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Tenth Circuit

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UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

TMJ IMPLANTS, INC.; ROBERT W. CHRISTENSEN, Petitioners, v. UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Respondent.	No. 08-9539

PETITION FOR REVIEW FROM THE DEPARTMENTAL APPEALS BOARD OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
App. Div. Docket No. A-08-10
Decision No. 2163

Lynn M. Watwood, Jr., Counsel, TMJ Implants, Inc., Golden, Colorado, appearing for Petitioners.

Peter R. Maier, Attorney, Appellate Staff, Civil Division, United States Department of Justice, Washington, D.C. (Gregory G. Katsas, Assistant Attorney General, and Douglas N. Letter, Attorney, Appellate Staff, Civil Division, United States Department of Justice, Washington, D.C.; Thomas R. Barker, Acting General Counsel, Gerald F. Masoudi, Chief Counsel, Food and Drug Division, Eric M. Blumberg, Deputy Chief Counsel, and Michele Svonkin, Attorney, Food and Drug Administration, Rockville, Maryland, with him on the brief), appearing for Respondent.

Before **TACHA**, **EBEL**, and **HARTZ**, Circuit Judges.

TACHA, Circuit Judge.

TMJ Implants, Inc. ("TMJI") manufactures and distributes temporomandibular joint ("TMJ") implants. Dr. Robert W. Christensen is TMJI's founder and president. In July 2005, the Food and Drug Administration ("FDA") filed a complaint for money penalties ("CMP") against TMJI and Dr. Christensen (collectively, "petitioners") after concluding that they had knowingly failed to submit seventeen medical device reports ("MDRs") relating to TMJI's implants. That action culminated administratively in a Final Decision by the Departmental Appeals Board ("DAB") within FDA's parent agency, the Department of Health and Human Services. The Final Decision affirmed determinations by an administrative law judge ("ALJ") that petitioners had knowingly failed to submit each of the seventeen MDRs and that petitioners were each liable for penalties of $170,000 ($10,000 per violation).

TMJI and Dr. Christensen now petition this court for judicial review of the DAB's Final Decision. *See* 21 U.S.C. § 333(f)(6) (allowing appeals of the assessment of civil penalties directly to circuit courts). They contend that: (1) the CMP was premature; (2) they were not required to submit MDRs because Dr. Christensen reasonably concluded that the devices did not cause or contribute to a serious injury; (3) if petitioners were required to submit any MDRs, their failure to do so was not knowing; (4) monetary penalties cannot be assessed against Dr.

Christensen because he is an individual, not the manufacturer of the implants; and (5) the amount of the monetary penalties is unwarranted. We AFFIRM.

I. BACKGROUND

The TMJs are located slightly in front of the ears and form the interface between the lower jaw and the bottom of the skull. They are critical to several functions of daily life, such as speaking, eating, swallowing, and breathing. When the TMJs do not function properly, a variety of conditions or symptoms may develop. Common symptoms of TMJ disfunction include reduced ability or inability to open or close the jaw, pain, swelling, ankylosis (fusion of the joint bones), infections, chronic sinus pain, hearing loss, and chronic ear pain. When necessary, a medical provider may surgically remove one or both of the TMJs and replace them with prosthetic joint implants such as those manufactured and marketed by TMJI.

A. The Statutory and Regulatory System for Medical Device Reporting

TMJ implants are medical devices within the meaning of 21 U.S.C. § 321(h). Through the Federal Food, Drug and Cosmetic Act, Congress empowered FDA to require every manufacturer of a medical device to "establish and maintain such records, make such reports, and provide such information as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." 21 U.S.C. § 360i(a). Pursuant to this broad delegation of

authority, Congress created an expansive reporting system under which FDA must require that every "device manufacturer. . . [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." *Id*. § 360i(a)(1)(A). Congress clarified what types of events must be reported to FDA by defining a "serious injury" 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." *Id*. § 360i(a)(2)(A)–(C).

FDA has explained the purpose of the reporting requirement and its broad scope:

> To carry out its responsibilities, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information about device problems. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with a device and take whatever action is necessary to reduce or eliminate the public's exposure to this risk.

49 Fed. Reg. 36,326, 36,326 (Aug. 27, 1984). In response to public comments expressing concern that broad reporting requirements may impose unduly onerous burdens on medical device manufacturers, FDA reiterated the need for an expansive reporting system and adopted regulations that require manufacturers to file an MDR if they become aware of information suggesting that a device *may*

have caused or contributed to a death or serious injury rather than the more limited language proposed that would have required manufacturers to file an MDR only in cases where they receive information suggesting that a device *has* caused or contributed to a death or serious injury. *Id*. at 36,331. FDA explained that the broader language was necessary "because the agency needs to learn of instances in which there may be an association, as well as a causal connection, between the use of a device and a death or serious injury." *Id.*

The implementing regulations to § 360i adopt the statutory definition of "serious injury" and define its crucial term "permanent" as "irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage." 21 C.F.R. § 803.3. The implementing regulations also define the phrase "caused or contributed":

> Caused or contributed means that 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, including events occurring as a result of:
>
> (1) Failure;
> (2) Malfunction;
> (3) Improper or inadequate design;
> (4) Manufacture;
> (5) Labeling; or
> (6) User error.
>
> [User] means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility . . . .

Id.

Thus, focusing on the terms most relevant to this case, FDA mandates the filing of an MDR whenever the manufacturer of a medical device is aware of information that reasonably suggests its device (or an error on the part of the practitioner who or facility that implants or services the device) may have been a factor in the need to medically or surgically intervene in a particular individual's case, so long as the intervention is necessary to prevent irreversible, nontrivial impairment of a body function or irreversible, nontrivial damage to a body structure.

The implementing regulations also describe when a manufacturer is *not* obligated to submit an MDR: when the manufacturer "ha[s] 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." 21 C.F.R. § 803.20(c)(2). Put another way, if a qualified person rules out the device (or an error on the part of the practitioner who implants the device) as a factor in the need for medical or surgical intervention to prevent permanent harm to the body, and this conclusion is reasonable, then the manufacturer need not file an MDR. Particularly relevant to this case, however, is FDA's explanation that "[n]owhere in . . . the act 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." 49 Fed. Reg. at 36,338.

The submission of an MDR is not an admission that the device caused or

contributed to the serious injury and a manufacturer may deny that its device caused the injury in their MDR. 21 C.F.R. § 803.16. Indeed, the standard form for the submission of an MDR includes a disclaimer to that effect.

As part of this expansive reporting system, device manufacturers commonly receive information about their devices through FDA's MedWatch program. Under that program, any person may voluntarily report to FDA an adverse event or problem with a medical device. The voluntary MedWatch report form asks for the patient's name, a description of the event or problem, the name and manufacturer of the suspect device, and the name of the reporter. After FDA receives the report, the agency forwards it to the manufacturer identified on the report. If the reporter requests anonymity, however, regulations require FDA to redact any identifying information of the reporter before forwarding the report to the manufacturer. *See id.* § 20.63(f) (prohibiting FDA from disclosing any identifying information of a voluntary reporter).

A manufacturer is responsible for investigating events described in MedWatch forms to evaluate the cause of the event and whether to submit an MDR for it. *Id*. § 803.50(b)(3). A manufacturer is not absolved of this duty when a MedWatch report contains incomplete or redacted information; in those circumstances, the manufacturer is required to file an incomplete report explaining why the report is incomplete and what steps the manufacturer has taken to obtain the relevant information. *Id.* Ultimately, the manufacturer is

responsible for obtaining the relevant information to aid in its investigation and is required to supplement its report once it obtains such information. *Id*. § 803.50(b)(2), (3). Manufacturers must also maintain MDR event files that contain information regarding adverse events purportedly associated with their devices, including all documentation of the manufacturer's decisionmaking process used to determine whether the particular event is reportable. *Id*. § 803.18(b)(1)(i). Finally, manufacturers must permit FDA to access, copy, and verify its MDR files. *Id*. § 803.18(b)(2).

Under 21 U.S.C. § 333(f)(1)(A), "any person who violates [the MDR reporting requirements] shall be liable to the United States for a civil penalty." The penalty may not exceed $16,500 for each violation. 21 C.F.R. § 17.2. Liability for civil penalties requires proof that the violation was either a significant or knowing departure from the law, or that the violation posed a risk to public health. 21 U.S.C. § 333(f)(1)(B)(i).

B. The Events Giving Rise to the Imposition of Money Penalties Against Petitioners

FDA employees conducted an inspection of TMJI's facility and MDR files from July 29, 2003 to August 11, 2003. As a result of that inspection, FDA determined 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. According to information received by petitioners, these

surgical and medical interventions were performed due to, among other things, apparent infections, loose screws, swelling, pain, bone growth, decreased mobility of the jaw, headaches, seizures, inflamed tissue, vertigo, and foreign body reaction occurring after a TMJ had been implanted in the patient. FDA informed petitioners in a February 24, 2004 Warning Letter to Dr. Christensen that written MDRs must be submitted for the twenty-two events within fifteen days. The Warning Letter further notified petitioners that "[y]ou should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties."

Petitioners did not submit MDRs for these events. Instead, on March 4, Dr. Christensen wrote to FDA to express petitioners' "substantial disagreement with the FDA's position." Christensen requested a meeting with FDA personnel "to arrive at a proper decision with respect to what, if any, actions are required of the company in this matter." Dr. Christensen further expressed his view that FDA may be using Warning Letters to retaliate against TMJI.

Dr. Christensen and three colleagues met with FDA representatives at FDA's District Office in Lakewood, Colorado on March 10, 2004. The meeting can be summarized as follows: Dr. Christensen contended that in each of the disputed events TMJI's devices were not explanted because of any inherent problem with the device itself; rather, natural progression of the TMJ disease

necessitated removal of the device. For example, Dr. Christensen explained that bone growth may occur after a TMJI device is implanted, but that in such a case, "[t]he device didn't go bad[,] it just meant that the disease continued despite what we did and now we've got to go in and maybe build a bigger one or take out more bone or get rid of adhesions or something else." Petitioners' position was that pain, swelling, and loose screws are not serious injuries because they are temporary and are not unexpected following placement of the device; infections did not need to be reported because the devices are sterile when they leave the manufacturer's facility and therefore could not have caused any infection. Dr. Christensen explained that his thirty years of experience with the devices made it reasonable to conclude that the devices themselves did not cause the symptoms that necessitated the explant. Dr. Christensen and his colleagues also expressed concern that filing MDRs would expose TMJI to civil lawsuits and provide their competitors with an unfair advantage. They further contended that they could not conclusively determine that their devices were even associated with certain events, since the only information they had about those events came from voluntary MedWatch forms that did not contain sufficient information to conduct an investigation of the events.

FDA personnel disagreed with petitioners' position. The agency explained that the definition of serious injury is one that requires medical intervention to prevent a permanent impairment. Thus, while pain and loose screws may not be

serious injuries in and of themselves, the failure to medically intervene to treat those conditions could lead to permanent impairment of the TMJ or jaw function. According to FDA, the relevant regulations require TMJI to report all explants and medical interventions when TMJI's devices *may have* been a contributing factor in the need for such interventions, and that if TMJI did not have sufficient information to rule out its device as a potential cause of the interventions then it must report them. FDA made clear that submitting an MDR did not constitute an admission from TMJI that its devices contributed to any injury, and the agency suggested that TMJI articulate a response to the warning letter that addressed each one of the events and why petitioners did not consider them to be reportable.

Thereafter, petitioners initiated a series of phone calls and letters to FDA. The communications, which included petitioners' written position on each of the twenty-two events, continued to express petitioners' views that filing MDRs would subject them to liability; disease progression was the reason for each device explant or medical treatment; FDA's interpretation of § 360i was overly broad; petitioners could not determine whether TMJI's devices were involved in many events; and FDA was not as experienced as Dr. Christensen and thus incorrectly determined that TMJI devices may have caused or contributed to the reported events. Petitioners sought another face-to-face meeting with FDA.

In its letters in response, FDA adhered to its position as articulated during the March meeting. On July 14, the agency emphasized the statutory and

regulatory language requiring MDRs whenever a manufacturer has information reasonably suggesting that its device "may have caused or contributed [to]" a serious injury. FDA concluded: "For the reasons discussed in this letter, the events identified in the Warning Letter are reportable under the MDR regulation. Because these reports are already past due under the MDR regulation, we expect these reports within thirty days of the date of your receipt of this letter."

Petitioners did not submit the twenty-two MDRs. Instead, they continued to send letters to FDA, pressing for a more comprehensive definition of "serious injury" and noting that petitioners were undertaking another review of the twenty-two events identified in the Warning Letter. Petitioners also continued to request another meeting with FDA to further discuss their concerns. On August 12, petitioners determined that user error was involved in five of the twenty-two events and filed MDRs for those five events.

In a September 7 letter, the director of FDA's Center for Devices and Radiological Health ("CDRH") reiterated FDA's position that petitioners' construction of the MDR reporting requirements was too constrained. The letter explained that "[b]ecause of their unique knowledge about their devices, manufacturers often look for a direct causal link between the device and the adverse event, overlooking the possibility that the device 'may have contributed' to a reportable event [as articulated in 21 U.S.C. § 360i(a)(1)(A)]." FDA reminded petitioners that the "remaining . . . serious injury reports should have

been submitted to FDA by 30 days from the date of your receipt of our July 14, 2004 letter. . . . Please submit all outstanding MDR reports within the next 15 working days." The letter concluded:

> FDA's regulations provide avenues for individuals to appeal decisions within the agency. In particular, individuals may appeal the decision of an FDA employee to the employee's supervisor under 21 CFR Part 10.75, Internal agency review of decisions. Under this regulation, the proper avenue of appeal of the Center for Devices and Radiological Health's decision that you are required to submit the . . . additional MDR reports identified in the February 24, 2004, Warning Letter, as well as any other additional reports concerning other adverse events that meet the requirements of 21 CFR Part 803 – MDR regulation, is to the Commissioner of the Food and Drug Administration.

After petitioners again refused to submit additional MDRs and instead reiterated their explanations as to why each event was not reportable, CDRH responded on November 10 with an offer to treat the explanations as MDRs in full satisfaction of petitioners' statutory and regulatory obligations. CDRH further explained that the agency had expended significant resources responding to petitioners' correspondence and that they had exhausted their appellate rights at that level of the agency. Finally, CDRH again explained petitioners' appellate rights:

> As stated in [the] letter of September 7, 2004, FDA's regulations provide avenues for individuals to appeal decisions within the agency. In particular, individuals may appeal the decision of an FDA employee to the employee's supervisor under 21 Code of Federal Regulations (CFDR) part 10.75, internal agency review of decisions. Under this regulation, the proper avenue of appeal of CDRH's decision that you are required to submit the . . . additional MDR

> reports identified in the February 24, 2004, Warning Letter as well as any other reports concerning adverse events that meet the requirements of 21 CFR Part 803 – MDR regulation, is to the Commissioner of the Food and Drug Administration. Accordingly, any further correspondence from TMJ Implants, Inc. to CDRH contesting the reportability of the MDR events listed in our February 24, 2004, Warning Letter will be considered an appeal and forwarded to the Commissioner. *You should be aware that pendency of such an appeal does not preclude the Agency from taking action to enforce the requirements of the Food, Drug, and Cosmetic Act. See* 21 C.F.R. § 10.35(d).

(Emphasis added.)

On November 16, petitioners refused FDA's offer to consider their explanations as MDRs and requested internal agency review under 21 C.F.R. § 10.75. On July 14, 2005, CDRH filed a CMP against petitioners based on their failure to submit MDRs for the remaining seventeen events identified in the February 2004 Warning Letter.[1] One week later, FDA denied petitioners' request for agency review under 21 C.F.R. § 10.75. The agency reasoned that because the issues were now the subject of a CMP and would be fully developed and determined by a neutral ALJ, it would be inefficient and duplicative for FDA simultaneously to review the matter at that point.

Petitioners and FDA conducted extensive discovery and submitted comprehensive briefs in the CMP action. The ALJ held an evidentiary hearing and ultimately issued an Initial Decision against petitioners on July 6, 2007. In

[1]The CMP also named another TMJI employee. She was ultimately dismissed from the administrative enforcement action, and her role at TMJI is not relevant to the issues in this appeal.

its Final Order of September 25, 2007, the ALJ imposed sanctions in the amount of $170,000 on both TMJI and Dr. Christensen individually. Petitioners appealed to the DAB, *see* 21 C.F.R. § 17.47, which affirmed the ALJ's decision and order against them. Petitioners now petition for judicial review in this court.

II. ANALYSIS

A. Jurisdiction and Standard of Review

"The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved." 21 C.F.R. § 17.51. Under 21 U.S.C. § 333(f)(6), petitioners may petition for judicial review directly in this court.

"Under the APA, we may set aside agency action only if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *St. Mark's Charities Liquidating Trust v. Shalala*, 141 F.3d 978, 980 (10th Cir. 1998) (quoting 5 U.S.C. § 706(2)(A)). An agency's factual findings must be "supported by 'substantial evidence' in the administrative record." *Pennaco Energy, Inc. v. U.S. Dep't of the Interior*, 377 F.3d 1147, 1156 (10th Cir. 2004); *see also Newton v. F.A.A.*, 457 F.3d 1133, 1136 (10th Cir. 2006). In this context, "substantial evidence" is "something more than a mere scintilla but something less than the weight of the evidence." *Pennaco Energy, Inc.*, 377 F.3d at 1156 (quotations and citations omitted). It is "such relevant evidence as a reasonable

mind might accept as adequate to support a conclusion." *Id.* (quotations and citations omitted). Finally, to the extent the agency action hinges on the agency's interpretation of its own regulations, such interpretation is generally given deference. *See Newton*, 457 F.3d at 1137 (10th Cir. 2006) (discussing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

B. The DAB's Determination that the CMP Was Not Premature Was Reasonable

Petitioners first argue that the law did not permit FDA to initiate CMP proceedings before the agency had ruled on their request for internal agency review under 21 C.F.R. § 10.75(c). Petitioners contend that serving them with the CMP in these circumstances deprived them of due process and constituted a breach of contract. In the alternative, they maintain that FDA should have been estopped from filing the CMP.

The DAB's contrary interpretation of the applicable law was not erroneous. 21 C.F.R. § 10.35(d) states:

> no[] action taken by an interested person in accordance with any other administrative procedure in this part [i.e., part 10] or in any other section of this chapter, e.g., the filing of a citizen petition under § 10.30 or a petition for reconsideration under § 10.33 or a request for an advisory opinion under § 10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind . . . .

As noted, petitioners sought administrative review pursuant to part 10 of title 21 of the Code of Federal Regulations. *See* 21 C.F.R. § 10.75(c). Therefore,

petitioners argument that the CMP was premature is belied by the language of 21 C.F.R. § 10.35(d). That language, when applied to the facts of this case, provides that the commencement of petitioners' review proceedings did not preclude FDA from filing a CMP to enforce the provisions of 21 U.S.C. § 360i(a)(1)(A), even though those proceedings had not yet culminated in a decision from the Commissioner.[2] Simply put, whether or not the Commissioner had made a final decision regarding petitioners' review request at the time the CMP was filed was irrelevant to FDA's authority to file the CMP at that time. Therefore, the DAB's similar interpretation of FDA's authority under 21 C.F.R. § 10.35(d) was reasonable.

Furthermore, as the DAB recognized, petitioners participated in a hearing before the ALJ in which they were afforded the opportunity to present their positions regarding whether they were required to file the MDRs at issue and whether monetary penalties were appropriate. That hearing certainly provided the due process to which petitioners are entitled. *See Mathews v. Eldridge*, 424 U.S. 319, 334 (1976) (finding "[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner'")

[2]21 C.F.R. § 10.35(d) contains three exceptions to the general rule that an administrative appeal will not stay or delay enforcement action. None apply in this case, and petitioners do not contend otherwise. *See* 21 C.F.R. § 10.35(d)(1)–(3) (enforcement action will be stayed or delayed if the Commissioner determines that it is in the public interest and orders the stay, a statute requires a stay, or a court orders a stay).

(quotations omitted). Therefore, petitioners' argument that they were denied due process is without merit.

Petitioners' additional contentions also lack merit. Petitioners point to CDRH's statement in its November 10 letter that the proper avenue of appeal was to the Commissioner, and that any further correspondence from petitioners to CDRH would be considered an appeal and forwarded to the Commissioner. According to petitioners, this constituted an agreement not to initiate CMP proceedings until the Commissioner had decided petitioners' review request. The same letter, however, cited § 10.35(d) and explicitly informed petitioners that "[y]ou should be aware that pendency of such an appeal [under 21 C.F.R. § 10.75] does not preclude the Agency from taking action to enforce the requirements of the Food, Drug, and Cosmetic Act." Contrary to petitioners' position, the agency never represented otherwise. Accordingly, this communication did not bind FDA in contract or equity to stay any enforcement action until the Commissioner made a final decision regarding petitioners' review request.

C. The DAB Did Not Err in Determining that TMJI Must Submit MDRs for the Seventeen Events Identified in the CMP.

Petitioners contend that the events at issue do not represent serious injuries under 21 U.S.C. § 360i(a)(1)(A). They argue that the physical conditions preceding the device explant or medical treatment—such as pain, swelling, bone

growth, and infection—are relatively trivial and are to be expected following the surgical implant of any medical device.

Again, the DAB's contrary interpretation of the applicable law was reasonable. Indeed, petitioners misread the applicable regulation, which does not define "serious injury" in terms of physical significance. Instead, a "serious injury" is a condition that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 C.F.R. § 803.3. In each of the seventeen events at issue, a physician surgically explanted the device or otherwise medically treated the patient as a result of the aforementioned physical conditions—conditions which, if left untreated, could permanently impair the TMJ function. Accordingly, the DAB's decision in accordance with FDA's position 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" was reasonable.

The DAB's expansive construction of the causation element is also reasonable. 21 C.F.R. § 803.3 states: "Caused or contributed means that a death or 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 death or serious injury." As the DAB explained: "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."

Moreover, the DAB's determination that MDRs were required for the seventeen events at issue is supported by the evidence in the record. This evidence includes: (1) MedWatch reports describing the device and the patients' symptoms following the implantation of the device; (2) information received from petitioners' investigations; and (3) testimony from two FDA expert witnesses stating that the physical conditions constitute serious injuries to which TMJI devices may have caused or contributed. The same evidence amply supports the DAB's rejection of petitioners' claim that Dr. Christensen reasonably concluded that TMJI's devices did not cause or contribute to serious injuries.

Finally, the DAB properly rejected petitioners' claim that they should not be required to submit MDRs for events reported on voluntary MedWatch forms because they could not conclusively determine whether their devices were involved in those events. Petitioners contend that redacting the name of the patient, the name of the reporter, the date of the implant, and the date of the event makes it impossible to conduct an investigation about the event. As noted, neither the statute nor its implementing regulations limit FDA's authority to require MDRs to events that are confirmed by the manufacturer. To the contrary,

FDA regulations require a manufacturer to file an MDR when it has information "from any source[] that reasonably suggests" its device caused or contributed to a serious injury. 21 C.F.R. § 803.50(a)(1). The voluntary MedWatch reports at issue identify TMJI as the device manufacturer. Thus, TMJI had information reasonably suggesting its devices caused or contributed to a serious injury and should have filed MDRs for those events. To the extent petitioners did not subjectively believe that their devices were actually involved and sought to insulate themselves from civil liability based in part on the MDRs, they are permitted to "deny that the report or information submitted under this part constitutes an admission that the device [or petitioners] caused or contributed to a reportable event." 21 C.F.R. § 803.16. They are not permitted, however, to ignore the broad reporting requirements of the statute and its implementing regulations simply because they do not feel that they have all of the information they need to confirm that their device caused a serious injury.

D. The DAB Did Not Err in Concluding that Petitioners' Violations Were Knowing

Liability for a money penalty lies only when the violation constitutes a knowing or significant departure from the § 360i requirements or when the violation poses a risk to public health. 21 U.S.C. § 333(f)(1)(B)(i). The regulations define a "knowing departure" as "a departure from a requirement taken: (a) With actual knowledge that the action is such a departure, or (b) in

deliberate ignorance of a requirement, or (c) in reckless disregard of a requirement." 21 C.F.R. § 17.3(a)(2).

The DAB properly determined that petitioners' violations were knowing. From February to November 2004, FDA repeatedly and consistently informed petitioners of FDA's position that they needed to submit MDRs for the events at issue. This position, as explained above, is entirely reasonable given the clear and broad language of § 360i. Petitioners' failure to file those MDRs was thus done either in deliberate ignorance of the § 360i requirements or in reckless disregard of them.

Petitioners contend that they could not have knowingly violated § 360i at the time the CMP was served because the Commissioner had not yet responded to their appeal request. In their view, a knowing violation could have occurred in this case only if petitioners had refused to comply with the Commissioner's ultimate determination that MDRs were required. This argument is belied by the applicable regulation, which requires only deliberate indifference to or reckless disregard of the reporting requirements. Those requirements are clearly and broadly articulated in the statute and its implementing regulations, and petitioners did not require the FDA Commissioner's final decision regarding their review request to be fairly apprised of them. Therefore, the DAB did not err in concluding that petitioners' violations were knowing.

E. The DAB Reasonably Affirmed the Money Penalties Assessed Against Dr.

Christensen

Dr. Christensen argues that only the manufacturer of the devices, not an individual, may be subject to money penalties under 21 U.S.C. § 333(f). This contention is not supported by the clear language of the governing statutes. Section 333(f) states that "any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty." Section 321(e) defines "person" to include an "individual, partnership, corporation, and association." Moreover, in analogous circumstances, the Supreme Court has explicitly held that corporate officers may be liable for violations of the Food, Drug, and Cosmetic Act. *See United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943). While Dr. Christensen attempts to distinguish these cases because they involved criminal prosecutions rather than civil money penalties, "the rationale for holding corporate officers criminally responsible for acts of the corporation, which could lead to incarceration, is even more persuasive where only civil liability is involved, which at most would result in a monetary penalty." *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 561 (6th Cir. 1985). Accordingly, "[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." *Id.* Therefore, the DAB's similar conclusion was reasonable.

We also reject Dr. Christensen's argument that § 333(f) should be interpreted to exclude individuals with extensive medical backgrounds who act as a manufacturer's expert under 21 C.F.R. § 803.20(c)(2). Such an interpretation is not founded in the letter or purpose of § 333(f). Therefore, the DAB reasonably affirmed the assessment of monetary penalties against Dr. Christensen.

F. The DAB Reasonably Affirmed the Amount of the Money Penalties

Under § 333(f)(1)(A) and the implementing regulations, a civil penalty may not exceed $16,500 for each violation. 21 U.S.C. § 333(f)(1)(A); 21 C.F.R. § 17.2. The appropriate amount of a money penalty is determined by considering mitigating and aggravating factors. 21 C.F.R. § 17.45(b)(3).

FDA sought penalties of $10,000 for each violation from each petitioner, which the ALJ imposed and which the DAB ultimately affirmed. In their petition before this Court, petitioners contend their financial condition was "ignored" in assessing the penalty amount and that several mitigating factors justify a lower penalty. Petitioners' first argument is unfounded. The DAB meticulously explained why petitioners' financial disclosures were inadequate to give a reliable picture of petitioners' ability to pay a $170,000 penalty. TMJI, for example, refused to submit complete tax returns. Dr. Christensen refused to disclose money or property transfers. Neither petitioner explained a significant drop in profitability from 2004 to 2005 ($624,690 in ordinary business income on approximately $2.7 million in net sales in 2004 versus $203,108 in ordinary

business income on the same amount of net sales in 2005) combined with a 52% increase in salaries during the same time period. Far from "ignoring" petitioners' financial condition, the DAB justifiably concluded that "the ALJ's findings that TMJI and Dr. Christensen failed to make full financial disclosures are supported by substantial evidence in the record [as] a whole. His inference that a full disclosure would not have supported their assertions of an inability to pay is reasonable."

The DAB also properly evaluated all factors petitioners characterize as mitigating. First, petitioners contend that they never refused to file the seventeen MDRs but only sought a dialogue with FDA to discuss their disagreement regarding whether MDRs were required before they filed them. As the DAB explained, however, the law does not require an explicit "refusal" to file; rather, the failure to file an MDR when the statute and regulations require it constitutes a violation of § 360i. Furthermore, petitioners do not have the authority to make the ultimate determinations of whether and when an MDR must be filed. That authority lies with Congress and FDA, which have clearly articulated their determinations in the statutes and implementing regulations. Accordingly, petitioners' failure to file MDRs and their recalcitrant responses to the repeated FDA warnings can reasonably be interpreted as explicit refusals to file.

Second, the DAB reasonably rejected petitioners' contention that their failure to file MDRs after being informed that they were required to do so was in

good faith. This finding is supported by substantial evidence in the administrative record, and petitioners' statement that TMJI's devices are not a threat to the public health is simply petitioners' own opinion. The DAB did not err in failing to accord significant weight to this self-serving assertion.

Third, petitioners' offer to file the required MDRs if FDA promised to drop the CMP is also not a mitigating factor, and FDA's rejection of that offer does not violate the Small Business and Regulatory Enforcement Fairness Act. Indeed, petitioners only made the offer to file MDRs after the ALJ had held them liable and after the DAB had affirmed that decision. Offering to abide by the law only after being punished for not doing so does not mitigate the culpability of the initial unlawful conduct and the DAB's similar conclusion was not error.

Finally, to the extent petitioners contend that other mitigating factors exist, we have carefully reviewed the extensive record in this case and conclude that the DAB's decision is legally tenable and supported by substantial evidence.

IV. CONCLUSION

The DAB's Final Decision is AFFIRMED.