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Government Setback "Resulting From" Another Court Adopting the "But For" Causation Standard for False Claims Act Cases Furthering Court Split

By George P. Varghese, Benjamin Conery and Melissa Morel*

In this article, the authors discuss a recent federal district court decision adopting an approach that puts a higher burden on the federal government to prove Medicare reimbursement submissions were directly caused by allegedly illegal kickback payments.

The U.S. District Court for the District of Massachusetts recently weighed in on burgeoning court split in False Claims Act (FCA) cases, adopting an approach that puts a higher burden on the federal government to prove that Medicare reimbursement submissions were directly caused by allegedly illegal kickback payments.[1] At issue was the FCA's language that the Medicare submission "resulting from" an alleged kickback is a per se false claim.

In interpreting the statutory language, Chief Judge F. Dennis Saylor IV ruled that the alleged kickbacks must be the "but for" cause of improper Medicare reimbursement submissions to violate the FCA. Judge Saylor's ruling sets up an intra-circuit split after another judge in the District of Massachusetts in a similar case previously rejected the "but for" test in favor of a less exacting approach.[2]

BACKGROUND

This most recent case, *United States v. Regeneron Pharmaceuticals*, involves a pharmaceutical company that manufactures Eylea, a drug to treat an eye disease that primarily affects elderly people. The government's theory stems from an amendment to the Antikickback Statute (AKS) as part of the 2010 Patient Protection and Affordable Care Act that makes any Medicare claim "resulting from" a violation of the AKS a false or fraudulent claim for purposes of the FCA.[3] This statutory change was long sought by the government, who have

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1 United States v. Regeneron Pharmaceuticals, No. 1:20-cv-11217-FDS (D. Mass. Sept. 27, 2023).

2 United States v. Teva Pharmaceuticals USA et al., No. 1:20-cv-11548-NMG (D. Mass. July 14, 2023).

3 A violation of the AKS includes paying a kickback or other remuneration to induce a

argued that reimbursements for health care services tainted by kickbacks were per se false claims.

In *Regeneron*, the government is arguing that the company induced physicians to prescribe Elyea by donating millions of dollars to a patient-assistance foundation to help patients cover copays for the medication.

Regeneron is one of a series of "copay cases" brought by the U.S. Attorney's Office in the District of Massachusetts that has alleged that pharmaceutical companies' donations to copay charities that assist patients to purchase their medication were kickbacks.[4]

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healthcare provider to refer a patient for a treatment that is paid at least in part by a federal health care program, such as Medicare. See 42. U.S.C. § 1320a-7b(b)(2). A violation of the FCA includes presenting a false or fraudulent claim to the government for payment, including false or fraudulent Medicare reimbursement claims. See 31 U.S.C. § 3729(a)(1)(A).

[4] In recent years, twelve pharmaceutical companies (Actelion Pharmaceuticals, Alexion Pharmaceuticals, Amgen Inc., Astellas Pharma US, Biogen, Gilead, Jazz Pharmaceuticals, Lundbeck LLC, Novartis, Pfizer, Sanofi-Aventis U.S., and United Therapeutics) have reached settlements with the U.S. Attorney's Office for the District of Massachusetts to resolve allegations that they used third-party foundations as kickback conduits. See Settlement Agreement between the U.S. Dep't of Justice and Actelion Pharmaceuticals US, Inc., https://www.justice.gov/d9/press-releases/attachments/2018/12/06/actelion_settlement_agreement_0.pdf; Settlement Agreement between the U.S. Dep't of Justice and Alexion Pharmaceuticals, Inc., https://www.justice.gov/d9/press-releases/attachments/2019/04/04/alexion_settlement_0.pdf; Settlement between the U.S. Dep't of Justice and Amgen Inc., https://www.justice.gov/d9/press-releases/attachments/2019/04/25/amgen_settlement_agreement__0.pdf; Settlement between the U.S. Dep't of Justice and Astellas Pharma US, Inc., https://www.justice.gov/d9/press-releases/attachments/2019/04/25/astellas_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Biogen Inc. and Paul Nee, https://www.justice.gov/d9/press-releases/attachments/2020/12/17/biogen_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Gilead Science, Inc., https://www.justice.gov/d9/press-releases/attachments/2020/09/23/gilead_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Jazz Pharmaceuticals, Inc., https://www.justice.gov/d9/press-releases/attachments/2019/04/04/jazz_settlement_0.pdf; Settlement between the U.S. Dep't of Justice and Lundbeck LLC, https://www.justice.gov/d9/press-releases/attachments/2019/04/04/lundbeck_settlement_0.pdf; Settlement between the U.S. Dep't of Justice and Novartis Pharmaceuticals Corporation, https://www.justice.gov/d9/press-releases/attachments/2021/01/19/novartis_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Pfizer, Inc., https://www.justice.gov/d9/press-releases/attachments/2018/05/24/pfizer_settlement_agreement_0.pdf; Press Release, United States Attorney's Office Dist. of Mass., Sanofi Agrees to Pay $11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation (Feb. 28, 2020) (https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay); Settlement between the U.S. Dep't of Justice and United Therapeutics Corporation, https://www.justice.gov/d9/press-releases/attachments/2017/12/20/utsettlementagreement_0.pdf. The U.S. Attorney's Office for the District of Massachusetts has also reached settlements with four foundations and a pharmacy that allegedly conspired with pharmaceutical companies to advance the kickback

THE COURT'S DECISION

In his summary judgment order, Judge Saylor held that "improperly structured donations to copay-assistance charities may violate the AKS if they are made with the intent to induce Medicare-funded referrals or drug purchases."[5]

Judge Saylor's ruling will soon be reviewed—either directly or indirectly—by the U.S. Court of Appeals for the First Circuit, which is set to consider the issue in another copay case, *United States v. Teva Pharmaceuticals USA et al.*[6]

According to a report in Law360, Judge Saylor said on October 18, 2023 that he may allow for an appeal of his summary judgment order in light of the conflicting ruling in *Teva Pharmaceuticals*.[7] In that case, Judge Nathaniel M. Gorton rejected a strict "but for" test, adopting instead a standard requiring only "some" or "sufficient causal connection" between the kickback and reimbursement claim.[8]

Last August, Judge Gorton granted Teva Pharmaceuticals' motion to certify the court's order for interlocutory appeal and stayed the pending trial. To date, the First Circuit has addressed the issue only in passing, noting 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."[9] The court did not, however, specify a standard for whether a "sufficient causal connection" had been established.

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schemes. See Settlement between the U.S. Dep't of Justice and Patient Services, Inc., https://www.justice.gov/d9/press-releases/attachments/2020/01/21/psi_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and The Assistance Fund, https://www.justice.gov/d9/press-releases/attachments/2019/11/20/taf_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Chronic Disease Fund, Inc., https://www.justice.gov/d9/press-releases/attachments/2019/10/25/cdf_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Patient Access Network Foundation, https://www.justice.gov/d9/press-releases/attachments/2019/10/25/panf_settlement_agreement_0.pdf; Settlement between the U.S. Dep't of Justice and Advanced Care Scripts, Inc., https://www.justice.gov/d9/press-releases/attachments/2020/08/13/acs_settlement_agreement_0.pdf.

[5] Regeneron Pharmaceuticals, supra.

[6] No. 1:20-cv-11548-NMG (D. Mass.).

[7] See https://www.law360.com/massachusetts/articles/1734141?nl_pk=3a8fb34e-57a2-4154-b862-10180fc6058d&utm_source=newsletter&utm_medium=email&utm_campaign=massachusetts&utm_content=2023-10-19&read_more=1&nlsidx=0&nlaidx=4.

[8] Teva, supra.

[9] Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019).

CIRCUIT SPLIT

Outside of the First Circuit, the circuit courts are already split. The "but for" approach has been adopted by the Sixth[10] and Eighth[11] Circuits, though rejected by the Third Circuit.[12]

Specifically, the Third Circuit adopted a more lenient "some connection" standard in which the federal government need only identify claims that were "exposed to" illegal renumeration.[13] That court concluded that once the government has established an AKS violation occurred, proving a causal link requires "a particular patient [to be] exposed to an illegal recommendation or referral and a provider [that] submits a claim for reimbursement pertaining to that patient."[14]

In its motion for partial summary judgment in *Regeneron*, the government argued that the First Circuit had endorsed the "some connection" standard which it had cited in passing. Judge Saylor rejected that argument, concluding that the issue had only been addressed at "a relatively superficial level," and without the benefit of subsequent rulings from the Sixth and Eighth Circuits.[15]

CONCLUSION

Judge Saylor ultimately adopted those circuits' "but for" standard finding their analysis to be persuasive. The Eighth Circuit held that the "resulting from" language in the FCA discussing the AKS expresses a "but-for causal relationship" so "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 kickback."[16]

Adopting this reasoning, the Sixth Circuit cautioned that a loose reading of causation would sweep too broadly, failing "to protect doctors of good intent, sweeping in the vice-ridden and virtuous alike."[17] Judge Saylor found these case to be persuasive, concluding in *Regeneron* that "[t]he adoption by Congress of

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[10] United States ex rel. Martin v. Hathaway, 63 F.4th 1043 (6th Cir. 2023).

[11] United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828 (8th Cir. 2022).

[12] United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 97, 100 (3d. Cir. 2018).

[13] 880 F.3d 89, 96–98 (3d. Cir. 2018).

[14] Id. at 100.

[15] Regeneron, supra.

[16] 42 F.4th 828, 836 (8th Cir. 2022).

[17] 63 F.4th 1043, 1054 (6th Cir. 2023).

the 'resulting from' language in the statute requires a finding that the appropriate standard is but-for causation."[18]

But this will certainly not be the last word on the issue.

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[18] Regeneron, supra.