The United States’ recent False Claims Act (“FCA”) prosecution in United States v. Prometheus Group, et al., is a reminder that the government will use the FCA to target medical device manufacturers for off-label use of medical devices, even where healthcare providers have decided the use is safe and effective. In Prometheus Group, the government alleges that the defendant medical device manufacturer trained providers to re-use disposable rectal probes against U.S. Food and Drug Administration (“FDA”) recommendations, causing the providers to submit false claims for payment to Medicare for the services mis-using the probes. The complaint alleges that Prometheus put vulnerable Medicare patients at risk to gain a marketing advantage by reducing overhead costs associated with its systems. The message to medical device manufacturers is clear: even without submitting claims to the government themselves, manufacturers can face FCA liability for suggesting providers use their devices in any way the FDA has not approved (and in this case, warned against).
Prometheus manufactures a pelvic muscle rehabilitation system and accompanying rectal pressure probe used to treat pelvic floor disorders. The FDA approved the probe for single-person use, but Prometheus allegedly trained providers to reuse the device on multiple patients by covering the probe with a glove or condom. Prometheus also allegedly instructed providers to re-use another company’s probe with a different pelvic rehabilitation system it manufactures, despite the FDA having approved the probe only for one-time use. The FDA even required warnings on the probes’ packaging, “restricted for single person use only,” and “[d]o not re-use.”

To prove an FCA violation, the government will have to show that Prometheus’ alleged off-label use instructions caused providers to submit false claims, that Prometheus knew this (or recklessly disregarded the falsity), and that the contraindicated use was material to Medicare’s decision to pay the providers’ claims. To establish the knowledge element, the government alleges that Prometheus knew the probes were single-user or single use, and also knew that its provider customers were submitting claims to Medicare for procedures using the devices because Prometheus instructed providers on how to bill the pelvic rehabilitation services. The government is attempting to prove materiality using Medicare’s coverage requirement that procedures must be “reasonable and necessary.” The Centers for Medicare and Medicaid codified the definition of “reasonable and necessary” just last year, including the requirement that procedures be “[f]urnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition ...” The government alleges that re-using the rectal probes was not “reasonable and necessary,” even if the underlying procedures and treatment might have been. It seems that the government is also attempting to show falsity based on the failure to satisfy the “reasonable and necessary” requirement.

This is not the first time the government has wielded the FCA against medical device manufacturers for off-label uses of their products. In 2018, AngioDynamics settled for $12.5 million over allegations that it misleadingly promoted its drug-delivery product LC Bead as doing more than the FDA had approved. Some of the largest FCA settlements on record have been with pharmaceutical manufacturers promoting off-label use of their drugs: Pfizer settled for $2.3 billion—$1 billion of which was an FCA settlement—for off-label marketing of Bextra, and Warner-Lambert pled guilty in 2004 and paid a $430 million settlement in connection with promoting its drug Neurontin for off-label uses.

But all hope is not lost for medical device manufacturers. The 9th Circuit recently declined to penalize a medical device manufacturer for marketing its products for a use that FDA expressly contraindicated on the labels. In Dan Abrams Co. v. Medtronic Inc., Case No. 19-56377 (9th Cir. Apr. 2, 2021), the 9th Circuit affirmed partial dismissal of relator’s FCA claim and found that Medicare does not distinguish between on-label and off-label uses in determining whether to pay claims, and that even contraindicated uses are eligible for payment if they are medically necessary and reasonable. The court went on to note that merely showing that harm can occur from off-label or contraindicated use is not enough to satisfy materiality, because every surgery carries risk. The Southern District of Florida followed suit with its recent decision in United States ex rel. Watt v. VirtuOx, Inc., dismissing relator’s allegation that defendant’s use of a medical device was not medically necessary or
reasonable simply because it was off-label.

Prometheus declined to file a motion to dismiss and instead proceeded to file its Answer on July 18, 2022. Thus, if not settled, the case will be decided on either a motion for summary judgment or at trial. But even where the government’s and relators’ complaints do not survive a motion to dismiss, it can be costly to battle the allegations. Device manufacturers should keep this in mind when marketing their devices for off-label use.

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National Law Review, Volume XII, Number 215

Source URL: https://www.natlawreview.com/article/government-seeks-fca-liability-label-use-medical-devices