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Feds Look To 'False Certification' FCA Strategy

By **Dan McKay**

Law360 (November 18, 2025, 5:18 PM EST) -- Prosecutors' abrupt change in legal strategy as they pursue kickback allegations against biotech giant Regeneron offers a real-world look at how the U.S. Department of Justice is adapting to a tougher causation standard emerging for False Claims Act kickback cases, experts say.

In recent pretrial filings, the U.S. Attorney's Office for the District of Massachusetts asked a judge to rule that the stringent "but-for" causation standard doesn't apply to their new theory of the case — that Regeneron caused providers to falsely certify anti-kickback law compliance when they submitted bills for an eye drug.

The shift to the "false certification" path comes after the First Circuit in February ruled prosecutors would have to show proof that the alleged kickbacks outlined in their complaint directly changed treatment decisions, not just led to reimbursements.

It was the third federal appellate court to determine the tougher but-for standard applied to FCA cases brought under a 2010 amendment to the Anti-Kickback Statute.

Prosecutors in the Regeneron case are now arguing it was the false certification of compliance — not the kickback-tainted billing claims — that violated the False Claims Act.

FCA attorneys on both sides of the bar are closely watching the Regeneron case, brought by Massachusetts federal prosecutors known for their False Claims Act expertise. The evolving strategy may offer a peek at how the DOJ will pursue FCA kickback cases in a growing number of states implicated by some circuit courts' tougher causation standard.

The strength of the government's new argument "remains to be seen," said J.D. Thomas, a former federal prosecutor and partner at Barnes & Thornburg LLP.

"I think it's where they're going in circuits that have adopted the but-for causation standard," he said in an interview.

Colette G. Matzzie, a Phillips & Cohen LLP partner who represents whistleblowers, said the false certification argument is "not at all new or novel" and represents a longstanding path to FCA liability when a company is accused of illegal kickbacks.

"As for whether other litigants and courts will adopt the government's approach, yes, that is quite likely," she said. "This was a well-established method of pleading and proving falsity and causation under the FCA separate from the 2010 amendment to the AKS."

The false certification avenue to FCA liability isn't always easy. The government must show defendants participated in an illegal kickback scheme and knowingly caused the submission of a reimbursement claim that falsely certified compliance with the anti-kickback law.

Under the certification theory, prosecutors must show the compliance sign-off was material to the government's decision to pay the bill.

"Historically, they have not been good at connecting the dots in the way that they are going to have to connect the dots here," Thomas said.

As part of their summary motion on the causation standard, prosecutors in the Regeneron case are asking the judge to rule in their favor on two key issues. The first is that reimbursement claims all contained the certification of compliance with kickback laws. Second, they must convince the judge that the certification itself was central to the government's payment decision.

Scott Armstrong, a former federal prosecutor who's now a principal at McGovern Weems, described the summary judgment skirmish as "pretrial positioning" that skirts around a central issue in the case — whether Regeneron actually violated the Anti-Kickback Statute.

"The cookie is going to crumble, or not, on whether this actually was an AKS violation,"said Armstrong, who defends clients facing government investigations.

FCA and government investigation attorneys are tracking the back-and-forth closely.

"People will, of course, be monitoring this case going forward because it is high profile obviously, and it does wrangle with a lot of issues that are kind of being shaken out in real time," Armstrong said.

Broader Causation Debate

The case began in 2020 when federal prosecutors accused Regeneron of violating the FCA through an illegal scheme in which the company covered the copays of certain patients who used Eylea, an eye drug that can cost $2,000 per injection. The scheme amounted to a kickback that tainted any subsequent Medicare reimbursement claim for the rest of the cost, the government contends.

Federal prosecutors at first pursued the case under a 2010 amendment to the Anti-Kickback Statute, which makes any bill to Medicare or Medicaid that resulted from a kickback a violation of the FCA.

The government and Regeneron dueled over what causation standard was necessary to show the kickback resulted in a reimbursement claim. In February, the First Circuit said prosecutors had to show the Medicare claims wouldn't have been submitted at all if not for Regeneron covering the patients' copay.

The Sixth and Eighth circuits have adopted a similar but-for causation standard. One appellate court — the Third Circuit, in 2018 — adopted a less-demanding standard requiring only some link between a kickback violation and the reimbursement claim.

Following the First Circuit ruling, prosecutors shifted to the alternate certification-focused path to liability.

In August, U.S. District Judge F. Dennis Saylor IV granted the government permission to pursue the alternative tack.

But the false certification argument still faces hurdles, and FCA attorneys are eager to see how the government carries out the case.

Regeneron isn't the one that actually submitted the bills to the government, and its copay assistance didn't go directly from the company to patients.

Instead, Regeneron donated to a foundation, which in turn helped cover the cost of the medicine for patients with a type of age-related macular degeneration, known as wet AMD.

Regeneron contends the charity was entirely legal. In fact, the Centers for Medicare & Medicaid Services had encouraged drugmakers to donate to copay charities and knew about Regeneron's charity arrangement, the company said, undermining prosecutors' argument that CMS wouldn't have paid the bills if it knew about the alleged kickbacks.

"If the government is really saying that it would not have covered necessary medicine for needy patients because Regeneron allegedly violated one of five guidelines in informal guidance from CMS, it should say so — loudly and proudly — and let a jury decide whether that is credible," the company said in a recent memo to the court.

The government offers a more straightforward appraisal of its case. Prosecutors say it's clear every reimbursement claim certificated compliance with the AKS and that the compliance was material to the government's payment decisions. They asked the court to rule that but-for causation isn't required.

"Instead, the government need only show that Regeneron's conduct naturally and foreseeably caused providers to present false claims for Eylea under [the False Claims Act], or naturally and foreseeably caused a provider to make or use such a false record or statement — i.e., the certification — material to a claim under" the act, prosecutors said.

'Evidentiary Headwinds'

Jason M. Crawford, a former federal prosecutor who now handles FCA defense as a partner at Crowell & Moring LLP, said the First Circuit decision earlier this year "undeniably made it more difficult to establish FCA liability under an AKS-based theory because this standard requires the examination of individual claims to assess whether the AKS violation caused the provider to deliver a different treatment than they would have absent the violation."

A 2016 U.S. Supreme Court ruling is also expected to come into play. In Universal Health Services v. Escobar, the justices described materiality as a rigorous requirement. That standard could shape the district court's analysis of whether the compliance assurance was central to the government's payment of the bills.

"Even though the government is now pursuing a false certification theory, they will likely still face

evidentiary headwinds when it comes to the analysis of individual claims because Escobar requires the application of a demanding and fact-specific materiality inquiry into whether a defendant's certification of AKS compliance was material to CMS' payment decision," Crawford said.

Matthew L. Knowles, a partner at McDermott Will & Schulte, said the government's shift in strategy is important because it signals that prosecutors don't think they can prove their case under the but-for standard.

The government faces a "more difficult factual burden" under the false certification approach, in part, because it was providers, not Regeneron, that actually submitted the bills to the government, he said.

"AKS cases against entities that do not themselves submit claims for reimbursement to the government are unquestionably going to be harder to prove," he said.

"Many of these cases sound better in the conference room where the government focuses only on its best evidence than they do when pressure-tested in court, where the government must prevail on each required element for FCA liability," Knowles added.

Others say the government is sensibly adapting to court rulings as it tries to protect public funds.

Matzzie, who represents whistleblowers, said the U.S. attorney's office in Massachusetts is known as a "preeminent district" for litigating FCA cases against life sciences companies.

The prosecutors are likely to have a very strong case with "important public interest considerations" for getting the case to a jury, she said.

"The stakes are high: The government alleges serious misconduct, and the Medicare program paid out over $11 billion for the macular degeneration drug over a decade," Matzzie said.

Regeneron and its counsel didn't immediately respond to requests for comment.

The U.S. Attorney's Office for the District of Massachusetts had no comment beyond its court filings.

The government is represented by Abraham R. George, Charles B. Weinograd, Lindsey Ross and Diane Seol of the U.S. Attorney's Office for the District of Massachusetts.

Regeneron is represented by Richard L. Scheff, Katharine M. Ladd and Alec P. Harris of Faegre Drinker Biddle & Reath LLP; Paul D. Clement and Matthew D. Rowen of Clement & Murphy PLLC; John P. Bueker of Ropes & Gray LLP; and Theodore V. Wells Jr., H. Christopher Boehning and David K. Kessler of Paul Weiss Rifkind Wharton & Garrison LLP.

The case is U.S. v. Regeneron Pharmaceuticals Inc., case number 1:20-cv-11217, in the U.S. District Court for the District of Massachusetts.

--Additional reporting by Julie Manganis and Jeff Overley. Editing by Abbie Sarfo.
