

# United States Court of Appeals For the First Circuit

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No. 23-2086

UNITED STATES OF AMERICA,

Plaintiff, Appellant,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant, Appellee.

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor IV, U.S. District Judge]

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Before

Montecalvo, Thompson, and Kayatta,  
Circuit Judges.

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Daniel Winik, Attorney, Civil Division, U.S. Department of Justice, with whom Brian M. Boynton, Principal Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice, Joshua S. Levy, Acting U.S. Attorney, District of Massachusetts, Michael S. Raab, Attorney, Civil Division, U.S. Department of Justice, and Charles W. Scarborough, Attorney, Civil Division, U.S. Department of Justice, were on brief, for appellant.

Paul D. Clement, with whom Matthew D. Rowen, Clement & Murphy, PLLC, Theodore V. Wells, Jr., H. Christopher Boehning, Paul Weiss Rifkind Wharton & Garrison LLP, Richard L. Scheff, Katharine Ladd, Faegre Drinker Biddle & Reath LLP, Brien T. O'Connor, John P. Bueker, and Ropes & Gray LLP were on brief, for appellee.

Tara S. Morrissey, Andrew R. Varcoe, U.S. Chamber Litigation

Center, Jeffrey S. Bucholtz, Matthew V.H. Noller, and King & Spalding LLP on brief for Chamber of Commerce of the United States of America, amicus curiae.

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February 18, 2025

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**KAYATTA, Circuit Judge.** This appeal calls for us to determine the meaning of the words "resulting from" as used in a 2010 amendment to the federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(g)). That 2010 amendment states that "a claim [for payment by a federal healthcare program] that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the False Claims Act (FCA), 31 U.S.C. §§ 3729-33. Id. (emphasis added). The FCA, in turn, imposes civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). Whether a violation of the AKS is also a false claim under the FCA makes a difference because the FCA allows both the government and whistleblowers to bring civil actions for damages.

The government alleges that, in violation of the AKS, Regeneron Pharmaceuticals knowingly induced prescriptions of a drug called Eylea by covering copayments for certain patients who received the drug. Further, contends the government, when doctors filed Medicare claims for Eylea prescribed to patients receiving copayment assistance, those claims "resulted from" a violation of

the AKS whether or not those claims would have been made even had Regeneron not covered the co-pay. Accordingly, as the government sees it, those Medicare claims were "false or fraudulent" for purposes of the FCA.

Regeneron begs to differ. The company says that a claim only "result[s] from" an AKS violation if it includes "items or services" that would not have been paid for by the government absent the AKS violation. Put differently, Regeneron contends that an AKS violation must be a but-for cause of the challenged claim. So, reasons Regeneron, if a doctor would have purchased (and sought reimbursement for) Eylea anyway, then the subsequent Medicare claim cannot have "result[ed] from" Regeneron's allegedly illicit payments. As we will explain, we agree with Regeneron.

**I.**

**A.**

Regeneron manufactures Eylea. Eylea is one of just a few drugs approved by the Food and Drug Administration (FDA) for treating an ophthalmological condition called neovascular age-related macular degeneration, also known as wet AMD. Eylea is a "buy and bill" drug under Medicare Part B. This means that physicians buy the drug, prescribe it, administer it in their offices, and then submit a reimbursement claim to Medicare. It also means that Eylea is subject to Part B's cost-sharing

requirement: Medicare covers eighty percent of the cost while the patient pays the remaining twenty percent.

Eylea is expensive. Since 2013, Medicare Part B has spent over \$11.5 billion on Eylea. A single injection costs \$1,850. Because a patient requires multiple injections per year, annual per-patient co-pays routinely exceed \$2,000. For some patients, that co-pay can deter the patients from using Eylea. And while only a few drugs are FDA-approved to treat wet AMD, at least one other drug that is much cheaper than Eylea is available for off-label use.

These economics create an incentive for Regeneron to price Eylea in a way that frees the patient from the co-pay. An injection that sells for \$1,850 with a \$330 co-pay will likely sell less well than an injection that costs \$2,000 with no co-pay. Of course, the insurer -- not the manufacturer -- sets the co-pay (to ensure that the patient has economic skin in the game when deciding whether to use the drug). But if the patient knows that the manufacturer will rebate that co-pay, that is more or less equivalent to having no co-pay.

Here enters the AKS, which prohibits kickbacks.<sup>1</sup> All parties assume for purposes of this appeal that a rebate by the

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<sup>1</sup> The AKS imposes criminal liability on anyone who "knowingly and willfully offers or pays any remuneration . . . to any person to induce such person[] . . . to purchase, lease, order . . . or

manufacturer to the patient or doctor would be a kickback. So some creative manufacturers have tried a less direct work-around by supporting charitable foundations that help patients with co-pays. The manufacturer gives the foundation a donation, and the foundation gives patients (or doctors) the co-pay.

Suffice it to say, such an arrangement can easily be seen as a conduit for manufacturer rebates. The Department of Health and Human Services therefore issued guidance attempting to differentiate truly independent co-pay assistance charities from rebate conduits. See Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005).

In this case brought under the FCA, the government alleges that Regeneron crossed well into the conduit side of that difference when it paid more than \$60 million over the course of four to five years to the Chronic Disease Fund (CDF), a foundation that provides copayment assistance to patients suffering from wet AMD. For purposes of this appeal, we follow the parties' lead by assuming, without deciding, that some or all of those donations were unlawful kickbacks. We focus our attention, instead, on the

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recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

proper standard of causation required to turn an AKS kickback into a per se FCA violation.

**B.**

A 2010 amendment to the AKS provides that a "claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). In other words, an "AKS violation that results in a federal [healthcare] payment is a per se false claim under the FCA." Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019) (quoting United States ex rel. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017)).

Turning their attention on the issue of causation, the parties filed competing motions under Federal Rule of Civil Procedure 56. Regeneron argued that, under the 2010 amendment, the government "b[ore] the burden of proving that an AKS violation . . . actually caused [a] physician to provide different medical treatment (and thus caused the false claims)." United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 WL 6296393, at \*10 (D. Mass. Sept. 27, 2023). In other words, Regeneron asserted that the phrase "resulting from" in the 2010 amendment imposed a "'but-for' causation standard." Id. The government disagreed, and it urged the district court to adopt the Third Circuit's view that "all that is required to prove a causal link [under the 2010 amendment] is that 'a particular patient is exposed

to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient.'" Id. (quoting United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 100 (3d Cir. 2018)).

Citing cases from the Sixth and Eighth Circuits, the district court agreed with Regeneron's interpretation. See United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1052-55 (6th Cir. 2023) (interpreting the phrase "resulting from" in the 2010 amendment as imposing a but-for causation requirement); United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 834-35 (8th Cir. 2022) (same). Nevertheless, noting the conflict in the case law and explaining that the issue was pivotal to the outcome in this and another case in the circuit, see United States v. Teva Pharms. USA, Inc., 682 F. Supp. 3d 142, 148 (D. Mass. Jul. 14, 2023), the district court concluded that an immediate appeal would materially advance the ending of the case. Accordingly, the district court sought and we granted interlocutory review pursuant to 28 U.S.C. § 1292(b). We now affirm the district court's ruling that to treat an AKS violation as a false or fraudulent claim under the FCA, the government must prove that the AKS violation was a but-for cause of the false claim. Our reasoning follows.

## II.

As a threshold matter, the government contends that another panel of this court already did our work for us by stating,



with reference to the 2010 amendment, 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." Guilfoile, 913 F.3d at 190. That statement says nothing about what "causal connection" is sufficient. But, as the government stresses, the statement is directly followed by a citation to the Third Circuit's opinion in Greenfield, 880 F.3d at 96-98, and to a district court opinion, United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-cv-10601, 2018 WL 1996829, at \*5-6 (D. Mass. April 27, 2018). In each case, the court indicated that it was sufficient that a patient chose to use the defendant's services or product after being "exposed" to an inducement, even if the patient would have made the same decision in the absence of the inducement. See Greenfield, 880 F.3d at 100; Biogen, 2018 WL 1996829, at \*5-6. So, reasons the government, we should read Guilfoile as having adopted both what it said (that there must be a sufficient causal connection) and what those cited cases said was sufficient.

We disagree. "The mere fact that a court cites a case approvingly for one point does not imply the court's wholesale acceptance of each and every proposition for which the cited case stands." Kholi v. Wall, 582 F.3d 147, 152 n.5 (1st Cir. 2009). This rule applies with special force here. The Guilfoile court stressed that "the issue before us is not the standard for proving

an FCA violation based on the AKS, but rather the requirements for pleading an FCA retaliation claim." 913 F.3d at 190. The plaintiff in Guilfoile therefore did not need to prove an FCA violation, by virtue of the AKS or otherwise. He only needed to prove that the conduct he reported "could reasonably lead to an FCA action." Guilfoile, 913 F.3d at 189. Hence, the court said that it was not "assess[ing] the full implications" of the 2010 amendment. Id. at 190.

Finding that Guilfoile therefore does not guide -- much less control -- our analysis of the phrase "resulting from" in the 2010 amendment, we turn now to analyzing the phrase as a matter of first impression in this circuit.

### **III.**

The proper interpretation of the 2010 amendment's "resulting from" language is a question of law, so we review the district court's interpretation de novo. See Kenyon v. Cedeno-Rivera, 47 F.4th 12, 20 (1st Cir. 2022).

#### **A.**

The Supreme Court has held that a phrase like "resulting from" "imposes . . . a requirement of actual causality." Burrage v. United States, 571 U.S. 204, 211 (2014); see also Paroline v. United States, 572 U.S. 434, 445 (2014) ("The words 'as a result of' plainly suggest causation."). "In the usual course," such a requirement of actual causality as imposed by the words "resulting

from" demands proof "'that the harm would not have occurred' . . . but for . . . the defendant's conduct." Univ. of Tex. Sw. Med. Ctr. v. Nassar, 570 U.S. 338, 346-47 (2013) (quoting Restatement (First) of Torts § 431, cmt. a (Am. L. Inst. 1934)). Accordingly, "it is one of the traditional background principles 'against which Congress legislate[s]' that a phrase such as 'result[ing] from' imposes a requirement of but-for causation." Burrage, 571 U.S. at 214 (first alteration in original) (quoting Nassar, 570 U.S. at 347).

But the fact that "resulting from" is read as calling for but-for causation in "the usual course," Nassar, 570 U.S. at 346, does not mean that such a reading applies in every situation. Rather, that reading serves as a default assumption, not an immutable rule. See Paroline, 572 U.S. at 458. A court may read a phrase like "resulting from" to impose an alternative causation standard if there are "textual or contextual indication[s]" supporting that approach. Burrage, 571 U.S. at 212; see also Paroline, 572 U.S. at 458 ("[T]he availability of alternative causal standards where circumstances warrant is, no less than the but-for test itself as the default, part of the background legal tradition against which Congress has legislated.").

The concept of a "textual" indication seems clear enough: We look at the statutory language at issue to see what it indicates. See Paroline, 572 U.S. at 458. The concept of a

"contextual indication" is perhaps less clear, but at a minimum includes (as evidenced by Paroline) a signal of legislative purpose gleaned from related statutory text. In other words, if the text at issue, when read in the context of the statutory scheme as a whole, indicates that a but-for standard would "undermine congressional intent," it may be inappropriate to read a phrase like "resulting from" as imposing such a standard. Id.

The Court's analysis in Paroline elucidates this point. That case involved a statute -- 18 U.S.C. § 2259 -- that required restitution for victims of child pornography. Id. at 439. The statute defined a victim as a person "harmed as a result of" possession of child pornography, 18 U.S.C. § 2259(c)(4) (emphasis added), and required that a court determine "the full amount of the victim's losses . . . incurred by the victim as a result of the trafficking in child pornography depicting the victim," id. § 2259(b)(2)(A) (emphasis added). Ordinarily, this kind of language would impose a but-for causation standard. See Burrage, 571 U.S. at 214; Paroline, 572 U.S. at 458. But six Justices nevertheless found such a standard inappropriate.

A five-Justice majority concluded that the statute as a whole left "no doubt [that] Congress wanted victims [of child pornography] to receive restitution," because § 2259 expressly made restitution "mandatory" for child pornography offenses. Paroline, 572 U.S. at 457 (quoting 18 U.S.C. § 2259(b)(4)). A

but-for causation standard would render this "mandatory" language "a dead letter," because it would be impossible to determine the "discrete" injury caused by each individual possessor of child pornography. Id. at 456-57. So, given the context provided by the statute as a whole, the majority found that a but-for standard would not serve § 2259's "twin goals of helping the victim achieve . . . restitution . . . and impressing upon offenders the fact that child-pornography crimes . . . affect real victims." Id. at 459. Justice Sotomayor -- writing in dissent -- agreed with the majority on this point. She noted that there was a strong "contextual" argument against applying a but-for causation standard to § 2259: Such a standard would "swallow [the statute's] 'mandatory' restitution command, leaving victims with little hope of recovery." Id. at 477 (Sotomayor, J., dissenting).

In sum, the phrase "resulting from" imposes a requirement of actual causality, which in ordinary course takes the form of but-for causation, but we may deviate from this ordinary course if the statute in question provides "textual or contextual indications" for doing so. A "textual" indication draws on the plain text of the statute's causation language, while a "contextual" indication arises from the substance or structure of the statutory scheme as a whole. With these principles in mind, we turn to addressing the parties' respective interpretations of the 2010 amendment.

**B.**

The government cannot show that the text of the 2010 amendment itself contraindicates a but-for causation standard. Simply put, there is no language in the 2010 amendment that by itself runs counter to the presumption that "resulting from" calls for proof of but-for causation. So, the government finds itself relying on three contextual arguments.

**1.**

First, throughout its brief, the government stresses that the AKS itself -- including its imposition of criminal liability -- requires no proof that the government would not have paid a claim but for the inducement of the offered kickback. Rather, contends the government, the "animating principle" of the AKS is "that financial conflicts in themselves corrupt medical decisionmaking." So, contends the government, because the 2010 amendment was "built on" such a statutory scheme, it too should require only that payments are meant to induce the provision of items or services and that those items or services are subsequently provided. At least one other court in this circuit has accepted this contention. See United States ex rel. Witkin v. Medtronic, Inc., No. 11-cv-10790, 2024 WL 1892405, at \*18 (D. Mass. Mar. 31, 2024) ("It would be counterintuitive for the [AKS] to define illegal remuneration under an indirect causation standard in the criminal context . . . [while] ascrib[ing] a more stringent

causation standard in the civil context (e.g., an associated FCA violation)."). But see Omni Healthcare, Inc. v. MD Spine Sols. LLC, No. 18-cv-12558, 2025 WL 32676, at \*8-9 (D. Mass. Jan. 6, 2025) (concluding that the phrase "resulting from" in the 2010 amendment requires a showing of but-for causation).

We do not follow the government's logic. As the government concedes, the words "resulting from" require proof of some type of actual causality. See Burrage, 571 U.S. at 211 ("'Results from' imposes . . . a requirement of actual causality."). Hence, the question posed here is whether the type of actual causality required is (as in ordinary course) but-for causation. AKS liability, by contrast, does not require any causal link between an inducement and any payment. See 42 U.S.C. § 1320a-7b(b)(2). So, the premise that the 2010 amendment's causation requirement must track that of the AKS fails to get out of the starting blocks.

Nor is this surprising. When Congress wants to make a violation of one statute or statutory section generate liability under another statute or section, it may or may not require proof of added elements not required to prove the predicate violation. Wire fraud, for example, is a federal offense that is necessary but not sufficient for establishing additional liability under the Racketeer Influenced and Corrupt Organizations (RICO) Act. 18 U.S.C. §§ 1961-1962. Similarly, certain firearm offenses can

generate additional liability under the Armed Career Criminal Act, but only if the defendant has three previous convictions for violent felonies or serious drug offenses. 18 U.S.C. § 924(e)(1). So, the mere fact that one liability is built on another says nothing about whether any additional elements are required to establish the subsequent liability. Moreover, if Congress wants to make a violation of one statute a per se violation of another, it can easily say so. See, e.g., 15 U.S.C. § 16921(a) (stating that violations of the Fair Debt Collection Practices Act also constitute violations of the Federal Trade Commission Act); 16 U.S.C. § 2465 (stating that violations of the Antarctic Mineral Resources Protection Act also constitute violations of the Antarctic Marine Living Resources Convention Act).

Nor does the addition of a causation element in the 2010 amendment leave the AKS any less able to pursue its "animating principle." Rather, by establishing a new pathway to liability for AKS violations, the 2010 amendment clearly furthers the aims of the AKS. The only question is how much further and on what terms that added support extends.

So, our interpretative challenge is to select among alternative forms of causation, one of which (but-for) is presumptively correct, and all of which require some proof of "actual causality." See Burrage, 571 U.S. at 211, 217; see also Paroline, 572 U.S. at 458-59 (adopting an "alternative



causa[tion]" standard where the defendant played an "indisputable role . . . in the causal process"). As to that choice, the absence of any causation requirement in establishing AKS liability provides little interpretative insight.

So framed, our interpretative inquiry does not preclude (at least in theory) a less ambitious version of the government's argument: Because no causation is required to establish criminal AKS liability, then that suggests that "not much" causation -- that is to say, causation short of but-for causation -- should be needed for civil FCA liability. But even this more nuanced argument falls short of supporting the government's position because the government's proposed standard requires no proof of actual causation at all. Instead, the government posits that Medicare claims for Eylea can "result from" a kickback even if that kickback had no causal impact whatsoever on a patient's decision to opt for Eylea. While Burrage and Paroline recognize that "resulting from" may in some instances not require but-for causation, they provide no license to read "resulting from" as requiring no actual causality whatsoever.

Finally, as Regeneron points out, it is not unheard of for the same statute to impose different evidentiary burdens for related civil and criminal claims. See, e.g., McCool v. Strata Oil Co., 972 F.2d 1452, 1466 (7th Cir. 1992) (noting that civil RICO claims require proof of injury to a plaintiff, while criminal

RICO prosecutions do not require injury and instead punish the defendant's "participation in the pattern as a whole"). Here, the criminal provisions of the AKS serve a different purpose than the provisions linking an AKS violation to FCA falsity. Criminal liability under the AKS exists "to protect patients from doctors whose medical judgments might be clouded by improper financial considerations." See United States v. Patel, 778 F.3d 607, 612 (7th Cir. 2015). So, it makes sense for the AKS to criminalize even those kickbacks that do not ultimately cause a referral or purchase. By contrast, "the chief purpose" of the FCA's civil penalties is "to provide for restitution to the government of money taken from it by fraud." United States v. Bornstein, 423 U.S. 303, 314 (1976) (quoting United States ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943)). Furthermore, the FCA creates a civil cause of action for multiple damages that can be initiated and prosecuted by private individuals without any affirmative approval by the government. So, it also makes sense for the 2010 amendment to render a claim false (for FCA purposes) only when a kickback is the cause of that claim's submission to the government.

## 2.

That brings us to the government's next contextual argument, rooted in statutory history. Before addressing that second contextual argument, we follow the lead of the parties and first discuss what the government describes as the "false-

certification" theory linking the FCA and AKS.<sup>2</sup> Under this theory, a defendant violates the FCA when presenting (or causing to be presented) a claim that misrepresents compliance with a "statutory, regulatory, or contractual requirement" that "the defendant knows is material to the [g]overnment's payment decision." Universal Health Servs., Inc. v. United States, 579 U.S. 176, 181 (2016).

**a.**

Before the 2010 amendment, many courts broadly agreed that AKS compliance could be a material precondition of Medicare reimbursement. See United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 54-55 (D. Mass. 2011) (collecting cases). So, a defendant who falsely represented AKS compliance when seeking a payment from Medicare could be liable under the FCA. See, e.g., United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009) ("Falsely certifying compliance with the [AKS] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.").

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<sup>2</sup> The parties use the phrase "false-certification" to describe the body of case law linking the FCA and AKS without reference to the 2010 amendment. Purely for the sake of simplicity, we follow their lead. However, we have previously noted that the term "certification" never appears in the text of the FCA and is more likely to "obscure than clarify the issues before us." United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 385-86 (1st Cir. 2011).

In United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011), we considered an FCA claim that the defendant offered remuneration to doctors to use the defendant's medical devices, and doctors and hospitals then sought reimbursement for those medical devices from federal healthcare programs. We held that the defendant could be liable under the FCA for causing the doctors and hospitals to submit false claims even if the defendant itself submitted no claims and even though the hospitals knew of no AKS violation. Id. at 389-91. We also held that where a provider agreement and a hospital cost report made clear that the government healthcare program would not pay claims if the underlying transaction that gave rise to the claim violated the AKS, the claim could be false under the FCA. Id. at 392-94. In so holding, we eschewed reliance on terms like "false certification" that are not mentioned in the statute, see id. at 389-90, but we reached a result identical to what a false certification theory would have produced.

In sum, there is certainly a pathway to FCA liability for an AKS violation when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim. Under that pathway, it is not the AKS violation itself that renders the claim false. Rather, it is the false representation that there is no AKS violation. And, as we will explain, it is that pathway which the government claims is

relevant to its position on this appeal. See also William A. Escobar & Philip D. Robben, The False Claims Act, in 15 Business & Commercial Litigation in Federal Courts §§ 160:1, :17 (Robert L. Haig ed., 5th ed. 2022) (outlining the elements of a false-certification claim).

**b.**

We now turn to the government's argument about the context provided by statutory history. At the outset, we reiterate that Paroline appeared to define a "contextual" indication as a signal of legislative intent derived from the text of the statute when read as a whole. See 572 U.S. at 456-58. Paroline does not clearly permit us to cite statutory history as a "contextual" reason for deviating from the default but-for causation standard. On the other hand, the Supreme Court has often relied on the evolution of a statute over time as informative. See, e.g., Shamrock Oil & Gas Corp. v. Sheets, 313 U.S. 100, 104-07 (1941); Van Buren v. United States, 593 U.S. 374, 392-93 (2021). In any event, even accepting the history of the statute's evolution as potentially informative, we find the government's spin on that history unconvincing.

The government begins by noting that Congress passed the 2010 amendment against a backdrop of false-certification cases. As explained above, those cases did not require proof of causation to demonstrate falsity under the FCA; a material misrepresentation

of compliance with the AKS was enough. The government further argues that, when Congress passed the 2010 amendment, it did not clearly intend to alter false-certification caselaw by imposing a but-for causation requirement. Cf. Midlantic Nat'l Bank v. N.J. Dep't of Env't Prot., 474 U.S. 494, 501 (1986) ("The normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific.").

On both points, we agree. But there is nothing in the 2010 amendment that requires proof of but-for causation in a false-certification FCA case. Rather, as the government itself points out, the 2010 amendment "offer[s] a pathway to establish falsity in FCA actions based on AKS violations without reliance on [the false certification] theory." The circuit courts that read the 2010 amendment as imposing a but-for causation requirement also agree that the 2010 amendment did not disturb alternative theories of FCA liability (e.g., false certification). See Cairns, 42 F.4th at 836 (rejecting the argument that the 2010 amendment "codified" pre-2010 false-certification law, and then limiting the but-for causation requirement to cases where "a plaintiff seeks to establish falsity or fraud through the 2010 amendment" (emphasis added)); United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1053 (6th Cir. 2023) (agreeing with the Cairns court's analysis).

Nor is the causation requirement the only difference between false-certification cases and claims under the 2010 amendment. For example, under the false-certification theory, FCA liability lies when a defendant falsely represents AKS compliance on a federal agency form. Hutcheson, 647 F.3d at 392. But the 2010 amendment does not require any representation -- implied or express -- of AKS compliance. Instead, any AKS violation that "results in a federal health care payment" gives rise to a "per se false claim under the FCA." Guilfoile, 913 F.3d at 190 (emphasis added) (quoting Lutz, 853 F.3d at 135). Furthermore, under the implied false-certification theory, the government must show that the defendant's misrepresentation of AKS compliance was material to the government's payment decision. See Universal Health Servs., 579 U.S. at 181. There is no such materiality requirement for claims brought under the 2010 amendment. Guilfoile, 913 F.3d at 190.

Put simply, claims under the 2010 amendment run on a separate track than do claims under a false-certification theory. There is no reason to think that, because false-certification claims require no proof of causation, Congress therefore eschewed any actual causation requirement under the 2010 amendment. By its own terms, the 2010 amendment requires some proof of causation; the only question is what type of causation. On that question, the statutory history provides no reason to deviate from the

ordinary course, in which we treat "resulting from" as requiring but-for causation.

**3.**

At its last source of context, the government points to the legislative history of the 2010 amendment. Once more, nothing in Paroline instructs that we may consider such evidence when interpreting the phrase "resulting from." But even presuming that such evidence is relevant, the legislative history simply offers too little to justify the government's position.

The government primarily relies on a floor statement by Senator Ted Kaufman, who sponsored the bill that originally included what became the 2010 amendment. See United States ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323, 332-33 (detailing the legislative genesis of the 2010 amendment). Senator Kaufman stated that the provision would "ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10852-01 (2009), 2009 WL 3460582, at \*S10853. So, an ostensible purpose of the 2010 amendment was to circumvent an arguable weakness in the false-certification theory.

Senator Kaufman himself appeared to cite an example of this arguable weakness: United States ex rel. Thomas v. Bailey, No. 06CV00465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008). See 155 Cong. Rec. S10852-01 (2009), 2009 WL 3460582, at \*S10853



(describing the facts of the case). That case involved a surgeon who received kickbacks from a medical device company to use their cervical plating devices. Thomas, 2008 WL 4853630, at \*1-3. The hospital then submitted claims for reimbursement for the surgeon's services, including the typical costs of products and devices purchased for that type of procedure. Id. at \*3. The court found that Medicare claims submitted by the hospital were not false under the FCA. Id. at \*13-14. Because the hospital knew nothing about the surgeon's AKS violations (and because it had only certified its own AKS compliance "to the best of [its] knowledge"), the court held that the requests for Medicare reimbursement were not false. Id. at \*10-13.

According to Senator Kaufman, the 2010 amendment would prevent something like this from happening again. Under the 2010 amendment, the claims for the medical devices would still be deemed false or fraudulent under the AKS, because they "result[ed] from" the surgeon's acceptance of illicit kickbacks. 155 Cong. Rec. S10852-01 (2009), 2009 WL 3460582, at \*S10853. It would, therefore, be no defense that the surgeon had never personally certified compliance with the AKS.

Nothing about Senator Kaufman's floor statement is inconsistent with an interpretation of the 2010 amendment that imposes but-for causation. Rather, the floor statement simply reinforces the government's view that the 2010 amendment creates

a different "pathway to establish falsity in FCA actions based on AKS violations without reliance on [the false-certification] theory." If a medical provider accepts kickbacks, and then personally represents compliance with the AKS, then FCA liability can flow from that false representation. But if the medical provider does not represent compliance with the AKS (expressly or otherwise), then a claim submitted on that provider's behalf can still be "per se false" under the 2010 amendment. Guilfoile, 913 F.3d at 190 (quoting Lutz, 853 F.3d at 135). That is, if the government can show that the illicit kickback was a but-for cause of the submitted claim, then the claim is "per se false" even absent a false certification of AKS compliance.

We therefore disagree with the government that the legislative history of the 2010 amendment requires us to interpret the phrase "resulting from" as imposing something other than a but-for causation standard.

#### 4.

We respond, finally, to the government's contention that it can "sometimes be difficult" to prove why a doctor prescribed a particular drug. We do not doubt that such proof may be more difficult to nail down in some cases. But the same could be said about the requirement to prove other elements of a successful action under the FCA, such as scienter. See, e.g., United States ex rel. Hart v. McKesson Corp., 96 F.4th 145, 160-62 (2d Cir. 2024)

(finding that the defendant lacked the requisite scienter to bring a claim under the FCA), cert. denied, 145 S. Ct. 163 (2024); United States ex rel. Gugenheim v. Meridian Senior Living, LLC, 36 F.4th 173, 181-82 (4th Cir. 2022) (same).

Nor is it the case that giving "resulting from" its ordinary meaning renders it so difficult to establish liability that the 2010 amendment would have no practical effect. As we have explained in this opinion, the 2010 amendment made it easier to bring an FCA action for damages by creating a pathway that does not require proof of a false certification. And not even the government argues that it will rarely be able to prove but-for causation. Indeed, in this very case, the government's position is that it has proffered enough evidence to get to a jury on the issue of but-for causation. See U.S.'s Surreply to Regeneron's Motion for Summary Judgment at 10, United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 WL 7016900 (D. Mass. Oct. 25, 2023) ("Even if the government were required to prove but-for causation, it at least has identified sufficient evidence to defeat summary judgment."). And the district court ultimately agreed, finding that the government had alleged enough evidence "to withstand summary judgment on the issue of [but-for] causation." See Regeneron, 2023 WL 6296393, at \*12-14.

#### **IV.**

In sum, we find no convincing "textual or contextual" reason to deviate from the default presumption that the phrase "resulting from" as used in the 2010 amendment imposes a but-for causation standard. We therefore hold that, to demonstrate falsity under the 2010 amendment, the government must show that an illicit kickback was the but-for cause of a submitted claim.

#### **V.**

For the foregoing reasons, the judgment of the district court is affirmed.