ARNOLD & PORTER LLP

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FEDERAL APPEALS COURT AFFIRMS IMPOSITION OF CIVIL MONEY PENALTIES AGAINST DEVICE MANUFACTURER AND INDIVIDUAL CORPORATE OFFICER FOR FAILURE TO FILE MEDICAL DEVICE REPORTS

In *TMJ Implants, Inc. v. United States Department of Health & Human Services*,[1] the United States Court of Appeals for the Tenth Circuit addressed the standards for liability for civil monetary penalties (CMPs) for the failure to file medical device reports (MDRs), and affirmed the US Food and Drug Administration's (FDA) interpretation of the MDR regulations, which require medical device manufacturers, importers, and user facilities to submit device-related adverse event reports to FDA. The court held, in relevant part, that: (1) manufacturers need not confirm or believe that their device actually caused the adverse event to be required to submit an MDR; and (2) the responsible corporate officer liability standards of *United States v. Park*[2] apply to the imposition of CMPs against individuals for violations of the Federal Food, Drug, and Cosmetic Act (FDCA). The favorable ruling may signal a renewed focus on MDR requirements by FDA as well as increased use of CMPs as an enforcement tool.

BACKGROUND

TMJ Implants, Inc. (TMJI) manufactures and distributes temporomandibular joint (TMJ) implants. In 2003, FDA employees conducted an inspection of TMJI's facility and MDR files. FDA determined, based on that inspection, "that TMJI should have submitted MDRs for twenty-two events, each of which involved either a device explant (the device was surgically removed) or antibiotic treatment."[3] In 2004, FDA issued a Warning Letter to TMJI, addressed to Dr. Robert W. Christensen, TMJI's founder and president, instructing TMJI to submit written MDRs for the 22 events within 15 days, and further instructing TMJI to "take prompt action to correct these deviations." The letter also stated that failure to promptly correct these deviations

1 Arnold & Porter LLP counsel Vernessa Pollard handled the CMP action and appeal to the US Department of Health and Human Services Departmental Appeals Board on behalf of FDA during her tenure as Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel. This advisory is a summary and analysis of a decision that was issued after her departure from FDA, and does not represent or reflect the views of the Agency.

2 421 US 658 (1975) (holding that corporate officers and individuals in positions of authority and responsibility in a company can be held criminally liable for violations of the FDCA, even if those individuals were not "conscious of wrongdoing" and did not intentionally cause the violation).

3 *TMJ Implants, Inc. v. United States Department of Health & Human Services*, No. 08-9539 (10th Cir. Oct. 27, 2009), at 8.

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may result in regulatory action including seizure, injunction, or civil penalties, without further notice.[4]

TMJI maintained that it was not required to submit MDRs because in each case the devices were not explanted because of any problem with the device itself, but rather due to natural progression of the TMJ disease. Furthermore, they maintained that infections did not need to be reported because the devices are sterile when they leave the facility and therefore could not have caused any infection.[5] Dr. Christensen said that, based on his 30 years of experience with the devices, he believed it was reasonable to conclude that the devices themselves did not cause the symptoms that necessitated the explant.

RELEVANT LAW

The FDCA authorizes FDA to require medical device manufacturers[6] to file an MDR "whenever the manufacturer… receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices *may have caused or contributed* to a death or serious injury…."[7] "Serious injury" is defined as one that "is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, *or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure*."[8]

The implementing regulations define the phrase "caused or contributed" to mean a "serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a…serious injury…."[9] The regulations also provide that a manufacturer is *not* required to submit an MDR when it has "information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a…serious injury…."[10] Thus, while a manufacturer need not submit an MDR if a qualified person rules out the device as a factor in the need for medical or surgical intervention to prevent permanent bodily harm, in the preamble to its implementing regulations FDA clarified that "[n]owhere in…the [FDCA] or its legislative history is FDA's authority limited to requiring only information about reportable events that have been confirmed by the manufacturer or importer of the device."[11]

The FDCA also provides for the imposition of CMPs against "any person who violates a requirement of this Act which relates to devices," if such violation was "a significant or knowing departure from such requirements, or [] a risk to public health."[12] *United States v. Park* allows the imposition of criminal penalties against a responsible corporate officer regardless of whether that individual knew of the violation.

CMP ACTION

In July 2005, FDA filed a complaint for CMPs against TMJI, Dr. Christensen, and Maureen Mooney, TMJI's Regulatory Affairs and Quality Assurance Manager, after concluding that they had knowingly failed to submit 17 MDRs relating to TMJI's implants. An administrative law judge (ALJ) determined that TMJI, Dr. Christensen, and Ms. Mooney had knowingly failed to submit each of the 17 MDRs and were each liable for penalties of US$170,000. The Department of Health and Human Services (HHS) Departmental Appeals Board (DAB), which handles appeals of administrative decisions from HHS agencies, affirmed the decision of the ALJ as to TMJI and Dr. Christensen, but overruled the finding of liability as to Ms. Mooney. The DAB concluded that Ms. Mooney was not responsible for the violations because it found that she lacked the authority to make the ultimate decision whether to submit the MDRs in question.

TMJI and Dr. Christensen petitioned the Tenth Circuit for review of the DAB decision contending, in relevant part, that: (1) they were not required to submit MDRs because Dr. Christensen reasonably concluded that the devices

4 Warning Letter from FDA, Southwest Region, Denver District Office, to Dr. Robert W. Christensen, President/CEO, TMJ Implants, Inc. (Feb. 24, 2004).

5 *TMJ Implants, Inc.*, at 10.

6 The MDR requirements also apply to importers, distributors, and user facilities such as ambulatory surgical facilities and hospitals. *See* 21 C.F.R. § 803.1(a).

7 21 U.S.C. § 360i(a)(1)(A) (emphasis added).

8 21 U.S.C. § 360i(a)(2) (emphasis added).

9 21 C.F.R. § 803.3.

10 21 C.F.R. § 803.20(c)(2).

11 49 Fed. Reg. 36326, 36338 (Aug. 27, 1984).

12 21 U.S.C. § 333(f)(1).

did not cause or contribute to a serious injury; (2) if they were required to submit MDRs, their failure to do so was not knowing; and (3) CMPs cannot be assessed against Dr. Christensen because he is an individual and not the manufacturer of the implants.

The Tenth Circuit affirmed the DAB, concluding that:

- Adverse events that meet the definition of a "serious injury" must be reported, even if they are deemed to be "clinically insignificant" or otherwise known to be associated with the use of a device. Specifically, the court noted that "[a]lthough some of these consequences may be deemed clinically insignificant, they are considered to be serious injuries when coupled with the interventions, e.g., administration of antibiotics or other medications, explant, reconstruction, debridement, or revision surgery."[13]
- Manufacturers must submit MDRs even if the device was not the "cause in fact" of the reported injury. In affirming FDA's interpretation of "caused or contributed," the court noted that "FDA set out a reasonable explanation… for reading the statute as justifying broad collection of information about adverse events associated with medical devices in order to discern patterns and surface possible concerns not only with design and manufacture of devices but also with their use and performance in practice and under various circumstances."[14]
- Manufacturers must submit MDRs for adverse events that describe serious injuries even if "they do not feel that they have all of the information they need to confirm that their device caused a serious injury."[15]
- Individuals as well as manufacturers may be subject to CMPs under the responsible corporate officer theory of *United States v. Park*.[16] The court stated that "[t]he fact that a corporate officer could be subjected to criminal punishment upon a showing of a responsible relationship to the acts of a corporation that violate health and safety statutes renders civil liability appropriate as well."[17]

Although the court found that both TMJI and Dr. Christensen committed "knowing" violations, the court's discussion of the application of the *Park* doctrine to CMP actions may spur both renewed focus on MDR compliance and increased use of CMPs as an enforcement tool to address these and other violations of the FDCA, including against responsible corporate officers.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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13 *TMJ Implants, Inc.*, at 19 (quoting the DAB opinion).

14 *Id.*, at 19-20.

15 *Id.*, at 21.

16 The responsible corporate officer doctrine dates back to *United States v. Dotterweich*, 320 U.S. 277 (1943), in which the U.S. Supreme Court held that the FDCA is a strict liability statute and that responsible individuals in positions of authority can be held vicariously and criminally liable for violations of the FDCA. In *Park*, the court relied on *Dotterweich* in concluding that "the [FDCA] imposes [upon responsible corporate officers] not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *Park*, 421 U.S. at 672.

17 *TMJ Implants, Inc.*, at 23 (quoting *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 561 (6th Cir. 1985) (affirming imposition of CMPs against individuals for violations of the Radiation Control for Health and Safety Act of 1968)).