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Device Manufacturers Take Note: Recent Oregon Settlements Could Lead To a Potential Uptick in State Enforcement Under Consumer Protection Laws

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The Oregon Attorney General recently challenged certain financial relationships between a medical device manufacturer and physicians, raising potentially broader implications for medical device manufacturers in all U.S. jurisdictions.

In August, two Oregon cardiologists each agreed to pay $25,000 to settle claims brought by the Oregon Attorney General alleging that the physicians willfully violated the Oregon Unlawful Trade Practices Act (the "Oregon UTPA")[1] by accepting payments from a medical device manufacturer, Biotronik, Inc. ("Biotronik"), a maker of heart rhythm devices, in exchange for training Biotronik sales representatives during patient procedures and concealing such payments from patients in whom the Biotronik devices were implanted. These settlements occurred in the midst of a broader, ongoing federal investigation of Biotronik's marketing and sales practices.

Medical device manufacturers have a responsibility to make appropriate training and education on their products and medical technologies available to health care providers. To that end, some medical device manufacturers offer certain technical expertise to physicians during patient implant procedures. Notably, both the AdvaMed Code, which provides industry guidance to medical device manufacturers, and the American Medical Association ("AMA"), which has published a national code of professional ethics for physicians, have recognized a medical device manufacturer's legitimate use of qualified personnel to provide appropriate training to medical professionals on the safe and effective use of the company's medical technologies.[2] In order for personnel to provide such technical support to their customers, they must first be appropriately trained, and some device manufacturers arrange for their physician-customers to train their personnel.

Notwithstanding the potential *bona fide* purposes for compensating physicians to train a manufacturer's personnel in a clinical setting when such arrangements are structured appropriately and other compliance considerations are addressed, the Oregon Attorney General argued that the two Oregon cardiologists should have disclosed their financial relationships with Biotronik to their patients. According to the Oregon Attorney General, the physicians knew or should have known that their patients would want to know that their physician was receiving a payment in connection with their procedure and that their procedure was part of a manufacturer's training program for its sales representatives.

[1] *See* Or. Rev. Stat. §§ 646.605 to 646.656.

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[2] *See* AdvaMed Code, at § III; AMA Code of Medical Ethics, Opinion 8.047 ("Industry Representatives in Clinical Settings), available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8047.page (last visited Oct. 2, 2013) (hereinafter, "AMA Code of Ethics").

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These lawsuits are an example of a state taking a long-standing consumer fraud statute and applying it in a manner that was likely never intended by its drafters to establish broader and more exacting disclosure requirements that go beyond existing law. While these Oregon lawsuits were brought against physicians, the same laws could, depending on the specific circumstances, conceivably be used to pursue medical device manufacturers through allegations that the manufacturer aided and abetted the physician in concealing its financial arrangements with the manufacturer. Given that almost every state has some form of consumer protection or unfair trade practices laws, manufacturers should take proactive steps to mitigate their risk in the states where they do business.

Background

The Oregon UTPA is a broad statute that generally requires open disclosure of information when dealing with consumers. Essentially, the Oregon Attorney General alleged that the cardiologists ''misrepresented'' their services as being ''for the exclusive benefit of the patient'' and ''conceal[ed]'' payments that created a potential conflict of interest.[3] Under the Oregon UTPA, a failure to disclose information and an affirmative representation of misinformation are equally actionable.[4]

Specifically, the Amended Complaints filed against the two cardiologists allege that the physicians received compensation from Biotronik to serve as physician-trainers for certain Biotronik employees and agents and permitted such individuals to be present in the operating room when the physicians implanted Biotronik devices, without notification to the patient and without seeking the patient's consent.[5] According to the Amended Complaints, ''[t]he Biotronik training program allows the company to train its sales representatives—and other employees involved in the manufacture, implantation, or monitoring of heart rhythm devices—about how to program and calibrate a device during an implant procedure, enabling a trainee to become 'certified' by the manufacturer on a particular device and to assist a physician at a later implant procedure.''[6]

Under the arrangements, the physicians were paid a fixed amount per training session, but the precise amount varied depending on the type of device implanted (*e.g.*, pacemaker, implantable cardioverter defibrillator, etc.).[7] In other words, the physicians would receive a payment from Biotronik each time they prescribed a Biotronik device and a Biotronik employee or agent was present for training.[8] In total, Dr. Turk performed 126 operations with a Biotronik representative present[9] and Dr. Fedor performed 257 operations with a Biotronik representative present.[10] According to the government's complaints, the physicians did not (i) inform any of the patients that their procedure would be a component of Biotronik's training program, (ii) inform any patients that a Biotronik trainee would be present during the procedure, or (iii) ask the patients whether they wished to participate in the program.[11] Further, the cardiologists both practiced at the same hospital, and the government alleged that the hospital was unaware that the physicians were being compensated for having trainees present and that such a practice was against the hospital's policies.[12]

In addition to the $25,000 settlement amount, the physicians also agreed to several nonmonetary conditions. First, the cardiologists agreed that any present or future websites they maintained must include a clear hyperlink to the publicly-available payment database that will be created pursuant to the federal Physician Payment Sunshine Act, 42 U.S.C. § 1320a-7h(c)(1)(C) (the ''Sunshine Act'').[13] Under the terms of the settlement, this hyperlink must be accompanied by text that plainly describes the information that patients can learn by accessing the hyperlink.

Second, the cardiologists are barred from receiving any consideration of any kind from any drug or device manufacturer for services provided to the manufacturer in connection with patient care, unless the cardiologists make clear to the patient the nature of their arrangement with such manufacturer, including that they will receive compensation from the manufacturer, and obtain prior written consent from the patient.[14]

Finally, the physicians are also barred from permitting an employee or agent of any medical device manufacturer who has not completed all of the applicable manufacturer's relevant training requirements to be present for a patient's procedure, unless the defendants clearly disclose this fact to the patient and obtain prior written consent from the patient for the employee or agent's participation.[15]

Broader Implications for State Enforcement

Although the legal theories underlying these settlements remain untested, the Oregon Attorney General's creative use of the Oregon UTPA establishes yet another example of state prosecutors' innovative approaches to utilizing theories of statutory and common law fraud to target healthcare fraud and abuse. While these settlements occurred in Oregon and were brought under the Oregon UTPA, there could be broader impli-

[3] *See* Amended Complaint, State of Oregon *ex rel.* Rosenblum v. Fedor, No. 12C21301, at ¶ 39 (Cir. Ct. Or. 2013) (hereinafter, ''Fedor Amended Complaint''); Amended Complaint, State of Oregon *ex rel.* Rosenblum v. Turk, No. 12C21302, at ¶ 36 (Cir. Ct. Or. 2013) (hereinafter, ''Turk Amended Complaint'').

[4] *See*, *e.g.*, Turk Amended Complaint, at ¶ 6.

[5] *See* Fedor Amended Complaint, at ¶ 15; Turk Amended Complaint, at ¶ 15.

[6] *See, e.g.*, Turk Amended Complaint, at ¶ 16.

[7] *Id*. at ¶ 18.

[8] *Id*. at ¶ 20.

[9] *Id*. at ¶ 19.

[10] Fedor Amended Complaint, at ¶ 22.

[11] Fedor Amended Complaint at ¶ 24; Turk Amended Complaint, at ¶ 21.

[12] Fedor Amended Complaint at ¶ 28; Turk Amended Complaint, at ¶ 25.

[13] Stipulated General Judgment, State of Oregon *ex rel.* Rosenblum v. Fedor, No. 12C21301, at ¶ 4 (Cir. Ct. Or. 2013) (hereinafter, ''Fedor Settlement Agreement''); Stipulated General Judgment, State of Oregon *ex rel.* Rosenblum v. Turk, No. 12C21302, at ¶ 4 (Cir. Ct. Or. 2013) (hereinafter, ''Turk Settlement Agreement'').

[14] Fedor Settlement Agreement, at ¶ 5(A); Turk Settlement Agreement, at ¶ 5(A).

[15] Fedor Settlement Agreement, at ¶ 5(B); Turk Settlement Agreement, at ¶ 5(B).

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cations, as almost every state has implemented consumer protection or unfair trade practices laws that could be used to target such practices by both physicians and manufacturers alike. Moreover, although such laws vary from state-to-state, some state consumer protection laws provide for a private right of action. Therefore, not only might such lawsuits be initiated by the government, but patients who can allege damages could also potentially bring claims against medical device manufacturers or others.

Settlements Suggest Disclosure Obligations Beyond Sunshine Act

On March 31, 2014, manufacturers, like Biotronik, will submit their first transparency reports to the Centers for Medicare and Medicare Services (''CMS''), pursuant to the Sunshine Act, which will reflect most payments such manufacturers make to U.S.–licensed physicians and teaching hospitals, including payments for consulting services like those provided by the Oregon cardiologists to Biotronik.

While information about payments received by physicians from pharmaceutical and device manufacturers, among others, will be reported by those manufacturers, the Sunshine Act does not prohibit financial relationships between physicians and industry. Moreover, the Sunshine Act does not impose any reporting or disclosure obligations on physicians. Notably, the AMA Code of Medical Ethics requires only that physicians disclose to patients the anticipated presence and roles of industry representatives during clinical encounters, and obtain patient approval.[16] Neither disclosure of the representative's specific identity nor a formal informed consent process are required.[17] Therefore, in effect, what Oregon enforcement officials have done in the lawsuits against Drs. Fedor and Turk is use a broad state consumer fraud statute to essentially impose additional disclosure requirements that go above and beyond existing law.

[16] *See* AMA Code of Ethics, Opinion 8.047.
[17] *Id*.

Considerations for Device Manufacturers

In light of these settlements, medical device manufacturers should consider taking proactive steps to ensure that their physician-consultants report compensation received from the manufacturer to the physician's hospital, pursuant to applicable hospital policies, as well as to their patients. This can be addressed by including a provision to this effect in the written agreement that governs the parties' relationship. Such a contractual provision could also require the physician-consultant to maintain written documentation reflecting the patient's consent. Undertaking such safeguards may mitigate the risk that the manufacturer will be accused of aiding or abetting a physician in concealing the financial arrangement.

Further, given that CMS will make the payment information reported by manufacturers pursuant to the Sunshine Act publicly available, beginning in 2014, and in light of CMS' acknowledgement that other government agencies may access assumptions documents and other materials submitted by the manufacturer as part of an audit or investigation into the manufacturer, device manufacturers may wish to consider taking proactive steps to mitigate their potential exposure. For example, manufacturers might analyze their payment trends prior to submission of their transparency reports to CMS to assess how such data may be perceived by the government and third parties when made available on the CMS public website and make adjustments to current practices on a prospective basis, as applicable. Manufacturers may also consider documenting their assumptions and any limitations on certification of their Sunshine Act transparency reports. Once the publicly-available payment database required under the Sunshine Act goes live, state prosecutors, among others, will undoubtedly canvass the database in search of actual or perceived fraud and abuse, and manufacturers will want to implement as many safeguards as possible to mitigate the risk that they will be targeted for investigation and enforcement.