



April 15, 2016

Volume 24 Issue 2

## From the Substantive Litigation Groups

### **Discovering Originality: Why the Third Circuit's Expansion of False Claims Act Liability Makes Other Litigation a Lot More Dangerous for Pharmaceutical and Medical-Device Companies**

by Timothy M. Moore



Pharmaceutical and medical-device companies, often in the crosshairs of fraud litigation brought under the federal False Claims Act, need to know about *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294 (3rd Cir. 2016). In that case, the Fourth Circuit concluded that a law firm could pursue a False Claims Act case based on facts it discovers while conducting discovery in unrelated litigation. The consequences of that novel understanding are far reaching. But, as discussed below, they are not unmanageable.

#### **I. The False Claims Act**

The False Claims Act is federal legislation imposing civil liability on people and companies that defraud the federal government. 31 U.S.C. §§ 3729 et seq. The federal government, as well as private parties called "relators," may file lawsuits under the Act. *Id.* at § 3730. Defendants may be liable for treble the government's damages, a penalty ranging from \$5,500 to \$11,000 per false claim, and costs. *Id.* at § 3729(a)(1), (3). As an incentive to bring these suits, the Act offers relators up to 30 % of the government's recovery in the suit. *Id.* at § 3730(d).

#### **II. Overview of *Moore & Company v. Majestic Blue Fisheries***

In 2010, a fishing vessel sank in the South Pacific, killing its captain. *Moore & Company*, 812 F.3d at 304. Moore & Company (no relation to the author) represented the captain's widow in a wrongful death case against Majestic Blue Fisheries, LLC ("Majestic Blue"), which appeared to own and operate the ship, and Dongwon, the South Korean tuna-fishing company that sold the ship to Majestic Blue. *Id.* at 304. During discovery, the law firm found evidence allegedly supporting a claim that Majestic Blue obtained its U.S.-government-issued fishing license by falsely certifying to the U.S. Coast Guard that Americans controlled Majestic Blue and captained its ship. *Id.* at 300-04. In fact, according to Moore & Company, Dongwon created Majestic Blue, continued controlling Majestic Blue after selling it and its ship to straw purchasers, had its employees use an alias to apply for the fishing license Majestic Blue used, and employed Koreans to captain the ship. *Id.* at 304-08. Moore & Company used that discovery and information in various media reports to initiate a False Claims Act suit against Majestic Blue, Dongwon, and others. *Id.* at 304.

The defendants moved to dismiss the case based upon the public disclosure bar (31 U.S.C. § 3730(e)(4)), which prohibits relators from filing cases based upon information disclosed to the public through any of several statutorily-specified sources, such as litigation brought by the government, congressional reports, or "the news media." *Id.* at 301-02. The defendants argued that the information upon which Moore & Company based their case came from either published media stories or responses to FOIA requests. *Id.* The Fourth Circuit agreed that Moore & Company relied upon information that was a public disclosure. *Id.* at 304. But that did not end the case: Moore & Company had argued that the information it obtained during discovery made it an "original source," which is an exception to the public disclosure bar.

Before the Patient Protection and Affordable Care Act ("PPACA"), an "original source" was "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B) (2009). Courts, including the Fourth Circuit, had construed this to require "the relator's knowledge needed to be independent from information readily available in the public domain." *Moore & Company*, 812 F.3d at 305. Now, an "original source" is someone who (1) before a public disclosure, "voluntarily disclosed to the

Government the information on which allegations or transactions in a claim are based" or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2015). The court observed that this change, along with two others that the PPACA made to the False Claims Act, "radically changed the 'hurdle' for relators" and "evince[d] Congress's intent to lower the bar for relators . . ." *Moore & Company*, 812 F.3d at 298-99. In fact, this "new definition of original source require[d] an entirely different analysis." *Id.* at 305.

Now, whether *Moore & Company* was an original source turned on two questions.

First, did *Moore & Company* have knowledge independent of a public disclosure? Under the new standard, information disclosed in a civil proceeding would be a "public disclosure" only if the matter was a federal case in which the government was a party. *Id.* at 299. The federal government was not party to the *Moore & Company*'s case, so the discovery it obtained was independent of a public disclosure. *Id.* at 299, 304-05. Second, did *Moore & Company*'s knowledge materially add to the publicly disclosed information? The Court explained that "a relator materially adds to the publicly disclosed allegation or transaction of fraud when it contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: "the who, what, when, where and how of the events at issue." *Moore & Company* allegedly learned through discovery in the wrongful death case that the fraud existed, the scheme through which the defendants committed the fraud, the fraud's purpose, who participated in the fraud, and each participant's role. Armed with those details, *Moore & Company* showed the Fourth Circuit that they were an "original source" and cleared the public disclosure bar.

### **III. Impact on Pharmaceutical and Medical-Device Companies**

The False Claims Act provides a strong financial incentive for plaintiffs and their lawyers to identify plausible theories. Defending against a False Claims Act investigation or suit can be burdensome, distracting for business colleagues, and hurt the bottom line. Plaintiffs' lawyers know all this and are likely to see *Moore & Company* as a green light to develop and pursue False Claims Act cases so they can increase their fee recovery overall and create leverage for other litigation.

For instance, product liability lawsuits are a prime source plaintiffs' lawyers could mine for material to use in a False Claims Act case. Those cases often involve allegations of improper (e.g., off-label) marketing by pharmaceutical and medical-device companies. With the possibility of filing a False Claims Act case based upon discovery stemming from a product liability case, pharmaceutical and medical-device companies can expect plaintiffs' lawyers to be more aggressive about including and pursuing discovery on those allegations. Furthermore, plaintiffs' lawyers are likely to include and seek discovery regarding allegations of other practices that have led to False Claims Act enforcement actions, such as sham consultancies or other disguised kickbacks.

Cases brought by former employees are another top candidate. Disgruntled employees often seek to cast the company in a bad light. Allegations that the company pressured the employee to act illegally can accomplish that and fit within a common narrative of, "I was wrongfully terminated because I refused to participate in illegal practices." As with product liability cases, plaintiffs' lawyers will probably include allegations that the company was committing the improper-practice-du-jour and more aggressively seek discovery on the same.

### **IV. How Pharmaceutical and Medical-Device Companies Can Mitigate Ensuing Risk**

Fortunately, companies have a variety of means through which they can mute the danger and burden posed by *Moore & Company*. A few of those are below:

- Evaluate new cases for False Claims Act potential. Even if nothing jumps out at you right away, remember that plaintiffs' lawyers will always seek new ways to expand liability. Analyze creatively.
- Redouble efforts to knock out claims that are likely to lead to discovery of facts that often lead to False Claims Act cases. For instance, companies will want to dismiss claims or strike allegations addressing product promotion and arrangements with physicians.
- Consider using a "Lone Pine" order. Those orders (which take their name from *Lore v. Lone Pine Corp.*, No. L-33606-85, 1986 WL 637507, at \*1-2 (N.J. Sup. Ct. Law Div. Nov. 18, 1986)) require plaintiffs in mass tort cases to substantiate key parts of their case, such as causation, early in discovery. If you can obtain dismissal or summary judgment on causation before discovery on any other issue, you may be able to avoid discovery on facts relevant to a False Claims Act case.
- Use extra caution when responding to discovery. For instance, companies may want to be more assertive with objections now. Also, although companies may not always be able to prevent disclosure of information that could be used for a False Claims Act case, companies should consider employing extra scrutiny when answering discovery on topics that have often led to False Claims Act cases.

- Use confidentiality agreements during discovery to prevent disclosure of information or documents gained.
- Implement measures to reduce potential exposure from disgruntled employees. After all, former employees are often the relators. Companies may want to revise how they conduct exit interviews with employees so that they can obtain representations from the employee that he or she was not aware of any fraud before departing the company. Companies may also reduce risk by securing a general release of claims from an employee before his or her departure. See, e.g., *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 600 F.3d 319, 326-29 (4th Cir. 2010) (holding that a pre-filing release barred subsequent False Claims Act claim); *United States ex rel. Ritchie v. Lockheed Martin Corp.*, 558 F.3d 1161, 1168-69 (10th Cir. 2009) (same); *United States ex rel. Hall v. Teledyne Wah Chang Albany*, 104 F.3d 230, 231-33 (9th Cir. 1997) (same).
- Retain counsel knowledgeable about False Claims Act to assist with analyzing the case, developing your defense strategy, and responding to discovery. Lawyers experienced in handling False Claims Act matters may be able to spot a trap lying in wait from twenty interrogatories away.

**Tim Moore** is a Senior Associate in the Miami office of Shook, Hardy & Bacon. A former state and federal prosecutor, Tim counsels life sciences companies on compliance and data privacy matters, conducts internal investigations, and litigates False Claims Act and product liability cases. You can reach Tim at [tmoore@shb.com](mailto:tmoore@shb.com).

**The Defending Against Governmental Actions SLG focuses its efforts on strategies and best practices for defending against actions brought by State Attorneys General and US Attorneys. These types of actions present unique theories and legal issues, and this SLG is designed to best posture your clients for investigations or lawsuits. This SLG is underway with planning for articles, webinars, membership recruitment, and other activities. If you would like to participate in the SLG, please contact Peter Pappas at [ppappas@nexsenpaltet.com](mailto:ppappas@nexsenpaltet.com).**

To learn more about DRI, an international membership organization of attorneys defending the interests of business and individuals in civil litigation, visit [www.dri.org](http://www.dri.org).