UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA EX REL. CRYSTAL DERRICK, Plaintiff-Relator, v. **ROCHE DIAGNOSTICS CORP.; ROCHE DIABETES CARE, INC.; HUMANA, INC.; HUMANA PHARMACY, INC.; AND HUMANA PHARMACY SOLUTIONS, INC.** Defendants.	**Case No. 14-cv-04601** **PLAINTIFF-RELATOR'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION

Roche and Humana traded a private debt forgiveness in exchange for Humana providing Roche preferred access to Humana's Medicare Advantage members and purchasing Roche products for disbursement to those members. Defendants' conduct constitutes a textbook violation of the Anti-Kickback Statute ("AKS") which prohibits providing remuneration for referrals of Government business. Roche's remuneration tainted Humana's decision making process – the very ill that the AKS was intended to prevent – causing Humana to reverse its decision to terminate its relationship with Roche mere months after the decision was made.

Defendants argue that they there is not sufficient evidence of a kickback, but they ask the Court to ignore extensive evidence that the debt reduction was provided expressly for the purpose of obtaining future referral of Government business. They also ignore the law of the case, and the case law generally, which holds that there did not need to be an agreement between Defendants on the precise amount Humana owed in order for there to be "remuneration."

Given the straightforward evidence of a violation, Defendants take an extreme position that would immunize Medicare Advantage Organizations ("MAOs") from False Claims Act ("FCA") liability based on violations of the AKS. They argue that if an MAO receives remuneration of any kind it is protected by safe harbors; if an MAO pays claims resulting from an AKS violation, those are not "claims" under the FCA; and if an MAO disburses Government money to benefit a company that paid kickbacks, the Government cannot recover that money as damages.

Defendants' positions ignore Department of Health and Human Services Office of Inspector General ("OIG") decisions and Seventh Circuit precedent which make clear that: (1) the safe harbors protect narrow conduct, not whole industries; (2) claims paid by intermediaries who receive Government money do constitute "claims" under the FCA, and (3) the entire amount of

the claims constitute damages when there is an AKS violation. Defendants' excuses would immunize MAOs and their contracting partners from liability for fraud and must be rejected.

II. PROCEDURAL BACKGROUND

Relator filed this FCA action on June 18, 2014. Defendants filed motions to dismiss on October 2, 2017. On June 7, 2018, Judge Bucklo denied Defendants' motions to dismiss the case. Judge Bucklo rejected Defendants' argument that Roche's forgiveness of Humana's debt was "simply a routine, arms-length compromise involving a disputed contractual obligation . . . that . . . does not amount to 'remuneration' under the AKS" as "unavailing because the AKS defines 'remuneration' broadly to include 'anything of value.'" Dkt. 84 at 11-12 (citing cases).

Judge Bucklo concluded, "Roche's alleged acceptance of an amount less than Humana's debt to it plausibly amounts to 'remuneration' for purposes of the AKS." *Id.* at 12. She reasoned, "[E]ven assuming the transfer of value had a legitimate business purpose, it may nevertheless have amounted to illegal remuneration for AKS purposes if one reason for it was to 'compensate[] past or induce[] future referrals.'" *Id.* (quoting *U.S. v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011)). Judge Bucklo also emphasized that the fact that "defendants had not agreed about the precise amount of Roche's overpayment before settling the debt for a lesser amount does not compel a contrary conclusion." (*Id.* at 13). [1]

III. FACTUAL BACKGROUND

In 2013, Humana was in the process of completely ending its relationship with Roche. In March, Humana terminated its Mail Order Purchase Agreement ending Roche's preferred access

[1] Judge Bucklo's opinion denying Defendants' motions to dismiss is the law of this case and should be followed by the Court in considering this motion. *See Best v. Shell Oil Co.*, 107 F.3d 544, 546 (7th Cir. 1997) (the doctrine applies to "a different member of the same court" due to "the rightful expectation of litigants that a change of judges mid-way through a case will not mean going back to square one" and a judge is not free to alter previous rulings "merely because he has a different view of the law or facts.")

to Humana's mail-order customers. As of June, Humana intended to terminate its Retail Rebate Agreement with Roche, ending Roche's preferred access to Humana's retail pharmacy customers. But by the end of that year, Humana and Roche had executed two new agreements making Roche the preferred manufacturer of diabetes testing supplies for Humana's MA members in both the Retail and Mail Order business through the end of 2015.

Roche's dramatic reversal of fortune was facilitated by a kickback. In July 2013, Defendants understood that Humana owed Roche over $27 million. Both understood that Humana could offer Roche access to MA business in exchange for a reduction in the repayment amount. And both understood that the other was willing to trade for this access despite the patent illegality of the arrangement. The evidence demonstrates that:

- Roche and Humana independently calculated that Humana owed Roche over $27 million.
- Defendants explicitly traded a reduction in the debt for access to Government business.
- Both Roche and Humana believed that if Humana did not enter into new purchase and rebate agreements with Roche, Humana would not receive the debt reduction.

A. Background on the Defendants' contractual relationships.[2]

[redacted]

[2] Relator provides further background information in her motion for summary judgment. Dkt. 370 at 5-8.

[redacted]

B. Roche and Humana agreed upon a reduction in Humana's repayment in exchange for future formulary placement.

[redacted]

[redacted]

[redacted]

C. Roche drafted an agreement memorializing the forgiveness of Humana's obligation in exchange for access to Humana's MA business.

[redacted]

[redacted]

No documents have been produced showing a basis for the $22.5 million number and the number was not based on any specific calculation of what Humana owed Roche. *Id.* ¶ 95.

[redacted]

D. Despite Humana's insistence on not expressly linking the Settlement Agreement with the future agreements, Defendants understood the unwritten agreement that they were linked.

[redacted]

[redacted]

E. Roche's market share dramatically increases following the Agreement.

[redacted]

IV. ARGUMENT

Under Rule 56(a) summary judgment is appropriate 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." A disputed fact is material if it might affect the outcome of the suit under the governing law. *Hampton v. Ford Motor Co.*, 561 F.3d 709, 713 (7th Cir. 2009).

A. Roche paid and Humana received remuneration in return for referrals in violation of the AKS.

Under the AKS, it is a crime to offer or pay "any remuneration"[7] to induce a person purchase, order, or recommend purchasing or ordering any good; or to refer an individual for

[redacted]

[7] The remuneration can "includ[e] any kickback, bribe, or rebate" made "directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(1). This Court held that "the AKS defines

"arranging for the furnishing of an item" paid for, in whole or part, by a Federal health care program.[8] 42 U.S.C. § 1320a-7b(b)(2)(B). It is also a crime to solicit or receive any remuneration "in return for referring an individual" for an item or for purchasing, ordering, or "arranging for or recommending purchasing . . . or ordering" an item paid for , in whole or part, by a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A).

The AKS "seeks to … preserve freedom of choice and preserve competition." *U.S. v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (citation omitted). "[T]he statute includes no requirement . . . that a kickback . . . harmed patients or resulted in unnecessary procedures." *U.S. v. The Health All. of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at *5 (S.D. Ohio Dec. 18, 2008).

Defendants' conduct is a paradigmatic violation of the AKS. As this Court held, "Roche's alleged acceptance of an amount less than Humana's debt to it plausibly amounts to 'remuneration' for purposes of the AKS." Dkt. 84 at 12.[9] Roche paid this remuneration with the "intent to induce" and Humana received it "in return for" Humana purchasing Roche's products through RightSource, referring patients to Roche products, and recommending the purchase of Roche products through formulary placement by HPS. These products were paid for by the Government "through [Medicare Advantage] insurance." 42 U.S.C. § 1320a-7b(f).

1. Defendants are liable if "one purpose" of the debt forgiveness was to induce referrals or if it was in return for referrals.

'remuneration' broadly to include 'anything of value'. . . such as rebates, payments disguised as rent or consulting fees, facility time, or waived insurance deductibles." Dkt. 84 at 12 (collecting cases).

[8] A "federal health care program" includes "any . . . program that provides health benefits . . . through insurance . . . which is funded directly, in whole or in part" by the Government. 42 U.S.C. § 1320a-7b(f).

[9] *See also U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc*., No. 2:08-CV-00114, 2012 WL 628515, at *7 (S.D. Ohio Feb. 27, 2012) (finding remuneration existed where defendant decided "not to pursue collection of its billables").

The AKS is violated if one purpose of the payment is to induce referrals, even if other lawful purposes exist for the payment. *Borrasi*, 639 F.3d at 782 ("Nothing in the . . . statute implies that only the primary motivation . . . is to be considered in assessing [defendant's] conduct").[10]

Defendants argue that they "had a legitimate business incentive . . . to compromise . . . at an amount less than what Roche . . . demanded." Defs' Br. ("Br.") at 12. But as this Court held, "Even assuming the transfer of value had a legitimate business purpose, it may nevertheless have amounted to illegal remuneration for AKS purposes if one reason for it was to 'compensate[] past or induce[] future referrals.'" Dkt. 84 at 12 (quoting *Borrasi*, 639 F.3d at 782).

The relevant question, therefore, is not whether there were legitimate reasons for the debt reduction, but "if one reason for it was to . . . induce future referrals," *id.*, or if it was received in return for referrals. The evidence clearly demonstrates that the forgiveness was paid with the intent to induce referrals and received in return for referrals:[11]

- [redacted]
- [redacted]

[10] The Seventh Circuit affirmed in *U.S. v. Nagelvoort* that "the jury [is allowed] to find a violation if 'any part or purpose' of the payments was meant to induce referrals." 856 F.3d 1117, 1130 (7th Cir. 2017) ("We see no reason to overturn *Borassi* . . . . We reject [Defendant's] contention that our interpretation . . . criminalized his otherwise 'innocent, legitimate business arrangements and conduct.'"). *See also U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("[A] person who . . . pays remuneration . . . violates the Act so long as one purpose of the … payment is to induce Medicare . . . patient referrals."); *U.S. v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (the AKS is violated whenever the benefits extended were partially to induce patient referrals); *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (the law is violated if "one purpose of the payment was to induce future referrals.").

[11] Defendants argue that "any pre-settlement negotiations . . . were superseded by . . . written agreements." Br. at 15. This is irrelevant. These communications provide evidence of Roche's "intent to induce", and Humana's acceptance of remuneration "in return for" referrals.

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Moreover, the "legitimate business incentives" do not withstand scrutiny. It was not "extremely challenging" to determine the amount Humana owed Roche. About a month after the

initial meeting regarding the breach, [redacted]

Both parties recognized that Humana owed at least $26 million, and Humana never argued that it owed less based on actual calculations. Instead, Humana offered baseless excuses for repaying a lower amount. [redacted]

In fact, Humana backed away from some of the excuses. [redacted]

Both parties understood that Roche did not accept the baseless excuses, and that the actual reason for the reduction was Humana's ability to refer business. [redacted]

[13] Defendants do not present any evidence that Humana argued that Roche was also responsible for Humana's compliance failure because of the structuring of the 2009 Agreement and Roche employees were not aware of Humana arguing that Roche had failed to raise concerns. *Id.*

[14] This view is also supported by Relator's expert, Theodore Boehm, who is a former justice of the Indiana Supreme Court, and a practitioner of Indiana law. [redacted]

[redacted]

2. Remuneration exists even if Defendants did not agree on the amount owed before agreeing on a lesser amount.

Defendants argue that remuneration cannot be demonstrated because there was not "a sum certain owed by express agreement of the parties."[16] This Court has held exactly the opposite: "That defendants had not agreed about the precise amount of Roche's overpayment before settling the debt for a lesser amount does not compel a . . . conclusion" that there was no remuneration. Dkt. 84 at 13. In fact, Relator had not alleged in her Complaint, and therefore this Court was not privy to, [redacted] This Court found as a matter of law that such an agreement was not required.

The law of the case, therefore, forecloses Defendants' argument. So does the broad definition of remuneration. Courts do not shy away from finding "remuneration" because the provider and recipient of the kickback do not have a mutual understanding of the value of the remuneration. For example, in *U.S. ex rel. Fontanive v. Caris Life Scis., Inc.*, the court found an AKS violation had adequately been alleged where the defendant waived bills for hospitals even

[16] Defendants take issue with Relator referring to the amount Humana owed as a "debt" even though both parties acknowledge Humana owed at least $26 million and Humana employees referred to the amount owed as a "debt." SOMF ¶90. In any case, the parlance is not material. The AKS proscribes providing "**any remuneration**," interpreted as "**anything of value**." Whether or not the amount forgiven was a "debt" or an "amount owed' or a "liability," the forgiveness of it was of value to Humana.

though hospitals resisted payment and disputed the charge. No. 3:10-CV-02237, 2013 WL 11579021, at *9 (N.D. Tex. Oct. 23, 2013).[17]

Defendants' reliance on *U.S. ex rel. Ruscher v. Omnicare, Inc.* is unavailing. No. 4:08-CV-3396, 2015 WL 5178074 (S.D. Tex. Sept. 3, 2015). In *Ruscher*, the relator alleged that the defendant forgave Medicare Part A amounts owed by eight nursing facilities to induce the referral of Part D business. In granting summary judgment, the court stressed that relator "point[ed] to no document . . . in which an . . . employee discusses a trade-off of . . . Part A revenue for . . . Part D revenue." *Id.* at *24. By contrast, the record here demonstrates that the repayment *precipitated* the contract negotiations, and affected them. The record is replete with discussions of the tradeoffs between Humana's debt to Roche and the future deals. *See supra* at 4-8; SOMF ¶¶ 90-91.

Moreover, in *Ruscher*, the court found plentiful evidence of actual disputes between the defendant and skilled nursing facilities, including hiring of "a full-time auditor to audit Omnicare's invoices," Omnicare "retain[ing] legal counsel to pursue the unpaid balances," Omnicare "su[ing] [skilled nursing facilities] for the unpaid [accounts receivable]," "parties conduct[ing] third-party audits of the billing and pricing disputes," and "settlements follow[ing] vigorous, multi-year disputes between the parties." *Id*. at *15, *16, *19, *22. [18]

The facts of this case are clearly distinct. [redacted] SOMF ⁋ 91. There was no

[17] Defendants characterization of *Fontanive* as a case where there was a "waiver of fixed payment amounts due . . . for services clearly rendered" is not accurate. The court noted that the defendant had "unsuccessfully tried to bill hospitals," "hospitals resisted" payment, and "questioned the charge." *Id.*

[18] Defendants also cite to *U.S. v. Catholic Health Initiatives*, which bears no resemblance to this case. 312 F. Supp. 3d 584, 596 (S.D. Tex. 2018). In *Catholic Health Initiatives*, the alleged kickback was a rescission payment made to shareholders by a physician-owned hospital after "Congress . . . placed limits on the expansion of physician-owned hospitals" and "all physicians were compensated at the same rate regardless of their referral volume." The court found that it was not clear what defendant "could have done to respond to Congress's new discouragement of physician ownership while complying with health care fraud statutes."

disagreement between the Defendants about the amount owed, and the negotiations were swiftly concluded. The final number was less than the number both sides agreed was owed, and it was picked in exchange for access to government business.

3. Defendants' argument that Humana would have selected Roche even without a kickback is incorrect and irrelevant.

Defendants contend that "independent market events, and not the rebate dispute, forced Humana and Roche to renegotiate their business relationship" and Humana had independent reasons for selecting Roche over LifeScan. Br. at 12. Even if this were true (it is not), it is not of any legal significance.

"[T]he FCA does not require the kickback to be the 'but for' cause of the prescription." *U.S. v. Teva Pharm. USA, Inc.*, No. 13 CIV. 3702, 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019). Even if Humana would have purchased Roche products and placed them on formulary regardless of the kickback, there would still be a violation so long as the kickback was provided with the intent to induce the referrals or received in return for referrals.

The "independent market event" Defendants point to is the CMS decision to cut reimbursement for diabetes testing strips. [redacted]

Humana then *reversed* its decisions. Contrary to the CMS decision, Humana preferred Roche instead of subjecting Roche to MAC pricing, as Humana did with all other brands. Internal Humana documents were clear on the chronology and the rationales: [redacted]

[redacted] SOMF ¶ 81.

Defendants argue Humana had independent reasons for selecting Roche over LifeScan.[19] The evidence demonstrates that Humana selected Roche over LifeScan because of the audit issue:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

B. The safe harbors relied upon by Defendants do not protect debt forgiveness.

Defendants assert their conduct falls within the protection of two regulatory safe harbors, entitled "Price reductions offered to health plans" and "Price reductions offered to eligible managed care organizations." Br. at 15-25.

Both provisions ensure that entities providing discounts on health care items to health plans are protected from violating the AKS. This protection is intended to reduce the cost for providing services to members covered by the health plans. Defendants' arrangement of Roche partially

[19] Apart from being irrelevant, this is not true. [redacted]

forgiving Humana's debt does not satisfy the regulations. The debt forgiveness was not a "price reduction" on any health care items, and Humana never utilized or reflected the debt forgiveness as a reduction in the cost of providing diabetes testing supplies.

Parties must comply fully with all of the safe harbor requirements. Fraud and Abuse OIG Anti-Kickback Provisions, 54 FR 3088-01 ("[W]here . . . entities have entered into arrangements that are covered by the [AKS], where they have chosen not to fully comply with. . . [safe harbors], they would risk scrutiny . . . and may be subject to civil or criminal enforcement."); *see also Re: OIG Advisory Opinion No. 02-9*, 2002 WL 34483384, at *3 ("Strict compliance with all elements is required for safe harbor protection") (emphasis in original). [20]

Defendants must "demonstrate by a preponderance of the evidence that [the] conduct fell within the safe harbor provision of the [AKS]." *U.S. v. George*, 900 F.3d 405, 413 (7th Cir. 2018).[21] Defendants do not demonstrate their compliance with the requirements of the safe harbors which require that the remuneration be provided pursuant to a written agreement that meets specific requirements. In fact, Defendants do not even address all of the safe harbors requirements.

1. MAOs are not exempted from complying with the AKS.

As the remuneration from Roche to Humana was not a price reduction on Roche's products, Defendants resort to making broad arguments that "the Medicare Advantage program eliminates the potential for abuse that was present in original . . . Medicare and led to the enactment of the AKS." Br. at 17-18. But the safe harbors do not exempt MAOs from compliance with the AKS.

[20] *See also Health Choice Alliance, LLC, on behalf of U.S. v. Eli Lilly and Company, Inc*., 2018 WL 4026986, at *17 (E.D. Tex., 2018) ("[T]he defendants must prove strict compliance with a safe harbor to avoid liability for an arrangement that might otherwise violate the statute.").

[21] S*ee also U.S. v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. Sept. 29, 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) ("[T]he [plaintiff] need not prove, as an element of its case, that defendant's conduct does not fit within a safe harbor or exception.").

MAOs are clearly required to comply with the AKS. 42 C.F.R. § 422.504 (h)(1); *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 299 (3d Cir. 2011), *abrogated on other grounds* by *U.S. ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101, 106 (3d Cir. 2018). Indeed, Humana agreed to comply with the AKS in its CMS contracts. SOMF ⁋ 113.

The OIG made this clear in an Advisory Opinion addressing an arrangement where a manufacturer funded a program for an MAO to monitor patient records. *OIG Advisory Opinion No. 17-07*, 2017 WL 6555001, at *8 (Dec. 4, 2017). The OIG found the program "could result in remuneration to the MA Plan" and a pharmaceutical manufacturer "providing free technology" to an MA plan could "present **a high level of risk**" under the AKS because **"[s]uch remuneration . . . could influence the MA plan to give the manufacturer's products favorable formulary placement.**" *Id.* at *6. The OIG would likely find a violation "**if the [computer interface] was designed to recommend one drug over another**." *Id.* (emphasis added). [22]

Therefore, remuneration from a manufacturer to a MAO to induce the plan to place the manufacturer's products on formulary violates the AKS. Notably, the OIG – the entity that promulgated the safe harbors – did not opine that the safe harbors asserted by Defendants would protect remuneration by a manufacturer to a MAO to induce formulary placement.[23]

Defendants' unwarranted expansion of the safe harbors would expand them to protect conduct that they were never intended to protect. If reducing a debt in return for referrals were protected under the safe harbor, MAOs and manufacturers could exchange remuneration for

[22] The OIG approved of the arrangement because it found that the arrangement had safeguards to reduce the risk that the remuneration would induce formulary placement. It noted that the parties to the arrangement had "**expressly certified that agreements . . . would make clear that collaboration . . . would have no direct or indirect bearing on formulary recommendations or referrals of business**" and that "**nothing in the Interface would guide the MTM pharmacist to choose one product over another**." *Id.* at *8-9.

[23] OIG Advisory Opinions regularly analyze safe harbors when they are relevant to the arrangement in question. *See e.g. OIG Advisory Opinion No. 01-6*, 2001 WL 36190945, at *1 (May 29, 2001).

referrals outside the very specific and narrow circumstances permitted by the safe harbors, so long as the parties refer to the remuneration as a "price reduction" made for providing health care items.

2. Defendants' conduct is not protected by the Price Reductions to Health Plans Safe Harbor.

The "Price reductions offered to health plans" safe harbor states that "'remuneration' does not include a reduction in price . . . to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services" so long as certain additional conditions are met.

- The term of the agreement must be at least one year.
- The agreement must specify in advance the covered items, which party will file claims or requests for payment with Medicare, and the fees for furnishing the items.
- The fees must remain in effect throughout the term of the agreement.
- The party claiming payment from Medicare must not claim amounts in excess of the fees in the agreement.
- The parties must accurately report the fee amounts charged in the agreement on any cost report filed with Medicare.
- The party to the agreement which is not responsible for filing claims for payment must not claim any payment from the Government, or otherwise shift the burden of the agreement to the extent increased payments are claimed from Medicare.

42 C.F.R. § 1001.952 (m)(1)(iii)(A-F).[24]

Defendants must satisfy each of the conditions to merit protection of the safe harbor. However, Defendants do not even address several of the requirements.

a. The forgiveness of Humana's debt was not a "reduction in price."

[24] The safe harbor sets out different requirements based upon the type of entity involved in the agreement. As HPS is not the type of entity for which 42 C.F.R. § 1001.952(m)(1)(i) or (m)(1)(ii) applies, Relator utilizes the requirements set out in (m)(1)(iii), which is a catch-all provision for health plans "not described in paragraphs (m)(1)(i) or (m)(1)(ii)." 42 C.F.R. § 1001.952 (m)(1)(iii). Defendants appear to apply the standard in 42 C.F.R. § 1001.952(m)(1)(i) which applies to plans "under contract with CMS" even though HPS does not satisfy the standard because Defendants argue that Humana Inc. plans would satisfy it. But there is a separate category for entities such as HPS which cannot satisfy 42 C.F.R. § 1001.952 (m)(1)(i).

The safe harbor only applies to a "reduction in price." 42 C.F.R. § 1001.952 (m)(1). The OIG made clear that the safe harbor was "only protecting . . . the price reduction . . . to make clear that any other forms of remuneration . . . paid by a . . . provider to a health plan are not protected under this safe harbor provision." Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 57 FR 52723-01. In fact the OIG would "closely review any forms of other such remuneration to **ensure that improper payments are not employed to induce the health plan to issue a contract or otherwise steer patients to the person paying the remuneration."** *Id.* (emphasis added).

The debt forgiveness from Roche to Humana was not a "reduction in price" of any goods and was "employed to induce [Humana] to . . . steer patients to [Roche]." *Id.* Humana's Rule 30(b)(6) witness on Humana's processes for compiling and submitting MA bids in 2013 – 2015 [redacted] SOMF ¶ 110. As Humana did not account for the debt forgiveness as a reduction in price in its accounting or bids to CMS, it is not entitled to the protection of the safe harbor for price reductions. [25]

b. <u>The forgiveness was not "in accordance with the terms of a written agreement . . . for the sole purpose of furnishing . . . items or services"</u>

Even if the debt forgiveness was considered a "reduction in price," it was not "in accordance with the terms of a written agreement." 42 C.F.R. § 1001.952 (m)(1). Humana and Roche never entered into a written agreement that set out that Humana would receive forgiveness in an amount of $5 million. [redacted]

[25] Defendants do not actually explain how the debt reduction constitutes a "reduction in price" when it did not lower prices on any Roche goods.

[redacted] The amount of the debt forgiveness was the result of an *ad hoc* agreement between Roche and Humana that was never set out in writing. [26]

The Settlement Agreement was also not executed "for the sole purpose of furnishing to enrollees items or services." *Id.* The OIG made clear that this was a strict requirement. In issuing the rule, it stated the safe harbor's intent "was to protect only those discounts given by . . . providers for the items . . . they furnish to enrollees" and "[i]n order to ensure that . . . it is necessary to have a separate agreement that covers only the discounted arrangements that fall within the scope of the safe harbor." Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 FR 2122-01 (emphasis added). The Settlement Agreement was executed to release Humana's liability in exchange for a sum of money. Providing discounts "for the items and services . . . furnish[ed] to enrollees" was not a purpose of the agreement at all, much less the sole purpose.[27]

Moreover, the Settlement Agreement does not meet the requirements specific to subsection (m)(1)(iii). The agreement was not for at least one year, it did not specify in advance the covered items and services, and it did not set out fees for the items and services that would remain in effect throughout the term of the agreement. 42 C.F.R. § 1001.952 (m)(1)(iii)(A-C).

c. Defendants "shift[ed] the burden of [their] agreement" to Medicare beneficiaries.

[26] Defendants baldly assert, without any support, that the Settlement Agreement satisfies the requirement "that the pricing or discount arrangement must be documented in writing." Br. at 19.

[27] Recognizing this basic issue, Defendants attempt to shift the Court's attention to the 2009 Agreement, arguing that the 2009 Agreement was for the sole purpose of making Roche products available to Humana members. Br. at 20. Defendants do not provide any support for interpreting the two agreements, executed four years apart, together. Nor does this position make much sense in light of the guidance that "**it is necessary to have a separate agreement that covers only the discounted arrangements that fall within the scope of the safe harbor."** 61 FR 2122-01 (emphasis added).

The safe harbor also requires that the party must not "shift the burden of such an agreement to the extent that increased payments are claimed from Medicare." 42 C.F.R. § 1001.952 (m)(1)(iii)(F).[28] Money paid by Medicare beneficiaries constitutes "payments . . . from Medicare" for purposes of the safe harbor. The OIG has made this clear: "Certainly, in any case where a plan or provider raises its costs or fees to others or reduces the services it provides to others as a result of an incentive or a discount, prohibited cost shifting has occurred." 61 FR 2122-01.[29]

The debt forgiveness did "shift the burden" of the agreement to Medicare members. 42 C.F.R. § 1001.952 (m)(1)(iii)(F). [redacted] SOMF ¶ 112. Roche and Humana "**raise[d] . . . costs or fees to others . . . as a result of an incentive or a discount.**" 61 FR 2122-01 (emphasis added). Therefore, they shifted the burden and are not able to satisfy the safe harbor.

3. The debt forgiveness was not a price reductions offered to eligible managed care organizations.

The "Price reductions offered to eligible managed care organizations" safe harbor excludes from the AKS definition of "remuneration," "any payment between . . . [a] first tier contractor and a downstream contractor . . . to provide or arrange for items or services" as long as the following conditions are also met:

- The parties have a written agreement that meets certain specifications.
- Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business for which payment may be made in by a Federal health care program on a fee-for-service or cost basis.

[28] This requirement applies to entities seeking to comply with other provisions of the "price reductions to health plans" safe harbor as well. *See* 42 C.F.R. § 1001.952 (m)(1)(i); 42 C.F.R. § 1001.952 (m)(1)(ii)(D).
[29] The OIG also specifically referenced "increased costs to . . . customers." *Id.*

- Neither party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.
- The agreement between the managed care organization and first tier contractor does not involve certain services.[30]

42 C.F.R. § 1001.952 (t)(1)(ii)(A-D).[31] Defendants fail to satisfy these requirements.

a. The debt forgiveness was not a payment for arranging for items or services.

The safe harbor, entitled "Price reductions offered to eligible managed care organizations," exempts from the AKS "any payment. . . for providing or arranging for items or services." 42 C.F.R. § 1001.952 (t)(1)(ii). The safe harbor defines "items and services" as "health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services" and excludes "[m]arketing and other pre-enrollment activities" 42 C.F.R. § 1001.952 (t)(2)(iv). By excluding "marketing and other pre-enrollment activities," the safe harbor makes clear it is not intended to cover benefits for the MAO that are not actually "for providing or arranging for" health care benefits for members. *Id.*

The arrangement between Defendants does not fall within the scope of this protection. Defendants do not provide any evidence that Roche's forgiveness of Humana's obligation to repay Roche was actually "a price reduction" or payment made "for providing or arranging for items or services." As described above, Humana's 30(b)(6) witness testified that [redacted]

[30] Defendants do not address this requirement.

[31] Defendants analyze the section of the safe harbor that addresses agreements between an eligible managed care organization and a "first tier contractor" claiming that Roche "had a contract directly with . . . Humana." Br. at 22. That is not true. Humana, Inc. contracted with HPS, which in turn contracted with Roche. SOMF ⁋ 108. A "first tier contractor" is an "entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services." 42 C.F.R. § 1001.952 (t)(2)(iii). A "downstream contractor" is an "entity that has a subcontract . . . with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor." 42 C.F.R. § 1001.952 (t)(2)(i). Therefore, Relator analyzes the section of the agreement addressing contracts between a first-tier contractor and downstream contractor. Defendants do not satisfy the safe harbor regardless of the standard.

[redacted]

b. The debt forgiveness was not set out in writing.

The safe harbor requires that the first tier and downstream contractor's agreement:

- is set out in writing and signed by both parties;
- specifies the items and services covered by the agreement;
- is for a period of at least one year; and
- specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal healthcare program for items or services covered under the agreement. . . .

42 C.F.R. § 1001.952 (t)(1)(ii)(A)(1-4).

Roche's remuneration in the form of debt forgiveness was not pursuant to an agreement "set out in writing and signed by both parties." 42 C.F.R. § 1001.952 (t)(1)(ii)(A)(1). The Settlement Agreement that Defendants executed does not state that Humana is no longer obliged to repay Roche the full amount; that arrangement was surreptitious.[32]

Even if the Settlement Agreement is construed as memorializing the debt forgiveness, it still would not satisfy the safe harbor, *prima facie*. The Settlement Agreement did not "specif[y] the items and services covered by the agreement" because it was not an agreement for the providing or arranging for services for Humana's members.[33]

[redacted]

[33] Defendants argue that "[t]he 2009 Retail Rebate Agreement, as amended by the Settlement Agreement" meets these requirements. Br. at 23. The Settlement Agreement, on its face, is not an amendment of the 2009 Agreement and does not incorporate its terms.

The Settlement Agreement was also not "for a period of at least one year"; in fact it required that the payment under the Agreement should be made within 30 days.[34] The Agreement also did not "specif[y] that the party providing the items . . . cannot claim payment in any form from a Federal health care program." *Id.* at (t)(1)(ii)(A)(2–4). In fact, the 2009 Agreement also did not specify that Roche could not claim payment from the Government.[35] Defs' Ex. 5.

c. The debt forgiveness shifted the financial burden to the government.

The safe harbor also requires that "[n]either party . . . shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program." 42 C.F.R. § 1001.952 (t)(1)(ii)(C). As described *supra* at 21-22, Defendants cannot satisfy this element because they did shift the burden of their arrangement to Medicare beneficiaries.

C. Defendants caused false submissions to be made in violation of the FCA.

1. Defendants are not entitled to summary judgment on the submission of false claims.

Under the FCA, a claim resulting from a violation of the AKS submitted to a private entity administering a Medicare plan is false. The FCA defines a "claim" as "any request or demand . . . for money . . . whether or not the United States has title to the money . . . that . . . is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used . . . to advance

[34] Defendants argue that the Settlement Agreement complies because the parties "forever discharged" all liabilities and obligations. Nothing makes clearer the fundamental incongruity between the arrangements protected by the safe harbor and the Defendants' illegal agreement than this argument. The regulatory history makes clear that the one year requirement was not to protect permanent releases of liability. *See* 61 FR 2122-01 (noting that "the one-year term [refers] to the length of time within which the fees for the services covered by the agreement may not be changed.").

[35] Defendants attempt to side-step this issue by arguing that it was "impossible for Roche to bill CMS for items disbursed to beneficiaries in Humana Inc.'s Medicare Advantage plans[.]" Br. at 24. But Defendants must prove they strictly complied with all elements of the safe harbor, which includes the requirement that agreement state that Roche could not claim payment in any form from a federal health care program.

a Government program or interest, and if the United States Government provides or has provided any portion of the money or property requested or demanded." 31 U.S.C.A. § 3729.

a. The claims for Roche products from pharmacies to Humana are "claims" under the FCA.

"FCA liability attaches to any false claim to any entity—public or private—implementing a government program or a program using government funds." *U.S. ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 638 (7th Cir. 2016). In *Kmart,* the Seventh Circuit held that claims made by a pharmacy to private health plans administering the Medicare program were "claims" for purposes of the FCA because the program was largely funded by Government money. [36]

> There is little doubt that much of the money paid to Kmart under Medicare Part D came from government coffers. See, *e.g., 2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* 103 (funds from U.S. Treasury made up 73.1% of total revenue disbursed by Medicare Part D trust fund in fiscal year 2013).

Kmart, 824 F.3d at 639 (7th Cir. 2016).[37] The Seventh Circuit also stressed that the relator "is not required to trace the movement of currency from the U.S. . . . through the Medicare Part D funding" as Medicare is funded by the Government. *Id.*

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[36] While *Kmart* addressed Part D, "Part C, also known as Medicare Advantage ("MA"), works through a similar model [as Part D]." *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 2012 WL 3399789, at *4 (D. Md. Aug. 14, 2012), aff'd, 745 F.3d 694 (4th Cir. 2014) ("Under MA, the government pays the private insurer a monthly amount per enrolled beneficiary"); *see also MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.,* 935 F.3d 573, 577 (7th Cir. 2019) ("For each Medicare enrollee covered by a [MAO], the Organization receives a per capita reimbursement from the federal government."). As the Seventh Circuit explained, "Part D allows beneficiaries to . . . enroll[] in a private insurance plan. . . . . **CMS does not administer the program; instead, it uses Plan Sponsors, which are private entities . . . manage Part D beneficiaries' claim submissions and payment processes**. Most Plan Sponsors subcontract with Pharmacy Benefit Managers, which are other private entities that work directly with retail pharmacies to provide prescriptions to Part D beneficiaries. **CMS pays Plan Sponsors fixed monthly payments according to certain benchmarks**. . . . .**CMS thus does not directly pay or reimburse any individual prescriptions through the program**." *Kmart*, 824 F.3d at 635–36 (7th Cir. 2016) (emphasis added).

[37] *See also U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, No. 02 C 6074, 2005 WL 2667207, at *2 (N.D. Ill. Oct. 17, 2005) ("Congress . . . recognized that claims made under Medicare . . . 'are not submitted directly to the Federal agency, but rather to private intermediaries,' nevertheless, . . . such claims have been 'uniformly held to be within the ambit of the FCA.'") (quoting S. Rep. 99-345 at 19.); *U.S. ex rel. McGee*

Defendants' argument that it is a "mere assumption" that money paid by Humana for disbursement of Roche supplies to its *Medicare Advantage members* came from money CMS paid to Humana for administration of the MA program does not pass the smell test. [redacted] for its administration of MA plans from December 2013 through December 2015. SOMF ¶ 115. [38] [redacted] of the money received for administering MA plans, paying pharmacy (including RightSource) claims for Roche supplies disbursed to Humana's MA members. SOMF ¶ 116. Through the entire period, Humana was a profitable enterprise and [redacted]

Defendants ignore controlling Seventh Circuit precedent in *Kmart* concerning the application of the FCA to private Medicare plans, and rely instead upon an out-of-circuit district court case regarding Freddie Mac. *U.S. ex rel. Todd v. Fid. Nat'l Fin., Inc.*, No. 1:12-CV-666, 2014 WL 4636394, at *1 (D. Colo. Sept. 16, 2014). In *Todd,* Freddie Mac received private and public

v. IBM Corp., No. 11-C-3482, 2017 WL 4467458, at *6 (N.D. Ill. Oct. 6, 2017) (where the federal government provided a block grant to a county which entered into contracts with the defendant, claims from the defendant to the county were "claims" under the statute).

Defendants cited cases regarding private Medicare plans are inapposite. In *U.S. v. UnitedHealthcare Ins. Co.*, the relator's claim assumed that "in-home examinations were improper" but CMS had stated that "it will not exclude, for payment purposes, diagnoses obtained through in-home examinations." No. 15-CV-7137, 2018 WL 2933674, at *5 (N.D. Ill. June 12, 2018). The Court also found that the kickback claim failed because the MAO did not receive any remuneration, nor did it pay any false claims but "provided services to its plan participants free of charge." *Id*. at *10.

U.S. v. Grp. Health Co-op. was not a kickback case at all. No. CIV. C09-603, 2011 WL 814261, at *2 (W.D. Wash. Mar. 3, 2011). The case addressed unnecessary services provided by a defendant receiving fixed payments from the Government. The court found that there were no claims submitted for those services. Here, there were claims submitted to Humana, which resulted in the payment of claims resulting from a kickback. To the extent that *Grp. Health Co-op* is relevant, it is contradicted by controlling precedent in *Kmart* and *Rogan*, which state a rule that any claims resulting from a kickback to a private entity administering a government program are false.

[38] During this time period, over half the premiums Humana, Inc. received were for MA members. *Id.*

[39] Even if Humana did not earn a profit during the relevant period, and spent more providing MA benefits than it received from CMS, it is incredible for Defendants to suggest that even if they violated the AKS and defrauded the Government, they should not be held liable because they ran an unprofitable business.

revenue, and it was unclear which funded its contract with the defendant. Here, Humana has distinct lines of business: Medicare Advantage is federally funded, and the Commercial business is not.[40] As described above, the Roche diabetes testing supplies for Medicare Advantage members were purchased with Government money.

Moreover, unlike the Seventh Circuit, which found it sufficient that "*much* of the money paid to Kmart under Medicare Part D came from government coffers," *Kmart*, 824 F.3d at 639, *Todd* required a showing that "only federal funds filled Freddie Mac's coffers." *Todd*, 2014 WL 4636394, at *1. This different treatment may be because Medicare is a "government program" and therefore claims to an MA program are fundamentally different than claims to Freddie Mac. In any case, the Seventh Circuit held a false claim may be to an entity "implementing a government program **or** a program using government funds." *Kmart*, 824 F.3d at 639 (emphasis added).

b. The claims from pharmacies to Humana resulted from a violation of the AKS, and were therefore false.

"[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g). The claims from pharmacies to Humana were false claims because they were claims to an "entity . . . implementing a government program or a program using government funds" *Kmart*, 824 F. 3d at 638, that included "items . . . resulting from a violation of [the AKS]." 42 U.S.C. § 1320a-7b(g).

An FCA claim does not require proof that "a kickback actually influenced a patient's or medical professional's judgment." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89,

[40] *U.S. ex rel. Brooks v. Wells Fargo Bank N.A.*, cited by Defendants, also concerns Freddie Mac. 2019 WL 1125834 (N.D. Ill. Mar. 12, 2019). *U.S. ex rel. Dolan v. Long Grove Manor, Inc.*, stands for the entirely unrelated proposition that a plaintiff may not rely upon high levels of therapy to argue there was a "statistical probability that defendants provided unnecessary . . . care." 2019 WL 2774149, at *4 (N.D. Ill. July 2, 2019).

97 (3d Cir. 2018);[41] *see also Teva Pharm. USA, Inc.*, 2019 WL 1245656, at *23 ("[T]he FCA does not require the kickback to be the 'but for' cause of the prescription."); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 335 (S.D.N.Y. 2014) ("[A]ny claim connected in any way to an AKS violation was ineligible for reimbursement."); *U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("Relators need not show . . . a quid pro quo . . . or that the physicians would not have prescribed . . . medication but for the kickbacks. It is sufficient . . . that Defendant paid kickbacks . . . for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback") (emphasis in original).

Here Roche provided Humana with a kickback and Humana placed Roche's products on its formulary and purchased Roche products. Humana's MA members were subject to the formulary decision to prefer Roche [redacted] SOMF ¶ 111. Therefore the claims for Roche products resulted from the kickback and are false. *See U.S. v. Patel*, 778 F.3d 607, 614 (7th Cir. 2015) (finding that where defendant "acted as a gatekeeper to federally-reimbursed care" the defendant referred patients within the meaning of the AKS).

[41] In 2010, the AKS was amended to add § 1320a-7b(g), which makes clear that violations of the AKS lead to violations of the FCA, an issue that was previously disputed by defendants. Defendants argue that the "resulting from" language narrowly circumscribes the scope of liability (Br. at 15), but courts have rejected those arguments. "Although the legislative history . . . does not explain the term 'resulting from,' the Congressional Record indicates it was enacted to avert 'legal challenges that sometimes defeat legitimate enforcement efforts.'" *Medco,* 880 F.3d at 97 (stating that reading the provision to create an enhanced causation requirement "would hamper [FCA] cases under [§ 1320a-7b(g)] even though Congress enacted it to 'strengthen[] whistleblower actions based on medical care kickbacks.'") (citation omitted); *see also U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *5 (D. Mass. Apr. 27, 2018) (rejecting the argument that "the 2010 amendment to the statute narrowed the claims that may be subject to FCA liability. The court finds no support for that notion. The legislative history. . . leads to the opposite conclusion.") (collecting cases); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 332 (S.D.N.Y. 2014) ("There is no indication in . . . the law itself or the legislative history that Congress intended to narrow the scope of 'falsity' under the FCA when it amended the AKS.").

c. Relator has not waived the ability to rely upon claims data produced by Humana.

Defendants frivolously argue that Relator waived the right to argue that pharmacy claims paid by Humana using CMS funds are "false claims." Defendants' conduct in litigation forecloses this argument. While Relator alleged in her Complaint that Humana submitted encounter data to the Government,[42] Humana refused to produce the encounter data to Relator on the ground that Humana's "compromise proposal" of producing "summary spreadsheets with claims data" from pharmacies to Humana for Roche products was sufficient. Dkts. 170 p. 11-13; 170-8. As Humana represented to Judge Gilbert in opposing Relator's motion to compel the encounter data:

> [Iverson]: And so it's not even certain that all submissions of -- or all sales of diabetes testing strips would even be included in the encounter data. Where that shows up is in the claims data. That's the claims that are made from the providers or the pharmacies to Humana. . . . And Humana's produced the claims data of all Roche diabetes test strips sold during the relevant time period
>
> Pl's Ex. 172 (July 26, 2019 Status Hr'g Tr.) 54:22-55:5.[43]

After opposing Relator's request for encounter data based on the argument that Humana produced the claims data of all Roche diabetes test strips," Defendants absurdly argue that Relator should not be allowed to rely upon the claims data in opposing summary judgment.[44]

Defendants claim that Relator's analysis "is inconsistent with the liability theory Relator alleged" in her Complaint is incorrect. Relator broadly alleged that Defendants caused the submission of false claims for Roche products paid through federal funds provided by CMS:

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[42] As the Complaint alleges, encounter data is data submitted by Humana to CMS which reflects services provided to members, and would reflect the sale of Roche diabetes testing supplies. Dkt. 240 ¶¶ 33, 74.

[43] Relator's motion to compel encounter data was denied. Dkt. 300 at 2. Relator does not rely upon encounter data or bids data in opposing Defendants' motion for summary judgment.

[44] Defendants' changed position is subject to judicial estoppel, "a doctrine intended to prevent the perversion of the judicial process." *Matter of Cassidy*, 892 F.2d 637, 641 (7th Cir. 1990) ("Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position.").

- "The federal government compensates the private insurance companies . . . at a capitated rate" and "Humana was paid a capitated rate for its members." Dkt. 240 ¶¶ 26, 77.
- Defendants "cause[d] to be submitted false or fraudulent claims for payment by the United States" through the submission of "claims to Federal healthcare programs [for] services tainted by Defendants' payment and receipt of remuneration." *Id.* ¶ 94.
- The Government "paid false claims when it paid for Roche's products on Humana's formularies." *Id.* ¶ 95.

Relator's liability theory is consistent with these allegations in the complaint.

In any case, "plaintiffs are not required to plead legal theories." *Whitaker v. Milwaukee Cty., Wisconsin*, 772 F.3d 802, 808-09 (7th Cir. 2014). Plaintiffs may raise arguments for the first time at summary judgment where they do not create a surprise. *Id.* (where plaintiff "abandoned" theory of agency relationship between defendant and third party alleged in complaint, and argued in opposition to summary judgment that defendant and third-party were "joint employers," it was error to not consider the "alternative legal characterization" which did not create "any unfair surprise").[45] Here, there is no unfair surprise. In fact, Defendants advised the Court and Relator that the claims data could and should be used as the relevant "claims" in this case as a justification to avoid discovery and were aware of the theory from the Complaint and Relator's expert report.[46]

[45] *See also Vidimos, Inc. v. Laser Lab Ltd.*, 99 F.3d 217, 221-22 (7th Cir. 1996) (finding error where district court refused to consider promissory estoppel theory plaintiff "argued for the first time" in response to summary judgment motion as defendant "should not have been surprised" "the claim asserted . . . to avoid . . . problems with the third party beneficiary claim that were urged. . . as grounds for summary judgment.").

[46] Defendants rely on cases with where the plaintiff's new argument changed the *factual* allegations of the case in a way that would lead to delay. *See Chessie Logistics Co. v. Krinos Holdings, Inc.*, 867 F.3d 852, 860 (7th Cir. 2017) (disagreeing with district court's dismissal at summary judgment insofar as dismissal was based on the fact that the plaintiff "did not assert negligence *per se* in its complaint" but failing to find abuse of discretion because the "new factual and legal theory at such a late stage of the case would have led inevitably to further discovery, delay, and expense" as it required a showing of a different type of harm); *Delaware Motel Assocs., Inc. v. Capital Crossing Servicing Co. LLC*, 2017 WL 4512709, at *2-3 (N.D. Ill. Oct. 10, 2017) (plaintiff relied on "an entirely new factual theory" that former employees stripped assets from company, transferred them to defendants, and defendants concealed the efforts to steal assets, which was not alleged in complaint); *U.S. v. Long Grove Manor, Inc.*, 2019 WL 2774149, at *6 (N.D. Ill. July 2, 2019) (plaintiff argued that defendant's claims were false because "the patients . . . were transferred. . . from a psychiatric facility" when "nothing in [the] complaint so much as hints that defendants . . . violated the FCA . . . by providing . . . care to patients who had previously undergone psychiatric hospitalization").

2. Defendants are liable for the submission of false statements and the claims for payment from Humana plans to CMS.

In each of the contracts Humana entered into with CMS, Humana committed that it would comply with the AKS. [redacted] SOMF ⁋ 113. These statements were therefore false when they were made and are actionable under the FCA.

These statements also fraudulently induced the Government to enter into the contracts. "Courts in this district have recognized false inducement as a basis for alleging an FCA violation. . . . if a contractor makes a false statement to induce a government entity to award a . . . contract . . . which is awarded based on this false statement. All resulting requests for payment are then fraudulent because they are based on the original false statement." *U.S. ex rel. McGee v. IBM Corp.*, 81 F. Supp. 3d 643, 662 (N.D. Ill. 2015) (citation omitted). Humana induced the Government to enter into the contracts with false statements regarding compliance with the AKS.

Humana also made [redacted] SOMF ⁋ 113. A claim for payment is false where "the claim . . . makes specific representations about the goods or services provided; and . . . the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *U.S. v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016). Here Humana made extensive representations about the services provided in its claims for payment, but neglected to inform the Government that it had violated the AKS, a material contractual and statutory requirement. Therefore, Humana's monthly requests for payment under the contract were also false claims.

3. Defendants are liable for their conspiracy to violate the FCA.

Defendants cursorily argue that they are not liable for conspiring to violate the FCA because there was no agreement to violate the AKS, but the facts demonstrate precisely that. *Supra* at 10-16. Defendants came to an unwritten agreement that Roche would provide Humana debt forgiveness in exchange for access Humana's Medicare Advantage business and cause the submission of false claims. The conspiracy to violate the law need not be put down in writing. *Allen v. U.S.*, 4 F.2d 688, 691 (7th Cir. 1924).

D. Defendants' position on damages is contrary to controlling precedent.

Defendants assert that their kickback arrangement did not result in any damages because Humana's receipt of a kickback did not affect the amount paid by the Government.

Defendants' analysis has been wrong since the 1986 amendments to the FCA. The amendments "made clear. . . the concept of loss to the United States" should "be considered broadly." *U.S. ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 739 (D.C. Cir. 1998). The amendment was "'intend[ed] ... to overrule . . . cases which . . . limited the ability of the United States to . . . reach fraud perpetrated on federal grantees, contractors or other recipients of Federal funds'" where the Government "would have paid out the same amount regardless [of] whether contractors submitted false claims" to intermediaries. *Id.* (quoting S. Rep. No. 99–345, at 22). [47]

[47] For example, in *U.S. v. Azzarelli Construction Co.*, 647 F.2d 757 (7th Cir.1981), the court ruled "that there was no loss to the United States . . . where the federal government had contributed a fixed sum to Illinois . . . and thus would have paid out the same amount regardless whether contractors submitted false claims to the State." *Yesudian*, 153 F.3d at 739. In response, the Senate Judiciary Committee advised that the amended FCA was explicitly "intend[ed] [to] overrule *Azzarelli*." *Id.* (quoting S. Rep. No. 99–345, at 22). *See also U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 495 (D.C. Cir. 2004) (Roberts, J.) (characterizing *Azzarelli* as "the decision that the Senate Judiciary Committee most clearly intended to overrule" and stating that "[**u]nder our reading of subsections (a) and (c) of Section 3729, the fixed nature of a federal grant would be no bar to a claimant's liability . . .**") (emphasis added). *Totten* itself was abrogated by statute, on other grounds, for holding that the FCA required a claim to be presented to the Government. In 2009, Congress amended the statute to clarify that there was no requirement that a claim be presented to the Government. *Kmart*, 824 F. 3d at 638.

The FCA mandates three times the damages that the "Government sustains because of the act of [the violator]." 31 U.S.C.A. § 3729 (a)(1).[48] Seventh Circuit law establishes two principles. First, as described *supra* at 26-27, claims submitted to private entities administering Medicare plans are actionable. Second, when a claim results from a kickback, the entire value of the claim constitutes damages. In *U.S. v. Rogan*, the seminal Seventh Circuit case on damages in an FCA case predicated on AKS violations, the Court upheld a $62 million award, ruling that "**the entire amount . . . received on [the] claims must be paid back."** 517 F. 3d 449, 453 (7th Cir. 2008).[49]

Defendants argue they should not be required to repay money to the Government because Humana would have received the same payment regardless of the alleged AKS violation. Br. at 33. Remarkably, Defendants' ignore *Rogan*, which held that in the event of an AKS violation, "**the entire amount . . . received on [the] claims must be paid back**," not the difference between the amount paid and what would have been paid absent a kickback. *Rogan*, 517 F. 3d at 453.[50]

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[48] The FCA also mandates penalties. Defendants do not seek summary judgment on the issue of penalties.

[49] The Seventh Circuit held that Medicare funds come "with conditions" and "[w]hen the conditions are not satisfied, nothing is due." *Id.* at 453. It is not "important that most … patients received . . . perhaps all the care" or "if the patients had gone elsewhere, the United States would have paid for their care." *Id*. Those possibilities do not "allow [the defendant] to keep money obtained from the Treasury by false pretenses, or avoid the penalty for deceit." *Id.* at 453. Defendants argue that the violation of a "gatekeeping" requirement does not render claims false. However, the Seventh Circuit reaffirmed that when there is a violation of the AKS, "each and every form filed by the defendant was false. Thus, in *Rogan* . . . evidence of how many forms were *filed* was sufficient to establish how many of those forms were *false*." *U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014) (emphasis in original). *See also U.S. v. Sound Sols. Windows & Doors, Inc.*, No. 09 C 6948, 2017 WL 9517514, at *2 (N.D. Ill. May 11, 2017) (Rowland, J.), *report and recommendation adopted*, 2017 WL 6723765 (N.D. Ill. Dec. 18, 2017) (finding where fraud is on "programs designed to benefit third-parties rather than the government itself," the "taint theory" of damages applies and "the government is entitled to three times what it actually paid."); *Wilkins*, 659 F.3d at 314 (3d Cir. 2011) ("The Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback.").

[50] *Rogan* has been cited by courts around the country as the correct standard for damages. *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 792 F.3d 364, 386 (4th Cir. 2015); *Hill v. Federal Communications Commission*, 496 F. App'x 396, 404 n.14 (5th Cir. 2012); *U.S. v. Speqtrum, Inc.*, 47 F. Supp. 3d 81, 97 (D.D.C. 2014); *U.S. ex rel. Feldman v. van Gorp*, 2010 WL 2911606, at *4 (S.D.N.Y. July 8, 2010).

Defendants focus on the causation standard to circumvent the plain law on damages. Their reliance on *U.S. v. Luce* is misplaced. *Luce* held that once a federally-insured loan defaults (which may occur years after any fraudulent representation on the loan document), the court must analyze whether the damage from the default was proximately caused by the false representation on the loan document, instead of utilizing a but-for causation test. 873 F. 3d 999 (7th Cir. 2017).[51]

Under *Rogan*, the Government is damaged as soon as a claim resulting from a violation of the AKS is paid. There is no attenuation between the submission of the claim and the payment of it. Unlike the loan insurance context, the payment does not come years later for reasons potentially unconnected to the fraud.

Relator easily satisfies the proximate cause standard, which asks "whether the injury is of a type that a reasonable person would see as a likely result of his or her conduct." *U.S. v. Luce*, 2019 WL 3003300, at *7 (N.D. Ill. July 10, 2019). The evidence demonstrates that Defendants understood that as a "likely result" of Humana placing Roche's products on its formularies in exchange for a kickback, claims would be submitted to Humana's MA plans and paid by Humana. Further, Defendants understood that Humana received payment from the Government under its Medicare Advantage contracts, which required compliance with the AKS, and their conduct would cause Humana to be in violation of the AKS.

V. CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment should be denied.

[51] Luce was indicted for fraud but continued to make certifications that his company's principals were not involved in a criminal investigation. *Luce*, 873 F. 3d at 1002. Some of the loans eventually defaulted. The Court held that the Government must show that Luce's "falsehood was the proximate cause of the Government's harm." *Id.* at 1014. Similarly, in *U.S. v. Hibbs*, the defendant filed false certificates regarding "plumbing, electrical and heating systems" of homes with mortgages insured by the FHA. 568 F.2d 347, 349 (3d Cir. 1977). The mortgagors defaulted due to "changed financial circumstances or irresponsibility" having nothing to do with the plumbing electrical and heating systems, and the court found that the Government's loss on the defaulted loans was not caused by the false certifications. *Id.* at 349-51.

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Respectfully submitted,

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