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A Hefty Speaking Fee: Biogen Inc. Agrees to Settle False Claims Act Suit In Violation of Anti-Kickback Statute for $900 Million

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by Samuel F.B. Audley

On July 20, 2022, Biogen Inc. ("Biogen") disclosed in a quarterly earnings report that it had agreed to pay $900 million to resolve a *qui tam* claim by a former employee that the company had violated the False Claims Act ("FCA") and the Federal Anti-Kickback Statute ("AKS"). *See Biogen Reports Second Quarter 2022 Results*; *see also United States ex rel. Bawduniak v. Biogen Idec, Inc.,* No. 12-cv-10601-IT, ECF No. 132 (Third Amended Complaint), ECF 615 (Notice of Settlement) (D. Mass. Apr. 27, 2018).

In the original *qui tam* suit, former employee Michael Bawduniak accused Biogen of FCA and AKS violations through its payment of "millions of dollars in kickbacks to influence health care providers" to prescribe Biogen's multiple sclerosis ("MS") products in order to preserve Biogen's market share of one of its MS drugs, to increase the market share of another, and to ensure that a third MS drug would be prescribed at a high rate once approved. ECF No. 132 at 1. The former sales representative alleged that Biogen's "massive scheme" had "defraud[ed] Medicare, Medicaid, and other federal programs by providing financial rewards to physicians" to induce them to prescribe Biogen MS treatments. ECF No. 20 (Second Amended Complaint). In particular, he alleged that Biogen had classified and targeted physicians "based upon criteria that measured their ability to influence the prescription of MS treatments" such that Biogen paid lucrative consultation and speaking fees, travel expenses, and stipends to induce physicians to prescribe Biogen drugs. *Id.* ECF No. 132.

On July 1, 2015, the United States declined to intervene in the suit a full investigation of FCA and AKS claims, as authorized by 31 U.S.C. § 3730(a). ECF No. 68. Following the United States' decision, the District Court merged and unsealed all the claims related to Biogen's alleged scheme.

On July 22, 2016, Biogen filed a motion to dismiss, arguing that there was no proof of any *quid pro quo* to induce physicians to make prescriptions, and that the mere engagement of a prescriber as a consultant or speaker did not imply that the claims filed by the prescriber were "tainted." Biogen focused on the nature of the pharmaceutical

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industry in justifying that its contractual arrangements with prescribers were both ordinary and appropriate based on safe harbor provisions in the AKS statute. Biogen argued that the complaint's failure to identify a specific *quid pro quo* payment with particularity was fatal to the FCA and AKS claims.

On April 27, 2018, the District Court denied Biogen's motion to dismiss, holding that the complaint sufficiently alleged that Biogen had paid consulting and speaking fees exceeding those "reasonably necessary" for the services provided by the providers. ECF No. 179 at 6. For the AKS claim, the District Court further concluded that *quid pro quo* need not have been pled with particularity for specific payments; instead, it was sufficient to allege that Biogen paid kickbacks "for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs" in violation of the AKS. *Id.* at 7.

Biogen's agreement to settle the claims for $900 million on the eve of trial is one of the largest recoveries in the history of the FCA without the intervention or participation of the United States. Biogen's settlement highlights the risks for pharmaceutical manufacturers involved in designing and implementing consultant and speakers programs. While the recent decision in *United States ex rel. Cairns v. D.S. Med. LLC* arguably provides more robust protections for parties accused of AKS violations in the Eighth Circuit, Biogen's settlement emphasizes the more recent focus and scrutiny on speaker programs targeted at physicians given the potential fraud and abuse risks, even in instances where the United States is not involved. Accordingly, pharmaceutical companies and medical device manufacturers should ensure that their internal policies and procedures are carefully designed to document the legitimate underlying business rationales for each speaking and consultant engagement to ensure compliance with the FCA and AKS.