

# ENFORCEMENT CORNER



## The Pursuit of Civil Money Penalties — An Important Weapon in FDA’s Enforcement Arsenal

by John R. Fleder

**T**he Food and Drug Administration (FDA) has a variety of weapons in its enforcement arsenal, including seizures, injunctions, criminal prosecutions, and civil money penalties. On July 6, 2007, FDA reminded regulated industry that it still uses the latter, civil money penalties, when Administrative Law Judge (ALJ) Daniel Davidson found TMJ Implants Inc. and two employees, President Robert Christensen, and Regulatory Affairs and Quality Assurance Manager Maureen Mooney (collectively, TMJI), liable for civil money penalties for failing to submit Medical Device Reports (MDRs).<sup>1</sup> The decision is the latest milestone in a five-year old dispute that centers on TMJI’s interpretation of FDA’s device adverse event reporting requirements as they relate to TMJI’s temporomandibular joint (TMJ) implants and accessories.

### FDA’s Civil Penalty Authority

Congress granted FDA the authority to pursue civil money penalties for medical devices in the Safe Medical Devices Act of 1990 (SMDA).<sup>2</sup> Under SMDA, the provision relevant to the TMJI matter, FDA must grant a respondent the opportunity for a hearing before a civil money penalty may be imposed.<sup>3</sup> In addition, FDA may seek no more than \$15,000 per violation, with a maximum of \$1,000,000 for all violations adjudicated in a single proceeding.<sup>4</sup> For MDR or Good Manufacturing Practice (GMP) matters, only those violations that constitute a “significant or knowing departure from such requirements” or a “risk to public health” can be subject to civil penalties.<sup>5</sup>

FDA can also seek civil penalties for other statutory violations. These include practices involving prescription drug marketing, pesticide residues, generic drugs, electronic products, biologic recall orders, mammography products and vaccines.<sup>6</sup>

In 1995, FDA issued regulations outlining the procedures for the agency’s imposition of a civil money penalty.<sup>7</sup> FDA’s regulations outline how the agency may pursue and assess civil money penalties administratively. FDA may seek civil penalties (under some statutes) by initiating an administrative proceeding, whereby FDA is the prosecutor, judge and jury concerning the imposition of civil penalties.

In general, the matter is commenced with the filing of a complaint, followed by an answer by the defendant (respondent). The parties are allowed to seek discovery from each other, file motions, and ultimately participate in a hearing before an ALJ to resolve disputed factual issues. After completion of the hearing, the ALJ renders an Initial Decision that determines if FDA proved the allegations in the Complaint, if civil penalties should be assessed, and the amount thereof. The “losing” party can then appeal the decision to the FDA Commissioner.

Alternatively, FDA (through the Department of Justice), may seek civil penalties by filing a civil suit in a federal district court. This procedure is followed when the applicable civil penalty statute does not authorize FDA to impose the penalties through an administrative proceeding.<sup>8</sup>

In 1999, FDA issued a draft guidance document, which contains a decision tree to assist FDA personnel in determining whether to pursue a civil money penalty case.<sup>9</sup> The decision tree suggests considering, *inter alia*, the suitability of other regulatory enforcement options, prior warnings and the clarity of the FDA policy at issue.<sup>10</sup>

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## A Battle Fought on Several Fronts

FDA discovered the 21 adverse events at issue in the TMJ Implants case during an inspection in 2003. The agency issued a Warning Letter in February 2004, requiring the submission of the events as MDRs. An extensive letter exchange between the Center for Devices and Radiological Health (CDRH) and TMJI ensued, as TMJI sought clarification of FDA's basis for requiring the MDRs. Then, in November 2004, TMJI filed an appeal with the FDA Commissioner regarding its dispute with CDRH over the MDRs.

In July 2005—before the Commissioner rendered a decision on the appeal—CDRH filed an administrative complaint against TMJI. This led to an extensive prehearing battle between CDRH and TMJI. TMJI argued that TMJI's qualified medical personnel determined that the events did not cause or contribute to a serious injury and were not, therefore, required to be reported under the “reasonable-ness” standard in 21 C.F.R. Part 803.<sup>11</sup> Judge Davidson, the ALJ assigned to the case, disagreed, finding that any event that falls under the definition of a “serious injury” must be submitted as an MDR. Judge Davidson also concluded that TMJI's actions constituted “knowing and significant violations,” justifying the imposition of civil money penalties.

Judge Davidson also rejected TMJI's argument that civil money penalties were not appropriate in part because TMJI had made “good faith” attempts to comply with the MDR regulation and to use the administrative process to appeal CDRH's decisions. Instead, Judge Davidson concluded that, because FDA notified TMJI several times that the agency did not accept TMJI's interpretation of the MDR regulation and because the evidence indicated that the events met the MDR requirements, civil money penalties were appropriate.

Also, Judge Davidson dismissed TMJI's concern that filing “unnecessary” MDRs would have financial and legal repercussions, noting simply that the regulation states that submitting an MDR does not constitute an admission that a device caused an injury.

In his Initial Decision, Judge Davidson ordered TMJI to submit information regarding its ability to pay the civil money penalties, and he provided CDRH the opportunity to respond. The parties have done so and a final order is expected soon. At that point, TMJI will need to decide whether to appeal the decision administratively under 21 C.F.R. § 17.47. If TMJI decides not to so appeal, they may

forgo the option of later appealing Judge Davidson's decision to a federal appeals court.<sup>12</sup>

Although FDA does not pursue civil money penalties often,<sup>13</sup> the *TMJ Implants* case reminds regulated industry that the authority still exists in FDA's weapons cache. ▲

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- 1 FDA initially asserted that there were twenty-one violations and sought \$210,000 in civil money penalties from each party for a total of \$630,000 (\$10,000 per violation per party). Administrative Complaint for Civil Money Penalties, In re TMJ Implants, Inc., No. 2005H-0271 (FDA July 14, 2005). After discovery, FDA decided to seek penalties for only seventeen events, Initial Decision at 1, In re TMJ Implants, Inc., No. 2005H-0271 (FDA Jul. 6, 2007), and reduced the penalty it was seeking to \$170,000 per party for a total of \$510,000, Complainant's Brief on Penalty Amounts, In re TMJ Implants, Inc., No. 2005H-0271 (FDA Sept. 7, 2007).
- 2 21 U.S.C. § 333(g).
- 3 21 U.S.C. § 333(g)(3)(A); *see also* 21 C.F.R. § 17.9(a) (providing the opportunity to request a hearing in the answer to a complaint).
- 4 21 U.S.C. § 333(g)(1)(A). These numbers are adjusted periodically. Currently, the limits are \$16,500 per violation with a combined total of \$1,100,000. 21 C.F.R. § 17.2.
- 5 21 U.S.C. § 333(g)(1)(B)(i).
- 6 *See* Prescription Drug Marketing Act of 1987, 21 U.S.C. § 333(b)(2), (3); Food Quality Protection Act of 1996, 21 U.S.C. § 333(g)(2); Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335b; Radiation Control for Health and Safety Act of 1968, 21 U.S.C. § 360pp(b)(1); Public Health Service Act, 42 U.S.C. § 262(d)(2), Mammography Quality Standards Act of 1992 and Mammography Quality Standards Reauthorization Act of 1998, 42 U.S.C. § 263b(h)(3); and National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-28(b)(1).
- 7 60 Fed. Reg. 38,612 (Jul. 27, 1995) (21 C.F.R. Part 17).
- 8 For example, the Radiation Control for Health and Safety Act of 1968, specifically requires that a civil penalty action be filed in federal court. 21 C.F.R. § 17.1 lists the statutes that authorize FDA to impose civil penalties through an administrative proceeding. Section 17.2 identifies all the statutes administered by FDA that allow for the agency to seek penalties.
- 9 CDRH, FDA, *Draft Guidance for FDA Staff: Civil Money Penalty Policy*, “Safe Medical Devices Act Civil Money Penalty Decision Tree” (Jun. 8, 1999).
- 10 *Id.* at 2.
- 11 21 C.F.R. § 803.20(c)(2) (An event need not be reported “if you have 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 death or serious injury....”).
- 12 *See* 21 C.F.R. § 17.51(c). FDA takes the position that “[e]xhaustion of an appeal to the entity deciding the appeal...is a jurisdictional prerequisite to judicial review.” The SMDA provides for judicial review in a federal appeals court of “an order assessing a civil penalty.” 21 U.S.C. § 333(g)(4).
- 13 Some examples of FDA civil penalty actions in the last ten years include: In re Ecumed Health Group, No. 2004H-0322 (FDA 2004); In re LaHaye Center for Advanced Eye Care of Lafayette d/b/a LaHaye Total Eye Care, No. 2002H-0443 (FDA 2002); In re First Check Home Drug Test Devices, No. 2001H-0065 (FDA 2001); In re LaserVision Ctrs., Inc., No. 2000H-1242 (FDA 2000); In re Cmty. Med. Imaging Inc., 1997H-0379 (FDA 1997).