

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA *et al., ex rel.*
ADAM WITKIN,

Plaintiffs,

v.

MEDTRONIC, INC., *et al.*,

Defendants.

No. 11-cv-10790-IT

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

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I. INTRODUCTION

The United States respectfully submits this statement of interest in connection with the pending motion for summary judgment filed by Defendants Medtronic, Inc. & Medtronic Minimed, Inc. ECF Nos. 175, 176.

Defendants' Reply asks the Court to re-write the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, to gut a law that Congress designed to protect patients and the federal health care programs. *See* ECF No. 249 (the "Reply"). First, the Reply encourages the Court to apply out-of-circuit case law on causation, even where the weight of in-circuit authority is contrary. Second, it invites the Court to stretch an isolated out-of-circuit ruling on the meaning of "remuneration" in the AKS, even where that ruling does not fit the facts of this case and where consideration of it is not necessary to resolve the motion actually pending before the Court. And, finally, it asks the Court to extend to the AKS a Supreme Court opinion interpreting a statutory prohibition on aiding and abetting illegal immigration, even where the AKS's plain language makes clear that the suggested inference is improper. Respectfully, the Court should decline to do any of these. The United States takes no position on the sufficiency of Relator's evidence, but rather submits this statement because the United States has an interest in the proper application of the False Claims Act and the AKS.

II. STATUTORY BACKGROUND

The False Claims Act, 31 U.S.C. §§ 3729-33, ("FCA") permits private "relators" to bring suit to redress fraud against the United States and to seek a recovery on behalf of the United States. Although the United States declined to intervene in this action, it will be the principal beneficiary should Relator prevail. *See United States ex rel. Eisenstein v. New York*, 556 U.S. 928, 930 (2009). Moreover, because the FCA is the government's principal tool to combat fraud

and recover losses involving federal funds, and because the majority of successful actions under the FCA are prosecuted by the Department of Justice, the United States has a substantial interest in the proper interpretation and application of the FCA. In addition, the United States also has a strong interest in the proper interpretation of other federal laws governing healthcare providers, including the AKS.

The AKS serves to protect patients “from doctors whose medical judgments *might* be clouded by improper financial considerations,” *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (emphasis added), in recognition of the fact that it is often difficult to ascertain what judgments a provider would have made in the absence of the kickback. Courts have accordingly recognized that “[t]he Government does not get what it bargained for when a defendant is paid by [Medicare or Medicaid] for services tainted by a kickback,” whether or not it can show that a conflict-free provider would have given the same care. *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 314 (3d Cir. 2011), *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016).

Paying remuneration “to induce” referrals for the provision of Medicare-reimbursed items or services violates the AKS when the conduct was knowing and willful. 42 U.S.C. § 1320a-7b(b)(2). In other words, the AKS does not require that the kickback be successful for it to be illegal. *See, e.g., United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013) (“The AKS’s plain language . . . makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results.”). Congress chose to forbid *kickbacks themselves* (not just successful kickbacks) because they inherently corrupt medical decision-making. *United States v. Teva Pharms. USA, Inc.*, No.

13-cv-3702, 2019 WL 1245656, at *10 (S.D.N.Y. Feb. 27, 2019) (“[T]he [AKS] does not require evidence of a ‘*quid pro quo*’ in the sense that each bribe must successfully generate referrals.”).

AKS violations can lead to FCA liability in multiple ways. For instance, when a provider requests payment and expressly but falsely certifies compliance with the AKS, that certification is actionable under the FCA. 31 U.S.C. § 3729(a)(1)(B). Likewise, if a provider “makes specific representations about the goods or services provided” but “fail[s] to disclose noncompliance with material statutory, regulatory, or contractual requirements” in a way that “makes those representations misleading half-truths,” that too is actionable. *Universal Health Servs.*, 579 U.S. at 190. The First Circuit accepted such a theory of liability over a decade ago in *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-94 (1st Cir. 2011).

In 2010, Congress amended the AKS to add an additional way of establishing FCA liability for AKS violations, namely, that any “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). In amending the AKS, Congress intended to “strengthen[] whistleblower actions based on medical care kickbacks” by overruling a then-recent decision that had found a hospital’s reimbursement claims for surgeries were not false, even though the surgeon had violated the AKS, because the hospital had not itself violated the AKS or been aware of the surgeon’s violation. 155 Cong. Rec. S10,853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). The amendment made clear “that all claims resulting from illegal kickbacks are ‘false or fraudulent,’ even when the claims are not submitted directly by the wrongdoers themselves.” *Id.*; *see id.* at S10,854 (Sen. Leahy, making the same point); *see also, e.g., United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 333 (S.D.N.Y. 2014) (discussing this legislative history).

III. BUT-FOR CAUSATION IS NOT THE APPLICABLE STANDARD

A. Section 1320a-7b(g) Does Not Require But-For Causation

Defendants urge the Court to apply a but-for causation standard to the Relator's AKS-based FCA claims. But the weight of authority in the First Circuit (and elsewhere outside the Sixth and Eighth Circuits) rejects a but-for causation standard. In the words of the First Circuit, where a FCA cause of action is predicated on violation of the AKS, the government (or the Relator) must show only that there "is a *sufficient causal connection* between an AKS violation and a claim submitted to the federal government." *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (emphasis added) (citing *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96-98 (3d Cir. 2018); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601-IT, 2018 WL 1996829, at *5-6 (D. Mass. Apr. 27, 2018)).

Because compliance with the AKS "is a precondition" of reimbursement from federal health care programs, *Hutcheson*, 647 F.3d at 393, courts had long held (even before the enactment of Section 1320a-7b(g)) "that non-compliance with the AKS rendered a claim non-payable and that a FCA claim could therefore be premised on an AKS violation," *United States ex rel. Brown v. Celgene Corp.*, No. 10-cv-3165, 2014 WL 3605896, at *7 (C.D. Cal. July 10, 2014). When it enacted Section 1320a-7b(g), Congress reaffirmed that AKS compliance is condition precedent for Medicare reimbursement by adding a provision to the AKS itself that provides that any "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).

Defendants contend that Section 1320a-7b(g)'s use of the words "resulting from" should be interpreted to mean that claims are rendered false by an underlying AKS violation only if the claims would not have been submitted *but for* the AKS violation. That argument rests on the 6

66flawed analysis of two recent out-of-circuit decisions. See *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1053-55 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828, 834-36 (8th Cir. 2022). Those out-of-circuit decisions concluded, based on the Supreme Court’s holding in *Burrage v. United States*, 571 U.S. 204 (2014), that the phrase “[r]esults from’ imposes . . . a requirement of actual causality” (i.e., causation in fact) and that, “[i]n the usual course,” causation in fact means that a given outcome “would not have occurred in the absence of—that is, but for”—a given event. *Id.* at 211 (quotation marks and citations omitted); see *Martin*, 63 F.4th at 1052-53; *Cairns*, 42 F.4th at 834-35.

This Court should not follow the Sixth and Eighth Circuits for several reasons. First, and perhaps most importantly, the First Circuit has, at a minimum, strongly suggested that but-for causation is not the appropriate standard for evaluating causation in AKS-predicated FCA cases. In *Guilfoile*, the First Circuit approvingly cited two cases for the proposition that “if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA.” 913 F.3d at 190. One was *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018), in which the Third Circuit squarely considered and rejected a but-for causation standard. The First Circuit also cited this Court’s 2018 decision in *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, 12-cv-10601-IT, 2018 WL 1996829 (D. Mass. Apr. 27, 2018), which likewise rejected a but-for causation standard. *Bawduniak* recognized instead that a plaintiff can establish falsity for FCA claims based on AKS violations by showing that the defendant “paid kickbacks to a physician 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.” *Id.* at *3. The First Circuit reinforced its apparent agreement with

Greenfield and *Bawduniak* by explaining that its “reading of § 1320a-7b(g)” was “consistent with the legislative history” of that provision, “which indicates Congress’s intent . . . to ‘strengthen [] whistleblower actions based on medical care kickbacks.’” *Guilfoile*, 913 F.3d at 190. As Judge Gorton recently recognized in rejecting the exact argument that Defendants make here, “the First Circuit’s analysis [in *Guilfoile* is] persuasive, if not binding.” *United States v. Teva Pharms. USA, Inc.*, No. 20-cv-11548-NMG, 2023 WL 4565105, at *5 (D. Mass. July 14, 2023).¹

As the First Circuit recognized, this Court’s decision in *Bawduniak* correctly interpreted Section 1320a-7b(g)’s “resulting from” language, and the Court should apply that standard here. In other words:

Relators need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant’s medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician 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.

Bawduniak, 2018 WL 1996829, at *3. Courts across the country agree that this standard is the right one. *See, e.g., Teva*, 2023 WL 4565105, at *5 (Judge Gorton adopting causation standard articulated in *Bawduniak*, *Greenfield*, and *Guilfoile*); Op. & Order at 89, *United States ex rel. Heller v. Guardian Pharm.*, No. 1:18-cv-03728-SDG (N.D. Ga. Sept. 30, 2023), ECF No. 226 (rejecting *Cairns* and *Martin* and finding “if Heller proves at trial that Guardian violated the

¹ In August 2023, Judge Gorton certified interlocutory appeal in *Teva*. No. 1:20-cv-11548-NMG, ECF No. 235 (D. Mass. Aug. 14, 2023). Approximately a month later, Judge Saylor issued an order ruling that the “appropriate standard is but-for causation.” *United States v. Regeneron Pharm., Inc.*, No. 20-cv-11217-FDS, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023). On October 25, Judge Saylor certified *sua sponte* his causation ruling for interlocutory appeal. *Regeneron*, No. 20-cv-11217-FDS, ECF No. 366 (D. Mass. Oct. 25, 2023).

AKS, he will have proved that Guardian caused materially false claims to be submitted to the Government in violation of the FCA”); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-cv-00668-SAG, 2022 WL 3599139, at *9 (D. Md. Aug. 23, 2022) (relying on *Bawduniak* and refusing to follow *Cairns*); *Kuzma v. N. Ariz. Healthcare Corp.*, 607 F. Supp. 3d 942, 956 (D. Ariz. 2022) (observing that most courts conclude that “but-for causation is not required,” and applying the “sufficient causal link” standard); *Teva*, 2019 WL 1245656, at *23 (“[T]he FCA does not require the kickback to be the ‘but for’ cause of the prescription.”); *see also United States ex rel. Schroeder v. Medtronic, Inc.*, No. 17-cv-2060, 2021 WL 4168140, at *23-24 (D. Kan. Sept. 14, 2021) (rejecting a but-for causation requirement); *Kester*, 41 F. Supp. 3d at 331-35 (same). The Court, therefore, should again apply *Bawduniak*’s interpretation of Section 1320a-7b(g) here.

The Court should also reject the Sixth and Eighth Circuits’ interpretation of Section 1320a-7b(g) because those circuits’ reasoning is unsound. While the Sixth and Eighth Circuits relied on *Burrage*, they failed to heed that decision’s admonition that courts properly “read phrases like ‘results from’ to require but-for causality” *only* if “there is no textual or contextual indication to the contrary.” *Burrage*, 571 U.S. at 212. Indeed, in a recent FCA case, the Supreme Court emphasized the importance of construing statutory terms “in their particular . . . context.” *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 754 (2023). In interpreting Section 1320a-7b(g), however, the Sixth and Eighth Circuits ignored the powerful textual and contextual evidence against interpreting “resulting from” as a but-for standard. *See Fitzer*, 2022 WL 3599139, at *10.

As an initial matter, the AKS contains its own nexus requirement: Remuneration can support liability when it is solicited or received “in return for,” or offered or paid with the intent

“to induce,” the provision of items or services or referrals to provide them. 42 U.S.C.

§ 1320a-7b(b)(1), (2). As its “plain language” makes clear, that standard does not limit AKS liability to situations where the desired outcome of the kickbacks actually materializes, much less where the kickback is the but-for cause of the outcome. *Parikh*, 977 F. Supp. 2d at 665. Such a nexus requirement is consistent with the AKS’s animating principle, namely that financial conflicts make it impossible to trust that treatment or referral decisions were motivated solely by the best interests of the patient, whether or not such conflicts can actually be shown to have altered the provider’s specific treatment or referral choices.

Other “contextual” factors undermine the Sixth and Eighth Circuits’ reading of Section 1320a-7b(g). *See Burrage*, 571 U.S. at 212. Congress imposed *criminal* liability for paying a kickback with no need to also show that the kickback actually led to the intended outcome, i.e., the physician’s use of the company’s medical device. There is nothing to suggest that Congress meant to require that *civil* FCA liability predicated on the very same kickback had to show not just that the intended outcome came about, i.e., the physician used the company’s medical device, but also that the physician would not have done so absent the kickback. *See Greenfield*, 880 F.3d at 96; *Fitzer*, 2022 WL 3599139, at *10. And such a standard would be flatly inconsistent with the legislative history of Section 1320a-7b(g), which makes clear that Congress enacted that provision to “strengthen[] whistleblower actions based on medical care kickbacks.” 155 Cong. Rec. S10,853. This, of course, is the point that the First Circuit made in *Guilfoile*. 913 F.3d at 190.²

² As a practical matter, if Defendants are somehow right that Congress weakened (rather than strengthened) the FCA through its 2010 enactment of Section 1320a-7b(g), the consequences would be absurd. For instance, if a device company gave a doctor suitcases of cash intending to induce his use of the company’s devices, but that doctor (perhaps fearing

B. Proof of But-For Causation Is Not Required under an Implied Certification Theory

Defendants take the position that, regardless of how “resulting from” is construed, Relator has not identified sufficient evidence in the record to survive summary judgment. Reply at 9-11. In the course of that discussion, Defendants correctly observe that there is another theory of liability available to Relator—implied certification. *See id.* at 10 (describing “any theory of liability”). As the Eighth Circuit expressly stated, *Cairns* is limited to circumstances “when a plaintiff seeks to establish falsity or fraud through” Section 1320a-7b(g). *Cairns*, 42 F.4th at 836; *see also United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-cv-3003, 2023 WL 36174, at *2-3 (D. Minn. Jan. 4, 2023) (under *Cairns*, but-for causation standard does not apply where plaintiffs seek to establish falsity under other theories). Thus, to the extent a plaintiff sought to establish the falsity of the claims on implied certification grounds, *Cairns* leaves that longstanding theory undisturbed. Both before and after Congress enacted Section 1320a-7b(g) in 2010, courts have widely recognized that, because the government agrees to pay only for conflict-free medical care, an AKS violation can render subsequent claims false or fraudulent. In *Hutcheson*, for example, the First Circuit recognized that even claims submitted by providers that had no knowledge of underlying kickbacks were false or fraudulent because they misrepresented compliance with the AKS. 647 F.3d at 392-94. Because of the underlying kickback, the claims were false regardless of whether they would have been submitted absent the kickback. In other words, even if Defendants here were right about the meaning of Section 1320a-7b(g)’s “resulting from” language (and they are not), Relator could alternatively prove

prosecution, revocation of medical license, or even loss of future patients) claimed that he would have selected that company’s devices regardless, the device company could argue that there is no FCA liability.

falsity under an implied certification theory recognized by the First Circuit, as well as the Supreme Court. *See id.*; *see also Universal Health Servs.*, 579 U.S. at 190. This theory requires a plaintiff to prove that the defendant knowingly failed to comply with a requirement that was material to the government’s payment decision. *See Universal Health Servs.*, 579 U.S. at 190, 192. In the context of a kickback case, a plaintiff must show that the defendant violated the AKS and that compliance with the AKS is material to the government’s payment decision. *See Teva*, 2023 WL 4565105, at *4 (citing cases). Under this theory of liability, the government does *not* need to prove whether the referrals that the kickback was meant to induce, and that in fact came to pass, would have been provided even absent the kickback.

Defendants argue that the Court should look past the binding First Circuit case law of *Hutcheson* and find that, even under an implied certification theory, but-for causation is required. They note that the FCA imposes liability not just on those who themselves submit false claims, but also on those who “cause[]” false claims to be submitted. *See Reply* at 10-11 (citing 31 U.S.C. § 3729(a)(1)(A)). Defendants further observe that courts typically apply common law principles when construing the FCA, including applying common-law concepts of causation. *Id.* While these statements of the law are uncontroversial, the inference that Defendants draws—that but-for causation is required—misses the mark.

The fact that causation generally includes both causation in fact and proximate causation does not necessarily mean that but-for causation is required under an implied certification theory. Causation in fact requires only that there is “‘in fact *some causal relationship* between the conduct and the outcome.’” *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, No. 96-cv-11651PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003) (quoting *Rodriguez-Cirilo v. Garcia*, 115 F.3d 50, 54 (1st Cir. 1997) (Campbell, J., concurring))

(emphasis added). It does not mean, as Defendants appear to suggest, that “but for” is the only or even correct standard under the FCA. *See, e.g., United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 406-07 (D. Mass. 2010) (finding substantial-factor test satisfied even where the causation “gruel is very thin”) (citing *Parke-Davis*, 2003 WL 22048255, at *4). Indeed, the primary case on which Defendants rely does not even use the term “but for” causation. *See generally Parke-Davis*, 2003 WL 22048255. To rule otherwise would not only undermine the purpose of the AKS, it would lead to an absurd result. If Defendants are right, then under the FCA the government need *not* prove that a bribe-paying, claim-submitting entity (e.g., a hospital) was the but-for cause of a false claim, merely because the bribe-payor itself submitted claims. But, say Defendants, the government *must* prove but-for causation when a non-submitting entity, like a device manufacturer, does the same thing.

IV. THE COURT NEED NOT DECIDE WHETHER AN OPPORTUNITY TO BILL CONSTITUTES REMUNERATION

Defendants argue that one of the Relator’s alleged schemes—that Defendants provided services at diabetes management device (“iPro”) clinics at no cost to the host doctors, and then instructed the doctors to bill for those services—must fail because an “opportunity to bill” is not a “legally viable theory of remuneration.” Reply at 12. As a threshold matter, Defendants’ fundamental assumption that the Relator is proceeding on only an “opportunity to bill” remuneration theory does not appear to be correct. *See* ECF No. 188 at 14-15 (explaining that the remuneration as part of the clinic scheme involved a package of free benefits including “running the iPro clinics, doing medical insertions, giving physicians an opportunity to bill, downloading and assisting interpretations, reviewing a practice’s health records to select patients for CGM, loaning equipment, providing free sensors, providing lucrative training payments, and

providing office hours or office days by clinical and sales people to become an extension of office staff”).

The Court need not, therefore, decide whether an “opportunity to bill” alone constitutes remuneration. But even if the Court did opt to tackle this question, the answer lies in First Circuit controlling precedent. In *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989), the court of appeals affirmed a criminal AKS conviction, holding that “[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.” Defendants do not mention *Bay State* in their Reply.

Rather, citing *Guilfoile*, Defendants contend that *Guilfoile* “assumed” that remuneration means payment, but not an opportunity for payment. Reply at 13. First, *Guilfoile* did not (because it could not) overturn *Bay State*, and *Bay State* is the law of this circuit. *San Juan Cable LLC v. Puerto Rico Tel. Co.*, 612 F.3d 25, 33 (1st Cir. 2010) (“Under the [‘law of the circuit’] rule, newly constituted panels in a multi-panel circuit court are bound by prior panel decisions that are closely on point.”). Second, Defendants’ assumption is based on one sentence in *Guilfoile* where the Court noted that the AKS targets “any remunerative scheme” where a person “is paid in return for referrals.” 913 F.3d at 189. But looking at the context of the entire paragraph, it is clear the Court was simply explaining that the act of paying remuneration is one of the ways that a person can violate the AKS. *See id.* at 188 (stating earlier in the same paragraph that the AKS criminalizes an “offer *or* payment of any remuneration” under 42 U.S.C. § 1320a-7b(b)(2)) (emphasis added); *see also* 42 U.S.C. § 1320a-7b(b)(1) (prohibiting soliciting

or receiving any remuneration). *Guilfoile* did not limit the AKS definition of remuneration to only payments, to the exclusion of everything else as Defendants suggest.

Not only is *Bay State* the law of the circuit, the law of this case also counsels against adoption of Defendants' legal position. *See Ellis v. United States*, 313 F.3d 636, 646 (1st Cir. 2022) (citing cases) ("The orderly functioning of the judicial process requires that judges of coordinate jurisdiction honor one another's orders and revisit them only in special circumstances."). In ruling on Defendants' motion to dismiss, the Court already determined that the Relator's allegation related to the clinic scheme was a legally viable theory of remuneration: "The allegation that Medtronic effectively instructed physicians on billing Medicare for procedures that Medtronic provided for free transforms what would be an otherwise innocuous patient-promotion practice into an offer of remuneration to the physicians." ECF No. 86 at 14. The Court further held that "even a physician legitimately billing Medicare for properly[]supervised iPro clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do." *Id.* at 15. There have been no changes in the law that warrant the Court revisiting its decision that the Relator's clinic scheme is a legally viable theory of remuneration.

Urging the Court to look past the law of the circuit and the law of the case, Defendants argue that "providing an opportunity to bill" does not constitute remuneration under *Martin*, 63 F.4th at 1048-52. *See Reply* at 13-14. *Martin* is an isolated, out-of-circuit case that is both distinguishable on the facts and inconsistent with the case law in this district. In *Martin*, the relator alleged that the hospital decided not to hire Physician A because of threats from Physician B, a competitor of Physician A, that he would no longer make referrals to the hospital if it hired Physician A. The court held that a hospital's decision not to hire Physician A was not

remuneration to Physician B because there was “no evidence that anyone paid anyone anything or changed the value or cost of any services that otherwise would have been received.” 63 F.4th at 1052 (emphasis added). In contrast to a mere decision not to hire, the Relator here argues that the record evidence supports his claim that Defendants provided free services and benefits through the clinics, which had inherent value and changed the cost of those services to the doctors.

Martin’s interpretation of the term “remuneration,” is also inconsistent with the vast majority of courts, including those in this district. This court has held that the AKS “makes it illegal to offer, pay, solicit or receive *anything of value* as an inducement to generate business payable by Medicare or Medicaid.” *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (emphasis added) (citing Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.”)); *see also Regeneron*, 2023 WL 6296393, at *5 (noting *Martin*’s “interpretation” of remuneration in a footnote, but nevertheless holding that “[r]emuneration means ‘anything of value’”).

V. *HANSEN IS INAPPOSITE*

Defendants argue that *United States v. Hansen*, 599 U.S. 762 (2023), counsels in favor of construing the AKS to require some specialized proof of “intent to solicit a crime on the part of” those whom they allegedly bribed. Reply at 15. In *Hansen*, the Supreme Court interpreted an aiding and abetting statute that criminalized inducing an illegal alien to enter the United States. 599 U.S. at 77. The Supreme Court concluded that the term “induce” carried a specialized meaning in that particular statute, 8 U.S.C. § 1324(a)(1)(A)(iv), which criminalizes

“‘encouraging’ and ‘inducing’ a violation of law.” 599 U.S. at 77 (emphasis in original). In that context, the Supreme Court afforded the term “induce” the specialized meaning it is typically given in criminal solicitation and facilitation statutes. *See id.* at 776 (“[T]he context of these words—the water in which they swim—indicates that Congress used them as terms of art.”). Here, relying on *Hansen*, Defendants argue that the Court should impose this same meaning on the term “induce” in the AKS because the statute at issue in *Hansen* and the AKS are both criminal statutes.

There is no basis for applying *Hansen*’s reasoning to the AKS. As an initial matter, the Court in *Hansen* did not hold that the term “induce” should always be read as a term of art whenever it is used in a criminal statute. The statute in *Hansen* criminalizes inducing another to violate the law (in that case, entering the United States illegally)—i.e., it penalizes not just the principal (the one who illegally enters the United States), but also the one who facilitates and aids and abets the principal. *See Hansen*, 599 U.S. at 771 (noting that solicitation and aiding and abetting “both are longstanding criminal theories targeting those who support the crimes of a principal wrongdoer”). It thus was designed to target the solicitation of a criminal act. Because of that, the Court afforded the term “induce” the specialized meaning it is typically given in criminal solicitation and facilitation statutes. Here, the key point that drove the Court’s analysis in *Hansen* is missing. The AKS criminalizes the payment of a kickback to “induce” a person “to refer an individual . . . for the furnishing . . . of” or “to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering” items or services paid for by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Nothing in the text of the AKS suggests it is an aiding and abetting statute like the one at issue in *Hansen*, which applied only where the defendant seeks to “induce” a thing that is independently unlawful. *Id.* § 1320a-7b.

In addition, application of *Hansen* as Defendants suggest would have perverse consequences. For example, under Defendants' reading, presumably even if a company gave a doctor money to induce the doctors to use its devices over a competitor's, there would be no liability under the AKS unless the doctor's use of the devices was somehow illegal. 42 U.S.C. § 1320a-7b(b)(2). Such a result makes no sense in the context of the AKS where neither the act of making a referral nor the provision of goods or services are independently unlawful. *Cf. Pfizer, Inc v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67, 78 (2d Cir. 2022) (rejecting a similar attempt "to read a corruption element into the AKS's relationship with the [FCA]"); *Patel*, 778 F.3d at 612 (noting that a purpose of the AKS is to "protect patients from doctors whose medical judgments might be clouded by improper financial considerations"). This Court, therefore, should read "induce" in the AKS's particular context, not in the context of dissimilar federal criminal solicitation and facilitation statutes, as Defendants suggest. *Cf. Schutte*, 598 U.S. at 754 (noting that the Supreme Court's interpretation of statutory terms in a prior case "was ultimately tied to the [other statute's] particular text," and to read the prior case as "establishing categorical rules for those terms would accordingly 'abandon the care we have traditionally taken to construe . . . words in their particular statutory context'").

VI. CONCLUSION

For the foregoing reasons, the Court should reject the legal standards that Defendants' Reply advances.

Respectfully submitted,

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