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ALERT

False Claims Act

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Ninth Circuit Rejects FCA Suit Alleging Medical Device Inaccuracies

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In *United States ex rel. Ruhe v. Masimo Corp.*, 640 Fed. App'x 666 (9th Cir. 2016), the Court of Appeals for the Ninth Circuit affirmed a grant of summary judgment for defendant Masimo Corporation, a medical device manufacturer. The relators in this False Claims Act ("FCA") case had alleged that Masimo made fraudulent statements about the accuracy of the company's pulse oximeter devices, rendering false any subsequent claims for payment to federal health care programs relating to the devices. The Ninth Circuit rejected those claims outright, holding that the relators had presented no evidence of false statements to customers or to the Food & Drug Administration ("FDA"), and no evidence of the required scienter.

Background

Masimo manufactures and develops pulse oximeters, medical devices that measure blood characteristics. The products at issue in this litigation, known commercially as the Pronto devices, are oximeters capable of measuring both oxygen and total hemoglobin levels without drawing a blood sample. The Pronto devices are "point-of-care" tools that enable physicians to obtain real-time test results on-site without the need for laboratory tests. Such point-of-care devices are typically less accurate than laboratory tests, but carry the advantage of greater convenience and speed.

Between 2008 and 2011, the FDA cleared for marketing several iterations of the Pronto devices through the 510(k) premarket notification process. *See* 21 C.F.R. § 807 *et seq*.

The relators were Masimo sales representatives from 2009 until 2010, when they resigned allegedly over concerns about the Pronto devices' performance. The relators reported their concerns in resignation letters to the company. Masimo responded by requesting additional information from the relators, conducting an internal investigation, and voluntarily notifying the FDA of the allegations. The relators then filed suit under the FCA.

On February 2, 2011, FDA investigators arrived unannounced at Masimo to perform an audit inspection. The FDA concluded its inspection without taking any enforcement action.

The relators alleged that Masimo knowingly made false or fraudulent statements relating to the Pronto devices by misrepresenting validation study data that Masimo submitted to the FDA during the 510(k) process and by failing to inform the FDA that the Pronto devices were less accurate in clinical use than in laboratory conditions. Indeed, the relators alleged that the Pronto devices were so clinically inaccurate as to be effectively worthless. Finally, the relators alleged that Masimo had knowingly provided false information to the American Medical Association ("AMA") when requesting the creation of new billing codes for use by healthcare providers who bill for the Pronto devices.

Ninth Circuit Decision

The Ninth Circuit affirmed in whole the District Court's grant of summary judgment in Masimo's favor. The Court of Appeals held that Masimo had not misled the FDA about the Pronto devices' accuracy, because the information

Masimo submitted to the FDA "correctly stated the accuracy ranges at which the devices had been validated in laboratory testing conducted pursuant to" the FDA's recommended standards, and the relators "pointed to no evidence undermining either the studies or tests results underpinning these accuracy specifications." 640 Fed. App'x at 668.

While the relators had pointed to evidence of some customer feedback on the Pronto devices' accuracy and internal Masimo discussions about improving accuracy, the District Court's earlier decision held that Masimo had "in no way concealed or misrepresented the [FDA-cleared] accuracy specification for its devices" as determined through lab tests. 977 F. Supp. 2d 981, 994 (C.D. Cal. 2013). The Court of Appeals agreed, holding that "[i]solated complaints and anecdotal feedback about the accuracy of the Pronto Devices do not support an inference that Masimo committed knowing fraud by continuing to sell the devices with a stated FDA-clearance accuracy specification." The Court of Appeals also rejected the "worthless services" allegation, holding that the company had provided "unrebutted testimony that the Pronto devices have clinical utility even with accuracy deviations beyond those cleared by the FDA." 640 Fed. App'x at 669.

The Ninth Circuit summarily rejected the relator's allegations that Masimo had knowingly provided false information to the AMA, noting that Masimo had provided the AMA with copies of its 510(k) clearance materials and FDA-cleared product manuals.

Finally, the Ninth Circuit held that even if Masimo had made some kind of false statement to customers concerning the Pronto devices' accuracy, the relators had nonetheless failed to submit evidence establishing scienter as required by the FCA. That ruling endorsed the District Court's earlier determination that the relators "presented no evidence that Masimo did not have a good faith belief that its devices were accurate." 977 F. Supp. 2d at 995. In so holding, the Ninth Circuit adopted the reasoning of Masimo's counsel during oral argument that an FCA suit is "not a referendum about how good are [the] devices" but rather the pertinent question is "[d]id we lie? Did we have scienter to mislead, to cause false claims against the government?"

Implications

The Ninth Circuit's opinion makes clear that the FCA is not a mechanism for whistleblowers to second-guess the FDA's regulatory decision-making process. When medical device manufacturers are transparent with the agency through the pre-market approval or clearance procedures, relators face a steep challenge to undermine the agency's safety and efficacy determinations in subsequent civil litigation.

The decision is also a further reminder that the FCA's scienter requirements have real bite. To survive summary judgment, relators must identify more than data trends or scientific inaccuracies; they must identify evidence that the defendant failed to act in good faith and, in short, that the defendant lied.

If you would like to discuss the foregoing or any related FCA matter, please contact the Ropes & Gray attorney with whom you regularly work, or any attorney in our False Claims Act practice.