

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No. 20-11548
TEVA PHARMACEUTICALS USA, INC., and)	
TEVA NEUROSCIENCE, INC.,)	
)	
Defendants.)	
)	
)	

**DEFENDANTS’ MOTION TO CERTIFY INTERLOCUTORY APPEAL AND
POSTPONE TRIAL PENDING APPEAL**

Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively, “Teva”) respectfully submit this motion to certify an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and to postpone trial in this matter pending appeal.

Dated: July 26, 2023

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

Undersigned counsel for Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. certify pursuant to Local Rule 7.1(a)(2) that counsel for Defendants conferred with counsel for Plaintiff regarding the subject matter of this motion and the parties were unable to agree on a resolution or narrow the issues presented above.

/s/ Emily Renshaw
Emily Renshaw (BBO #675316)

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF filing on July 26, 2023.

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**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO
CERTIFY INTERLOCUTORY APPEAL AND POSTPONE TRIAL PENDING APPEAL**

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 intensifies](https://www.law360.com/employment-authority/articles/1564033/fca-chases-shrewder-kickbacks-as-50-year-hunt-intensifies)7

Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively, “Teva”) respectfully submit this memorandum of law in support of their motion to certify an interlocutory appeal.

INTRODUCTION

Teva respectfully requests that this Court certify for interlocutory appeal its July 14 ruling that the government need not prove “but for” causation between an alleged Anti-Kickback Statute (“AKS”) violation and the submission of a claim. The causation standard is a controlling, dispositive, and purely legal issue on which there is an active circuit split and no controlling First Circuit authority. If the First Circuit were to join the Sixth and Eighth Circuits in requiring “but for” causation—as Teva submits the statute’s plain language mandates—then Teva would be entitled to summary judgment, averting the need for a six-week jury trial that would consume both the parties’ and the Court’s resources. On the other hand, if an interlocutory appeal is not permitted and Teva loses at trial, Teva faces a judgment that may exceed \$10 billion, an enterprise-threatening amount that may render a post-judgment appeal impossible. No substantial interest of the government will be prejudiced by an interlocutory appeal. Certification should be granted.

ARGUMENT

Section 1292(b) allows a district court to certify an order for interlocutory appeal when the order “involves a controlling question of law as to which there is substantial ground for difference of opinion and ... an immediate appeal from the order may materially advance the ultimate termination of the litigation.” 28 U.S.C. § 1292(b). That standard is easily met here.

I. There Is Substantial Ground for Difference of Opinion on the Causation Standard.

“A substantial ground for a difference of opinion arises where an issue involves ‘one or more difficult and pivotal questions of law not settled by controlling authority.’” *Meijer, Inc. v. Ranbaxy Inc.*, 245 F. Supp. 3d 312, 315 (D. Mass. 2017) (quoting *Philip Morris Inc. v.*

Harshbarger, 957 F. Supp. 327, 330 (D. Mass. 1997)). In this case, there is no controlling First Circuit authority on point, and two out of the three circuits to address the question have reached conclusions opposite to that reached by this Court.

The AKS criminalizes “knowingly and willingly offer[ing] or pay[ing] any remuneration . . . to any person to induce such person” to recommend the purchase of a drug covered by a “Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Under 2010 Amendments to the AKS, “a claim that includes items or services **resulting from** a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g) (emphasis added).

As Teva argued in its summary judgment briefing, the statutory language demands that the government prove a “but for” causal connection between the AKS violation and the allegedly false claim. In construing a statute, the court’s “analysis begins and ends with the text.” *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014)). Here, the language is clear. As the Supreme Court has observed, “[a] thing ‘results’ when it ‘[a]rise[s] as an effect, issue, or outcome *from* some action, process or design.” *Burrage v. United States*, 571 U.S. 204, 210-11 (2014) (emphasis original) (quoting 2 The New Shorter Oxford English Dictionary 2570 (1993)). “‘Results from’ imposes, in other words, a requirement of *actual causality*.” *Id.* at 211 (emphasis added). Thus, when Congress chose the phrase “resulting from,” it chose language that has an “ordinary, accepted meaning,” one that “imports but-for causality.” *Id.* at 16 (holding that phrase “results from” used in Controlled Substance Act requires proof of “but for” causation).

Even were the meaning of the statute not plain on its face, “the same language creates civil *and* criminal liability” and “if ambiguity exists . . . the rule of lenity favors the narrower definition.”

United States ex. rel. Martin v. Hathaway, 63 F.4th 1043, 1050 (2023); *see also Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) (“Because we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies.”).

We recognize that this Court indicated it found the First Circuit’s decision in *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019), “persuasive, if not binding,” on the issue here. ECF 195 at 13. However, we respectfully submit that the First Circuit has not squarely addressed the causation requirements for proving a claim under Section 1320a-7b(g). In *Guilfoile*, the First Circuit observed that a claim is “false within the meaning of the FCA” when there is a “sufficient causal connection between an AKS violation and a claim submitted to the federal government.” *Id.* at 190. But, as the First Circuit put it, “the issue before us is not the standard for *proving* an *FCA violation* based on the AKS, but rather the requirements for *pleading* and *FCA retaliation claim*.” *Guilfoile*, 913 F.3d at 190 (emphasis original). For a retaliation claim, the plaintiff “need only plausibly plead a reasonable amount of smoke—conduct that could reasonably lead to an FCA action based on the submission of a false claim,” but not “the existence of a fire—the actual submission of a false claim.” *Id.* at 189. Given this posture, the First Circuit did “not attempt to assess the full implications of the AKS.” *Id.* at 190.¹

¹ Even setting aside its various disclaimers, the First Circuit’s ruling in *Guilfoile* suggests that “but for” causation is required to link an AKS violation with a false claim under the FCA. The First Circuit acknowledged the need for proof of causation, and “but for” causation “is the minimum concept of cause” known to the law. *United States v. Hatfield*, 591 F.3d 945, 948 (7th Cir. 2010) (quoted in *Burrage*, 571 U.S. at 211). Moreover, when the First Circuit concluded that the employee had sufficiently alleged a retaliation claim, it spoke in the language of “but for” causation, holding that “the complaint permits the reasonable inference that, *if not for the agreement [with the consultant]*, [the healthcare company] would not have been in a position to benefit from federal health care payments.” *Guilfoile*, 913 F.3d at 191 (emphasis added).

At the time *Guilfoile* was decided, only the Third Circuit had addressed the causation requirement. The Third Circuit’s decision in *United States ex. rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. 2018), however, was not based on the statutory text, but on the court’s determinations regarding the overall legislative purpose of the AKS and its 2010 Amendments. The Third Circuit acknowledged that the phrase “resulting from” has been construed to require “but for” causation. 880 F.3d at 96. Nonetheless, the Third Circuit found that the legislative history “counsels requiring something less than proof that the underlying medical care would not have been provided but for a kickback.” *Id.*

“But legislative history is not the law,” *Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612, 1631 (2018), and the supposed “policy and purpose” of a legislative enactment cannot overcome the plain meaning of the statutory text, *Slack Technologies, LLC v. Pirani*, 143 S. Ct. 1433, 1441 (2023). Indeed, such purpose-focused analysis is a disfavored “relic from a ‘bygone era of statutory construction.” *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019).

Accordingly, the Sixth Circuit and Eighth Circuits have disagreed with the Third Circuit’s analysis in *Greenfield*. By contrast, both have given effect to the plain meaning of “resulting from” in interpreting the 2010 Amendment to the AKS. As the Sixth Circuit explained, “[t]he ordinary meaning of ‘resulting from’ is but-for causation.” *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023) (citing *Burrage*, 571 U.S. at 210-11)); *see also United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022) (“[T]he phrase ‘resulting from,’ as we have already explained, is unambiguously causal.” (citing *Burrage*, 571 U.S. at 211-13)). Under the rule from these circuits, “when a plaintiff seeks to establish falsity or fraud through the

2010 Amendment, it must prove that a defendant would not have included particular ‘items or services’ but for the illegal kickbacks.” *Cairns*, 42 F.4th at 836.

“The clearest evidence of ‘substantial grounds for difference of opinion’ is where ‘there are conflicting interpretations from numerous courts.’” *Knopick v. Downey*, 963 F. Supp. 2d 378, 398 (M.D. Pa. 2013) (quoting *Beazer E., Inc. v. The Mead Corp.*, Civ. No. 91–0408, 2006 WL 2927627, at *2 (W.D.Pa. Oct. 12, 2006)); see also *Waters v. Day & Zimmermann NPS, Inc.*, No. CV 19-11585-NMG, 2020 WL 4754984, at *3 (D. Mass. Aug. 14, 2020) (“Such a split [among district judges] clearly constitutes a substantial difference of opinion.”). Here, the circuit split necessarily demonstrates substantial ground for difference of opinion.

II. The Causation Standard Is a Controlling Question of Law, and Immediate Appeal May Materially Advance the Ultimate Termination of the Litigation.

“[A] controlling question typically implicates a pure legal principle that can be resolved without extensive consultation to the record and commonly involves ‘a question of the meaning of a statutory or constitutional provision.’” *Waters*, 2020 WL 4754984, at *2 (quoting *S. Orange Chiropractic Ctr., LLC v. Cayan LLC*, No. 15-c-13069PBS, 2016 WL 3064054, at *2 (D. Mass. May 31, 2016)). Typically, “[a] question of law is ‘controlling’ if reversal of the district court’s order would terminate the action.” *Philip Morris*, 957 F. Supp. at 330 (quoting *Klinghoffer v. S.N.C. Achille Lauro*, 921 F.2d 21, 24 (2d Cir. 1990)). However, even if the interlocutory appeal does not terminate the case, an immediate appeal may still “advance the ultimate termination of the litigation” by “drastically curtail[ing] and simplify[ing] pretrial and trial proceedings.” *Waters*, 2020 WL 4754984, at *2 (citing *Simmons v. Galvin*, No. CV 01-11040-MLW, 2008 WL 11456109, at *3 (D. Mass. Jan. 16, 2008)).

This issue easily satisfies these standards. Teva seeks certification regarding a pure question of law regarding the meaning of a statute. The First Circuit can review this issue “with

minimal review of the factual record because it only requires statutory and case law interpretation.” *Meijer*, 245 F. Supp. 3d at 315.

If Teva is correct that the government must demonstrate “but for” causation, then summary judgment should be granted because the government has not identified any particular claims for reimbursement that would not have been submitted to Medicare in the absence of Teva’s donations. ECF 159. The costs of an unnecessary trial to the parties and the court’s resources will be significant. Trial is anticipated to last six weeks and involve more than two dozen witnesses and hundreds, perhaps even thousands, of exhibits.

Even if a decision in favor of Teva does not terminate the litigation, the causation standard will still affect the scope of evidence, the length and complexity of trial, and the time, money, and effort that must be expended in this case. And if trial is conducted under the incorrect causation standard, then a new trial will eventually be necessary, wasting the time and resources expended on the first trial. *See Cairns*, 42 F.4th at 831 (“The district court did not instruct the jury along these lines, so we reverse and remand for a new trial.”).

Summary judgment orders presenting discrete questions of law that might avoid the need for protracted trials are particularly appropriate for interlocutory appeal under Section 1292(b). Even where trials are not likely to be as lengthy and burdensome as trial would be here, courts have certified immediate interlocutory appeals where the law on a crucial issue is so unsettled that a trial could result in “potentially unnecessary expense for the parties and the Court.” *Smilovits v. First Solar Inc.*, 119 F. Supp. 3d 978, 981, 992 (D. Ariz. 2015), *aff’d sub nom. Mineworkers’ Pension Scheme v. First Solar Inc.*, 881 F.3d 750 (9th Cir. 2018) (certifying causation issue to Ninth Circuit because “two competing lines of cases” dictated wholly opposite summary judgment outcomes and upcoming trial would be “lengthy and expensive”); *see also, e.g., Wray v. City of*

New York, 490 F.3d 189, 191 (2d Cir. 2007) (on interlocutory review of decision denying summary judgment, reversing and remanding for entry of judgment in favor of defendants).

The exceptional circumstances of this case further weigh in favor of interlocutory review. As a result of this Court’s ruling on the standard for damages (an issue on which Teva does not seek certification), the liability Teva faces may well exceed \$10 billion, an enterprise-threatening amount, the consequences of which could hinder Teva’s ability to proceed with a post-judgment appeal of this critical issue. Given the potential stakes, an interlocutory appeal may well be the only way for the First Circuit to provide guidance on this unsettled and important issue.

Moreover, given the frequency with which the issue arises, the “system-wide costs and benefits of allowing the appeal” further weigh in favor certification. *Klinghoffer*, 921 F.2d at 24. Numerous False Claims Act cases are based on the Anti-Kickback Statute. *See, e.g.*, Jeff Overly, *FCA Chases ‘Shrewder’ Kickbacks As 50-Year Hunt Intensifies*, LAW360 (May 10, 2023), <https://www.law360.com/employment-authority/articles/1564033/fca-chases-shrewder-kickbacks-as-50-year-hunt-intensifies>. Commentators likewise recognize the circuit split at issue here is a “critically sensitive” issue. Jeff Overly, *‘Critically Sensitive’ Kickback Issue Hurtles Toward High Court*, LAW360 (Apr. 7, 2023), <https://www.law360.com/employment-authority/articles/1570462> (“Among the most noteworthy are the recent appellate decisions addressing whether there has to be a direct link between alleged kickbacks and billing claims.”).

The possibility of inconsistent results is far from hypothetical. Indeed, the causation issue is currently pending before Judge Saylor, *see United States v. Regeneron Pharmaceuticals, Inc.*, No. 20-11217-FDS, Dkt. 246 (D. Mass) (seeking summary judgment based on “resulting from”), who has previously suggested that proof of “but for” causation is required, *see United States ex rel. Flanigan v. Fresenius Med. Care Holdings, Inc.*, No. 21-cv-11627, 2022 WL 17417577, at

*18-19 (D. Mass. Dec. 5, 2022). This creates the very real prospect that cases in this district could be tried using conflicting causation standards and that the disposition on whichever side of the issue is ultimately rejected by the First Circuit would need to be reversed. Taking this issue to the First Circuit now could avoid that otherwise inevitable waste of judicial resources.

Guidance on this critical issue from the First Circuit would not only benefit the parties to this case but would benefit litigants throughout the circuit and, potentially, across the country.

CONCLUSION

The causation standard when a plaintiff seeks to prove falsity by relying on the 2010 Amendment to the Anti-Kickback Statute is “a controlling question of law as to which there is substantial ground for difference of opinion,” and an immediate appeal may “materially advance the ultimate termination of th[is] litigation.” 28 U.S.C. § 1292(b). Certification is proper.

For the reasons set forth above, Teva respectfully requests that this Court certify the order for interlocutory appeal to the United States Court of Appeals for the First Circuit and stay trial pending resolution of that interlocutory appeal.

Dated: July 26, 2023

Respectfully Submitted,

/s/ Emily Renshaw

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