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Whistleblower Suit Against Pharmaceutical Company Heads to Trial

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Update: In January 2020, Teva Pharmaceuticals agreed to pay $54 million to settle FCA claims.

Last month the United States District Court for the Southern District of New York ruled in favor of whistleblowers against a pharmaceutical company's motion for summary judgment, setting up a trial on the whistleblowers' claim that the company defrauded federal and state governments by illegally bribing and rewarding doctors for prescribing its drugs. The case shows the powerful reach of the False Claims Act and the Anti-Kickback Statute, two federal laws that work together to ensure healthcare providers who bill government insurance programs make decisions based on sound medical judgment rather than to gain lucrative benefits from drug companies.

The Facts

Charles Arnstein and Hossam Senousy, former sales representatives at Teva Neuroscience, brought a *qui tam* suit against Teva Pharmaceuticals USA, Inc. and affiliated companies, under the federal False Claims Act (FCA) and its analog in twenty-seven states, Washington, D.C., and two cities. The *qui tam* provision of the FCA allows whistleblowers, called "relators," to bring lawsuits on behalf of the federal government against those who submit fraudulent claims for reimbursement to the government or cause such fraudulent claims to be submitted. The FCA covers claims to government health insurance programs like Medicare, Medicaid, and the military's TRICARE.

The relators alleged that Teva ran a sham "speaker program" designed to channel money and lavish meals to doctors who frequently prescribed two Teva drugs used in the treatment of Parkinson's disease and relapsing-remitting multiple sclerosis. Speaker programs are common marketing tools in the pharmaceutical industry through which pharmaceutical companies pay healthcare providers to educate practitioners and patients about the companies' drugs and the diseases they treat. Providers who speak at the programs can earn thousands of dollars in fees and get complimentary travel, lodging, meals, and alcohol, so the speaker programs are fraught with risk of abuse. In an effort to keep pharmaceutical companies happy and continue receiving invitations to speak, healthcare providers may prescribe the companies' drugs at high rates, even when not medically indicated.

The relators presented evidence that Teva's speaker program specifically targeted doctors who had high prescription numbers for these speaking opportunities, even if the doctors were not the best candidates to give educational lectures. Furthermore, the relators offered expert testimony that many of the programs were not genuinely educational. Rather, the speakers were speaking to very small audiences, often filled with other doctors who were paid by Teva, and presenting rudimentary material that would be not useful to practitioners in the field. Although the relators could not demonstrate *quid pro quo* exchanges between Teva and participating doctors, such as explicitly offering speaker fees for more prescriptions, the relators argued that a jury could conclude from the

evidence that Teva's speaker program had the purpose of offering financial rewards to high prescribers.

The Law

Recognizing the danger of doctors pursuing their own financial interests at the expense of their patients' health, in 1972 Congress passed the Anti-Kickback Statute (AKS). The AKS makes it a crime to knowingly offer, pay, solicit, or receive "remuneration" to "induce" a person to "recommend" the purchase of a drug covered by a federal healthcare program. In 2010, as part of the Patient Protection and Affordable Care Act, Congress amended the AKS to state explicitly that any claim for reimbursement submitted to a government health insurance program which "includes items or services resulting from a violation" of the AKS constitutes a violation of the FCA.

In the context of speaker programs, the question is when fees paid to a doctor constitute "remuneration" to "induce" a doctor to prescribe a drug in violation of the AKS, as opposed to compensation for *bona fide* educational and marketing services? The Department of Health and Human Services ("HHS") promulgated "safe harbor" regulations in 1991 that allow pharmaceutical companies to avoid AKS liability if they follow certain rules. The safe harbor regulations explicitly state that the term "remuneration" does not include payments made as compensation for services so long as the payments meet seven conditions. The conditions include that the compensation must be consistent with fair market value for the services rendered and not take into account the volume or value of the prescriptions and referrals generated by the doctor. The services paid for must also be reasonably necessary to accomplish a commercially reasonable purpose.

The Decision

Teva urged the court to require the relators to produce evidence of explicit *quid pro quo* agreements, such as negotiations between Teva and the doctors in which the doctors promise to write prescriptions in exchange for speaker fees. It also argued forcefully that, despite relators' experts' testimony to the contrary, its speaker programs provided educational value to the audience members, and that it offered the speakers fair market value for their services. Teva insisted that any excess compensation to speakers for non-educational programs would have violated its written compliance policies.

The court rejected Teva's argument that relators needed to produce evidence of a *quid pro quo* agreement. Rather, the court held that the relators needed to prove that Teva implemented its speaker program with the intent to influence the speakers' prescribing behavior. Because the relators offered substantial evidence that Teva targeted high volume prescribers to participate in the speaker program, even when those doctors might not have been well-qualified educational speakers, the court held that a reasonable jury could conclude that Teva's speaker program was intended to influence prescriber behavior in violation of the AKS and FCA.

In response to Teva's arguments about the educational content of its speaker program and the fair market value of the compensation offered to speakers, the court held that these were factual disputes for a jury to decide. However, in its over 70-page decision, the court repeatedly signaled that the relators presented a strong case that Teva's speaker program was merely a "sham." The court noted that, although Teva's written compliance policies "contain all of the right language," the relators' evidence raised a genuine question "whether these policies are worth the paper they are written on." A jury will have the opportunity to answer this question when the case goes to trial.

The decision shows that federal law provides powerful tools to combat the dangerous influence of money in the healthcare system. Through the *qui tam* provision of the FCA, pharmaceutical

whistleblowers can play an important role in making sure that drug companies and healthcare providers do not take advantage of government health insurance programs at the expense of patient health.