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Teva FCA Decision Sheds Light on Varying Interpretations of the Elements of an FCA Claim

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How could alleged kickbacks threaten to render insolvent a publicly traded company with assets (taken from its latest SEC filing) in excess of $43 billion? The answer stems from a recent decision by the United States District Court for the District of Massachusetts. In its ruling denying the motion for summary judgment filed by defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively Teva) and granting the government's partial summary judgment motion, the court ruled that

1. The causation requirement for a False Claims Act (FCA) violation predicated on a kickback prohibited by the Anti-Kickback Statute (AKS) is, although ill-defined, less exacting than even a "but for" causation analysis;
2. Allegedly false statements made in the context of alleged kickbacks to federal payor programs like Medicare are *per se* material; and
3. Damages in an alleged kickback scheme encompass the full measure of what the government paid to the defendant, irrespective of any value the defendant provided.

In *U.S. v. Teva Pharmaceuticals USA, Inc. et al*, the government contends that Teva funded the copays of

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Medicare patients using Copaxone, a multiple sclerosis drug, through donations to nonprofits running patient assistance programs. Teva in turn allegedly benefited from these donations by increasing the cost of Copaxone to the government. As a result, the government posits, Teva filled Copaxone prescriptions that it otherwise would not have filled and the government paid more for Copaxone than it otherwise would have had to pay.

The court's decision here reflects, at the district court level, a growing trend within the First Circuit that began in 2019 to dilute the causation element of AKS-based FCA cases. Other circuits, such as the Courts of Appeals for the Sixth and the Eighth Circuits, utilize a "but-for" causation standard. The United States Court of Appeals for the Third Circuit and, seemingly, the First Circuit favor an ill-defined standard that is more friendly to the government and whistleblowers, only requiring a "sufficient causal connection" between the AKS violation and the claims submitted.

The court's decision also materially impacts the potential calculation of damages at trial. Teva argued for a benefit-of-the-bargain framework that calculates damages as the difference between the values of what Medicare paid and what its beneficiaries actually received. The court disagreed. It opined that Medicare would have otherwise denied the claims for Copaxone had patients not been in a position to pay the copays. If Teva is ultimately found liable, this decision lays the groundwork for Teva to have to repay every dollar it received for providing Copaxone to Medicare patients (presumably limited to those that funded copays through a patient assistance program) during the pertinent time period. Of course, this measure of damages would then likely be trebled before imposition of statutory penalties. All told, Teva estimates its exposure to exceed $10 billion.

Teva challenged this decision by seeking an interlocutory appeal under 28 U.S.C. § 1292(b), a

rarely used mid-case appellate procedure reserved for cases involving a controlling question of law with a substantial ground for difference of opinion and where an immediate appeal may materially advance the ultimate termination of the litigation. On August 14, 2023, the court granted Teva's motion for an interlocutory appeal, permitting Teva the opportunity to have the 1st Circuit chime in before trial.

Akerman's Health Law Rx blog will continue to monitor this case and the court's valuable interpretation of this longstanding circuit split.
