NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES ex rel. MICHAEL RUHE, VICENTE CATALA and KRISTINE SERWITZ, Plaintiffs - Appellants, v. MASIMO CORPORATION, Defendant - Appellee.	No. 13-56789 D.C. No. 2:10-cv-08169-CJC-VBK MEMORANDUM*

Appeal from the United States District Court

for the Central District of California
Cormac J. Carney, District Judge, Presiding

Argued and Submitted February 1, 2016
Pasadena, California

Before: PREGERSON, WARDLAW, and HURWITZ, Circuit Judges.

Michael Ruhe, Vincente Catala, and Kristine Serwitz (collectively, "Relators"), are former sales representatives for Masimo Corporation ("Masimo"), which manufactures pulse oximeters. Relators appeal the district court's grant of summary judgment to Masimo in this *qui tam* action under the False Claims Act

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This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

("FCA"), 31 U.S.C. §§ 3729-33. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

1. Relators contend that Masimo violated the FCA by failing to inform the Food and Drug Administration ("FDA") that clinical use of its Pronto devices demonstrated less accuracy than the specifications cleared by the agency. But, the information Masimo submitted to the FDA correctly stated the accuracy ranges at which the devices had been validated in laboratory testing conducted pursuant the International Organization of Standardization ("ISO") 9919, which has been approved by the FDA for validating pulse oximeter devices. Relators have pointed to no evidence undermining either the studies or test results underpinning these accuracy specifications.

2. Relators also contend that the Pronto devices were so inaccurate that every claim submitted to Medicare by doctors who used the devices is a "false or fraudulent claim" in violation of the FCA. 31 U.S.C. § 3729(a)(1). The district court correctly noted 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." Relators presented no evidence of false statements made by Masimo either to its customers or the FDA.

3. Masimo did not knowingly present false information to the FDA by using other

than "fully characterized devices," *see* ISO 9919, 14155-1-8.2(f), in its clinical testing; all material elements of the products used in testing were final production elements, and Masimo disclosed to the FDA its validation study method, including its "two phase" testing process for calculating the final calibration curve.

4. Masimo did not knowingly mislead the FDA by resubmitting its Pronto-7 device for 510(k) approval, *see* 21 C.F.R. § 807.92(a)(3), with an added oxygen saturation sensor. The FDA told Masimo it could file another 510(k) submission with that sensor added.

5. Masimo did not knowingly provide false information to the American Medical Association ("AMA") in requesting its billing codes. Masimo provided the AMA with copies of its 510(k) clearance materials and FDA-cleared product manuals.

6. Masimo is not liable under the "worthless services" doctrine, *see United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001), because Masimo provided unrebutted testimony that the Pronto devices have clinical utility even with accuracy deviations beyond those cleared by the FDA.

7. Even assuming Masimo made a false statement regarding the devices' accuracy, Relators have not submitted evidence establishing the requisite scienter. *See* 31 U.S.C. § 3729(b)(1) (defining terms "knowing" and "knowingly"); *United States ex rel. Anderson v. N. Telecom, Inc.*, 52 F.3d 810, 815-16 (9th Cir. 1995) ("The statutory phrase 'known to be false' does not mean scientifically untrue; it

means a lie." (internal quotation marks omitted)). The FCA is not violated simply if a product fails to perform well; a knowingly false statement is required for liability.

AFFIRMED.