

STATISTICAL EVIDENCE AND THE FALSE CLAIMS ACT

The False Claims Act¹ is a fraud statute; therefore, False Claims Act complaints must be pled with particularity,² identifying “the who, what, when, where, and how of an actual false claim” submitted to the government.³ Whistleblowers without evidence of specific claims have tried to circumvent the rule with statistics, showing a likelihood that false claims were submitted to the government. The courts have repeatedly rejected these attempts, saying, e.g.:

Rule 9(b) does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply ... that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted.”⁴

In 2013, it appeared the First Circuit Court of Appeals might have cracked open the door to the use of statistical evidence in False Claims Act cases. In *In re Neurontin Marketing and Sales Practices Litigation*,⁵ the court allowed a statistical expert to testify on the issue of causation, to offer his opinion that Pfizer’s marketing of Neurontin for off-label uses led to increased improper use of the drug.⁶

In 2017, the First Circuit Court of Appeals slammed the door on a whistleblower who tried to sneak through the crack left by the *Neurontin* cases.

In *United States ex rel. Booker et al. v. Pfizer, Inc.*,⁷ the whistleblowers had no evidence of actual false claims submitted to the government, but they argued that they could prove the case statistically, citing the *Neurontin* cases for support. The court rejected the comparison. It said the *Neurontin* cases did not stand for the proposition that the existence of false claims could be proven through statistics. Rather:

In those cases, we held that plaintiffs could use aggregate data together with strong circumstantial evidence to overcome summary judgment on the distinct issue of whether there was a causal link between fraudulent marketing and demonstrated off-label prescriptions in the distinct context of a civil RICO case — not that such proof could be used to demonstrate the existence of false claims in an FCA case.⁸

The court’s clarification and limitation of the statistical discussion in the *Neurontin* cases should come as a welcome relief to government contractors, including health care providers, who face under-informed bounty hunters⁹ hoping to strike it rich with the False Claims Act.

If you have any questions, please contact David B. Honig at dhonig@hallrender.com or (317) 977-1447 or your regular Hall Render attorney.

¹ 31 U.S.C. § 3729-3733.

² Fed.R.Civ.P. 9(b).

³ *United States ex rel. Lawton v. Takeda Pharm. Co.*, 842 F.3d 125, 130 (1st Cir. 2016)(citations omitted).

⁴ *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir.2006).

⁵ 712 F.3d 21 (1st Cir. 2013), 712 F.3d 51 (1st Cir. 2013), and 712 F.3d 0 (1st Cir. 2013).

⁶ *Id.* at 44-45.

⁷ Case No. 16-1805, 2017 WL 395094 (1st Cir. January 30, 2017).

⁸ *Id.* (emphasis in original).

⁹ *United States ex rel. Bogina III v. Medline Industries, Inc. et al.*, 809 F.3d 365, 367 (7th Cir. 2016).