jury could also find for Brown even if it accepted that there were some legitimate medical reasons for physicians to prescribe Celgene's drugs for off-label uses. At trial, Brown's burden is to show that Celgene's off-label marketing was a substantial factor in causing claims for off-label uses. It need not have been the *only* factor.

2. Celgene's Legal Arguments

Celgene makes two legal arguments as to why Brown's evidentiary showing is insufficient. First, Celgene argues that Brown cannot establish causation because she fails to identify a particular false claim that was presented as a result of its off-label promotion. It cites several cases for the proposition that a relator must submit "individualized evidence that promotional conduct caused specific physicians to write specific prescriptions." Doc. 325 at 20.[7] [1041] Brown counters that Celgene's standard would be impossible to meet, and cites cases of her own. *Id.* at 29-30.[8]

Having reviewed the parties' cases, we conclude that Brown is not required to identify a particular false claim caused by Celgene's off-label promotion. Of course, Brown must demonstrate a triable issue as to whether Celgene caused one or more false claims to be submitted. *See U.S. ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) ("an actual false claim is the *sine qua non* of a False Claims Act violation.") (internal quotation marks and citation omitted). But Brown need not identify a

specific claim; under *Aflatooni*, she can establish causation either by "com[ing] to court with a claim in hand" or by presenting "sufficiently detailed circumstantial evidence" that such a claim was submitted. *Id.* at 1002. We think Brown's evidence — which shows that Celgene engaged in a systematic campaign to promote off-label prescriptions of its drugs, that physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts, and that claims for off-label prescriptions were presented to the government in the hundreds of thousands following Celgene's promotional activities — constitutes "sufficiently detailed circumstantial evidence" that false claims were presented as a result of Celgene's conduct.

Courts have relied upon similar evidence to find causation in other FCA cases. In *Colquitt*, for example, the relator brought an FCA claim alleging that the defendants engaged in off-label promotion of their biliary stents. 2016 WL 80000 at *1. The court held that a triable issue existed as to whether the defendants' promotional conduct was a substantial factor in causing presentment of Medicare claims for these off-label uses. *Id.* at *6. In reaching this conclusion, the court relied on evidence that (1) the defendants "employed a multitude of sales representatives to market and sell biliary stents to cardiologists, vascular surgeons, and interventional radiologists performing vascular procedures," and (2) the defendants offered "training and advice on Medicare reimbursement procedures" in connection with these efforts. *Id.*[9]

Similarly, in *U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255 (D. Mass. Aug. 22, 2003), the relator brought an FCA claim alleging that the defendant engaged in off-label promotion of the drug Neurontin. *Id.* at *1. The court found a triable issue as to whether the defendant's promotional activities caused presentment of false claims, [1042] citing evidence that the rate of off-label prescriptions increased after the defendant's promotional events, and that doctors reported being more likely to write off-label prescriptions after these events. *Id.* at *5.

Also instructive is *In re Neurontin Mktg. & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013). In that case, an insurer brought a civil RICO action[10] against a drug manufacturer, seeking to recover the cost of prescriptions that would not have been written but for the defendant's off-label marketing. The insurer's expert "use[d] aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing" the relevant drug. *Id.* at 29. The expert performed a regression analysis[11] that found "a causal connection between the fraudulent marketing and the quantity of prescriptions written for off-label indications." *Id.* at 29-30. Based on this analysis, the expert opined that a significant portion of the off-label prescriptions would not have been written but for the off-label marketing. *Id.* at 30. The First Circuit found this report sufficient to support a finding of but-for causation, noting that "courts have long permitted parties to use statistical data to establish causal relationships." *Id.* at 42 (citations omitted).

Celgene cites *U.S. ex rel. Turner v. Michaelis Jackson & Associates, L.L.C.*, 2011 WL 13510 (S.D. Ill. Jan. 4, 2011) for the proposition that "a relator must establish actual presentment of a false claim `at an individualized transaction level.'" *Id.* at *7 (quoting *U.S. ex rel. Fowler v. Caremark RX, LLC*, 496 F.3d 730, 742 (7th Cir. 2007)). As *Turner* simply quotes *Fowler*, we focus our discussion on the latter case. *Fowler* involved allegations that a pharmacy resold medications that were returned to it without reimbursing the government for the original sale. 496 F.3d at 741. The court found the relator's failure to allege fraud at the "individualized transaction level" was fatal because the allegations in the complaint were consistent with the possibility that the defendant "replaced the returned prescription with another prescription without charge." *Id.* at 742. Even if the relator showed that a large percentage of the pharmacy's customers were enrolled in a government healthcare program, a large percentage of prescription drugs returned, and a large portion of the returned products resold, this would not show a likelihood that the government had been defrauded because the alleged scheme involved two independent steps, and the statistical evidence only bore on one. The only feasible way to demonstrate wrongdoing was to provide individualized evidence linking the two steps — two vouchers representing two charges for the same pill. *Id.* Those unique circumstances are not present here. There is no independent step in the causal chain that Brown's evidence fails to address. If, by way of example, the jury were to find that Celgene's promotional activities were a substantial factor in causing 50% of off-label Thalomid [1043] prescriptions between 1999 and 2005 and that 43,000 claims for off-label Thalomid prescriptions were presented to Medicare during the same time, the jury could infer that Celgene was responsible for causing the submission of 21,500 claims.[12]

Celgene's other cases are also distinguishable. The facts in *U.S. ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853 (7th Cir. 2006) are basically identical to *Fowler;* it is therefore subject to the same distinction. *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) was a civil RICO case, meaning that the plaintiffs were held to the more demanding but-for causation standard. Its holding was also limited to the class certification context. *See In re Neurontin*, 712 F.3d at 46 (*Eli Lilly* held that a group of third-party payors could not obtain class certification based on aggregate evidence, but found it "[un]clear" whether a single third-party payor could pursue such a theory) (citing *Eli Lilly*, 620 F.3d at 136). In *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009), the court dismissed an FCA claim under Rule 9 because the particular statistics offered by the plaintiff did not plausibly suggest causation. *See id.* at *9 (relator did not plausibly allege causal relationship between off-label marketing and off-label sales because "the increase in [the drug's] sales" following this marketing "[wa]s actually less than the ... increase ... in the sales of all [similar] medications" during the relevant time). In *U.S. ex rel. Drummond v. Solvay S.A.*, 2016 WL 1258401, 2016 U.S. Dist. LEXIS 43133 (S.D. Tex. Mar. 31, 2016), the court granted summary judgment because the relator sought to prove a nationwide scheme based on "incredibly" few instances of off-label marketing that were "isolated to one state." *Id.* at *11, 2016 U.S.

Dist. LEXIS 43133 at *43. The language quoted by Celgene is a comment on the weak evidentiary showing made by the relators in that case. *See id.* at *9-10, 2016 U.S. Dist. LEXIS 43133 at *36-37 (*"The evidence presented via briefing and at the hearing* would require a jury to draw inference upon inference ....") (emphasis added). *Louisiana v. Merck & Co.,* 2010 U.S. Dist. LEXIS 142767 (E.D. La. Mar. 31, 2010) was not an FCA case; it imposed an individualized proof requirement as a matter of state law.[13]

Celgene's second argument is that even if Brown can establish causation based on aggregate evidence, she must at least present a regression analysis or other statistical model that is capable of controlling for independent factors impacting doctors' [1044] prescribing decisions. *Id.* at 23-24. Celgene cites *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP,* 806 F.3d 71(2d Cir. 2015), for this proposition. *Id.* at 94-97. *Sergeants* is not controlling. For one thing, *Sergeants* was a civil RICO case, subject to the more demanding but-for causation standard. But more importantly, the plaintiffs in *Sergeants* had sufficient data to perform a regression analysis but chose not to. *Id.* at 96. "`At no time did Dr. Rosenthal say that a regression analysis could not be performed due to the lack of data or some other problem, or that a regression analysis would be inappropriate in this case.'" *Id.* (citation omitted). In our case, by contrast, Dr. Hay explained that a reliable regression analysis would not have been possible because Celgene destroyed all data related to its promotional activities before 2007. *See* Docs. 334-4 at 16-17, ¶¶ 33-35 & n.23; 331-99 at 11 (deposition of Dr. Hay, explaining: "without complete data, regression is unlikely to show causal relationships. It may show associations, but without complete data ... you have bias."). A reasonable jury could find Dr. Hay's explanation credible, and that a regression analysis is not required under the circumstances of this case.

B. Falsity

1. *Medicare*

Brown's theory is that claims submitted to Medicare seeking reimbursement for off-label uses of Thalomid and Revlimid were false because (1) Medicare claims impliedly certify that they are reimbursable; and (2) off-label uses of Thalomid and Revlimid were not reimbursable under the Medicare statute. Celgene disputes both premises.[14]

Celgene argues that Brown's theory fails because presentment of a claim to Medicare does not imply entitlement to be paid. It relies on *Universal Health Servs., Inc. v. U.S. ex rel. Escobar,* ___ U.S. ___, 136 S.Ct. 1989, 195 L.Ed.2d 348 (2016) (*"Escobar"*) to support this argument. In *Escobar,* the Court considered whether it was possible for an FCA relator to recover on a theory of "implied false certification" — the theory that anyone who submits a claim to the government impliedly certifies compliance with all conditions of payment. *Id.* at 1995. The Court held that such a theory was viable "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific

representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001.

Celgene argues that Brown cannot proceed on an implied certification theory because she cannot satisfy the two conditions mentioned in *Escobar.* Celgene misreads that decision. The Court explicitly declined to "resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment." 136 S.Ct. at 2000. Nor were the two conditions intended to describe the outer reaches of FCA liability: the Court stated that liability could be found *"at least"* where these conditions [1045] were satisfied. *Id.* at 2001 (emphasis added); *accord Rose v. Stephens Inst.,* 2016 WL 5076214, at *5 (N.D. Cal. Sept. 20, 2016) ("The Supreme Court's use of `at least' indicated that it need not decide whether the implied false certification theory was viable in all cases, because the particular claim before it contained `specific representations' that were `misleading half-truths.'"). Thus, *Escobar* leaves undisturbed cases in this circuit and elsewhere holding that a claim is "false" if it is statutorily ineligible for reimbursement. *See, e.g., Ebeid ex rel. U.S. v. Lungwitz,* 616 F.3d 993, 1001 (9th Cir. 2010); *Mikes v. Straus,* 274 F.3d 687, 700 (2d Cir. 2001).

We turn now to the question whether off-label uses of Thalomid and Revlimid were reimbursable under the Medicare statute. Medicare pays only for "covered part D drug," defined as:

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title;15 or(B) a biological product ... or insulin [and insulin products] ... and such term includes a vaccine licensed under [42 U.S.C. § 262] and any use of a covered part D drug for a medically accepted indication ....

42 U.S.C. § 1395w-102(e)(1).[16] "Medically accepted indication" is defined as "any use... which is approved under the Federal Food, Drug, and Cosmetics Act ... or the use of which is supported by one or more citations included or approved for inclusion in any of" three listed compendia. *See id.* at (e)(4)(A)(ii) (cross-referencing 42 U.S.C. § 1396r-8(k)(6)).

The parties agree that off-label uses of Thalomid and Revlimid were not "medically accepted" at the relevant times because they lacked compendia support. The only dispute is whether the lack of medical acceptance made these uses ineligible for reimbursement under Medicare. Brown and the United States contend that medical acceptance is a condition of reimbursement. Celgene argues that "`[m]edical acceptance' determines only when Medicare *must* reimburse" for a use, and that CMS has discretion to reimburse uses that are not medically accepted. Doc. 325 at 34.

In resolving this dispute, we do not start with a blank slate. CMS has adopted a regulation that interprets the Medicare statute to exclude from Part D's coverage all indications that are not "medically accepted." *See* 42 C.F.R. § 423.100. Under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984), we defer to this interpretation unless it is (1) contrary to "the unambiguously expressed intent of Congress" or (2) unreasonable. *Id.* at 842-43, 104 S.Ct. 2778.

Section '102(e)(4) is such a complicated maze one would be forgiven for thinking that it was designed to house a Minotaur. Making sense of it requires a long, winding journey through a series of cross-references. Nonetheless, we think it clear enough that a drug must be prescribed for a "medically accepted indication" in order to fall within the definition of "covered part D drug."

As relevant here, Medicare Part D covers drugs "that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of [§§ 'r-8(k)(2)]." 42 U.S.C. § 1395w-102(e)(1). Subparagraph A appears in subsection 'r-8(k)(2), which provides [1046] Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means —

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and —(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug; and (II) which has not been the subject of a final determination by the Secretary that it is a new drug (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and(B) a biological product, other than a vaccine which —(i)

may only be dispensed upon prescription,(ii) is licensed under section 262 of this title, and(iii) is produced at an establishment licensed under such section to produce such product; and(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

§ 1396r-8(k)(2). Paragraph (3) provides:

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.(B) Hospice services.(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.(D) Physicians' services.(E) Outpatient hospital services.(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.(G) Other laboratory and x-ray services.(H) Renal dialysis.Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication.

§ 1396r-8(k)(3).

Thus, the only prescription drugs covered by Medicare Part D are those that are "described in" the clauses that constitute subparagraph § 'r-8(k)(2)(A). That subparagraph defines the term "covered outpatient drug" to mean drugs that are FDA approved or otherwise lawful to market. But the entire subparagraph is "[s]ubject to the exceptions in paragraph (3)," and paragraph (3) states that "covered outpatient drug" excludes "a drug ... used for a medical indication which is not a medically accepted indication." Thus, the term "covered part D drug" is defined by reference to a subparagraph that, read in context, excludes drugs used for non-medically accepted uses. Although it is certainly laborious to discern the meaning of § '102(e)(1), we think anyone with the patience to peruse the statute will arrive at the same conclusion — a "covered part D drug" must have a "medically accepted indication."[17]

Because we conclude that section '102(e)(1)(A) incorporates the medical acceptance requirement, we need not consider the United States's alternative argument that this requirement is incorporated by the last clause of subsection (e)(1). *See* 42 U.S.C. § 1395w-102(e)(1) (the term "covered part D drug" "includes a vaccine licensed under [42 U.S.C. § 262] and any use of a covered part D drug for a medically accepted indication"). We note, however, that CMS and a clear majority of district courts have read this clause to incorporate the medical acceptance limitation,[18] while only one district court has read it differently. *See Layzer v.*

Leavitt, 770 F.Supp.2d 579 (S.D.N.Y. 2011). [1048] We conclude that a drug must be prescribed for a "medically accepted indication" in order to fall within the definition of "covered part D drug." Claims that sought reimbursement for non-medically accepted uses of Thalomid and Revlimid were false for purposes of the FCA.

2. Medicaid

The Medicaid statute provides that "[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if... the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). Courts and CMS have read this provision to allow states to exercise discretion in deciding whether to cover off-label uses. *See U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at *9 (E.D.N.Y. May 22, 2009); Doc. 329-22 at 184 (letter from CMS to Assistant Attorney General of Utah, explaining that the Medicaid statute "authorizes States to exclude... coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication," but does not "explicitly require them to do so").

Celgene submits declarations from (1) the Pharmacy Director for the Tennessee Medicaid Program, who states that the Tennessee Medicaid Program covers off-label uses of Thalomid and Revlimid (Doc. 329-50), and (2) the Pharmacy and Quality Section Chief for the Wisconsin Medicaid Program, who says that the Wisconsin Medicaid Program covers off-label uses of these drugs (Doc. 329-52). Brown does not address this evidence. We grant Celgene's motion for summary judgment with respect to claims presented to the Tennessee and Wisconsin Medicaid programs.

Celgene also submits a declaration from the Deputy Director of the Texas Medicaid/Chip Vendor Drug Program, who says that (1) the Texas Medicaid Program covers drugs listed on the Texas Drug Code Index ("TDCI"); (2) the Texas Medicaid program will not reject a claim for a TDCI drug based on the prescribed use unless the TDCI listing includes a prior authorization requirement; and (3) Thalomid and Revlimid are both TDCI drugs and neither was ever subject to a prior authorization requirement. Doc. 329-51. Texas responds that its Medicaid program is only authorized to cover medically accepted uses (Doc. 340 at 6), but it does not cite any statute, regulation, or guidance to this effect.[19] Because the undisputed evidence shows that Texas Medicaid program reimbursed prescriptions for Thalomid and Revlimid irrespective of use, we grant Celgene's motion for summary judgment with respect to claims presented to the Texas Medicaid program. We deny Celgene's motion for summary judgment as to the remaining Medicaid program, which Celgene does not address in its motion.

3. TRICARE and the VA

Brown does not point to any statute, regulation, or guidance that prohibits TRICARE or the VA from reimbursing off-label claims. Accordingly, Celgene is entitled to summary judgment with respect to claims submitted to TRICARE or the VA. [1049]

C. Materiality

A misrepresentation or omission is "material" for purposes of the FCA if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The FCA's materiality requirement is "rigorous" and "demanding." *Escobar,* 136 S.Ct. at 1996, 2003. A defendant is entitled to summary judgment if the undisputed evidence shows that its misrepresentation was not material to the government's payment decision. *See id.* at 2004, n.6.

In deciding whether the defendant's failure to disclose its noncompliance with a statutory, regulatory, or contractual requirement was material, it is "relevant, but not automatically dispositive," whether the government designated compliance with the requirement a condition of payment. *Id.* at 1996. The key question is whether the government is likely to attach significance to the requirement in deciding whether to tender payment. *Id.* at 2002-03. "[P]roof of materiality can include, but is not necessarily limited to, evidence that... the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 2003. But "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated... that is strong evidence that the requirements are not material." *Id.* at 2003-04.

Brown's theory is that claims for off-label prescriptions of Thalomid and Revlimid were false because providers failed to disclose that the claims were not for medically accepted indications. We think she can show that this non-disclosure was material. Medicare Part D may only reimburse "covered part D drugs," which must be "used for a medically accepted indication." 42 C.F.R. § 423.100. A medically accepted indication is thus an explicit condition of payment under this program. While that may not be "automatically dispositive" of the materiality inquiry, we think it highly "relevant." *Escobar,* 136 S.Ct. at 1996. We are not dealing with an extraneous condition included in a government contract, like the hypothetical requirement to buy American-made staplers discussed in *Escobar, id.* at 2004. Rather, we are dealing with an essential feature of the Medicare Part D program — a coverage limitation that is central to the balance Congress struck between expanding prescription drug coverage and containing costs. *Escobar* does not foreclose the possibility that a statutory requirement may be so central to the functioning of a government program that noncompliance is material as a matter of law. *Cf. id.* at 2004 (relator might be able to satisfy the FCA's materiality requirement by showing that the defendant violated "requirements ... so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of" the violation).

Even if the medical acceptance requirement is not per se material, we think a genuine dispute of material fact exists as to whether the requirement was material to the payment decisions at issue here. Celgene points to five lines of evidence in an effort to show an absence of such dispute. First, Celgene cites the expert

opinion of Leslie Norwalk, former Acting Administrator of CMS, who opined that Medicare contractors sometimes reimbursed prescription drug uses that were not medically accepted.[20] This evidence isn't helpful to Celgene. The fact that the [1050] government sometimes exercises its discretion to excuse non-compliance with a requirement does not establish that the requirement is immaterial as a matter of law.

Second, Celgene points to evidence that the FDA has been aware since it first approved Thalomid in 1998 that the drug would be prescribed off-label, and has received regular reports from Celgene disclosing off-label uses of Thalomid and Revlimid. *See, e.g.*, Docs. 329-1 at 5, ¶ 6; 329-6. This doesn't help Celgene either. The fact that the FDA knew generally about off-label use does not mean CMS knew about and agreed to reimburse particular off-label claims.

Third, Celgene cites to another section of Norwalk's declaration, which describes prior authorization and other programs that can be used to determine whether a particular prescription is for a medically accepted use. Doc. 329-22 at 28-31, ¶¶ 70-74. Norwalk notes that CMS rejected its Inspector General's recommendation that controls of this type be made mandatory. *Id.* at 25, ¶ 61. This argument misses the point. CMS's failure to follow the Inspector General's recommendation does not mean it thought the requirement immaterial, any more a homeowner's failure to install a home security system means she is indifferent to being burglarized. The relevant question is whether compliance with the medical acceptance requirement was material to CMS in deciding whether to pay particular claims. *See* 31 U.S.C. § 3729(b)(4) (a misrepresentation or omission is "material" if it has "a natural tendency to influence ... the *payment"* of a claim) (emphasis added).

Fourth, Celgene argues that CMS reimbursed off-label uses of Thalomid under the Medicare Replacement Drug Demonstration program. *See* 69 Fed. Reg. 38,898 (June 29, 2004). These reimbursements were authorized by section 641 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which allowed CMS to cover "certain self-injected or oral drugs ... not normally covered under Medicare Part B ... if they were a replacement for a non[-]self-administered drug or biological normally provided in a physician's office." *Id.* The program covered a variety of drugs, and was limited to 50,000 patients and total funding of $500 million. *Id.* at 38,899. This regulation doesn't help Celgene. The fact that CMS included off-label uses of Thalomid in a program designed to expand the scope of Medicare's prescription drug coverage on a temporary basis and for a limited number of patients does not show that CMS was willing to pay for these uses more generally.

Finally, Celgene cites Dr. Hay's expert report, which shows that CMS has continued to reimburse Thalomid and Revlimid since this case was initiated in 2010. Doc. 334-3 at 41. This evidence is insufficient to show that CMS "regularly pa[id]" claims for off-label uses of Thalomid and Revlimid "despite actual knowledge"

that these uses were not medically accepted. *Cf. Escobar*, 136 S.Ct. at 2003-04. Even if CMS knew after 2010 that incoming claims for Thalomid and Revlimid included claims that failed to meet the medical acceptance requirement, it does not follow that CMS had actual knowledge that particular claims were non-compliant and reimbursed them anyway.[21] This evidence does not establish

non-materiality as a matter of law. Celgene has not shown that it is entitled to summary judgment on materiality grounds.[22]

D. Scienter

To satisfy the FCA's scienter requirement, a relator must show that the defendant acted "knowingly." 31 U.S.C. § 3729(a)(1)(A). "Knowingly" means a person "has actual knowledge of the information" or "acts in deliberate ignorance" or "in reckless disregard" of the truth or falsity of that information. § 3729(b)(1)(A). Knowledge does not require "proof of specific intent to defraud." § 3729(b)(1)(B).

Celgene contends that it is entitled to judgment as a matter of law because its legal position (that Medicare is permitted to reimburse off-label, off-compendia uses) was "objectively reasonable." Doc. 325 at 47-48. Celgene cites *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 127 S.Ct. 2201, 167 L.Ed.2d 1045 (2007) to support this argument. In *Safeco*, the Court rejected the argument that "evidence of subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly." *Id.* at 70, n.20, 127 S.Ct. 2201. The Court explained that "[w]here... the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Id.* But if the defendant was "warned ... away from the view it took" by guidance from the courts or the agency charged with interpreting the statute, ambiguity in the underlying statute would not defeat a finding of willfulness. *Id.* at 70, 127 S.Ct. 2201; *see also U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) ("[E]ven if the [statute] is ambiguous and MWI's interpretation is reasonable, there remains the question whether MWI had been warned away from that interpretation."). Whether Celgene was warned away from the view it took is a question of fact. *See Purcell*, 807 F.3d at 288. [1052]

We do not think Celgene's position was objectively reasonable at the time of the alleged violations. Then, as now, there was a CMS regulation stating that Medicare would only reimburse medically accepted uses. 42 C.F.R. § 423.100. There was no judicial authority to the contrary.[23] At the time of the alleged violations, it was simply not the case that "the statutory text *and relevant court and agency guidance* allow[ed] for more than one reasonable interpretation." *Safeco*, 551 U.S. at 70, n.20, 127 S.Ct. 2201 (emphasis added).

Even if we were to hold otherwise, there would still be the factual question of whether Celgene was warned away from the view it took. *Purcell,* 807 F.3d at 289 ("Accepting the reasonableness of MWI's interpretation, the factual question remains whether there was sufficient evidence that MWI was warned away from its interpretation."). Celgene makes no effort to show the absence of a material dispute as to this factual question. That is just as well. The record includes no fewer than four presentations in which Celgene recognized that Medicare was prohibited from reimbursing uses that were not "medically accepted." *See* Docs. 334-77 at 12 (August 2008 presentation stating that "Part D plans take a risk of losing its 80% reinsurance subsidy from CMS if they cover a part D drug which does not have a FDA approved indication and not compendia listed in a reference guide which is officially recognized by CMS."); 334-68 at 38 (July 2010 presentation recognizing need for compendia support); 334-70 at 4 (undated presentation; "[d]rugs must be listed in 1 of 4 compendia or FDA labeled indication in order to get reimbursed by the government."); 334-81 at 21 ("The US Market Requires Indications or Compendia Listings for Reimbursement").

E. Conclusion

We conclude that genuine disputes of material fact exists as to whether Celgene caused the presentment of off-label claims, whether these claims were material to Medicare, and whether Celgene acted with scienter. We hold that Medicare claims that seek reimbursement for non-medically accepted uses are false as a matter of law, but that similar claims submitted to TRICARE, the VA, the Tennessee Medicaid Program, the Texas Medicaid Program, and the Wisconsin Medicaid Program are not necessarily false. Accordingly, Celgene's motion for summary judgment is granted with respect to claims submitted to the TRICARE, the VA, the Tennessee Medicaid Program, the Texas Medicaid Program, and the Wisconsin Medicaid Program, and otherwise denied.

IV. KICKBACKS

The Anti-Kickback Statute ("AKS") provides:

whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person — (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony ....

42 U.S.C. § 1320-a-7b(b)(2). Subparagraph B is the relevant provision in cases like this, where a drug company is alleged to have paid kickbacks in exchange for prescriptions of its drugs. *See generally United*

States v. Polin, 194 F.3d 863, 867 (7th Cir. 1999). A violation of subparagraph B occurs when the defendant: (1) knowingly and willfully makes a payment (2) as inducement to the payee (3) to purchase or recommend for purchase (4) any good or service that is reimbursable under a federal healthcare program. *See United States v. Miles,* 360 F.3d 472, 479-80 (5th Cir. 2004).

Although the AKS does not itself establish a civil cause of action, it states that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g).[24] Thus, Brown can establish an FCA claim by showing that (1) Celgene knowingly and willfully paid kickbacks to induce prescriptions of its drugs, and (2) claims for Celgene's drugs were presented to federal healthcare programs as a result. Celgene argues that Brown cannot show that it paid any kickbacks. Alternatively, Celgene argues that Brown cannot show that the alleged kickbacks caused any false claims to be submitted.

A. Payment of Kickbacks

A payment violates the AKS if "one purpose of the payment" was to induce prescriptions, "even if the payments were also intended to compensate for professional services." *United States v. Kats,* 871 F.2d 105, 108 (9th Cir. 1989) (internal citation and quotation marks omitted). Brown argues that Celgene violated the AKS in four ways: (1) by hiring physicians as promotional speakers in exchange for prescriptions, (2) by offering physicians paid clinical trials, advisory board positions, and ghost-written articles in exchange for prescriptions, (3) by paying physicians to recommend its drugs to other physicians, and (4) by using co-pay foundations to induce patients to buy its drugs.

1. Speaker Program

Brown's first theory is that Celgene violated the AKS by paying physicians, under the guise of a promotional speaker program, to induce them to write prescriptions of Thalomid and Revlimid. Celgene moves for summary judgment, arguing that the undisputed evidence shows its speakers were paid fair market value for providing a legitimate service. Celgene presents evidence that (1) the programs were organized by a third-party vendor (Doc. 329-1 at 6-7, ¶ 12), (2) speakers were paid a flat fee per event, based on experience and breadth of geographic recognition (Doc. 331-39 at 5-6), and (3) compensation was comparable to that provided by other drug companies (*see, e.g.*,Doc. 331-50 at 53). This evidence is sufficient to satisfy Celgene's initial summary judgment burden.

The burden now shifts to Brown "to designate specific facts demonstrating the existence of genuine issues for trial." *In re Oracle Corp.*,627 F.3d at 387. Brown offers [1054] three lines of evidence to show that Celgene's promotional speaker program was intended to induce speakers to prescribe the company's drugs. First, the honoraria paid to speakers were several times the amount of money the same doctors charged to perform other tasks. For example, one doctor was paid $3,000 an hour as a speaker, but charged only $500

an hour to prepare his expert report in this case. Docs. 334-23; 333-2 at 2. Second, although Celgene had a cap on the amount a doctor could earn as a promotional speaker each year, this cap was relatively high. In 2009, Celgene's vendor explained that "most companies have a cap which ranges from $50k to $100k and are typically inclusive of all activities/honoraria"; the same year, Celgene increased its annual cap from $100,000 to $200,000, non-inclusive of consulting fees and advisory board honoraria. Doc. 334-80 at 15-16. Third, Celgene did not limit the number of times a speaker could speak in a single day. One physician, Dr. Boccia, delivered ten speeches in a single day, and regularly spoke six or more times a day.[25]

This evidence does not create a triable issue as to whether Celgene's speaker program was intended to induce physicians to write prescriptions of Thalomid and Revlimid. The mere fact that some doctors were paid more on an hourly basis to give speeches than to perform other tasks for Celgene is unexceptional. The relevant question is whether Celgene's payments were excessive compared to the honoraria provided by other physician speaker programs. The undisputed evidence shows they were not. *See* Doc. 331-50 at 53-54 (Celgene's competitor Millennium Pharmaceutical paid honoraria of between $3,300 and $6,600 per speech); *see, e.g.,* Docs. 329-37 at 6, ¶ 14; 329-33 at 9, ¶ 21.

That Celgene's annual cap was higher than most of its competitors is similarly unexceptional. Celgene was not an outlier among its peers: Brown's evidence shows that at least one of the company's competitors had no salary cap at all. Doc. 334-80 at 15. Even if Celgene were an outlier, it would not be reasonable to infer much from that fact. Given that Celgene's hourly rate was comparable to that paid by its competitors, the only effect of an increase in the annual cap would be to allow speakers to give more speeches. The fact that Celgene allowed its speakers to work more does not give rise to the inference that speakers were being compensated for writing prescriptions.

As to Dr. Boccia, his schedule does not appear to be representative of Celgene's speakers as a whole,[26] and a reasonable jury could hardly find a company-wide kickback scheme based on the behavior of one individual. Moreover, although Brown had the opportunity to examine Dr. Boccia about his speaking schedule at his deposition, she apparently did not. As a result, there is nothing in the record to indicate that Dr. Boccia gave more speeches than could be justified by the number of physicians who wanted to attend them.

Two recent cases illustrate what is missing here. In *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.,* 50 F.Supp.3d 497 (S.D.N.Y. [1055] Sept. 30, 2014), the court held that the government intervenors adequately alleged that the defendant's speaker program was a pretext for paying kickbacks based on allegations that the defendant (1) "repeatedly invited the same participants and `speakers' to attend events concerning the same drug or topic in a short span of time;" (2) spent exorbitant amounts of money on individual events

and on its speaker program in general; (3) paid doctors for "speaking" at events that were purely social or never occurred at all; and (4) hosted "speaker" events at inappropriate venues, such as crowded sports bars, Hooters restaurants, and on fishing trips. *Id.* at 515. Also relevant was the intervenors' allegation that the defendant considered the number of prescriptions a doctor had written when deciding whether to employ the doctor as a speaker. *Id.*

In *U.S. ex rel. Arnstein v. TEVA Pharms., USA, Inc.*, 2016 WL 750720 (S.D.N.Y. Feb. 22, 2016), the court held that the relators adequately alleged that the defendant's speaker program was a sham based on allegations (1) the speaker programs were given to the same attendees repeatedly, or no one at all; (2) the defendant continually recruited doctors to be speakers without doing a needs-assessment or similar analysis to determine whether it needed more speakers to staff its presentations; and (3) eligibility to serve as a speaker was contingent on the number of prescriptions the physician wrote. *Id.* at *16-17.

The factors that were critical to the decisions in *Bilotta* and *Arnstein* are noticeably absent here. Brown has no evidence that Celgene considered the number of prescriptions a doctor had written in deciding whether to employ the doctor as a speaker. The evidence shows that Celgene selected doctors based on such unremarkable factors as the size of the doctor's practice and the doctor's interest in working with Celgene. *See* Docs. 331-43 at 18-19; 331-45 at 2.[27] There is no evidence that speeches were given at unconventional venues or in the absence of bona fide attendees. Nor is there evidence that Celgene tracked the number of prescriptions written by speakers. Celgene did track the number written by attendees (Docs. 334-21 at 7; 334-22 at 17-18), but if anything, that cuts against Brown's argument that the speaker program was intended to influence the *speakers'* prescribing decisions. *See United States v. Pfizer, Inc.*, 188 F.Supp.3d 122, 134-35, 2016 WL 3017381, at *7 (D. Mass. May 23, 2016). On this showing, no reasonable jury could find that Celgene's payments to physician-speakers violated the AKS.

2. Clinical Trials, Advisory Board Positions, and Ghost-Written Articles

Brown offers a single sentence in her brief asserting that Celgene "rewarded doctors with paid clinical trials, advisory board positions, and authorship of ghost-written articles to prescribe its drugs." [1056] Doc. 325 at 53. Brown provides no evidence that Celgene provided these benefits for the purpose of inducing the recipients to prescribe its drugs. No reasonable jury could find a violation of the AKS based on this underdeveloped theory.

3. Paying for Recommendations

Brown argues that Celgene violated the AKS by paying physician-speakers to recommend that other physicians prescribe its drugs. The parties devote very little attention to this theory, and we have been unable to locate any case law that squarely addresses it.[28] We think this theory is deficient.

The AKS makes it a crime to "knowingly and willfully ... pay[ ] any remuneration... to any person to induce such person ... to ... recommend purchasing... any good ... for which payment may be made ... under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). The term "recommendation" is defined as "[a] suggestion that someone should choose a particular thing or person that one thinks particularly good or meritorious." Black's Law Dictionary (recommendation, def. 2). We see no evidence that Celgene's speakers "suggest[ed]" that audience members prescribe Thalomid or Revlimid. Although there is evidence that the speaker program was intended to increase prescriptions of these drugs,[29] there is no evidence that speakers did anything other than convey truthful scientific information about the drugs.[30]

Even if some speakers generally encouraged audience members to prescribe Celgene's drugs, that would not be enough to establish liability under the AKS. Such generalized promotion might be described as a recommendation in ordinary parlance. But if "recommend" were understood this way, the AKS would effectively criminalize all promotion of medical goods and services, including such standard forms of promotion as television commercials and magazine inserts. The AKS has never been understood to have such a dramatic effect. We think the term "recommendation" was only intended to encompass recommendations that pertain to specific patients.[31] There is no evidence that Celgene's speakers made recommendations pertaining to [1057] specific patients. Therefore, even if Celgene's speakers generally promoted its drugs, Celgene could not be liable under the "recommend" subclause.

4. Co-Pay Foundations[32]

Brown argues that Celgene may be liable under the AKS for directing money through co-pay foundations to induce patients to buy its drugs. Brown refers us to the testimony of Celgene's 30(b)(6) deponents who testified that Celgene gave tens of millions of dollars per year to non-profit organizations for the purpose of helping patients (including those enrolled in Medicare) pay co-payments for MM and MDS drugs. Docs. 330-25 at 9-11; 331-93 at 8-9. But Brown presents no evidence that these donations were contingent on the foundation's agreement to purchase or recommend Celgene's drugs.[33] Absent evidence of this sort, Celgene cannot be liable for giving money to co-pay foundations.

B. Causation

Celgene argues, in the alternative, that Brown's kickback theory fails because she has not shown that any of the alleged kickbacks caused false claims. Because we conclude that Brown has not identified any actionable kickbacks, we decline to consider Celgene's alternative argument.

V. MISCELLANEOUS ISSUES

A. Statute of Limitations

The FCA's statute of limitations provides that a civil action may not be brought:

(1) more than 6 years after the date on which the violation of [the FCA] is committed or(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances...whichever occurs last.

31 U.S.C. § 3731(b). In a *qui tam* action, the pertinent question is when the *relator* discovered her right of action. *See U.S. ex rel. Hyatt v. Northrop Corp.,* 91 F.3d 1211, 1217-18 (9th Cir. 1996). Discovery occurs when the relator knows or reasonably should know that the government has been injured by the defendant's wrongful conduct. *See id.* at 1217; *cf. Winter v. United States,* 244 F.3d 1088, 1090 (9th Cir. 2001). In the FCA context, that means the relator must discover that the defendant is causing the submission of false claims. *Cf. Aflatooni,*314 F.3d at 1002 ("[A] false claim is the *sine qua non* of a False Claims Act violation."). The defendant has the burden to show that the statute of limitations applies. *See United States v. Carell,* 681 F.Supp.2d 874, 883 (M.D. Tenn. 2009); *cf. Cal. Sansome Co. v. U.S. Gypsum,* 55 F.3d 1402, 1406 (9th Cir. 1995).

Celgene moves for partial summary judgment with respect to all FCA violations that occurred before April 27, 2004. Celgene argues that these claims are time-barred because they occurred more than six years before Brown filed this case, and because Brown learned the essential facts [1058] of her case more than three years before filing her complaint. To support the latter proposition, Celgene cites Brown's testimony that (1) she went for a "ride-along" with other representatives in 2001 and watched them engage doctors in discussions about off-label uses of Thalomid; and (2) she began engaging doctors in similar discussions shortly thereafter. Doc. 333-16 at 6-8, 19-20.[34] This evidence is sufficient to satisfy Celgene's initial summary judgment burden.

The burden shifts to Brown to establish that a factual dispute exists as to when she discovered the facts essential to her case. In her declaration, Brown avers that (1) she did not initially realize she was engaged in marketing because Celgene hired her to serve as a medical liaison; (2) Celgene told her that it was permissible to discuss medical literature with physicians; and (3) Celgene assured her that it was permissible to discuss off-label uses of Thalomid and Revlimid because "cancer is different," and because these discussions constituted "profiling" — i.e., information gathering to assist in obtaining additional FDA indications. Doc. 333-48, ¶¶ 15, 27-30. She believed Celgene's representations, and was not disabused of them until late 2007 when she met with counsel and the FDA to discuss concerns about being asked to change billing codes. ¶¶ 63-64.

A reasonable jury could credit Brown's declaration, and find that she did not know or have reason to know the facts underlying her cause of action more than three years before she initiated this action. Although

Brown knew in 2001 that Celgene's representatives were discussing off-label uses with physicians, Celgene assured her this was lawful and offered facially plausible explanations for why this was so. A reasonable jury could find that Brown was entitled to rely on Celgene's representations. Because Brown has demonstrated a triable issue as to whether this action is timely under § 3731(b)(2), we deny Celgene's motion for partial summary judgment as to claims submitted before April 27, 2004.

B. Claims Post-Dating Lawsuit

Celgene seeks partial summary judgment with respect to all Medicare claims presented after Brown initiated this lawsuit, reasoning that these claims are immaterial as a matter of law. Doc. 325 at 63. We have already explained why we think a reasonable jury could find otherwise. *See supra* p. 19. Accordingly, we deny Celgene's motion for partial summary judgment as to these Medicare claims.

C. Certain Medicaid Claims

Brown has direct evidence regarding the number of off-label claims for Thalomid and Revlimid that were presented to the Florida Medicaid program. For all other Medicaid programs, Brown has direct evidence of the number of claims that were submitted for these drugs, but does not know how many of the claims were for off-label uses. Dr. Hay assumed that the percentage of off-label claims for these programs would likely be the same as for TRICARE. *See* Doc. 334-3 at 50, n.61. Based on this assumption, Dr. Hay estimated the number of off-label claims that were submitted to the relevant Medicaid programs. *See id.*

Celgene argues that it is entitled to partial summary judgment as to all Medicaid programs for which Brown lacks direct evidence as to the number of off-label [1059] claims. Doc. 325 at 63-64 (citing *Drummond,* 2016 WL 1258401 at *11-12, 13-14, 2016 U.S. Dist. LEXIS 43133 at *44, 49-50). We disagree. We have already explained that direct evidence is not required to establish an FCA violation. *See Aflatooni,* 314 F.3d at 1002. Celgene's case is in accord. *See Drummond,* 2016 WL 1258401 at *13, 2016 U.S. Dist. LEXIS 43133 at *49 (to survive summary judgment, relators "do not have to produce evidence of every single claim submitted to the Government, provided they can highlight sufficient evidence of claims submission in general") (citation, quotation marks, and formatting omitted). *Drummond* held only that summary judgment was appropriate where the relator failed to adduce "any claims data that would be admissible at trial." *Id.* (emphasis added).

That is not the case here. Brown has data as to the total number of Thalomid and Revlimid claims that were submitted to the relevant Medicaid programs. She also has claims data for TRICARE. A reasonable jury could use these two sets of data to estimate the number of off-label claims that were submitted to the relevant Medicaid programs. If Celgene has reason to think that Dr. Hay's methodology is unreliable for one or more Medicaid programs, those reasons can be explored in a *Daubert* hearing or during cross-examination at trial.

VI. CONCLUSION

We GRANT Celgene's motion for summary judgment (1) as to all claims submitted to TRICARE, the VA, the Tennessee Medicaid Program, the Texas Medicaid Program, and the Wisconsin Medicaid Program; and (2) as to all claims allegedly tainted by kickbacks. We DENYCelgene's motion as to all other issues. We will resolve Brown's Motion for Review (Doc. 320) by separate order.

Within 60 days hereof, Brown, Celgene, and any government plaintiffs that wish to appear SHALL return to mediation before a mutually agreeable mediator. The parties SHALL file a joint status report by January 23, 2017, apprising us of the mediator they have selected and the date when the mediation will take place. Within five days after this mediation, the parties SHALL file a joint status report apprising us of the results of this mediation and, if the case has not yet settled, setting forth each party's proposed time line for (a) additional mediation (if any), (b) the pre-trial conference, (c) motions in limine, (d) *Daubert* hearings, and (e) trial.

IT IS SO ORDERED.

FootNotes

1. According to the Mayo Clinic, "[m]ultiple myeloma is a cancer that forms in a type of white blood cell called a plasma cell," cells that ordinarily "fight infections by making antibodies that recognize and attack germs. Multiple myeloma causes cancer cells to accumulate in the bone marrow, where they crowd out healthy blood cells. Rather than produce helpful antibodies, the cancer cells produce abnormal proteins that can cause kidney problems." http://www.mayoclinic.org/ diseases-conditions/multiple-myeloma/basics/ definition/con-20026607.

2. According to the American Cancer Society, MDS refers to "conditions that can occur when the blood-forming cells in the bone marrow are damaged. This damage leads to low numbers of one or more type of blood cells. MDS is considered a type of cancer." http://www.cancer.org/cancer/myelodysplasticsyndrome/detailedguide/myelodysplastic-syndromes-what-is-m-d-s.

3. Although it is perfectly lawful for physicians to prescribe drugs for off-label uses, it is generally viewed that off-label marketing is unlawful. *See Carson v. Depuy Spine, Inc.*, 365 Fed.Appx. 812, 815 (9th Cir. 2010) ("the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the" Federal Food, Drug, and Cosmetic Act ("FDCA")); Marcia M. Boumil & Kaitlyn L. Dunn, *Off-Label Marketing of Pharmaceutical Products in the Wake of United States v. Caronia and United States v. Harkonen*, 9 J. HEALTH & BIOMEDICAL L. 385, 385 (2014) ("The FDA prohibits drug manufacturers from promoting approved drugs off-label despite the fact that physicians are free to prescribe FDA-approved products for any purpose they believe is indicated."); *see also Rosenbloom v. Pyott*, 765 F.3d 1137, 1157 (9th Cir. 2014) (demand excused in shareholder derivative action based on allegations that "a majority of the directors adopted a plan premised on illegal off-label marketing of

Botox"); *but see United States v. Caronia*, 703 F.3d 149, 160, 168 (2d Cir. 2012) (in light of First Amendment concerns, the FDCA should be construed "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs").

4. *See* Docs. 334-4 at 24, ¶ 49 (citing Field Activity Report which gave a representative credit for "ha[ving] a physician start" a patient on an off-label use of Thalomid); 334-17 at 2-3 (performance review of Hematology Oncology Consultant, commending employee for persuading several doctors to write more prescriptions for Revlimid; praising representative for "work[ing] with [a doctor's] entire office team to get a prescription"); 334-18 at 6-7 (2004 Strategic Business Plan for New Brunswick, NJ, district, reporting that promotional efforts had "[r]evers[ed] ... downward dosing trend" for Thalomid); 334-19 at 8 (2010 performance review of Hematology Oncology Consultant, crediting employee with "consistently exceed[ing] ... sales quotas" for Revlimid); 334-20 at 2 (April 2009 Field Contact Report, discussing employee's failure to achieve quarterly prescription goals). Some of this evidence appears to relate to on-label promotion. Nonetheless, it may be relevant to the extent it suggests Celgene's promotional efforts were generally effective in persuading physicians to prescribe the company's drugs.

5. *See* Doc. 330-14 at 23-25 (deposition of Celgene CEO Mark J. Alles, stating that sales representatives were compensated based on the number of prescriptions they generated and that, until recently, no distinction was made between on-label and off-label prescriptions); 330-3 (memorandum to sales representatives, congratulating one representative for winning an award for "tremendous sales growth").

6. Brown provides a declaration from Eric G. Campbell, Ph.D., who summarized recent scientific research showing that promotional efforts by pharmaceutical companies affect physicians' prescribing decisions. Doc. 330-26 at 4-6, ¶¶ 4-7. One study found that physicians who accepted at least one, modestly-priced meal from a pharmaceutical company were significantly more likely to prescribe the promoted drug over an existing generic. ¶ 7 (discussing Colette DeJong, et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176(8) JAMA INTERN. MED. 1114 (2016)).

7. Celgene's cases are: *U.S. ex rel. Turner v. Michaelis Jackson & Associates, L.L.C.*, 2011 WL 13510 (S.D. Ill. Jan. 4, 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *U.S. ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853 (7th Cir. 2006); *U.S. ex rel. Drummond v. Solvay S.A.*, 2016 WL 1258401, 2016 U.S. Dist. LEXIS 43133 (S.D. Tex. Mar. 31, 2016); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009); and *Louisiana v. Merck & Co.*, 2010 U.S. Dist. LEXIS 142767 (E.D. La. Mar. 31, 2010).

8. Brown's cases are: *Colquitt*, 2016 WL 80000; *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013); and *U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*,2003 WL 22048255, at *4-5 (D. Mass. Aug. 22, 2003). The United States agrees with Brown. *See* Doc. 328 at 15 ("requiring direct,

individualized proof would unduly burden and unnecessarily prolong a trial, and would also embolden drug companies to engage in large scale fraud.").

9. The court also cited evidence that one health care provider had used a Medicare coding guide provided by the defendants in connection with a successful claim for reimbursement. *Colquitt,* 2016 WL 80000 at *6. However, this claim was filed outside the limitations period.

10. RICO requires a showing of but-for causation, *In re Neurontin,* 712 F.3d at 34, in contrast to the FCA, which requires only substantial factor causation. Thus, evidence that is sufficient to establish causation in a civil RICO case will also suffice in an FCA case, but the opposite isn't necessarily true.

11. "Regression models are a well-known and widely accepted tool of economic analysis, and while they cannot explicitly determine causation or prove causality between ... variables, they can strongly support a causal relationship between two variables ... by ruling out or limiting the influence of other variables, or by demonstrating that those other variables are themselves merely a function of one of the first two." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP,* 806 F.3d 71, 95-96 (2d Cir. 2015) (quoting Andrew Dick & Peter Boberg, *Regression Analysis,* ANTITRUST 89 (Fall 2005)).

12. A reasonable jury would have non-speculative ways of deciding what percentage of prescriptions to attribute to Celgene. For example, Dr. Hay's analysis shows that in 2005, there were over 1,500 hematologist-oncologists and oncologists in the nation who were contacted more than ten times by Celgene's sales representatives, and that physicians contacted more than ten times that year wrote about 30 Thalomid prescriptions each. Doc. 334-4 at 27-28. If the jury were to find that Celgene was a substantial factor in all of the prescriptions written by doctors who received more than ten contacts, it would have a reasonable basis for finding that Celgene caused about 45,000 prescriptions in 2005. Comparing this number to the number of prescriptions written by doctors who received ten or fewer contacts would ultimately yield a percentage, which could then be multiplied by the total number of off-label Thalomid claims submitted to Medicare to determine the extent of Celgene's liability.

13. *City of Vernon v. S. Cal. Edison Co.,* 955 F.2d 1361 (9th Cir. 1992) is also distinguishable. The court held that summary judgment was properly granted against an antitrust plaintiff who "utter[ly] fail[ed] to make any segregation between damages attributable to lawful competition and that attributable to the unlawful scheme." *Id.* at 1372-73. As explained, we think a reasonable jury would have non-speculative ways of deciding what percentage of off-label prescriptions to attribute to Celgene. *See supra* n.12.

14. Celgene's position is internally inconsistent. At one point, Celgene concedes that, because Medicare may only reimburse for uses that are "reasonable and necessary," "a claim requesting reimbursement for a treatment that one knows is not reasonable and necessary is `false.'" Doc. 325 at 31 (citing *Strom ex rel. U.S. v. Scios, Inc.,* 676 F.Supp.2d 884, 891 (N.D. Cal. 2009)). Yet it devotes a separate section of its brief to arguing that presentment of a claim to a government payor does not imply entitlement to be paid. *Id.* at

39-41. We proceed on the assumption that Celgene's second argument — to which it devotes considerably more space — represents its actual view.

15. Hereinafter, we refer to this section as section 'r-8.

16. Hereinafter, we refer to this section as section '102.

17. Celgene argues against this reading of § '102(e)(1), reasoning that "Congress did not cross-reference the entirety of [§'8(k)(2)]," but instead "cross-referenced specific *subparagraphs."* Doc. 338 at 14. These specific subparagraphs, it notes, do not explicitly set forth the medical acceptance requirement. But everything that appears in subparagraph `§ 8(k)(2)(A) is "[s]ubject to the exceptions in paragraph (3)." When Congress legislates using a cross-reference, we presume it wants us to read the cross-referenced text in context. *Cf. Sekhar v. United States*, ___ U.S. ___, 133 S.Ct. 2720, 2724, 186 L.Ed.2d 794 (2013) ("`[I]f a word is obviously transplanted from another legal source, whether the common law or other legislation, it brings the old soil with it.") (quoting Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. REV. 527, 537 (1947)). When § 102(e)(1)(A) refers to drugs "that [are] described in subparagraph (A)(i), (A)(ii), or (A)(iii) of [§ '8(k)(2)]", it necessarily incorporates the medical acceptance requirement because the only drugs described in that subparagraph are those prescribed for a "medically accepted indication." *Accord Nievod v. Sebellius,* 2013 WL 503089 at *7-8, 2013 U.S. Dist. LEXIS 17550 at *19-20 (N.D. Cal. Feb. 7, 2013).

18. *See* 42 C.F.R. § 423.100; *Roeder v. Burwell*, 197 F.Supp.3d 887, 888-90, 2016 WL 3461280 at *2-3, 2016 U.S. Dist. LEXIS 81035 at *7 (E.D. Va. June 21, 2016); *Broome v. Burwell*, 2015 WL 1526532 at *3-5, 2015 U.S. Dist. LEXIS 44040 at *7-10 (D. Or. April 1, 2015); *Diamond v. Sec'y of Health & Human Servs.*, 2015 WL 367010 at *5 (N.D. Ohio Jan. 27, 2015); *Nievod*, 2013 WL 503089 at *5-9, 2013 U.S. Dist. LEXIS 17550 at *14-24; *Rickhoff v. Sec'y of Health and Human Servs.*, 2012 WL 6177411 at *1, 2012 U.S. Dist. LEXIS 175206 at *2-3 (D. Ariz. Dec. 11, 2012); *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 2012 WL 8020674 at *8 (N.D. Ga. Aug. 29, 2012); *Kilmer v. Leavitt*, 609 F.Supp.2d 750, 753 (S.D. Ohio 2009).

19. Texas cites a page from the Texas Medicaid Provider Procedures Manual ("Manual"), which states that the program "makes payments for prescriptions of covered outpatient drugs." Doc. 340-3. According to Texas, this shows that the program is limited to reimbursing medically accepted uses, because the term "covered outpatient drug" is defined in the Medicaid statute to incorporate such a limit. *See* 42 U.S.C. § 1396r-8(k)(3). It is not clear to us that the Manual formally incorporates the Medicaid statute's definition of "covered outpatient drug." In any case, the fact that the program "makes payments for prescriptions of covered outpatient drugs" does not mean it is forbidden to reimburse other drugs.

20. *See* Doc. 329-22 at 16, ¶ 39 ("[D]uring the relevant time period since 1998, carriers exercised their discretion to authorize off-label, off-compendia coverage when they believed, based on the facts of the particular case before them and the best available evidence, that the treatment would be beneficial to patients.").

21. This conclusion is not inconsistent with our causation analysis. At the summary judgment stage, our job "is not ... to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 248, 106 S.Ct. 2505. We think a reasonable jury could infer causation based on generalized evidence, but that doesn't mean it would be unreasonable for the jury to require particularized proof that false claims were submitted. The converse is true with respect to materiality. Although a reasonable jury could reject Celgene's materiality argument based on Celgene's failure to produce evidence that the government paid particular claims with actual knowledge of their falsity, that doesn't mean it would be unreasonable for the jury to rely on generalized evidence to find for Celgene. The bottom line is that both instances show triable issues of fact.

22. Even if we were to conclude that Celgene met its initial summary judgment burden, we could not grant summary judgment for Celgene because Brown has "designate[d] specific facts demonstrating the existence of genuine issues for trial." *In re Oracle Corp. Sec. Litig.*, 627 F.3d at 387. Specifically, Brown points to ten instances where CMS's contractor MAXIMUS refused to reimburse off-label prescriptions of Thalomid or Revlimid because the prescribed uses were not medically accepted. *See* Docs. 334-57 at 4 (denying reimbursement for off-label use of Revlimid because "the drug is not being prescribed for a medically accepted indication ... [it] cannot be covered ... for this condition. An exceptions request based on medical necessity cannot be considered because this drug, as prescribed, does not meet the definition of a Medicare Part D drug."); 334-58 (denying reimbursement for off-label use of Revlimid using similar language); 334-59 (denying reimbursement for off-label use of Revlimid); 334-60 (same); 334-61 (denying reimbursement for off-label use of Thalomid); 334-62 at 7 (denying reimbursement for off-label use of Revlimid because the requested use "is not FDA approved or compendia supported"); 334-63 (denying reimbursement for off-label use of Revlimid); 334-64 at 4-5 (denying reimbursement for off-label use of Revlimid; explaining that use is not covered under Part D unless it is approved by the FDA or supported by compendia); 335-65 (denying reimbursement off-label use of Revlimid); 335-66 (denying reimbursement for off-label use of Thalomid).

23. *Layzer*, 770 F.Supp.2d 579, the only district court case to adopt Celgene's view, was decided on March 7, 2011, after Brown filed her original complaint. Although this case was not unsealed and served on defendant until October 1, 2013, about two and a half years after *Layzer (see* Doc. 59), Celgene presents no evidence that it actually relied on this decision during the interim period.

24. Although § 1320a-7b(g) was enacted in 2010 — after most of the relevant conduct occurred — there are no retroactivity concerns because the provision merely codifies prior law. *See, e.g., U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F.Supp.2d 153, 160 (D.D.C. 2008) (pre-2010 case, "[f]inding near unanimity in support of relator's argument that actions alleging violations of the AKS ... may proceed under the FCA").

25. *See* Doc. 334-23 at 296-97 (Dr. Boccia delivered ten speeches on October 11, 2011); *see also id.* at 264 (Dr. Boccia delivered six speeches on November 4, 2010), 286 (same; June 2, 2011), 289 (same; June

27, 2011); 291 (same; August 3, 2011), 292 (same; August 23, 2011), 297 (same; October 13, 2011), 303 (Dr. Boccia delivered sixteen speeches over a two day period, from January 16 to January 17, 2012), 304 (Dr. Boccia delivered six speeches on January 20, 2012), 305 (Dr. Boccia spoke fourteen times over a two day period, from February 7 to February 8, 2012).

26. For example, Dr. Raza and Dr. Vescio, two other frequent speakers, rarely spoke more than twice a day. *See* Doc. 334-23.

27. Brown presents evidence suggesting that Celgene recruited one doctor who had given a presentation critical of Celgene's drugs in an effort to "neutralize" him. *See* Docs. 331-88 at 2 (in July 2005, the doctor delivered a program "bashing" Thalomid); 331-98 at 5 (between October 2006 and July 2013, Celgene paid the same doctor $269,000 in honoraria); *see also* Doc. 334-17 at 2 (praising sales representative for "trying to neutralize" the doctor); 329-95 at 50 (suggesting that Celgene viewed the doctor as a "loose cannon," and offered him an "appeasement trial"). Needless to say, bribing physicians in an attempt to silence their criticism of your drugs is hardly best practice. But the AKS doesn't prohibit all forms of unethical conduct that a drug company might engage in; it only prohibits payments made to induce prescriptions. Because there is no evidence that Celgene's payments were intended to affect Dr. Berenson's *prescribing* decisions, Brown has not raised a triable issue on her claim.

28. Celgene cites *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004), but that case is inapposite. The defendants in that case were convicted under subparagraph A of the AKS for paying a public relations firm to promote their home healthcare company to doctors. *Id.* at 479. The Fifth Circuit reversed the convictions because the public relations firm had not made any "refer[rals]" within the meaning of subparagraph A. *Id.* at 480. The court declined to "speculate" as to whether defendants could have been charged under subparagraph B, the provision of the AKS at issue here. *Id.* n.3.

29. *See, e.g.*, Docs. 329-105 at 22 (deposition of former area manager, stating that the speaker program was "100 percent promotional"); 334-21 at 7 (tracking effect of speeches on attendees' prescribing behavior).

30. The fact that Celgene's presentations were reviewed by the FDA (Doc. 329 at 7, ¶ 14) could raise an inference that these presentations were limited to providing truthful scientific information.

31. This holding is consistent with the only case we are aware of to recognize potential liability under the "recommend" subclause. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F.Supp.3d 242, 246-48, 263 (S.D.N.Y. 2014) (allegations that pharmacy accepted payment in exchange for recommending the defendant's drugs for particular patients were sufficient to state a claim). Our holding is also consistent with the general proposition that AKS liability does not attach "merely because [the defendant] sought to cultivate a business relationship ... that might ultimately affect one or more *unspecified* purchase or order decisions." *United States v. W. Carl Reichel*, No. 15-cr-10324-DPW: Doc. 244 (D. Mass. Oct. 28, 2015) (emphasis added).

32. Magistrate Judge Suzanne H. Segal struck certain portions of Dr. Hay's expert report related to this theory. Doc. 320. Brown asked us to review that ruling. Doc. 339. We have reviewed the relevant paragraphs in Dr. Hay's report (Doc. 334-3 at 67-73, ¶¶ 119-132), and conclude that they would not affect our analysis even if considered.

33. Brown's evidence suggests the opposite. According to Dr. Hay, the Chronic Disease Fund, one of the co-pay foundations funded by Celgene, would reimburse ten different MM drugs, only three of which were manufactured by Celgene. Doc. 334-3 at 71-72.

34. Celgene also cites certain allegations in Brown's TAC which suggest that Celgene was already engaging in off-label promotion by the time Brown joined the company. *See, e.g.*, Doc. 72, ¶ 130. These paragraphs do not help Celgene, as they do not allege that Brown had contemporaneous knowledge that Celgene was engaged in off-label marketing.