MASSACHUSETTS Lawyers Weekly

Part of the BRIDGETOWER MEDIA network NOVEMBER 9, 2023

Diametrically opposite rulings vex bar in closely watched health care law dispute

By DAVID S. SCHUMACHER

The U.S. District Court in Boston has become ground zero for a simmering dispute about one of the U.S. Department of Justice's most potent anti-fraud tools, with two highly respected judges issuing contrary opinions about the scope of the law.

David S. Schumacher

Health care defendants, and the local white-collar bar defending them, are closely watching the dispute play out, with millions of dollars in penalties and fines at stake.

ANTI-KICKBACK STATUTE, FALSE CLAIMS ACT

The federal Anti-Kickback Statute has emerged in recent years as a potent enforcement vehicle for the DOJ. Under the AKS, in general, it is illegal to offer or accept anything of value in exchange for referring or recommending an item or service that is reimbursed by the federal government.

Historically, the DOJ enforced the AKS through criminal prosecutions or Civil Monetary Penalties Law resolutions. In 2010, through the Affordable Care Act, Congress amended the AKS such that a violation also gave rise to liability under the federal False Claims Act.

With federal programs (Medicare, Medicaid, TriCare, VA) paying for more than 35 percent of health care services in the country, enforcing the AKS and the FCA has become a major priority for the federal government.

Deploying an army of prosecutors, agents, auditors and investigators to enforce the AKS through the FCA, the DOJ has used this provision to recover billions of dollars from life sciences companies, health care providers, and health plans. The U.S. Attorney's Office in Massachusetts has consistently been at the forefront of this enforcement effort.

To be sure, the DOJ wields substantial leverage over defendants in these investigations. A defendant convicted of an FCA conviction at trial must pay up to treble actual damages, per-claim penalties, and attorneys' fees, in addition to facing collateral consequences such as exclusion from the Medicare program.

Rather than risk these grisly outcomes at trial, most health care defendants make the rational decision to settle these investigations.

PATIENT ASSISTANCE PROGRAM CASES

In recent years, prosecutors from the Affirmative Civil Enforcement Unit of the U.S. Attorney's Office in Boston have used the rejuvenated FCA to investigate life sciences companies for their arrangements with Patient Assistance Programs.

PAPs provide crucial financial support to needy patients who require life-saving drugs but often cannot afford the copayments. PAPs, in turn, frequently rely on financial support from life sciences companies.

> *The implications of what appears at first blush to be a technical dispute over rote statutory language cannot be overstated.*

But when pharma donations are tied too closely to PAP awards to patients, the AKS and FCA can be implicated, because the government views the payments not as bona fide donations but rather as a method to funnel payments indirectly to patients, which pharma companies could not do directly.

The Affirmative Civil Enforcement Unit in Boston has recovered tens of millions of dollars from numerous life sciences companies over the years for PAP affiliations, including Pfizer, Novartis, Biogen and Sanofi, as well as reaching settlements with a number of PAPs.

The most recent Affirmative Civil Enforcement Unit investigations in this realm have targeted Regeneron Pharmaceuticals and Teva Pharmaceuticals USA. At issue are Regeneron's and Teva's donations to PAPs to defray copayments associated with Eylea and Copaxone, respectively.

The DOJ alleges that the payments were designed to earmark funds to patients through the PAPs in order induce physicians to order their drugs, in violation of the AKS and the FCA. The companies insist that the payments were bona fide donations to charities made in compliance with regulatory guidance.

Teva and Regeneron refused to settle, and the Affirmative Civil Enforcement Unit filed lawsuits against each company. The Teva case was filed in Judge Nathaniel M. Gorton's session, while the Regeneron case is pending before Chief Judge F. Dennis Saylor IV.

DUELING INTERPRETATIONS

In motions for summary judgment, each defendant highlighted a new trend in AKS/FCA jurisprudence, focusing on the 2010 amendment to the AKS providing that any Medicare claim "resulting from a violation" of the AKS constitutes a false claim.

What does "resulting from" mean in this context? The phrase, innocuous on its face, in fact supplies the indispensable causation link between a kickback and a false claim, and it has become the subject of a fierce legal debate. For years, the government assumed that the causation element was easily surpassed, and that any AKS violation, ipso facto, became a false claim under the 2010 amendment. But that assumption has been upended by recent circuit decisions.

The opening salvo in this battle went the government's way. In 2018, in *U.S. ex. rel. Greenfield v. Medco Health Sols. Inc.*, an FCA case was brought against a specialty pharmacy that had made donations to a charity, which recommended the pharmacy to patients.

The 3rd Circuit held that the phrase "resulting from" required only that the plaintiff establish "a link" or "some connection" between the alleged kickbacks and the service. The court rejected a more stringent "but for" causation test, which would require a showing that the patient would not have used the service "absent the alleged kickback scheme." According to the 3rd Circuit, requiring the government to prove that the kickback "directly influenced a patient's decision" was inconsistent with the broad remedial purpose of the AKS.

In addition, the court noted that the defendants' position would lead to an incongruous result: an FCA case based on an AKS violation would require a heightened causation requirement, but a standalone criminal AKS prosecution would not have to meet the same standard.

More recently, however, two circuits took a more restrictive view of the causation standard in *AKS/FCA cases. U.S. ex rel. Cairns v. D.S. Med. LLC* was an 8th Circuit case involving payments between a surgeon and a spinal implant distributor owned by the surgeon's fiancée.

The DOJ obtained a conviction at trial. On appeal, the 8th Circuit reversed and held that the government must show that the defendants would not have submitted the claims "but for the illegal kickbacks."

The court relied on a dictionary definition of "resulting from" and noted that, in a separate context, the Supreme Court interpreted a similar phrase to require but-for causation. Finding the statute unambiguous, the court declined to examine legislative history, which was crucial to the 3rd Circuit's holding in *Greenfield*.

Earlier this year, the 6th Circuit agreed in a case involving a hospital that reneged on an offer of employment to an ophthalmologist after the doctor's former practice threatened to withhold referrals from the hospital if it went through with the hire.

In that case, *U.S. ex rel. Martin v. Hathaway*, one question was whether claims from the practice and the hospital "resulted from" the alleged kickback — the hospital's employment decision. Following *Cairns*, the court held that the AKS requires a but-for causation standard in an FCA lawsuit. The court raised concerns about a looser standard, which would not "protect

doctors of good intent, sweeping in the vice-ridden and virtuous alike."

Between *Cairns* and *Hathaway*, a trend seemed to be forming requiring the government in AKS/FCA cases to prove direct causation.

'TEVA' AND 'REGENERON'

Against this recent backdrop, Teva and Regeneron moved for summary judgment in their respective cases. First came *Teva*, the case before Judge Gorton. There, the company urged the court to apply the but-for standard, arguing that the government could not show that any Copaxone claims would not have otherwise been submitted but for Teva's donations to a PAP.

In a July 14 decision, Judge Gorton disagreed, holding that the government merely needs to show that there is a "sufficient causal connection" between the kickback and the claim, relying on a 2019 1st Circuit case, *Guilfoile v. Shields*.

Based on the evidence proffered by the government, including a statistical analysis matching Copaxone claims with patients receiving PAP funds that were generated by Teva, Judge Gorton rejected Teva's motion for summary judgment, seemingly stopping the nascent restrictive causation trend in its tracks.

That is, until, less than three months later, Chief Judge Saylor came out precisely the other way in *Regeneron*. There, the company argued for a but-for causation standard, but the government urged the court to apply a more relaxed "exposure" theory to the causation element. Under this theory, once an AKS violation was established, the government merely must show that a patient was "exposed to" the kickback; if so, the subsequent federal health care claim is false.

Chief Judge Saylor ruled that the but-for causation standard governed, relying on the text of the statute ("resulting from") and basic principles of statutory interpretation, citing *Cairns* and *Hathaway* favorably.

Chief Judge Saylor was also concerned that the "exposure" theory would sweep in too many claims that were not actually influenced by the kickback. The court acknowledged the 1st Circuit's *Guilfoile* ruling, relied on by Judge Gorton in *Teva*, but noted that it arose in a slightly different context — a wrongful termination FCA claim, rather than a straight FCA lawsuit.

Even while announcing a stricter standard, the court nevertheless denied summary judgment for Regeneron, ruling that the government had proffered sufficient evidence to satisfy but-for causation under the FCA.

APPELLATE REVIEW

Recognizing the split in the district, Judge Gorton and Chief Judge Saylor each certified their cases to the 1st Circuit for an interlocutory appeal. Judge Gorton certified the interlocutory appeal on Aug. 14, and, on Oct. 25, Chief Judge Saylor followed suit, noting the disparate outcomes in the two cases as well as the circuit split regarding the appropriate causation standard.

All parties have petitioned the 1st Circuit to accept the appeals and consolidate the cases. Thus, assuming the petitions are granted, the stage is set for the 1st Circuit to determine which judge correctly interpreted the AKS/FCA causation element.

And yet, given the circuit split, the 1st Circuit will almost certainly not have the last word on this vexing issue, which seems destined for the U.S. Supreme Court. Predicting how the Supreme Court might rule is a fool's errand, although it is noteworthy that, in recent years, the court has curtailed the DOJ's expansive use of similar anti-fraud laws such as the Honest Services and Wire Fraud statutes.

The implications of what appears at first blush to be a technical dispute over rote statutory language cannot be overstated. If the causation standard in an AKS/FCA case is a mere "link" between the AKS violation and the claim, the DOJ will continue to secure convictions and multi-million-dollar settlements from health care defendants in these cases.

On the other hand, if the DOJ must show "but for" or "direct" causation between the claim and the violation, it will be much more difficult for the DOJ and whistleblowers to win FCA cases, and defendants will be much less likely to settle.

Ultimately, it may be up to Congress to speak more clearly about the meaning of this critical contested element in a law with such far-reaching impact.

David Schumacher is managing partner of Hooper, Lundy & Bookman's Boston office. Before joining HLB, he was deputy chief of the Health Care Fraud Unit at the U.S. Attorney's Office in Boston.