Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: March 24, 2008
TMJ Implants, Inc., Robert W. Christensen, and Maureen K. Mooney, Respondents,	FDA Docket No. 2005H-0271 App. Div. Docket No. A-08-10
- v. -	Decision No. 2163
Food and Drug Administration.	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

On December 10, 2007, respondents TMJ Implants, Inc., Robert W. Christensen, D.D.S., and Maureen K. Mooney, collectively referred to herein as Respondents, appealed the July 6, 2007 Initial Decision and the September 25, 2007 Final Order of Administrative Law Judge (ALJ) Daniel J. Davidson in TMJ Implants, Inc., Robert W. Christensen, and Maureen K. Mooney, FDA Docket No. 2005H-0271.

TMJ Implants (TMJI) manufactures medical devices known as temporomandibular joint implants. In the Initial Decision, the ALJ upheld the determination of the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) that, for 17 adverse event reports describing serious injuries associated with TMJI devices, Respondents violated the medical device reporting requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360i(a), by failing to file Medical Device Reports (MDRs). The ALJ also concluded that these violations constituted significant and knowing departures from the MDR requirements. In the Final Order, he assessed civil money penalties (CMPs) in the amount of $170,000 ($10,000 per violation) against each Respondent.

On appeal, Respondents except to the Initial Decision and the Final Order on a number of substantive and procedural grounds. 21 C.F.R. §§ 17.45, 17.47. For purposes of our review, the Final Order supplements and therefore is part of the Initial Decision.

For the reasons explained below, we reverse the ALJ's finding of liability and imposition of a CMP as to Ms. Mooney, but find no merit to any of Respondents' other exceptions.[1] We therefore affirm the Initial Decision and the Final Order, except as to Ms. Mooney. For the convenience of the reader, we set out here the organization of our analysis sections beginning on page 11:

1. Respondents were required to file MDRs for all of the 17 events at issue.

    A. The ALJ did not err in interpreting or applying the law on medical device reporting.

    B. FDA's redaction of information from the nine voluntary MedWatch forms at issue is not a justifiable basis for Respondents to fail to file MDRs for these events.

    C. The ALJ's factual findings about the 17 adverse events are supported by substantial evidence on the record as a whole.

2. FDA's CMP Complaint was neither "premature" nor violative of due process.

    A. FDA's CMP Complaint was not premature.

    B. Respondents received due process.

3. The ALJ did not err in concluding that Respondents' actions constituted "knowing departures" from applicable requirements.

4. The ALJ did not err by concluding that FDA may impose CMPs on individuals employed by the device manufacturing corporation.

5. The ALJ erred by concluding that FDA may impose CMPs on Ms. Mooney. The ALJ did not err by concluding that FDA may impose CMPs on Dr. Christensen.

    A. Ms. Mooney is not personally liable for a CMP.

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[1] Since we conclude that Ms. Mooney is not personally liable for the failure to file MDRs and therefore did not herself commit any violation, our references to "Respondents" in discussing specific exceptions to the conclusions on liability should be read as applying only to TMJI and Dr. Christensen.

B. Dr. Christensen is personally liable for a CMP.

6. The ALJ did not err in setting the CMP amounts for TMJI and Dr. Christensen.

A. The ALJ did not err in finding that these Respondents failed to make full financial disclosure.

B. The timing of the issuance of the Final Order does not demonstrate any lack of consideration by the ALJ.

C. Respondents did not demonstrate any mitigating factors.

Burden of Proof and Standard of Review

Section 17.33 of 21 C.F.R. provides in pertinent part:

> (b) In order to prevail, the [CDRH] must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.
> (c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

On appeal from an initial decision under 21 C.F.R. Part 17, "the standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous." 21 C.F.R. § 17.47(k).

Legal Authority

Congress charged FDA with responsibility for "ensuring that . . . there is reasonable assurance of the safety and effectiveness of [medical] devices intended for human use." 21 U.S.C. § 393(b)(2)(C).

To enable FDA to fulfill this responsibility, Congress passed the Medical Device Amendments of 1976, Public Law No. 94-295, 90 Stat. 539 (1976) (1976 Amendments), which enacted record keeping and reporting requirements for medical devices. Congress intended FDA to use its regulatory authority under section 360i(a) to protect the public from potentially unsafe devices by requiring manufacturers to file MDRs for device-related adverse events. See H.R. Rep. No. 853, 94th Cong., 2d Sess. 23 (1976). Pursuant to the 1976 Amendments, FDA issued a final rule in 1984

requiring medical device manufacturers and importers to file MDRs for device-related adverse events. See Final Rule: Medical Device Reporting, 49 Fed. Reg. 36,326 (Sept. 14, 1984). As the final rule explains –

> To carry out its responsibilities, the agency needs to be informed whenever a manufacturer . . . 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.

Id. at 36326 (emphasis added).[2]

At all relevant times, section 360i(a) of 21 U.S.C. provided in pertinent part:

> (a) General rule
>
> Every person who is a manufacturer . . . of a device intended for human use shall 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. Regulations prescribed under the preceding sentence—

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[2] Since the 1976 Amendments, Congress has twice amended the FDCA to expand FDA's authority to require the reporting of device-related adverse events. In 1990, Congress enacted the Safe Medical Devices Act of 1990 (SMDA), Public Law No. 101-629, 104 Stat. 4511 (1990), which amended the FDCA to address various regulatory gaps in the 1976 Amendments, to better protect the public health by increasing reports of device-related adverse events, and to specifically require that medical device user facilities and distributors file MDRs. See S. Rep. No. 513, 101st Cong., 2d Sess. 13 (1990); see also H. R. Conf. Rep. No. 959, 101st Cong., 2d Sess. (1990).

Two years later, Congress enacted the Medical Device Amendments of 1992, Public Law No. 102-300, 106 Stat. 238 (1992), which amended 21 U.S.C. § 360i, in part, by requiring medical device manufacturers to file MDRs "whenever the manufacturer . . . receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices -- (A) may have caused or contributed to a death or serious injury; or (B) Has malfunctioned . . . ." See 21 U.S.C. §§ 360i(a)(1)(A) & (B) (emphasis added).

> (1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer . . . receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—
>
> (A) may have caused or contributed to a death or serious injury,
>
> * * *
>
> (2) shall define the term "serious injury" to mean an injury that—
>
> (A) is life threatening,
>
> (B) results in permanent impairment of a body function or permanent damage to a body structure, or
>
> (C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure . . .

(Emphasis added.) In December 1995, FDA issued a final rule to implement amendments to section 360i requiring user facilities and manufacturers to report device-related adverse events using a uniform reporting system. See Final Rule: Medical Device User Facility and Manufacturer Reporting, Certification, and Registration, 60 Fed. Reg. 63,578 (Dec. 11, 1995). The MDR regulation, 21 C.F.R. Part 803,[3] describes the conditions under which MDRs must be submitted, the content and timing of MDRs, and how FDA will use MDRs to carry out its public health mandate. Subsections 803.50(a) and (b) of section 803.50 provide:

> (a) Reporting standards. Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:
>
> (1) May have caused or contributed to a death or serious injury; or
>
> (2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
>
> (b) Information that is reasonably known to manufacturers.

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[3] In accordance with the June 1, 1998 Presidential Memorandum on Plain Language, FDA revised 21 C.F.R. Part 803 to make it easier to understand. 70 Fed. Reg. 9516 (Feb. 28, 2005). The revision did not change the substantive regulatory requirements. Id. at 9517.

(1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, distributor and/or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, distributors, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event, and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under Sec. 803.56.

Subsection (c) of section 803.20 gives further guidance as to filing requirements. It provides:

(c) What kind of information reasonably suggests that a reportable event has occurred?

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

> (2) If you are a . . . manufacturer, you do not have to report an adverse event 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, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers . . . .

(Emphasis added.)

To address industry concerns about device-related product liability suits, an FDA regulation specifies that submission of a report to FDA does not constitute an admission that the medical device actually caused or contributed to the reportable event. See 21 C.F.R. § 803.16; see also 60 Fed. Reg. at 63587-63588 (Comment 25).[4]

The failure or refusal to furnish "any notification or other material or information required by or under section 360i . . . of this title" is defined as a "prohibited act." 21 U.S.C. § 331(q)(1)(B). Section 333(f)[5] sets forth penalties for violations of, among other things, section 360i. It provides as follows:

> (f) Violations related to devices
>
> (1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000

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[4] FDA Form 3500A, which is the standard form for submitting MDRs, also includes a disclaimer, which states that submission of a report does not constitute an admission that medical personnel, a user facility, an importer, a distributor, a manufacturer, or a product caused or contributed to the event. See Administrative Record Item (AR) 113 (sample FDA Form 3500A). In addition to the FDA disclaimer, "manufacturers may also include their own disclaimers in MDR reports." See Medical Device Reporting for Manufacturers, AR 86, at 28.

[5] This provision was previously codified as 21 U.S.C. § 333(g). It was redesignated as subsection (f). Pub. L. No. 110-85, § 226(b)(1), 121 Stat. 823 (2007).

> for all such violations adjudicated in a single proceeding . . . .
>
> (B) Subparagraph (A) shall not apply—
> (i) to any person who violates the requirements of section 360i(a) . . . of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health.

FDA regulations governing hearings on CMPs appear at 21 C.F.R. Part 17, and are made applicable to CMPs related to medical devices by section 17.1(b). These regulations set out the details of how a case is initiated by service of a complaint, provide for a hearing on the record before a presiding officer, and assign the burden of proof. 21 C.F.R. §§ 17.5, 17.7, 17.33. The regulations provide respondents a right of appeal from the presiding officer's initial decision to the Departmental Appeals Board, which was exercised by Respondents in the present appeal. 21 C.F.R. § 17.47.

The Temporomandibular Joint

The following undisputed description of the structure and function of the temporomandibular joint (TMJ) and of TMJ disorder is taken from the declaration of FDA expert, Dr. Gary W. Smagalski.

> The TMJs are located slightly in front of the ears and form the interface between the lower jaw (mandible) and bottom of the skull (temporal bone) . . . . The TMJs are critical to several functions of daily life such as speaking, eating, swallowing, and breathing. The TMJs are hinge/glide joints where the lower jaw bone forms a "ball" (condylar head) and the temporal skull bone forms a "socket or fossa." . . . Interposed between the condylar head of the mandible and the fossa of the temporal bone is a soft tissue disc or "meniscus," which acts a cushion to protect the bones from contacting each other . . . .
>
> TMJ Dysfunction is a general term that encompasses a variety of conditions or symptoms that adversely affect these joints. TMJ disorders are a series of pathological conditions that interfere with normal, pain free joint function that may result from direct trauma to the bony structures of the joint and/or to the soft tissue meniscus. These problems may also be a consequence of joint bone degeneration due to arthritis, systemic illnesses, micro-

> trauma from a mal-alignment of the teeth, teeth clenching and grinding habits, and facial bone fractures. Continued deterioration of the joint components often results in concomitant pain, restriction of function, and associated dysfunction of the supporting facial muscles (myofacial pain).
>
> Common signs (objective evidence observed by the doctor), symptoms (subjective evidence as perceived by the patient), and complications commonly associated with the TMJ disorders include: (1) mechanical dysfunctions (open or closed locking of the jaw, popping, clicking, and grating noises with jaw function); (2) pain; (3) soft tissue reactions (swelling, inflammation, foreign body reactions); (4) bone reactions (osteoarthritis, hypertrophic bone (excessive bone formation), heterotopic bone (abnormally located bone deposits), ankylosis (fusion of the joint bones)); (5) infections; and (6) effects on adjacent structures (chronic sinus pain, hearing loss, or chronic ear pain).

AR 394, at ¶¶ 12-14.

Procedural history

On July 14, 2005, FDA filed a CMP Complaint under 21 U.S.C. § 333(f) against Respondents, seeking CMPs against the corporation TMJI, Dr. Christensen (TMJI's President), and Ms. Mooney (TMJI's Regulatory Affairs and Quality Assurance Manager). AR 1, at ¶¶ 5-6. The CMP Complaint alleged that Respondents had violated 21 U.S.C. § 360i(a) and the MDR regulation, 21 C.F.R. Part 803, which require a medical device manufacturer to submit MDRs to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a serious injury. See 21 U.S.C. § 360i(a); 21 C.F.R. § 803.50(a). Specifically, the CMP Complaint alleged that, between October 22, 2002, and July 10, 2003, TMJI received 21 adverse event reports that reasonably suggested that its devices may have caused or contributed to serious injuries and that TMJI failed to file MDRs for these events. AR 1, at ¶¶ 24-25.

Respondents answered the CMP Complaint and, after several months of discovery, FDA and Respondents simultaneously filed motions for summary decision. AR 50 and 102. In its summary decision motion, FDA modified its position and sought to impose liability with respect to 17 of the 21 events.

On July 6, 2006, the ALJ denied both motions, stating that factual issues with respect to certain of the events at issue and

questions regarding the reasonableness of Respondents' decision not to file MDRs precluded granting summary relief. AR 134.

On April 16, 2007, the ALJ held a in-person hearing for the parties to conduct cross-examination of witnesses that had previously submitted declarations or written direct testimony. AR 520 (transcript). The parties filed respective post-hearing briefs. AR 524, 525. On July 6, 2007, the ALJ issued an Initial Decision finding each Respondent had committed knowing and significant violations of MDR requirements. AR 578. The ALJ, however, stayed the assessment of specific penalty amounts pending further consideration of each Respondent's ability to pay. The ALJ ordered Respondents to submit a "full disclosure" of their finances, and ordered both FDA and Respondents to submit their positions on Respondents' ability to pay the CMPs. AR 578. The ALJ also stated that "should [Respondents] fail to fully disclose their financial information as ordered, [CMPs] in the amount of . . . $170,000 for each [Respondent] ($10,000 for each violation) will be deemed the appropriate penalty assessed in this proceeding and an ORDER to that effect will be issued." Id. at 12. On September 22, 2007, after considering Respondents' financial information and the parties' briefs on penalty amounts, the ALJ issued a Final Order requiring each Respondent to pay CMPs in the amount of $170,000, which is a total of $510,000 in CMPs for the entire proceeding. AR 608.

On November 13, 2007, Respondents filed a notice of appeal and supporting brief contesting the ALJ's decisions on liability and the amount of the CMPs. AR 615.

Summary of Respondents' Exceptions

Respondent files a number of exceptions, which we discuss in the following order.

- Respondents dispute the ALJ's conclusion that MDRs were required for each of the 17 events at issue. R. Br. at 28-43.

- Respondents dispute the ALJ's conclusions that their due process rights were not violated and that they committed "knowing departures" from MDR requirements. Id. at 14-22.

- Dr. Christensen and Ms. Mooney dispute the ALJ's imposition of CMPs on individuals generally and on themselves specifically. Id. at 22-28.

- Respondents dispute the ALJ's final assessment of CMPs, asserting that the ALJ did not fully consider the financial

information that Respondents provided regarding ability to pay and mitigating factors. Id. at 43-50.

Analysis[6]

1. Respondents were required to file MDRs for all of the 17 events at issue.

Respondents raise a number of arguments as to why the ALJ erred in concluding that section 360i required MDRs to be filed for the 17 events at issue. The arguments involve the ALJ's construction of section 360i and the implementing regulations, FDA's redaction of information from nine of the reports, and the evidence on which the ALJ relied in support of his factual findings.

A. The ALJ did not err in interpreting or applying the law on medical device reporting.

Much of Respondents' appeal is founded on their persistent attack on FDA's interpretation of the requirements of the Act and the regulations, which Respondents view as overly broad or meaningless. The ALJ determined that FDA's interpretations were permissible and had been repeatedly disclosed to Respondents in preamble language, as well as in numerous communications directly with Respondents prior to the filing of the CMP Complaint.[7] We, like the courts, generally defer to an agency's reasonable interpretation of the statutory and regulatory provisions within its purview, unless the party against which the interpretation is to be enforced had no actual notice of it and relied on an alternative reasonable interpretation. Skidmore v. Swift & Co., 323 U.S. 134, at 140 (1944); 5 U.S.C. § 552(a)(1).

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[6] We note that, although some specific points made by Respondents may not be discussed in detail in this decision, all of the arguments in their appeal briefs were considered in reaching our conclusions. To the extent that any of Respondents' contentions are not explicitly addressed, the Initial Decision adequately covered the subject. The Board's role is not to reweigh the evidence and reevaluate the testimony but rather to ascertain whether the factual findings are supported by substantial evidence in the record as a whole, and, as we do below, determine whether the ALJ committed any of the asserted prejudicial legal errors.

[7] For the reasons discussed below, we reject Respondents' position that CDHR did not have the authority to interpret the MDR law and regulations and to instruct Respondents to file MDRs. See, e.g., R. Br. at 10.

Section 360i(a)(1) requires a manufacturer to file an MDR if, among other things, the manufacturer receives information (1) that reasonably suggests (2) that one of its devices (3) may have caused or contributed to (4) a serious injury. Section 360i is very broad – the information received by the manufacturer need only reasonably suggest that a device may have contributed to a serious injury. This is consistent with the purpose of the statute, which is to enable FDA to track and evaluate the ongoing efficacy and safety of medical devices that it has approved for use in humans. Congress established a low threshold for requiring manufacturers to file MDRs since the MDR system is intended to give FDA sufficient information "to detect and correct problems in a timely manner." Medical Device Reporting for Manufacturers, AR 86, at 1. Without such information, FDA cannot fulfill its duty to protect the public's health in relation to devices.

To generate information about the performance of devices, Congress not only requires device manufacturers to file MDRs but also to investigate reported events. Device manufacturers are in the best position to conduct such investigations since they have the most knowledge about their product and an inherent incentive to improve the design and use of their devices. In implementing section 360i, FDA relies on "the goodwill and cooperation of all affected groups to accomplish the objectives" of the statute. Id. FDA evaluates MDRs to determine whether corrective actions are necessary. Depending on the facts and circumstances, FDA may work with the manufacturer to respond to a problem, initiate consumer or user education programs, issue safety alerts, issue recalls, or take other actions necessary to protect the public health. AR 50, at 7.

i. FDA's construction of reporting requirements

FDA's implementing regulations further the statute's purpose to assure that a device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. FDA's position that MDR requirements should broadly cover significant adverse events associated with devices is consistent with this purpose. For example, FDA defined "caused or contributed" to include not only events occurring as a result of device failure, such as malfunction, or improper design or manufacture, but also as a result of "user error." 21 C.F.R. § 803.3. When it adopted this definition, a commenter objected that inclusion of user errors "would lead to the reporting of events properly attributable not to the device, but to its incorrect use." FDA responded that it needed to know about incorrect use since this information would enable FDA to better evaluate whether there were strategies, such as improved labeling, that would mitigate problems of whatever

source associated with the use of a specific device. 60 Fed. Reg. at 63,583.[8]

FDA also rejected a commenter's suggestion that manufacturers should not be required to report events where the device was "only indirectly responsible for a . . . serious injury, or was not a significant factor." FDA rejected this comment as inconsistent with the statute, which does not quantify the causal link between the device and the injury. Id. at 63,582. FDA did provide, however, that a manufacturer does not have to report an event "if [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 . . . ." 21 C.F.R. § 803.20(c)(2)(emphasis added).

Respondents except to the ALJ's conclusion that section 360i(a)(1) requires MDRs for the disputed events on the ground that the ALJ employed "'an absolute stricter standard,' advocated by [FDA], which does not appear in the statute or the MDR regulations." R. Br. at 40. Specifically, Respondents take issue with the ALJ's construction of what constitutes a "serious injury" and what constitutes sufficient causation. Id. at 39-40.[9] Below we explain why the ALJ's construction properly defers to FDA's reasonable interpretation of statutory and regulatory language of which Respondents had actual notice and why Respondents' construction is not consistent with section 360i. Finally, we explain why we conclude that the opinions of Respondents' experts were based on Respondents' incorrect reading of section 360i and, therefore, were properly disregarded by the ALJ.

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[8] Specifically, FDA stated:

> Device injuries attributed to user error may indicate that the device is misbranded within the meaning of [21 U.S.C. 352(f)] in that the device fails to bear adequate directions for use or adequate warnings. In such cases, reports of adverse events that result from user error may alert FDA to the need for improved labeling to prevent future injuries.

60 Fed. Reg. at 63,583.

[9] In their brief, Respondents referred the Board to specific parts of the record below, which we have reviewed. R. Br. at 38-39.

ii. The meaning of serious injury

Section 360i(a)(2) defines serious injury as an injury that –

> (A) is life threatening,
>
> (B) results in permanent impairment of a body function or permanent damage to a body structure, or
>
> (C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Section 803.3 of 21 C.F.R. uses this statutory language to define serious injury. Section 803.3 defines "permanent" to mean "irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage."

Respondents assert that Dr. Christensen, a person qualified to make a medical judgment, reasonably concluded that these events did not involve a "serious injury," and that his opinion was supported by two additional experts, Drs. James T. Curry, D.D.S., and Ricardo R. Alexander, D.D.S. R. Post-hearing Br., AR 524, at ¶ 76. They argued that –

> the real or potential "permanency" of the reported adverse event must be taken into consideration in determining whether the event falls with[in] the "serious injury" definition and that mere post-surgery intervention in the implanted joint to address normal complications of surgeries in general do not rise to the level of this definition . . . . Few if any of the [events at issue] should be considered as having a potential permanency, when most apply to symptoms continually subject to correction in operations generally, and do nothing to alert the public to a potential problem with the manufacturer's devices.

Id. at ¶ 84.

Respondents misconstrue how the term "permanent" is used in the definition of serious injury. Under section 360i(a)(2)(C), an injury is serious if it "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." (Emphasis added.)[10]

[10] As the FDA expert notes, the Respondents' expert relied on "only part of the MDR regulatory definition of 'serious injury'" in that he failed to acknowledge the section addressing when medical/surgical intervention is needed to preclude permanent impairment. AR 395, at ¶ 6, citing AR 117, at ¶ 33.

Thus, the fact that a post-operative condition such as swelling, pain, or infection did not result in an "irreversible impairment or damage to a body structure or function" does not make the injury "not serious" when medical or surgical intervention was necessary to address the condition in order to preclude the impairment or damage.[11] As discussed below, the FDA experts, Dr. Gary W. Smagalski, D.D.S. and F.A.C.D., and Dr. James Q. Swift, D.D.S., agreed that the conditions suffered by these patients required at least medical, but usually surgical, intervention to prevent nontrivial damage to their TMJs.

In arguing that their interpretation of serious injury should prevail, Respondents rely on a statement in a letter from the CDRH Director about how clinicians and the MDR standards characterize as a "serious injury" may differ as showing that FDA is not taking a properly clinical view of adverse events. AR 524, at ¶ 81. The Director's complete statement is as follows:

> There is often a distinction between what clinicians characterize as a serious injury and what the MDR regulation defines as a serious injury. A reportable serious injury under the MDR regulation includes events "where medical or surgical intervention is required to preclude permanent impairment of a body structure or function." The adverse event information reviewed for your device included the following representative types of injuries: swelling, inflammation; immobility of the joint; limited mobility of the joint; pain; infection; fracture; erosion, adhesions, seizure and headache. Although 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, reported in your adverse events.

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[11] We note that Respondents mischaracterize the facts in the record by describing the interventions as "mere post-surgery intervention in the implanted joint to address normal complications of surgeries in general." R. Findings of Fact, AR 524, at ¶ 84. This characterization implies that the signs and symptoms (such as pain and infection) that precipitated the interventions occurred only during the immediate post-surgery healing period. Instead, in most cases, the signs and symptoms resulting in the interventions either continued or arose months and years after the implant surgery.

AR 77, at 2.

Respondents argue that "the MDR regulations definitions of 'serious' and 'permanent' does not evidence such a loose 'poetic license' for [FDA's] interpretation and application." R. Findings of Fact, AR 524, at ¶ 81. The quoted passage does not take poetic license with the regulation or statute. The statement correctly restates the law and seeks to explain to Respondents, at a point when FDA was still willing to accept TMJI's submissions as timely MDRs, why Respondents' "clinician" characterization of these events is contrary to the terms of the statute and cannot be relied on.[12]

iii. The meaning of cause or contribute

Respondents also argue the ALJ erred in applying the requirement that the device cause or contribute to the injury. R. Br. at 40. Section 803.3 of 21 C.F.R. defines "caused or contributed" to mean 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.

Respondents argue that the symptoms described in the reported events (such as excruciating pain and decrease in opening of the mouth) were caused by other factors, principally the TMJ disease process or the patients' underlying condition, and not by the devices. See, e.g., AR 489, at 101; Item 168, at ¶¶ 8, 9. Respondents assert that for FDA --

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[12] In their brief to the Board, Respondents cited this quote and asserted it showed that FDA "has admitted that [prior to filing the CMP] it did not apply the same medical standard in review of adverse events that TMJI did []." R. Br. at 41, and n.4. This is, of course, the point CDRH was trying to impress on Respondents, i.e., that the standards for determining "serious injuries" for MDR events are different than those that may be used by clinicians for other purposes. Even in their reply brief to the Board, Respondents appear to continue to misunderstand or reject FDA's guidance, writing that FDA "has admitted . . . that it does not apply the clinical standard of a manufacturer medically expert in its field, but analyzes events from a regulatory viewpoint." R. Reply Br. at 7.

> to come back after FDA cited certain preexisting serious indications as justification for approval of the use of Respondent TMJI's devices, with demand for filing of MDR's for the continued post-operation existence of these very symptoms is completely unreasonable, adding nothing to any public awareness to potential problems with Respondent TMJI's devices.

AR 525, at ¶ 86.

We reject Respondents' arguments for several reasons. The role of the device in the injury, under the statute and regulations, need not be the only, or the most important, or even a definite factor in causing injury. 60 Fed. Reg. at 63,582. The information received by the manufacturer need only reasonably suggest that the injury may be attributed to the device or that the device may be a factor in the injury. 21 C.F.R. § 803.3. Contrary to Respondents' position, FDA set out a reasonable explanation in the language quoted earlier from the preamble 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. In other words, the data gathered through MDR are not viewed as proof that the device is responsible for particular events, but as a cumulative information base for early detection and quick response to any emerging problems. This point is reinforced by the regulation and the MDR forms expressly providing a disclaimer of any admission of liability in the filing of manufacturer MDRs.

Further, it is reasonable for FDA to view post-implant signs and symptoms requiring medical/surgical intervention to prevent permanent impairment or damage as a reportable event in part because the device was FDA-approved to address such symptoms and TMJI represents that it does so. AR 396 (Supplemental Declaration of Dr. Smagalski) at ¶¶ 7, 10-13. We reject Respondents' assertion that such reporting "add[s] nothing to any public awareness to potential problems with Respondent TMJI's devices." AR 524, at ¶ 86. TMJI presents the public with explicit claims and reports of its studies showing that its devices can be expected to improve TMJ problems such as pain and an inability to open the mouth. AR 88. The circumstances surrounding the failures of devices to fulfill such expectations could well be of interest to FDA as well as to doctors and to their patients in evaluating whether a particular patient is a good candidate for a TMJI implant.

Respondents repeatedly asserted that the reported signs and symptoms were caused solely by "disease progression." See AR 117, at ¶¶ 19, 29, 34, 35, 45, 50, 51, 53, 55; AR 168, at ¶ 151. The fact that some of the signs and symptoms described in the adverse event reports in this case are also signs and symptoms seen in TMJ disease does not establish, in itself, that disease progression was the exclusive cause of the signs and symptoms and that the implant was not a contributing factor. Such a precept would eviscerate standards for investigating and reporting adverse events since adverse conditions to which a device may contribute may often correspond to potential disease symptoms. See, e.g., AR 394, at ¶ 14; 396, at ¶ 15(a)-(c).

FDA's experts rejected the proposition that the disease progression could reasonably be relied on as the sole reason for the need for medical and surgical interventions in these cases. Dr. Swift testified:

> Dr. Christensen and Dr. Curry repeatedly state that the cause of a patient's conditions in the 17 events was not TMJI's device, but rather was the progression of the temporomandibular disorder ("TMD"). According to well-established research, the concept of TMD as a progressive disease state is erroneous. The failure of the TMJ prosthesis in these 17 events cannot be blamed on the 'progressive nature' of TMD. For the majority of individuals with TMD, the TMD symptoms can be alleviated with surgery and/or proper therapy. It is not scientifically justifiable to summarily blame every poor outcome or failed device post-implantation on the disease process when that disease process was the reason for the initial and, in some cases, subsequent implant. In my opinion, based on the information in the complaint files in this case, it is far more reasonably likely that TMJI's devices may have caused or contributed to the medical and/or surgical interventions that were required in these cases to preclude permanent impairment of a body function or permanent damage to a body structure.

AR 396, at ¶ 4.

Dr. Smagalski testified:

> In my opinion it is unreasonable to attribute these serious injuries to the "progression of the [TMJ] disease." The progression of degenerative joint disease has an etiology and a cause. As explained in ¶¶ 11-13 below, Dr. Curry [the Respondents' expert consultant] has stated that when a TMJ implant device is placed, the patient can anticipate that

> there will be significantly decreased pain and considerably increased mobility of the joint with a high degree of certainty, as degenerative problems of the joint are controlled and alleviated by the implant. If there is post-operative progression of the degenerative disease process that yields the opposite results (i.e., significantly increased pain or significantly restricted function of the joint), then an unintended complication of the device implantation must be suspected and the true etiology or source of the injury should be identified and treated.

AR 395, at ¶ 7.

iv. Medical judgment not to file reports

Respondents argue that their expert testimony proved that persons qualified to make a medical judgment reasonably concluded that the devices did not contribute to a serious injury, and, therefore, under 21 C.F.R. § 803.20(c)(2), MDRs were not required. R. Br. at 39. Under 21 C.F.R. § 17.33, the respondent has the burden of proof on any affirmative defenses and the exception to the reporting requirement in section 803.20(c)(2) is in the nature of an affirmative defense. We conclude the ALJ did not err in not relying on Respondents' expert testimony because, as explained below, Respondents failed to show that their experts' conclusions were reasonable under the applicable regulatory standards.

First, in order to be reasonable in this context, the medical judgment must be reached on the basis of congressional and FDA standards for determining serious injury and causation. It is evident, from Respondents' continuing attacks on these standards and from careful reading of Respondents' evidence, that Dr. Christensen's medical judgment and the opinions of Respondents' supporting experts were based on standards as they wished them to be, not as Congress enacted them or FDA implemented them. For example, an FDA expert, Dr. Smagalski, opined that Respondents' expert, Dr. Curry, "misapplied the definition [of serious injury] throughout his Declaration." Dr. Smagalski explained:

> Dr. Curry repeatedly characterized patient's injuries that required significant medical or surgical interventions to preclude permanent impairment of a body function or permanent damage to a body structure as 'trivial' (¶41), 'annoying' (¶29), and 'minor' (¶33), concluding that the events were not serious injuries. In my opinion, the medical and/or surgical interventions involved in the 17 events at issue in this proceeding were not performed to preclude 'trivial

> impairment or damage' to the TMJ and/or TMJ function. For example, in Dr. Curry's evaluation of an event involving an infection and loose hardware (¶41), he opined that 'it could be argued that the event was 'trivial' not 'serious' as it was solvable." To "solve" the infection and loose hardware complications for this patient, it was necessary for a surgeon to perform a medical and/or surgical intervention to preclude irreversible non-trivial impairment or damage to the TMJ and/or TMJ function.

AR 395, at ¶ 5 (emphasis in original); see also id., at ¶¶ 6-9 (Dr. Smagalski's additional description of Respondents' misapplication of the definition of serious injury and causation).

Even as late as the in-person part of the hearing, Respondents' experts acknowledged that they were unaware that serious injury caused by user error should be reported or that a serious injury must be reported even if the manufacturer cannot conclusively establish whether the device involved was from their company.[13] AR 250, at 250 and 296.

Second, a medical judgment cannot be reasonable where signs and symptoms are disregarded simply because they are among the possible effects anticipated or intrinsically caused by the device. FDA expressly addressed this question in promulgating

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[13] We note that, from the beginning, Respondents' interpretation of user error was inconsistent with FDA's interpretation of causation under section 360i. After its meeting with CDRH personnel in March 2004, TMJI informed the CDRH as follows:

> It is the Company's position that an event harmful to the patient but which is caused by user error, when the device labeling adequately covers the applicable procedures which were not met and where the device otherwise has not contributed to death or serious injury, is not an event caused by the device.

AR 60, at 2 (letter of March 22, 2004 to CDRH).

Although Dr. Christensen, in July of 2004, stated that he now "accepts" and "will apply" the criteria that user error "may trigger the requirement to submit an MDR report even when labeling is adequate, if other elements that trigger the report requirement are present" (AR 68), this ostensible change was not communicated to Dr. Curry as of the hearing. AR 250, at 250.

the implementing rules, rejecting the proposition that "reporting should not be required when events are anticipated or intrinsically caused by the device." 60 Fed. Reg. at 63,583.[14] FDA explained:

> The statute does not exempt events that were anticipated or intrinsically caused by the device . . . . Moreover, merely knowing that adverse events are anticipated or intrinsically caused by a device does not obviate the need for information contained in event reports. FDA needs to know the frequency and severity of adverse events in order to take appropriate action.

TMJI's user instruction publications identify a considerable list of "anticipated" side effects or complications associated with TMJI devices, including ankylosis, foreign body or allergic reactions, heterotropic bone formation, decreased opening, hearing loss/problems, degenerative joint changes, and increased pain. AR 88 (Instructions for Use publication), at 6. All of these effects were reported in one or more of the events at issue. Additionally, the TMJI materials state:

> The long-term effects of the TMJ Fossa-Eminence Prosthesis System on the natural mandibular condyle are unknown. Remodeling of the natural mandibular condyle has been observed. Other degenerative changes may be attributable to the TMJ Fossa-Eminence Prosthesis. Therefore, the physician/dentist should periodically monitor the condition of the natural mandibular condyle.

Id. at 5.

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[14] Respondents object to FDA's reliance on this language because it is not in the regulations, which Respondents argue are clear on their face and "need[] no further interpretation by reference to . . . Federal Register comments . . . ." R. Br. at 40. We disagree. The Secretary is charged by Congress with the responsibility of implementing the MDR reporting system. 21 U.S.C. § 360i. It is undisputed that the Secretary delegated this authority to FDA. Regulatory preambles are statements of agency intent about how a regulation is to be understood and applied on which an agency may rely so long as they are not inconsistent with the statute or regulations. New York State Dept. of Social Services, DAB No. 1536 (2005). Respondents have not shown that the preamble explanations are inconsistent with the plain language of the regulation or the statute here.

Further, as the FDA expert stated, since TMJI represents that patients who receive its implants should show improvement in pain and opening, "the expected result of implantation of TMJI's devices should not be increased pain and/or decreased mobility, and when these unintended consequences do occur, the implant devices must be suspected as the possible cause or contributor to the serious injury." AR 395, at ¶ 13; AR 88, at 6-7.

Finally, the medical judgment cannot reasonably conclude under the regulatory standard that the device was not a contributing factor simply because a patient's pre-existing condition created particular difficulties for the correct installation or operation of the device. See AR 117, at ¶¶ 19, 39, 41, 43, 48, 50, 52, 55 (Respondents' expert attributing the problems to "the patient's condition" or the "patient's own system.") For example, in Event 03-018, an explanting doctor alleged the screws provided for the device were not long enough; that the device became loose; and that the device had to be removed. AR 95, at 17. Respondents assert that the cause of the loose screw was the patient's poor bone quality, probably resulting from the fact that she had previously had a type of implant (since removed from the market) that is known to contribute to bone degeneration. AR 117, at ¶ 40. However, the purpose of the reporting system is to flag problems real people are experiencing using the devices. The fact that this patient may have had poor bone quality that made installing the device more difficult does not excuse failing to report.[15] The public interest is served precisely by alerting users of conditions and resulting potential problems they should consider in evaluating patients for devices.

In each of these events, not only did Respondents fail to prove by a preponderance of the evidence that a person qualified to make a medical judgment reasonably concluded that the devices did not contribute to a serious injury, but substantial evidence in the record as a whole supports the ALJ's conclusion that Dr. Christensen's medical judgment not to file MDRs was unreasonable for one or more of these reasons. Therefore, Respondents failed to prove, under 21 C.F.R. § 803.20(c)(2), that a person qualified to make a medical judgment reasonably concluded that the devices did not contribute to a serious injury.

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[15] The FDA expert stated that if "the bone was of such poor quality that it could not support an implant screw, the surgeon would have noted this problem during the surgical placement of the implant, unless 'user error' was involved. Even if there were user error in this case, then by the MDR definitions, the device may have 'caused or contributed' to this serious injury." AR 395, at 23.

v. Role of a manufacturer's investigation

Respondents argue that the ALJ's application of section 360i --

> renders the investigation of the adverse event required by the MDR regulation utterly meaningless and moots FDA's MDR regulations that require a company, under threat of sanctions for noncompliance, to investigate adverse events to reach a 'reasonable' determination.

R. Br. at 40-41.

We disagree. Under 21 U.S.C. § 360i(a), a manufacturer is required to file an MDR whenever the manufacturer receives information that reasonably suggests that one of its devices may have caused or contributed to serious injury. Further, under 21 C.F.R. § 803.50(b)(3), a manufacturer must also conduct an investigation whenever it receives information about the event that reasonably suggests that its device may have caused or contributed to a serious injury. The purpose of that investigation is not merely to enable a manufacturer to determine whether to file an MDR at all under the standards of 21 C.F.R. § 803.20(c)(2). Rather, the primary purpose is to determine facts relating to causation and severity and to identify potentially relevant surrounding circumstances so as to provide FDA and the public with a better understanding of the real world efficacy of the device. Where the information received is incomplete, the manufacturer's investigation should seek to obtain more complete information. To address situations in which it would truly be pointless to require a manufacturer to file an MDR, FDA adopted the narrow exception set forth in section 803.20(c)(2). To meet that exception the medical evidence must reasonably justify a conclusion that the device did not cause or contribute to the injury. The fact that a manufacturer may have difficulty satisfying the elements of section 803.20(c)(2) does not make it inconsistent with section 360i.[16] The essence of the FDA regulatory scheme here is that manufacturers must err on the side of reporting adverse events of which they learn that might

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[16] The ALJ stated that "when [serious injuries] are present, there is little point in further investigation and analysis." Final Order at 9. As explained above, however, the investigation still serves a valid public purpose in elucidating the nature and circumstances of an adverse event, particularly if the event is determined to be reportable. In developing the MDR system, the FDA exercised its expertise in determining what information collection would best serve the needs of protecting the public.

involve their device or its use unless they can rule out the involvement.

B. FDA's redaction of information from the nine Voluntary MedWatch Forms at issue is not a basis for Respondents to fail to file MDRs for these events.

The MDR regulation requires manufacturers, importers, and user facilities (mandatory reporters) to submit MDRs using FDA Form 3500A (AR 113), the mandatory MedWatch form. 21 C.F.R. § 803.11. FDA also receives and tracks voluntary, device-related adverse event reports from medical professionals and consumers (voluntary reporters). AR 112. These voluntary reports are submitted on FDA Form 3500 (AR 114), the voluntary MedWatch form. The voluntary MedWatch forms received by FDA are provided to the manufacturer identified in the sections of the form asking for the "device manufacturer." The voluntary form allows the reporter to request that the FDA withhold his or her identity from the manufacturer. Where such a request is made, FDA redacts information that could identify the reporter prior to sending the form to the manufacturer.

Nine of the events at issue involved voluntary reports for which identifying information had been redacted: 02-063; 02-064 (three separate MedWatch reports); 02-065; 03-022 (three separate MedWatch reports), and 03-024. The FDA does not redact a reporter's entries for "Brand name" of the device, "Type of device," and "Manufacturer's name & address." Each of the nine reports at issue had entries that identified the devices as TMJI devices and TMJI as the device manufacturer. See Initial Decision, at 10; AR 224, at 12; 225, at 16, 17 and 18; 226, at 12; 233, at 12, 13, and 14; 234, at 11.[17]

Respondents take exception to the ALJ's finding that they violated the MDR requirements by failing to submit MDRs for these nine voluntary reports. R. Br. at 28-38. Respondents contend that FDA's policy of removing patient identifying and personal

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[17] With respect to two voluntary reports that describe the device as a "Titanium Fossa", (Event 1026649, Event 1027891), Respondents state that TMJI does not make a titanium device while other manufacturers do. AR 168, at ¶ 15. Respondents also assert that one report (Event 1027890) "describes the device as a "Bilateral Fossa Disc Device" and, that, while TMJI makes a "Fossa Eminence Prothesis" it is not "a disc device." Id. at ¶ 16. As explained below, TMJI can include this information in its MDRs as a basis for questioning whether it manufactured these devices. Respondents cannot refuse to file MDRs on this basis.

privacy information from the voluntary MedWatch forms prevented them from "confirm[ing] if the devices involved in the events . . . belong to TMJI." Id. at 28. Respondents also state that "TMJI could not investigate the event by contacting the medical professional to ascertain the circumstances surrounding the event and determine the root cause of the event." Id. at 28-29.

FDA argues that 21 C.F.R. § 20.63(f) authorizes it to withhold this information as to voluntary reporters and that redaction of this information is not a valid basis for a manufacturer's refusing to file an MDR. FDA Br. at 19. Section 20.63(f) provides that –

> the names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a . . . medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

FDA interprets this provision to preclude disclosure to manufacturers of identifying details of voluntary reporters who sought full confidentiality. Despite Respondents' objections, FDA's interpretation of this language is reasonable and consistent with its preamble discussions when it adopted or modified section 20.63 as to why it viewed confidentiality as critical to voluntary reporting. For example, FDA explained:

> FDA believes that its success in encouraging health professionals to participate in the voluntary adverse event reporting system depends substantially on the guarantee of confidentiality given the identity of the reporter under FDA regulations §§20.111(c)(3), 314.430(e)(4), 601.51(e)(3), and 803.9(b). . . . The rationale for this policy was first articulated in the Federal Register of December 24, 1974, in the preamble to FDA's public information regulations. At that time, FDA determined that without a guarantee of confidentiality, "the possibility of persuading health professionals voluntarily to submit adverse reaction

> information is substantially diminished, and indeed perhaps wholly destroyed" (39 FR 44,602, at 44,616).

59 Fed. Reg. 3944, at 3946 (Jan. 27, 1994).

In the preamble, FDA went on to discuss further why it believed its confidentiality policy was fundamental to the voluntary reporting system and cited surveys of doctors that support its view that lack of confidentiality would discourage voluntary reporting. FDA also stated that it "encourages reporters to allow the agency to share the reporter's identity with the manufacturer in order to help FDA and the manufacturer conduct necessary followup." To that end, the voluntary MedWatch form provides:

> Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

AR 114, at 3. The front of the form provides: "If you do NOT want your Identity disclosed to the manufacturer, place an "X" in this box." Id. at 2.

Respondents had notice of FDA's interpretation through these preamble discussions, through their discussions of these events with CDRH, and through the language on the voluntary MedWatch forms.

Respondents present a number of arguments as to why FDA is not precluded, under the language of section 20.63(f), from releasing identifying information to manufacturers.[18] Respondents assert

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[18] Respondents argue that FDA's release of mandatory reporters' information to manufacturers and the publication of some of that information (such as device part and lot number) on its website creates a "double standard" and that FDA's interpretation of section 20.63(f) unreasonable. R. Br. at 31; 34. FDA's different handling of mandatory and voluntary filers is not unreasonable. Since mandatory reporters are required by law to report, concerns that disclosure of identifying information might discourage such reporting are not a factor as they are with voluntary reporting.

We also note that Respondents seem to argue that FDA previously took the position that the Freedom of Information Act (FOIA)

that the redactions on these nine reports excused TMJI from filing MDRs and, therefore, CMPs should not be imposed for these nine events.

We reject this argument. Whether or not Respondents' interpretation of section 20.63(f) could be considered reasonable, FDA's redaction of this information does not excuse Respondents from filing MDRs. Redactions can indeed hamper a full investigation of the event, or confirmation that the event involved a TMJI device (R. Br. at 28-29), but the MDR regulations expressly address situations in which a manufacturer is not able to conduct a full investigation. They protect the manufacturer from being held responsible for unobtainable information or being considered as admitting responsibility for a device it may not have manufactured as follows:

- Section 803.50(b)(3) provides that, if the manufacturer cannot "submit complete information on a report," it must provide a statement explaining why the information was incomplete and the steps it took to obtain the information. Thus, in an MDR in response to a redacted report, the manufacturer can explain why it was unable to conduct a complete investigation.

- Additionally, section 803.16 provides that the information in a MDR does not "constitute an admission that the device caused or contributed to the reportable event." It instructs manufacturers that "you do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event."

Thus, the manufacturer is simply being required to make as complete a reply as it is able (which may include denials) to a voluntary report that would be in the MEDWATCH system whether or not the manufacturer replied.

Finally, the fact that information is redacted does not mean that a manufacturer cannot investigate or provide relevant information at all. For example, a described event may corroborate or shed light on information a manufacturer receives from other sources

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privacy provisions also restricted the release of this information to TMJI. R. Br. at 32-34. FDA did not make that
(continued...)

[18] (...continued)
argument before us. Since we uphold FDA's redaction practices under its interpretation of section 20.63(f), we do not reach the question of FOIA's impact on the release of this information.

as to problems with a device, and the manufacturer can include that additional information in its MDR.

Another basis on which TMJI relied in not filing MDRs for voluntary reports is that "the majority [of them] were not provided by a health professional [and] only a qualified health professional would have an understanding of TMD and knowledge of how a device works." AR 168, at ¶ 17. There is no requirement that a report be filed by a health professional; indeed 21 C.F.R. § 803.50(a) provides the reporting requirement can be activated by information "from any source." The inclusion of reports from lay reporters reflects Congress and FDA's intention to receive a wide range of information on the operation of devices. As the FDA experts testified, the signs and symptoms reported in these MedWatches reasonably suggested that a TMJI device may have contributed to a serious injury. They precipitated TMJI's duty to investigate and report, unless it could satisfy the requirements of section 803.20(c)(2), which it could not.

C. The ALJ's factual findings about the 17 adverse events are supported by substantial evidence on the record as a whole.

Respondents' challenges to the ALJ's factual findings that each of the events presented information that reasonably suggested that a TMJI device may have caused or contributed to a serious injury are, as noted above, premised on Respondents' misunderstandings about the legal terms used in the reporting requirements. We have nevertheless reviewed the factual underpinnings of the adverse events to determine whether the evidence in the record as a whole supports the ALJ's conclusions that each was reportable under the proper legal standards. In doing so, we considered the individual events, since the CMP amount depends on the number of violations. Here, however, we do not discuss each event in detail since Respondents did not explain their basis for concluding that the facts in each specific event, as found by the ALJ, were unsupported by the evidence in the record as a whole. Rather, Respondents focused on disputing how the facts should be evaluated (which we have already addressed) and more generally disparaging the evidence on which the ALJ relied. First, we address our overall evaluation of the evidence. Then, because multiple events present similar or identical considerations, we organize our remaining discussion of the events in several groupings.

i. Overall evaluation of the record

Overall, we conclude, after reviewing the record, that substantial evidence in the record as a whole supports the ALJ's

conclusion that section 360i(a)(1) and the implementing regulations require Respondents to have filed an MDR for each of these events. The evidence that supports the ALJ findings concerning each event generally includes (1) reports filed by individuals and user facilities describing the device, the recipients' signs and symptoms and the resulting surgical/medical interventions, (2) information resulting from TMJI's investigations, and (3) testimony of two FDA expert witnesses stating that the documented conditions constitute serious injuries to which TMJI devices may have caused or contributed. For each event, the reports provided information suggesting that signs and/or symptoms arose after implantation of the device that resulted in the treating physician engaging in medical or surgical intervention and, in the majority of the cases, explanting the device. For each event, FDA experts explained how the devices might have caused or contributed to the development of the reported signs and symptoms of a serious injury and/or how the lack of intervention to address the adverse effects might have led to permanent non-trivial injury.

Respondents argue that the ALJ should have disregarded FDA experts' testimony because they "had never performed operations involving TMJI's devices"[19] and "were only hired for their role in this case." R. Br. at 42. Respondents point out that Dr. Christensen invented the devices and their other two experts "have performed literally hundreds up to a thousand operations involving TMJI's devices." Id. Based on this experience, Respondents argue that the ALJ should have accepted these experts' opinions on whether the events were reportable and should have disregarded the contrary opinions of the FDA experts.

None of Respondents' arguments is persuasive. First, the FDA experts were qualified by virtue of their extensive training and experience in the treatment of TMJ Disorder and implantation of TMJ devices. AR 84, at 40-44; 85, at 20-73. Respondents identified no basis for concluding that experience with a TMJI device was required in evaluating the event reports. Second, the testimony of both sets of experts was based on a record review of these events. Thus, the FDA experts had no less direct knowledge of these particular cases than TMJI's experts.

Finally, unlike the ALJ, we do not have the opportunity to evaluate the credibility of a witness by listening to the witness in person or observing the witness' demeanor. Therefore, we defer to the ALJ's evaluations of the credibility of such

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[19] This statement is incorrect as to Dr. Small, who testified that he had implanted "in excess" of a 100 TMJI devices. AR 520, at 136.

witnesses absent a showing of clear error. While the ALJ did not explicitly explain the bases for his reliance on the FDA experts' testimony, the ALJ could reasonably have weighed such factors as self-interest (in the case of Dr. Christensen's testimony and Dr. Curry's since Dr. Curry was a paid consultant for TMJI and, in 2006, became a member of its Board (AR 169, at ¶ 3)) and the fact that Respondents do not dispute that TMJI previously filed numerous MDRs for similar events in the past. Thus, Respondents have shown no basis for concluding the ALJ erred in relying on the FDA experts' testimony instead of Respondents' experts.

For the reasons explained above related to the applicable legal standards, we conclude that Respondents failed to prove that they had information that would lead a person who is qualified to make a medical judgment reasonably to conclude that TMJI's devices did not cause or contribute to a serious injury as defined by section 360i(a)(2) and implementing regulations. Substantial evidence in the record as a whole supports the ALJ's finding that the experts presented by Respondents were ultimately not able to reasonably rule out that a TMJI device was a factor in each of the adverse events, even if they believed that other factors were more important or more likely to be causative.

We also reject Respondents' argument that FDA failed in its burden of proof because it "presented no factual witnesses regarding the question of TMJI's compliance with FDA imposed complaint procedures for review and investigation of adverse events" and "presented no factual witnesses within FDA that actually reviewed the disputed adverse events prior to filing of the CMP" (R. Br. at 38-39), i.e., "CDRH's in-house staff" (id. at 42).

Respondents identify no requirement that FDA prove its case by presenting the testimony of FDA employees who initially reviewed the events or made the decision to file a CMP complaint. The issue before us is whether the record as a whole supports the factual findings reached by the ALJ. We find it does. Furthermore, we find no merit to TMJI's objection that FDA did not show that these experts were involved in FDA's review of these events for purposes of deciding whether to take enforcement action against TMJI. The fact that the FDA experts did not review the files prior to the filing of the CMP Complaint did not hamper their ability to formulate an opinion on these events.

Respondents' argument is related to their long-standing insistence that Dr. Christensen was entitled to discuss events with CDRH personnel whom he regarded as appropriately qualified prior to being required to file MDRs. As Dr. Christensen stated:

> In the two years prior to the agency filing this case, TMJI repeatedly attempted to engage in a dialogue with the agency at the "medical expert" level, but the agency refused. . . . When TMJI met with the agency, the personnel in attendance on behalf of the FDA lacked the type of medical expertise necessary to fully appreciate and understand some of TMJI's positions on the issues.

AR 168, at ¶ 5.

Respondents point to nothing in the statute or regulations that would entitle them to such discussions. Indeed, if the CDRH were required to engage in the type of individual professional consultation Respondents envision before taking action in every case of failure to report, the MDR system might well collapse. Further, given Respondents' disparagement of the qualifications of the FDA experts in this case, it is not apparent FDA could have satisfied Respondents' requirements for what Dr. Christensen regarded as a "medical expert" by anything short of accepting Dr. Christensen's opinions. Indeed, Respondents' response supports the inference that they would regard as sufficiently qualified only experts who agreed with Dr. Christensen. The record also suggests that the underlying problem with the pre-complaint discussions was Respondents' refusal to accept CDRH's interpretation of the statute and regulations, not Respondents' lack of appropriate guidance from FDA.

In summary, we conclude that the evidence in the record a whole clearly meets the standard of section 360i by showing that Respondents received information that reasonably suggested that one of TMJI's devices may have contributed to a serious injury and that Respondents' investigation did not produce information based on which they could reasonably conclude that its device did not cause or contribute to a serious injury. Below, we discuss the cases by common elements (allegations of loose or migrating screws, allegations of disease progression, allegations of inflammation due to infection or foreign body reaction) to give examples of how Respondents failed to prove that they had 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.

ii. Events involving loose or migrating screws

Six events involved reports of loose device screws: MW1026649, 03-010, 03-017, 03-018, 03-019, 03-21. For each of these events, the reporter reported adverse signs and symptoms that had resulted in the explant or the planned explant of all of these devices. Such signs and symptoms included "persistent migraine

and facial swelling, which has closed off the ear canal and causes black eyes . . . screws from fossa have loosened and penetrated through Zygomatic arch" (MW1026649 - AR 90, at 18); "severely displaced left eminence fossa prosthesis with loose screw fixation, and displaced left condylar prosthesis" (03-010 - AR 227, at 23); "infected hardware with draining fistula through external auditory canal" and loose screws "one of which was completely lifted out its hole" (03-017 - AR 94, at 36-37); "loose hardware, infection" (03-018 at AR 95, at 17); "severe bilateral facial pain," "screw that actually protrudes through the skull into the middle cranial fossa," "malpositioned [right] fossa and loose screws," "fossa area . . . had been eroded through changes due to mobility of implant" (03-019 - AR 96, at 39, 40, 32, 33); "screws were found to be loose and somewhat backed out [with] heterotrophic bone along these areas" (03-21 - AR 97, at 22). Respondents asserted that their medically qualified experts reasonably concluded that the devices did not cause or contribute to serious injuries in such cases. The ALJ's contrary conclusion is supported by substantial evidence in the record as a whole, including the following:

- FDA's expert Dr. Smagalski strongly disagreed with the assertion of Respondents' expert Dr. Curry that "[l]oose screws do not cause of contribute to . . . serious injury." AR 117, at ¶ 26. Dr. Smagalski stated –

> If a screw is 'loose' in the bone, a bio-film contaminated with bacteria forms and results in the formation of soft granulation tissue that invades down into the space between the screw and the surrounding bone. This is similar to a foreign body reaction. These screw holes would not 'merely fill in shortly after their [screw] removal,' as Dr. Curry stated ([AR 117, at] ¶27). Rather, a permanent structural defect, filled with granulation tissue, is left in the bone and can be a site for persistent infection. As this infective, degenerative process continues, the loose screw becomes even more mobile and can migrate to unintended places. If this process occurs in the area of the TMJ fossa, the screw can literally migrate through the bone to the infratemporal fossa or even into the intracranial fossa where the brain is located. If infection, bone fracture, or an inflammatory/granulomatous reaction is involved, the situation can be very complex and can result in a serious injury to the patient. Dr. Curry's assertion (¶26) that 'Loose screws do not cause or contribute to . . . serious injury' is thus misleading.

AR 395, at ¶ 17.

- Dr. Smagalski also disagreed with Dr. Curry's statement that loose screws are not a significant problem because it is "a fairly simple task to tighten them or replace them." AR 117, at ¶ 26. After explaining the skill required to first insert screws properly into bone and the risk of user error (AR 395, ¶¶ 15-16), Dr. Smagalski stated:

  > [I]f an implant screw becomes loose during the post-operative period, it is not "a fairly simple task to tighten [it] or replace [it]," as Dr. Curry states. It is true that if a wood screw was inserted into a piece of lumber and it vibrated loose, you would simply retighten it. Dr. Curry's statements suggest that bone and implant screws react in a similar fashion. Nothing could be further from the truth. It is physically impossible to tighten a bone or implant screw in this condition. To replace the screw, the patient would have to undergo general anesthesia, an open arthrotomy surgical procedure, and a reconstructive surgery to be able to place new screws into viable areas of bone.
  >
  > AR 395, at ¶ 18.

- For each of these events, FDA experts explained why they concluded that these patients suffered a "serious injury" as that term is defined by section 360i. They also explained why they concluded that TMJI devices may have caused or contributed to those serious injuries. AR 394-397.

We conclude that the ALJ could reasonably credit these expert opinions and that the record as a whole supports his finding that Respondents were required to file MDRs for these events.

iv. Events that Respondents attributed to underlying disease prognosis

In the following nine events, Respondents' experts asserted that they reasonably concluded that the reported signs and symptoms were attributable to "the progression of the disease" and that the devices did not contribute to a serious injury. See, AR 117, at ¶ 19 (MW1026641 - implants required removal after six months because of bone growth and jaw fusion), ¶ 29 (MW1026650 - patient experiencing "extreme pain" six months after implant), ¶ 34 (03-010 total joint prosthesis replaced because of hypertrophic bone formation), ¶ 35 (03-011 - bilateral fossa prosthesis was removed because of pain), ¶ 46 (03-021 - revision surgery replacing standard partial device with a total custom prosthetic joint

replacement because of adhesions and hypertrophic bone), ¶ 50 (MW1027890 - device explanted because of bone masses, fibrosis, and pain), ¶ 51 (MW1027890 - device removed because patient's jaw fusing together; patient had osteophytes ("bony projections that develop as chronically inflamed tissue is converted to bone" (AR 394, at ¶ 23(j)(2))); and ¶ 55 (03-030 - the patient was unable to open his/her mouth adequately because of adhesions and ankylosis); at AR 168, at ¶ 151 (MW 102789 - "problems with migraine headaches and jaw joint pain. Has been hospitalized. Pain is worse since device was implanted." (AR 98, at 14)). For the following reasons, we conclude that the record as a whole supports the ALJ's finding that Respondents were required to file MDRs for these events.

- The FDA experts testified that a medically qualified person could not reasonably conclude that the devices did not contribute to a serious injury in these cases. AR 394-397. Specifically, Dr. Smagalski testified that "the progression of degenerative joint disease has an etiology and a cause" and where there is "post-operative progression of the degenerative disease process . . . then an unintended complication of the device implantation must be suspected . . . ." AR 395, at ¶ 7.

- Five of these events involved abnormal bone formation. Respondents asserted that the bone growth was unrelated to the devices. See, e.g., AR 117, at ¶ 19. In contrast, Dr. Smagalski testified that such bone formation can be related to inflammation and foreign body reaction in response to the implanting of a device. AR 395, at ¶ 19(b)(1) ("The progression of inflammation and foreign body reactions causes a disruption of the bones' healthy remodeling and results in haphazard patterns of bone repair."); see also AR 394, at ¶ 18. He concluded that, based on the information available for these events, Respondents could not reasonably conclude that the device was not a contributing factor in the problems described in the reports. AR 394, at ¶¶ 23(b)(1), (d), (i), (j)(2), (m); AR 395, at ¶¶ 19(b)(1), (d), (i), (j)(2), (m).

- Two of the events involved pain. Respondents treat any report of pain as simply part of the TMJ Disorder: Event 03-011 - AR 168, at ¶ 136 ("pain is a common indicator of the progression of TMJ Disorder" (Christensen Direct Testimony), and Event MW1026650 AR 168, at ¶ 127 ("pain and related symptoms such as headaches are common symptoms of TMJ Disorder" (Christensen Direct Testimony)). In contrast, Dr. Smagalski testified that --

  > post-operative acute pain associated with the placement of a TMJ implant prostheses indicates the possibility

> of (1) abnormal impingement of the device on the adjacent ear canal, cranial base, or subjacent soft tissue anatomy; (2) the initiation of a destructive inflammatory process; (3) new onset of infection; (4) myofacial dysfunction; or (5) malfunction of the implant device. . . . [And] return of chronic pain after implant surgery can be indicative of exacerbated osteoarthritic degeneration, fulminating infection, or impingement on surrounding vital structures.

AR 394, at ¶ 16.

He therefore concluded that these devices may have been a factor in the reported pain and the consequent need for explants in these cases. AR 394, at ¶¶ 23(b)(3), (d); AR 395, at ¶¶ 19(b)(3), (d).

- Because four of these events involved voluntary reports for which the user and patient were redacted, Respondents could not conduct an investigation into the specific facts of the event. However, this lack of information is not grounds concluding the device did not contribute to a serious injury. The MDR regulations contemplate situations in which a manufacturer cannot obtain sufficient information to make a definitive determination. In such cases, the manufacturer is required to file an MDR explaining why such information was incomplete and the steps taken to obtain the information. 21 U.S.C. § 360i(B)(2).

We conclude that the ALJ could reasonably credit these expert opinions and that the record as a whole supports his finding that Respondents were required to file MDRs for these events.

iv. Events involving infection or foreign body reactions

Many of the events included allegations of inflammation due to infection or foreign body reaction. Of the events not previously discussed above, these include 02-063 (AR 89, at 13; total jaw replacement in which patient “experienced significant swelling, increased pain and eventually decreased mobility,” which got worse when he/she was taken off repeated courses of antibiotics); MW1028047 (AR 99, at 12; bilateral implants with "severe (disabling) headaches, muscle pain in and around the implant and serious tenderness in and around the implant area,” requiring “anti-inflammatory and pain medications . . . situation appears to be attributable to foreign body reaction or other problem with implant”); 03-025 (AR 100, at 39; “surrounding the condyle [prosthesis] was what appeared to be a significant amount of

granulation tissue" along with "several large submandibular nodes . . . which also gave indications of a significant amount of inflammatory response."). For the following reasons, we conclude that the record as a whole supports the ALJ's finding that Respondents were required to file MDRs for these events.

- Dr. Smagalski discussed the problems associated with foreign body reaction and TMJ devices. He stated:

  > Foreign body reactions are characterized by inflammation and swelling that occur when the patient's defenses react to the presence of any material it identifies as a "foreign body." Additional tissue responses activate cells that deposit substances to isolate and confine the foreign body. This process culminates in the formation of granulation tissue, a soft tissue replete with new blood vessels. This tissue surrounds a foreign body, such as an implant prosthetic device, eliminating bony contact with it. The foreign body is then rejected from the adjacent tissues in an attempt to eliminate its presence. If this occurs around an implant, the device becomes loose, mobile, and painful from the progressing inflammatory reactions. . . . Once the process of rejection is initiated, it is very difficult to control it or prevent its progression. A TMJ implant surgical procedure followed by unexplained swelling, excessive inflammation, a foreign body reaction, pain or any combination of these conditions typically requires medical or surgical intervention to preclude permanent damage to the joint structures and/or permanent impairment of vital joint functions.

  AR 394, at ¶ 12.

- Respondents asserted before the ALJ that they reasonably concluded that the TMJI devices could not be responsible for foreign body reaction because TMJI uses "biocompatible material" and its "materials do not cause a foreign body reaction." AR 489, at 96 (allegation in MW1028047). TMJ cited studies and manufacturing guidelines in support of this assertion. Id. However, TMJI's own materials for users identify "foreign body or allergic reactions to the device materials" as one of the possible "complications associated with temporomandibular joint surgery and reconstruction [that] may require further treatment." AR 88, at 6.

- Dr. Smagalski stated that Respondents could not reasonably conclude, under MDR standards, that a TMJI device did not

contribute to the reported foreign body reactions. While he agreed that today's implants are made of materials designed to minimize foreign body reaction, he explained that "mishandling of the implant can result in contamination of the implant surface with powder from surgical gloves, debris at the surgical preparation site, or bacteria from non-sterile, surgical techniques" which could result in foreign body reaction. AR 394, at ¶ 17. These factors would constitute user error, but since user error is explicitly included in FDA's definition of "caused or contributed," the events must be reported under MDR standards. 21 C.F.R. § 803.3.

- Dr. Smagalski discussed the problems associated with the two types of infection associated with TMJ devices - bacterial infections and osteomyelitis. As to bacterial infections, he stated:

> Growth of bacteria in a contaminated surgical field (the joint space) will result in responses of inflammation in the soft tissue (cellulitis), edema, swelling, diffuse foreign body reaction, and cellular destruction of the invading organisms. The area affected will be swollen, erythematous (red in color), hot to the touch, and painful. As the patient's immune system mounts a response to the proliferating bacteria, an accumulation of lymphocytes (white cells that destroy the bacteria) accounts for the formation of an abscess (pocket of pus). An abscess isolated in soft tissue can be treated surgically by an Incision and Drainage ("I & D") and irrigation, which often resolves the problem. However, purulence (pus) imbedded around an implant prosthesis or stabilizing screw is usually resistant to this effort, because the organisms cannot be completely removed. The infection will persist until the device, which then acts as a foreign body, is removed (explanted).

AR 394, at ¶ 19.

As to osteomyelitis (persistent bone infection), he stated:

> osteomyelitis occurs on the inside of a bone and can present a challenging dilemma. If the offending organism is not treated aggressively enough, then the soft inner bone (cancellous bone) will be destroyed by the bacterial actions and will be resorbed (dissolved and removed) by the immune system. During osteomyelitis, the bone deteriorates, loses its ability

> to repair the damage, and may eventually fracture. This "dead bone" must be surgically removed, and healthy bone harvested from the patient's hips, ribs, legs, or skull can be grafted into the surgical site to replace it. When a patient develops the signs and symptoms of a bacterial joint infection, it must be treated aggressively to prevent an osteomyelitis and the subsequent destruction of the joint bones. Appropriate antibiotic therapy is the first line of defense against this potentially devastating problem. If a patient has received long term antibiotic therapy (more than 2-3 weeks) or multiple types of antibiotic regimens for a TMJ infection there should be a tentative diagnosis of osteomyelitis. A TMJ implant device, once surrounded by infection, will act as a foreign body and the typical foreign body reaction will be initiated by the patient's immune defense system. Explantation of the prosthetic device is often the end result and an unavoidable consequence of this surgical complication. Infections of any nature within the area of a TMJ implant require medical or surgical intervention to prevent their destructive consequences and concomitant permanent impairment of vital TMJ functions.

Id.

- Respondents asserted before the ALJ that they reasonably concluded that the TMJI devices could not be responsible for infections because TMJI "has designed the devices to minimize infections." See, e.g., AR 489, at 48 (allegation in Event 02-063). TMJ cited studies and manufacturing guidelines in support of this assertion. Id. at 75. A design that minimizes infection does not rule out infection. Further, a manufacturer's internal sterilization controls can break down. The MDR reports are intended to identify unexpected problems a manufacturer may experience in producing its devices that cause negative impacts for patients.

- Dr. Smagalski asserted that Respondents could not reasonably conclude, under MDR standards, that a TMJI device did not contribute to the reported infections. He stated that bacterial infections "associated with TMJ are typically caused by intra-operative (during surgery) contamination of the surgical field or sterility issue with the prosthesis device itself." AR 394, at ¶ 19. Thus, even if we accept Respondents' assertions that TMJI's manufacturing practices minimize the risk of infection, the user may have

> contaminated the device or surgical field when implanting the device. As noted above, an MDR is required even if the injury results from a user's error in handling the device.

We conclude that the ALJ could reasonably credit these expert opinions and that the record as a whole supports his finding that Respondents were required to file MDRs for these events.

2. FDA's CMP Complaint was neither "premature" nor violative of due process.

A. FDA's CMP Complaint was not premature.

We reject Respondents' contention that the fact that FDA filed a CMP enforcement action before the FDA Commissioner issued a decision in TMJI's request for review under 21 C.F.R. § 10.75 made the enforcement action premature.

Section 10.75(a) provides in pertinent part:

> A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:
>
> * * *
>
> (3) At the request of an interested person outside the agency . . .

Under 21 C.F.R. § 10.75, TMJI requested a review, by the FDA Commissioner, of the CDRH Director's decision that MDRs were required for these events. AR 82. Respondents argue that FDA should not have filed the CMP Complaint prior to the issuance of a decision by the Commissioner adverse to TMJI and a further opportunity for TMJI to file MDRs after receipt of such a decision. Respondents assert:

> Arguably until there was a final determination by the Commissioner of FDA on the interpretation of the MDR regulations in dispute, Respondent TMJ Implants, Inc. could not be summarily deemed to be in knowing violation of these regulations. The Due Process provided by FDA's own published regulations in 21 C.F.R. § 10.75 and acknowledged by Complainant's Director in his letters to TMJI dated September 7, 2004 and November 10, 2004, should have been allowed to run its course. Only after refusing to comply with a possible adverse ruling by the Commissioner on the interpretation of the MDR regulations and Respondent TMJ Implants, Inc.'s refusal to comply would a CMP be appropriate.

R. Br. at 14.

Below we review the undisputed facts leading up to TMJI's request for a section 10.75 review and then explain why we reject Respondents' arguments.

On February 24, 2004, FDA issued a Warning Letter to TMJI instructing TMJI to file MDRs for the events at issue and making the following warning:

> You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions may include but are not limited to seizure, injunction and/or civil penalties.

AR 53, at 6.

Thereafter, FDA engaged in months of discussions with TMJI concerning questions about FDA's position that MDRs should be filed for these events. See AR 58-81. These discussions culminated in a November 10, 2004 letter (AR 81) from the Director of CDRH informing TMJI as follows:

- CDRH continued to believe that section 360i required TMJI to file MDRs for these events;

- CDRH was willing to process TMJI's letter of September 27, 2004 discussing these events as "incoming MDR submissions and enter the reports into our adverse event database" and TMJI had 10 days to object to this proposed resolution of the dispute;

- if TMJI did not agree to treat its September 27, 2004 letter as MDR submissions, CDRH would treat any further TMJI correspondence on the matter as a request for an appeal pursuant to 21 C.F.R. § 10.75 and forward it to the Commissioner;

- and "the 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)."

In a letter of November 16, 2004, TMJI rejected FDA's offer to accept TMJI's September 27, 2004 letter as timely MDRs and made "a formal request that this MDR matter . . . be forwarded to the Commissioner consistent with the internal agency review of decisions provisions contained in 21 C.F.R. § 10.75." AR 82, at 2.

On July 14, 2005, FDA filed the instant CMP Complaint seeking to impose CMPs against the Respondents. AR 1.

In July 2005, the FDA Associate Commissioner for External Relations contacted TMJI about its request for review under 21 C.F.R. § 10.75 and stated:

> We have learned that CDRH's determination concerning your MDR obligations is the subject of a Civil Money Penalties (CMP) complaint filed under 21 C.F.R. Part 17. The issues raised in the complaint, which has been sent to you, will be heard by a neutral Administrative Law Judge (ALJ), and will permit an opportunity for further development of factual and legal issues underlying CMP charges. Moreover, should you not be satisfied with the decision by the ALJ, you (as well as the FDA, should it be dissatisfied) may appeal the decision to the Commissioner's designate, the Departmental Appeals Board, as provided for under 21 C.F.R. § 17.47(a). Under these circumstances, we believe it would be inefficient and duplicative to review this matter now.

AR 83.

B. Due process

We reject Respondents' argument that due process principles precluded FDA's filing of an enforcement action until after the Commissioner ruled on TMJI's section 10.75 review request and TMJI had another opportunity to file the MDRs. Respondents appear to argue that their due process was violated because they did not receive adequate notice that an enforcement action could be filed prior to the Commissioner's decision in the section 10.75 review. See R. Br. at 14-18. Respondents thus represent that they relied in "good faith" on the fact TMJI had requested this review only to be "ambushed" by FDA. Id. at 14.

Inadequate notice can implicate due process concerns in some circumstances. General Electric Company v. United States Environmental Protection Agency, 53 F.3d 1324 (C.A.D.C. 1995). However, we do not reach the question of whether due process principles required FDA to give Respondents notice that the section 10.75 proceeding did not preclude an enforcement action, because, whether or not such notice was required, FDA gave it. Eight months before the filing of the CMP Complaint, the Director of CDRH wrote Respondents that the section 10.75 proceeding would "not preclude the Agency from taking action to enforce the requirements of the Food, Drug, and Cosmetic Act." AR 81. Further, the regulation cited by the Director in that letter, 21

C.F.R. § 10.35(d), gave Respondents notice that an administrative procedure under part 10 (such as a request for review under section 10.75) did not automatically stay or delay an enforcement action. Section 10.35(d) provides:

> Neither the filing of a petition for stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or any other section of this chapter . . . will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:
>
> (1) The Commissioner determines that a stay or delay is in the public interest and stays the action.
>
> (2) A statute requires that the matter be stayed.
>
> (3) A court orders that the matter be stayed.

(Emphasis added.) Respondents do not argue that any of the three enumerated conditions to stay an enforcement action applied here, nor that they even requested a stay of further enforcement action from the Commissioner in their section 10.75 review request.

Respondents argue, however, that section 10.35(d) is (and was) irrelevant and improperly cited by the CDRH Director because, Respondents argue, the section "does not apply to an appeal request to the Commissioner but instead to a Petition to Stay Action of an existing administrative action of the Commissioner, which was not the case at the time of the appeal and would not have been so until the filing of the CMP." R. Br. at 16. Respondents' conclusion that the Director improperly cited section 10.35(d) is simply wrong. As explained above, section 10.35(d) gives the public (and Respondents) express notice that no part 10 proceeding will automatically stay or otherwise delay an enforcement action. Thus, the Director correctly cited section 10.35(d) in support of his express caution to Respondents that TMJI's request for a section 10.75 review would not preclude FDA's filing of an enforcement action.

In light of this express notice to Respondents, their protestations that they were "waiting in good faith for a response from the Commissioner" and that they did not understand that they were at risk of an enforcement action (R. Br. at 14-15) are not credible or reasonable.[20] Nor does the evidence support

[20] Respondents make a number of pejorative allegations about the CDRH, such as that CDRH sought to "ambush" (R. Br. at 14) TMJI with the CMP Complaint, that it "purposely misl[ed]

Respondents' allegations that the section 10.75 proceeding was merely a bad faith diversion by CDRH and that the Commissioner "never intended to respond in good faith to Respondent's appeal request prior to filing the CMP." R. Br. at 17. First, Respondents identify no tactical advantage (and we see none) that CDRH gained by treating TMJI's further correspondence, at TMJI's request, as a section 10.75 request while simultaneously telling TMJI that a section 10.75 proceeding would not preclude an enforcement action. Second, according to the Associate Commissioner's letter closing the section 10.75 review, the Commissioner determined that the CMP Complaint proceeding under 21 C.F.R. Part 17 was a more appropriate forum for resolution of the issues. AR 83. Given the complexity of the resulting record, this was not an unreasonable conclusion.

The fact that TMJI had requested a section 10.75 review prior to the filing of the CMP Complaint did not create a due process entitlement to a determination by the Commissioner prior to an enforcement action. The component of FDA that is responsible for administering MDRs had repeatedly told TMJI that MDRs were required. The FDA "Administrative Practice and Procedures" regulations at 21 C.F.R. Part 10 provide several avenues for interested parties to affirmatively contest such an "administrative action" or decision of an FDA employee. See 21 C.F.R. §§ 10.25, 10.30, 10.33, 10.75. As discussed above,

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TMJI with citations to [section 10.75]" (id. at 16), that it "literally conspire[d] with the former Commissioner to 'sit on'" TMJI's review request (id. at 11), and that CDRH's objective was "punishment" and "not justice" (id. at 21). Respondents point to evidence indicating that the CDRH, the FDA Office of the General Counsel, and the Commissioner's Office communicated about the filing of the CMP Complaint after TMJI made the section 10.75 request. Id. at 16-17. None of these allegations or evidence is a basis for finding that the ALJ erred. As discussed above, CDRH warned TMJI that it was risking an enforcement action eight months before filing it. Moreover, Respondents failed to show any reason that communication between an agency's legal office, its administering component, and the

[20] (...continued)

supervising office of that component about an enforcement action would be improper or unusual. None of these offices had an obligation to further warn or inform Respondents that an enforcement action was being prepared. Finally, we note that the CDRH spent eight months in correspondence and meetings with Respondents trying to resolve this matter before it called an end to the discussions in November 2004. The CDRH's course of conduct indicates it tried at length to address Respondents' concerns and resorted to an enforcement action only when it concluded that informal resolution was not possible.

however, section 10.35(d) makes it clear that none of these proceedings "stay or otherwise delay" enforcement proceedings. Respondents cite no authority for the proposition that due process principles should allow the subject of an enforcement action to avoid or delay that action simply because the agency offers or the subject enters into an alternative agency review process. As FDA points out, such a proposition would enable people to shield themselves from enforcement actions that FDA determines are needed to fulfill its statutory responsibilities. FDA Br. at 13.

Finally, while the filing of the CMP Complaint resulted in the termination of the section 10.75 review, it did not deprive Respondents of due process since they then became entitled to a formal administrative hearing under 21 C.F.R. Part 17.[21] "The fundamental requirement of due process is the opportunity to be heard." Mathews v. Eldridge, 424 U.S. 319, 333 (1976). The administrative hearing process in 21 C.F.R. §§17.13 - 17.45 provided Respondents a full opportunity to present their claims and defenses before the ALJ prior to being deprived of any property interest. Respondents are additionally entitled to this review by the Board (21 C.F.R. § 17.47) and judicial review in a federal court after its administrative remedies have been exhausted (21 C.F.R. § 17.51).

Respondents further represent that this process has cost over $500,000 and resulted in great hardship to a small company. R. Br. at 21. We are not unsympathetic to the fact that litigation is time-consuming and expensive. As cited above, CDRH, however, gave TMJI repeated opportunities to file late MDRs without penalty and without admission of wrongdoing. Respondents chose to reject these offers and thereby chose to expose themselves to these costs.

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[21] Respondents devote considerable attention to the fact that, early in the ALJ proceeding, FDA incorrectly described the sequence of events, stating that the letter from the Office of the Commissioner preceded the filing of the CMP Complaint and to the fact that the ALJ repeated this mistake. R. Br. at 18, 22, 49; R. Reply Br. at 5. These errors provide no basis for concluding, as Respondents would have us do, that their due process rights were violated or that the ALJ's decision should be reversed. As explained above, Respondents had no due process right to a decision from the Commissioner prior to or in addition to their appeal of the enforcement action. Therefore, the fact that the Commissioner's rejection of TMJI's section 10.75 review request occurred after the CMP Complaint was filed is irrelevant and any misstatement of the sequence is harmless.

3. The ALJ did not err in concluding that Respondents' actions constituted "knowing departures" from applicable requirements.

Section 333(f)(1)(A) of 21 U.S.C. provides that any person violating a requirement of the chapter as to devices is liable for a CMP. Section 333(f)(1)(B) provides that this penalty provision shall not apply "to any person who violates section 360i(a) . . . unless such violation constitutes a significant or knowing departure from such requirements or a risk to public health." (Emphasis added.) Section 17.3(a)(2) of 21 C.F.R. defines "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.

The ALJ found that Respondents' violations constituted knowing and significant departures from the requirements. Initial Decision at 11.

Respondents argue that, at the time the CMP Complaint was filed, their failure to file MDRs could not be considered "knowing" violations of section 360i because the Commissioner, in the section 10.75 review, had not yet determined that MDRs were required.[22] Respondents assert that they were entitled to treat the Commissioner's "resolution as a condition precedent in deciding whether or not to file MDRs for these 17 adverse events . . . ." R. Br. at 49.

We reject this argument. Respondents were not entitled to a determination by the Commissioner before their failure to file MDRs became "a knowing departure" from the requirements of section 360i. The Commissioner delegated the authority to direct and monitor such device compliance and surveillance programs to CDRH. See, e.g., 48 Fed. Reg. 54,128 (Nov. 30, 1983). The CDRH Director's agent informed Respondents that TMJI's failure to file

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[22] Respondents also argue that the ALJ erred in concluding that their departures from applicable requirements were "significant." R. Br. at 20. We disagree. Respondents' failures to file MDRs were longstanding, numerous, and evidenced an intransigence that FDA could well regard as problematic for TMJI's future compliance with MDR standards.

MDRs for these events was a violation of the requirements (AR 53 - February 26, 2004 Warning Letter) and then, after eight months of discussions with CDRH personnel, the CDRH Director again informed TMJI in a final letter to that effect (AR 81 – November 10, 2000 letter). These determinations provided Respondents with "actual knowledge that [their] action [was] such a departure," as well as repeated opportunities to cure the failure to file, and Respondents' refusal to accept these determinations constituted, at the very least, "deliberate ignorance of a requirement" or "reckless disregard of a requirement."

Respondents mistakenly rely on Biotic Research Corporation v. Heckler, 710 F.2d 1375 (C.A. Nev. 1983) for the proposition that an individual does not have knowledge of a requirement until it receives a "final Agency action" (which the court refers to as a "final administrative determination") construing that requirement. R. Br. at 15, 19-20. Biotic concerns an individual's access to federal court, not what constitutes knowledge for purposes of 21 U.S.C. § 333(f)(1)(B) (or any other FDA knowledge requirement). Biotic holds that, in a case involving classification of a product as a drug, an individual cannot seek federal court review until FDA issues a final administrative determination, and the warning letter issued to Biotic was not such a determination. The court points out that individuals who receive warning letters (as TMJI did) can obtain such final administrative determinations through petitions to the Commissioner under 21 C.F.R. §§ 10.25 and 10.30. Biotic, supra, at 1377-1378. The Biotic ruling does not address directly or by inference what agency interactions with a party suffice to show that the party received specific individualized knowledge of applicable requirements under section 333(f)(1)(B).

Therefore, we conclude that the ALJ correctly determined that Respondents' due process rights were not violated and that their failure to file MDRs for these events was a knowing departure from the requirements of section 360i.

4. The ALJ did not err by concluding that FDA may impose CMPs on individuals employed by the manufacturing corporation.

Dr. Christensen and Ms. Mooney argue that the ALJ erred by concluding that FDA has authority to impose CMPs on employees of a manufacturing corporation for violating MDR requirements. R. Br. at 22-28.

The applicable CMP provision, 21 U.S.C. § 333(f)(1)(A), provides in pertinent part:

> (f) Violations related to devices
> (1)(A) . . . any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation . . . .

Section 321(e) of 21 U.S.C. provides that "[t]he term 'person' includes individual, partnership, corporation and association."

Dr. Christensen and Ms. Mooney state that they do "not dispute that individuals are not immunized [under section 333(f)(1)(A)] from liability where applicable." R. Br. at 23. Rather, they argue that section 333(f)(1)(A) is not applicable because FDA applied the manufacturer reporting requirements in 21 C.F.R. Part 803 solely to manufacturing entities. They conclude that, as individuals employed by a manufacturer, they did not violate any device reporting requirement. R. Br. at 22-24. They cite section 360i, which provides:

> Every person who is a manufacturer . . . of a device . . . shall . . . make such reports . . . <u>as the Secretary may by regulation reasonably require</u>.

(Emphasis added.) They then cite the language of 21 C.F.R. § 803.1(a), which provides:

> This part establishes the requirements for medical device reporting for device <u>user facilities, manufacturers, importers, and distributors</u>.

(Emphasis added.) They argue that section 803.1(a), "consistent with" section 360i of the statute, limits applicability of the requirements of 21 C.F.R. Part 803 to "user facilities, importers, distributors and manufacturers, not their employees." R. Br. at 23. They support this argument by citing 21 C.F.R. § 17.3(b), a regulation governing FDA CMP hearings, which defines the terms "person or respondent" to include:

> an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or other legal entity, or <u>as may be defined in the act or regulation pertinent to the civil penalty action being brought</u>.

(Emphasis added.)

Dr. Christensen and Ms. Mooney argue that, for the purpose of manufacturer device reporting requirements, FDA has "defined" the

term "person" as limited to the manufacturing entity. R. Br. at 22-24.

We reject this argument as contrary to FDA's expression of intent in promulgating 21 C.F.R. Part 803, to court decisions applying the FDCA, and to a reasonable reading of 21 C.F.R. § 17.3(b).

First, Dr. Christensen and Ms. Mooney's interpretation is contrary to the remedial purpose of the FDCA and unsupported by any FDA issuances indicating that FDA intended to exclude corporate employees from liability for violations of medical device reporting requirements. Indeed, the preamble to the final rule adopting part 803 indicates that FDA intended that reporting requirements be applied to employees of manufacturing entities. A commenter "argued that all employees of reporting entities should not be included under the reporting requirements of the SMDA, and that accordingly, the timeframes for reporting should not be triggered upon the knowledge of 'any employee' of a reporting entity." 60 Fed. Reg. at 63,581. FDA rejected this comment, writing:

> FDA . . . does not agree that employees of reporting entities should not be subject to the reporting requirements and that timeframes for reporting should not be triggered when employees of the reporting entities become aware of events. The scope of the act does not exclude any responsible persons who are employees of these entities from complying with section 519 of the act.

Id.[23]

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[23] Dr. Christensen and Ms. Mooney cite the fact that, under the FDA definition of "become aware," an employee's knowledge is imputed to the employing entity (such as a corporation) for purposes of calculating reporting deadlines. See 21 C.F.R. § 803.1(a). They write:

> information of the existence of reportable adverse events acquired by a manufacturer's employees is imputed to the manufacturer, not the other way around as would be implied by their inclusion in the CMP and by the logic of the ALJ's Order here.

R. Br. at 24 (emphasis in original).

This argument is without merit. An entity such as a corporation can only "know" what its employees know, but individuals are also responsible for their own knowledge; thus, knowledge cannot be imputed "the other way around." As the preamble discussion

Second, Dr. Christensen and Ms. Mooney's interpretation is contrary to federal court cases construing individuals' liability under the FDCA. FDA cites and relies on United States v. Dotterweich, 320 U.S. 277, 281 (1943) and United States v. Park, 421 U.S. 658, 672 (1975), two cases dealing with the applicability of criminal penalties under the FDCA. In Dotterweich, the Supreme Court discussed the important public purpose of the FDCA, the role of penalties in effectuating that purpose, and the fact that "the only way in which a corporation can act is through the individuals who act on its behalf." 320 U.S. at 282. It ruled that, consistent with that public purpose, the corporation's president and general manager could be held criminally liable for violations of the FDCA. Id. at 284. Thirty years later in Park, the Supreme Court relied on Dotterweich in holding a corporation's president criminally liable under the FDCA for the insanitary condition of the company's warehouse, even though he was not "personally concerned in the . . . violation." 421 U.S. 663.

Dr. Christensen and Ms. Mooney assert that they do "not dispute that employees and officers of corporations usually insulated from liability in civil matters may be held personally liable . . . in criminal acts harming the public . . . ." R. Br. at 24. Hence, they reason that they cannot be held liable for a CMP as this is a civil proceeding. However, they fail to explain why the considerations in Dotterweich and Park do not support the application of FDCA civil remedies to such individuals. See R. Br. at 24-25. Like the criminal remedies in Dotterweich and Park, civil remedies are tools for enforcing the FDCA and fulfilling its public purpose. Courts have therefore concluded that individuals are also subject to civil remedies under the FDCA. For example, in United States v. Undetermined Quantities of Articles of Drugs, 145 F. Supp.2d 692 (S.D. Md. 2001), the court held both the corporation and the corporation's president civilly liable under the FDCA. The court wrote:

> The FDA's statutory authority empowers the government to seek relief against corporate executives, as well as legal entities, in enforcement actions. "[C]orporate agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are

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shows, this definition of "become aware" simply establishes standards for determining when an entity is deemed to have knowledge that activates its duty to take action. Further, the fact that the definition of "become aware" imputes knowledge from a person to another entity does not mean that such knowledge (and any concomitant responsibility) is therefore transferred away from that person.

> necessary to ensure compliance with the Act bear a 'responsible relationship' to, or have a 'responsible share' in, violations." United States v. Park, 421 U.S. 658, 672 . . . (1975); see United States v. Dotterweich, 320 U.S. 277, 284 . . . (1943) . . . . While the Supreme Court cases imposed criminal liability upon the individual corporate officers for violations of the FDCA, "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). "The 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.

145 F. Supp.2d at 704 (emphasis added); see also United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp.2d 30 (E.D.N.Y. 2001) (United States was entitled to enjoin owner/employees of corporation from processing fish that was adulterated within the meaning of the FDCA).

Third, we disagree with the argument that section 17.3(b) of the FDA regulations on CMP hearings somehow supports a restrictive reading of "manufacturers" in 21 C.F.R. § 803.1(a) as excluding employees acting for corporations manufacturing medical devices.

As set out above, section 803.1(a) on its face states that FDA is by regulation establishing the reporting requirements for, inter alia, medical device manufacturers. It says nothing about whether liability for failure to comply with those requirements is limited only to the corporate entity per se or extends to its officers or responsible employees. Section 17.3(b) expressly defines potential respondents to include individuals.

Nevertheless, Dr. Christensen and Ms. Mooney rely on the final clause in section 17.3(b) as restricting the class of persons who may be subject to CMPs to those persons "as may be defined in the act or regulation pertinent to the civil penalty action being brought." Although use of "or" rather than "and" sometimes means that the listed items are alternatives, the history of section 17.3(a) indicates that the definition of "person" or "respondent" was modified to provide "additional examples," not to limit to limit the definition. 60 Fed. Reg. 38,612, at 38,614 (July 27, 1995). In any event, the relevant statutory provision defines "person" to include any "individual" and the regulations

implementing the reporting requirement do not exclude individuals, so the alleged restriction is irrelevant.

Therefore, we reject Dr. Christensen and Ms. Mooney's assertion that employees of manufacturers are not subject to civil remedies, specifically CMPs, under section 21 U.S.C. § 333(f)(1)(A) for failure to file MDR reports.

5. The ALJ erred by concluding that FDA may impose CMPs on Ms. Mooney. The ALJ did not err by concluding that FDA may impose CMPs on Dr. Christensen.

The FDA relied on Dotterweich and Park as setting standards for determining whether an individual employed by a corporation is subject to liability under the FDCA. FDA Br. at 15-18. In Dotterweich, the Supreme Court looked to whether the individual had a "responsible share in the furtherance of the transaction which the statute outlaws." 320 U.S. at 284. In Park, the Court looked to whether the individuals had a "responsible share in the furtherance of the transaction" and, if not, whether the individuals "by virtue of their managerial positions or other similar relation to the actor [who committed the criminal act] could be deemed responsible for its commission." 423 U.S. at 670. As explained below, Ms. Mooney satisfies neither of these tests and Dr. Christensen satisfies both.

A. Liability of Ms. Mooney

The ALJ stated that he was imposing a CMP on Respondents, including Ms. Mooney, for "knowing and significant violations [by failing to file MDRs for the 17 events] and to encourage future compliance with MDR requirements in the interest of protecting the public health." Initial Decision at 11. The FDA had the burden of proving by a preponderance of the evidence that Ms. Mooney met the applicable standards for personal liability. 21 C.F.R. § 17.33(b). We review the record as a whole to determine whether substantial evidence supports the ALJ's conclusion that FDA met this burden.

The FDA argues that Ms. Mooney, as TMJI's Regulatory Affairs and Quality Assurance Manager, is personally liable under the standards in Dotterweich and Park because, it asserts, "Mrs. Mooney, by virtue of [her] position and actions, bear[s] responsibility for TMJI's failure to file MDRs for the 17 events at issue in this proceeding." FDA Br. at 17 (emphasis added). We conclude, however, that evidence in the record as a whole does not support FDA's assertions, and therefore, it has failed to meet its burden of proof. Rather, the record shows that (1) in each event, TMJI's decision not to file an MDR was based on

section 803.20(c) of 21 C.F.R., which allows a manufacturer not to report an adverse event "if [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 death or serious injury"; (2) these medical judgments were all made by Dr. Christensen (alone or with qualified consultants); (3) Ms. Mooney did not have the expertise to make and did not make the medical judgments; and (4) Ms. Mooney was responsible for establishing and administering the procedures by which decisions on whether to file MDR reports were made and had no authority or ability to counteract Dr. Christensen's medical judgments that the standards of section 803.20(c) had been met.

The ALJ did not discuss the evidence on which he relied in concluding that Ms. Mooney met the standards in Park for personal liability. Further, the ALJ did not state that he did not find credible Ms. Mooney's or Dr. Christensen's testimony about Ms. Mooney's role in the MDR process or her status at TMJI. Finally, FDA points to no evidence that contradicts the Respondents' testimony and evidence as it relates to Ms. Mooney.
FDA relies on Dr. Christensen's testimony that Ms. Mooney and Bonnie Ray (who was TMJI's Quality Assurance Officer), along with himself, were "the core of the team that would made the decision" whether to file an MDR. AR 520, at 153-154. However, FDA fails to cite his further testimony that he alone, not Ms. Ray or Ms. Mooney, made "the medical evaluation" involved in an MDR determination, unless he brought in an outside consultant. Tr. at 240-241. In the full context, it is evident, where the decision not to file was based on medical judgment that an event was not reportable, that the only role of the rest of the "team" was to see that this decision was documented properly in TMJI's records.[24] This understanding of Dr. Christiansen's testimony is

[24] While we conclude that Dr. Christensen's medical judgments were not reasonable, in part, because he failed to use congressional and FDA standards for determining serious injury and causation, FDA has not shown that he relied on Ms. Mooney in misapplying these legal requirements. The evidence in the record indicates that Ms. Mooney's responsibility lay in ensuring that legal advice was sought when needed. Further, the evidence in the record shows that Dr. Christensen was advised and accompanied by corporate counsel throughout his dealings with CDRH about these disputed events. See AR 59 (transcript of March 2004 meeting with CDRH attended by Dr. Christensen, Dr. Curry, Ms. Mooney and corporate counsel), 63 (April letter to FDA Denver District Office signed by Dr. Christensen and corporate counsel), 64 (April letter to FDA Commissioner signed by Dr. Christensen and corporate counsel), 69 (July letter to FDA Denver District Office signed by corporate counsel).

consistent with Ms. Mooney's testimony that she did not have expertise to make such medical evaluations and that Dr. Christensen made them. AR at 357-358, 364-365, 367-368. For example, she testified as follows:

> [Q] Being part of a team does not mean that you had involvement in making the medical determination as to whether an adverse event rose to the level to be reported as an MDR?
>
> [A] That is correct. I did not make the medical evaluation. I made sure our procedures were followed, that a decision tree was completed, that all the files had all the correct documentation. I made sure that any referenced scientific study or manufacturing information, engineering testing, anything relevant to that decision in that file, was included in that report, and that our procedures again were followed. We do have numerous procedures on complaint handling and event reporting.

AR 520, at 367-368.

Further, FDA did not show that Ms. Mooney fell into the category of people that section 803.20(c) identifies as qualified to make medical judgments under that section. It provides that "[p]ersons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers." While FDA cross-examined Ms. Mooney as to whether she could be considered a "risk manager," she asserted that she was not a risk manager. AR 520, at 357-358. FDA identified no evidence as to whom it considers a risk manager under section 803.20(c), much less any evidence that would tend to show that Ms. Mooney was a risk manager despite her contrary testimony.

FDA also cites to evidence showing that Ms. Mooney signed "[MDR] Checklists and Complaint Closure memoranda to ensure that TMJI's complaint handling and reporting procedures have been followed (AR 163, at ¶ 6); ensured that "TMJI's procedures for logging in, processing and reviewing adverse events . . . are in compliance" with the relevant FDA regulation (AR 489, at ¶ 206); was required to be familiar with the MDR regulation (AR 520, at 356); and reviewed and approved TMJI's MDR procedures (AR 520, at 369-70). FDA Br. at 17-18.

The evidence cited by the FDA shows that Ms. Mooney was responsible for establishing and managing TMJI's <u>procedures</u> for deciding whether to file an MDR. This is consistent with her written direct testimony filed in support of Respondent's Motion for Partial Summary Judgment in which she stated as follows:

> I review the MDR decision trees located in the complaint file to make certain that the president (or his designated medical representative) documented the reportability decision. Per company procedures, if the decision is made to report the event, I work with the RA/QA Associate to ensure the MDR is reported within the 30 days.

AR 171, at ¶¶ 16-17.

Absent some showing that TMJI's procedures were not consistent with the regulations (which FDA did not make in this proceeding), we reject FDA's argument that evidence showing that Ms. Mooney was responsible for the TMJI adverse event review procedures made her responsible for the decisions that resulted from those procedures. Were TMJI being penalized for its failure to have a MDR process or to follow its MDR process, these responsibilities (and the others cited above by FDA) might be relevant in determining whether Ms. Mooney was individually liable. Since TMJI is being penalized here for failing to file MDRs based on individual medical determinations that Ms. Mooney did not make and had no expertise or authority to make, FDA has not proven a basis for imposing individual liability simply because she was responsible for seeing that TMJI had and followed adverse event review procedures.

In addition to looking at whether a person was personally responsible for a corporation's violation of the FDCA, Park looks to whether the person "by virtue of their managerial positions or other similar relation to the actor [who committed the criminal act] could be deemed responsible for its commission." 423 U.S. at 670. The evidence in the record as whole does not support a finding that Ms. Mooney could, by virtue of her position, "be deemed responsible" for TMJI's and Dr. Christensen's failure to file MDRs. Dr. Christensen was the President, Chief Executive Officer, the sole owner and the only corporate officer of TMJI. AR 297, at 3 (report dated 9/2003). Ms. Mooney had no authority over Dr. Christensen, nor does the record show that there was any superior person or board with authority over him or TMJI to whom she could have raised questions as to his judgments. As of May 2004, she was a part time employee earning less than $35,000 annually. AR 604. She testified that "I do not receive nor have I ever received a bonus or a draw from TMJI" (id. at ¶ 4) and that "I am not a Corporate Officer at TMJI. I do not have an interest in TMJI other than my part-time status and my bi-weekly salary paycheck" (id. at ¶ 6). FDA did not prove that her position encompassed general managerial authority over the operation of the corporation. While her position did have some relationship to ensuring that TMJI had in place and followed a procedure for review of adverse events in compliance with the

regulations, as we have noted that responsibility has not been shown to extend to authority over the content of medical judgments on which non-reportability decisions were based. Thus, she also had no "responsible relation" "by virtue of [her] managerial positions or other similar relation to" TMJI or Dr. Christensen so as to be responsible for his decisions.

For the preceding reasons, we conclude that substantial evidence in the record as a whole does not support a finding that Ms. Mooney had a responsible share in or a responsible relation to TMJI's failure to file MDRs for these events. Therefore, we conclude that the ALJ erred in imposing a CMP on her.

B. Liability of Dr. Christensen

In contrast, substantial evidence in the record as a whole supports the ALJ's conclusion that Dr. Christensen is liable. Dr. Christensen meets both the tests of Park. As the reason for not filing MDRs, TMJI relied on his qualifications to make a medical judgment that the devices did not cause or contribute to a serious injury. Therefore, he had a "responsible share" in the decision not to file the MDRs. Additionally, as President of the corporation, he was responsible for and had authority over all operations at TMJI. Therefore, he also had a "responsible relation" to the violation – his centrality to and responsibility for the actions of the corporation are evident from the record. See AR 61, 63-66, 68, and 70.

Dr. Christensen points to the Dr. Smagalski's statement that reasonable men may differ in their opinions of an adverse event. R. Br. at 27, citing AR 395 at 75-76. He argues that such "good faith differences of medical opinions" should insulate him from individual liability. Id. We disagree. The fact that there may be more than one reasonable opinion about whether an event is reportable does not, in itself, make Dr. Christensen's medical judgments reasonable. Indeed, we have explained why they were not reasonable. As discussed in the section addressing the legal standards applicable to MDRs, Dr. Christensen's medical judgments were not "reasonable" because they did not employ congressional and FDA standards for determining serious injury and causation for MDRs. Dr. Smagalski specifically noted this failure in his testimony. AR 395, at ¶ 5; see also id. at ¶¶ 6-9.

Furthermore, as we have already recounted, Dr. Christensen had ample guidance during his personal interactions with the FDA prior to the issuance of the CMP Complaint that he was not applying the correct standards. He was offered the opportunity to let his statements on the adverse events stand as timely reports and expressly declined to accept this option, which would

have permitted him to memorialize his reasons for not believing that TMJI's devices caused or contributed to the injuries or that the injuries were not serious. Given the evidence we have discussed, we conclude that Dr. Christensen, as the person with final authority over TMJI's compliance with MDR requirements, is personally responsible for the failure to file required MDRs.

6. The ALJ did not err in setting the CMP amounts for TMJI and Dr. Christensen.

In his Final Order, the ALJ imposed CMPs of $170,000 on each respondent. The ALJ set the amounts based on the following process and findings. In his Initial Decision, the ALJ concluded that "there appears to [be] very little in the way of mitigating or aggravating factors which would have any significant impact on the appropriateness of the CMPs to be assessed." Initial Decision at 11. He determined, however, that under 21 C.F.R. § 17.45(b)(3), he was "required to engage in further consideration of Respondents' finances before determining the appropriate amount of the CMPs to be imposed." Id. He stated:

> Accordingly, Respondents will be given time to fully disclose their financial information and submit arguments with respect to their ability to pay the CMP's. Complainant will have thirty (30) days to submit its position with respect to the appropriate amount of the CMPs after review of the Respondents' financial information. Respondents will then have fifteen (15) days to respond. Should the Respondents fail or refuse to fully disclose their financial information, the CMPs sought by Complainant will be imposed.

Id. at 12 (emphasis added). In the CMP Complaint, FDA requested CMPs of $10,000 per event be imposed on TMJI, Ms. Mooney and Dr. Christensen. AR 1, at 15-16.

Finally, the ALJ informed TMJI that --

> should Respondents fail to fully disclose their financial information as ordered, Civil Money Penalties in the amount of [$510,000], $170,000 for each Respondent ($10,000 for each violation) will be deemed the appropriate penalty assessed in this proceeding and an ORDER to that effect will be issued.

Id.

Respondents then filed submissions regarding their financial status. Thereafter, in his Final Order, the ALJ found that --

> it appears that the information submitted [by Respondents] falls considerably short of the full financial disclosure ordered. While each Respondent asserts an inability to pay a penalty of $170,000, the information submitted is incomplete and fails to explain various inconsistencies. This gives rise to an adverse inference that a full disclosure would not support the assertions of an inability to pay.

Final Order at 1-2. The ALJ then imposed CMPs in the amount of $170,000 on TMJI, on Dr. Christensen, and on Ms. Mooney. Since we have determined Ms. Mooney was not liable for CMPs, we discuss here only the CMPs imposed on TMJI and Dr. Christensen.

Before the Board, Respondents raise a number of objections to the amount of the CMPs. They argue that they made a full disclosure pursuant to the ALJ's order. R. Br. at 43-44. They argue that the brevity of the time between the final financial submission and the Final Order shows the ALJ did not properly consider their submissions. Id. at 45-46. They argue that they raised mitigating factors that should reduce the amount of the CMPs. Id. at 44-45. Below we explain why we reject these arguments.

A. Full disclosure

The ALJ instructed TMJI and Dr. Christensen "to fully disclose their financial information." Initial Decision at 12. Thereafter, FDA counsel requested TMJI to submit Department of Justice (DOJ) forms OBD-500 (Financial Statement of Debtor) and OBD-500C (Financial Statement of Corporate Debtor), "along with any other information that you intend to provide" as a means of making such full disclosure. AR 601. On August 7, 2007, TMJI and Dr. Christensen submitted declarations, and financial information (including partially completed DOJ forms) to the ALJ. AR 581-584. On September 7, 2007, FDA submitted briefing, a declaration alleging TMJI and Dr. Christensen had failed to make a full disclosure, and documents it had independently obtained as to TMJI's and Dr. Christensen's financial status. AR 587-599. On September 21, 2007, TMJI and Dr. Christensen submitted a response to FDA's briefing and additional declarations and documents. AR 600-607.

The ALJ found that TMJI and Dr. Christensen did not make full disclosure because the information they submitted "is incomplete and fails to explain various inconsistences." Final Order at 1-2. This finding is supported by the record as a whole, including the following evidence.

After TMJI's and Dr. Christensen's initial submission, FDA submitted the declaration of John V. Goldsmith, Ph.D., an industry economist in the Office of Planning at FDA. AR 589. His duties included "accounting for costs and benefits associated with agency regulations, providing economic analyses and projections for agency policies, and providing financial analyses, including analyses of the financial statements of FDA-regulated entities." Id. at 1. He reviewed the financial information submitted by TMJI and Dr. Christensen and addressed their assertions that they are unable to pay $170,000 in CMPs. He stated:

> In assessing a corporation's or individual's ability to pay a financial penalty, it is important to obtain from the corporation or individual a statement, signed and notarized, showing assets and liabilities, income and expenses. The Department of Justice Form OBD-500 (OBD-500C for a corporation) was designed to elicit that information. When a corporation or individual fails to complete this form (or a similar form) in its entirety, the government is without sufficient information to determine whether the corporation or individual is able pay the penalty.

Id. at ¶ 4.

In his declaration, he explained in detail as to each Respondent why the information submitted was incomplete and not sufficient to determine ability to pay the penalties. Based on reviewing the information submitted by TMJI and Dr. Christensen, he concluded:

> Although on their face, the limited information provided by [TMJI and Dr. Christensen] appears to demonstrate that they do not currently have the ability to pay the $170,000 penalty, the documentation submitted is wholly inadequate to make a determination whether they would be able to access this money to pay the penalty. In fact, as explained more fully below, a closer examination of the submitted financial information suggests that [TMJI and Dr. Christensen] may have access to substantially more assets than reported, have alternate sources of income or assets not identified in the submitted financial information, and/or they may have transferred assets to other parties or entities to avoid or reduce their ability to pay penalties in this proceeding.

AR 589, at ¶ 5. Dr. Goldsmith described the types of information that was missing from both parties and why the absence of this information prevented a determination as to financial inability to pay the CMPs.

In response, TMJI, through its Chief Financial Officer, and Dr. Christensen filed declarations and some additional documents. AR 603-607. They both pointed out that they were not required by the ALJ to complete the DOJ forms. AR 602, at ¶ 2; AR 603 at ¶ 4. In the accompanying brief, they argued that their failure to complete the DOJ forms should not be treated as a failure to fully disclose. AR 600, at 18.

Since the ALJ did not direct TMJI and Dr. Christensen to complete DOJ forms, we agree that failure to complete them is not, in itself, a failure to fully disclose. Indeed, Dr. Goldsmith recognized that TMJI and Dr. Christensen could have used a "similar form" instead of the DOJ forms. AR 589, ¶ 4.[25] On the other hand, since the DOJ forms were "designed to elicit" information necessary to evaluate a party's financial capacity (id.), TMJI and Dr. Christensen, in declining to fill out those forms, increased the risk that information necessary to making full financial disclosures would not be included in their submissions. Further, once Dr. Goldsmith explained the shortcomings of the information they elected to submit and why those shortcomings prevented a sound evaluation of their ability to pay the CMP (AR 589), TMJI and Dr. Christensen had notice of how their disclosures were deficient and an opportunity to correct those deficiencies. As discussed below, by not fully responding to the problems identified by Dr. Goldsmith in their final financial submissions, they further failed to ensure that their disclosures were complete.

We conclude that Dr. Goldsmith's testimony and the Respondents' inadequate responses to it amply support the ALJ's finding that TMJI and Dr. Christensen failed to make full disclosures. Below, we discuss in more detail several specific points from his testimony.

As to TMJI, Dr. Goldsmith identified a range of information that TMJI did not file that is needed for a complete financial analysis. AR 589, at ¶ 8. For example, he points out that for the two years of corporate tax returns TMJI did file (2004 and 2005), the returns refer to attachments but no attachments were included in TMJ's submission. He stated that "[t]o properly

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[25] TMJI and Dr. Christensen are incorrect when they argue that "Dr. Goldsmith's analysis in this Declaration was based solely on the assumption that [the DOJ forms] were mandated by the ALJ . . . ." R. Br. at 44. As explained above, Dr. Goldsmith explained why the types of information missing (such as attachments to both the corporate and personal income tax returns) prevented a sound analysis of the Respondents' financial abilities.

evaluate TMJI's finances, a financial analyst would need complete tax returns, including all attachments, descriptions, and supplementary statements TMJI provided to the IRS." AR 589, at ¶ 7. In its response, TMJI stated that the attachments "were omitted simply as a courtesy to avoid unnecessary analysis. Said attachments will be provided if requested by this Court." AR 602, at ¶ 7.[26] This representation is nonresponsive to Dr. Goldsmith's assertion that such attachments were necessary to show a full picture of TMJI's finances. Moreover, having already ordered full disclosure by a date certain, the ALJ was not obliged to specifically request the attachments before evaluating the documentation that was timely submitted.

Dr. Goldsmith further explained that he could not account for various financial patterns documented in the submitted documentation, making it impossible to conclude that TMJI could not pay the CMP. For example, he pointed out that TMJI had experienced an unexplained drop in profitability ($624,690 in ordinary business income on approximately $2.7 million in net sales in 2004 versus $203,108 in ordinary business income on approximately $2.7 million in net sales in 2005) combined with an unexplained increase in salaries ($599,950 in 2004 to $909,156 in 2005) and in "other deductions" ($739,261 in 2004 to $934,301 in 2005). AR 589, at ¶ 10. Dr. Goldsmith stated that TMJI had not explained this income/expense pattern nor shown that it could not reduce salaries or "other deductions" to cover the $170,000 CMP (id. at ¶ 12), which FDA has offered to accept over a three-year period (AR 587, at 19). In its response submission, TMJI did not explain the identified differences between 2004 and 2005, nor show that it could not make the reductions in expenses Dr. Goldsmith suggested.

As to Dr. Christensen, Dr. Goldstein again identified a range of information that Dr. Christensen failed to submit that was needed for a complete financial analysis of his ability to pay the CMP. AR 589, at ¶ 15. For example, Dr. Goldstein pointed out that Dr. Christensen had not answered the question (on the DOJ form) directed at transfers of property within the last three years, which "could be indicative of an effort to dispose of assets so as to avoid paying a penalty." Id. Dr. Goldstein concluded that the information provided failed to explain how a person "who earned $500,000 per year now has a net worth . . . of negative $1 million." Id. at ¶ 16.

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[26] TMJI states that it did not include its 2006 corporate tax return with its initial financial submission because the return was not available at that time. AR 602, at ¶ 9. TMJI did file the 2006 return with its final submission but, again, did not include attachments. See AR 607.

In his response declaration to Dr. Goldstein (AR 603), Dr. Christensen did not disclose transfer information or address in any meaningful way the problems identified by Dr. Goldstein in Dr. Christensen's initial submission.

We therefore conclude that the ALJ's findings that TMJI and Dr. Christensen failed to make full financial disclosures are supported by substantial evidence in the record a whole. His inference that a full disclosure would not have supported their assertions of an inability to pay is reasonable. See International Union, United Automobile v. NLRB, 459 F.2d 1329, 1336 (D.C. Cir. 1972).

B. Elapsed time

Respondents point out that the final submissions of financial information and briefing was received by the ALJ on September 24, 2007 and the Final Order was issued the next day. They argue that this timing makes the Order "arbitrary and capricious because it was virtually impossible for [the ALJ] to have absorbed and analyzed Respondents' Brief and attachments . . . in such a short time." R. Br. at 45 (emphasis in original).

We disagree. The ALJ had had most of the parties' financial submissions for over ten days prior to September 24, 2007. On September 24, 2007, TMJI and Dr. Christensen submitted a brief, two short declarations, and several exhibits. AR 600-607. As discussed above, Respondents' responses to the problems and questions identified by Dr. Goldsmith were completely inadequate and would have taken little time to review. Thus, one day was plainly sufficient time for the ALJ to evaluate Respondents' last financial submissions and conclude that they had failed to comply with his order to make full financial disclosures.

C. Mitigating factors

Section 17.33(a) of 21 C.F.R. provides that the presiding officer shall determine "the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors." Section 17.33(c) provides "the respondent must prove . . . any mitigating factors by a preponderance of the evidence." See also 21 C.F.R. § 17.34(a).

The ALJ considered mitigating and aggravating factors in his Initial Decision. He stated:

> In mitigation, Respondents refer to their oft repeated attempts to have their interpretation of the filing requirements approved by the FDA, and their extensive review

> process which led to the decisions not to file MDRs for the 17 events in issue. As aggravating factors, Complainant points to: 1) the numerous times Respondents were notified that their interpretation was not accepted, 2) the fact that the Statute clearly required the MDR filings and 3) that they were obviously aware of the requirements because they had filed numerous MDRs for similar events in the past.

Initial Decision at 11. He then stated, "there appears to be very little in the way of mitigating or aggravating circumstances which would have any significant impact on the appropriateness of the CMPS to be assessed." Id.

Respondents argue that, in their brief after the Initial Decision, they "set forth a myriad of mitigating factors that would justify the ALJ in reducing the penalty amount sought by [FDA]." R. Br. at 44. We have discussed most of these factors in rejecting them as grounds for concluding the ALJ erred in finding TMJI liable for CMPs. As explained below, we also find them unpersuasive as mitigating factors for lowering the CMPs.

- Respondents argue here and elsewhere that TMJI "never refused" to file the 17 MDRs. AR 600, at 4. Section 360i and the implementing regulations require MDRs to be filed under the circumstances presented by these adverse events. CDRH instructed TMJI repeatedly that MDRs were required. The law does not require the FDA to prove a "refusal" to file an MDR, but rather provides that any failure to file a required MDR constitutes a violation. The fact that Respondents did not see TMJI as "refusing" to file MDRs is irrelevant to the negative impact of its conduct on the FDA enforcement resources and the purposes of the MDR system.

- Respondents appear to argue, as a mitigating factor, that their dispute about the interpretation of the statute precludes a finding of significant or knowing violation, or at least mitigates it. AR 600, at 5. However, even if we were to accept that some misunderstanding could have mitigated some period of delay in filing, Respondents' "misunderstanding" exceeded any reasonable bounds. Moreover, once CDRH provided Respondents with explicit clarification of FDA's interpretation of the MDR requirements and an additional opportunity to timely file the late MDRs in November 2004, Respondents' continued failure to comply with the requirements can certainly not be viewed as a mitigating factor.

- Respondents allege again FDA's bad faith and punitive intent and their own good faith. AR 600, at 4-7, 11-12. We

previously concluded that these allegations are unsupported and contrary to the evidence in the record.

- Respondents argue that the fact that the majority of these CMPs result from a failure to file MDRs in response to Voluntary MedWatches that contained redacted information should be mitigating. Id. at 7-9. Again, we discussed the regulatory requirements that mandate MDRs even if the manufacturer cannot conduct a full investigation and permit the manufacturer to explain why the information is not complete. We see no reason why failure to file MDRs in response to Voluntary MedWatchs should be treated as less serious than failure to file in response to mandatory reports.

- Respondents point to Dr. Smagalski's testimony that its devices were "excellent," that reasonable men can differ in their opinions on MDRs, and that Dr. Christensen was qualified to evaluate adverse events. AR 600, at 10. Again, as we discussed previously, the fact that reasonable doctors can differ does not make Dr. Christensen's decision reasonable, and it was not reasonable under the MDR regulatory standards. Moreover, the fact that Dr. Smagalski said the TMJI device were excellent provided no basis for Respondents to fail to report adverse events. Nor do Dr. Christensen's qualifications override his failure to apply the proper standard.

- Respondents assert that these penalties should be reduced under the Small Business and Regulatory Fairness Act of 1996 (SBREFA), Public Law No. 104-121, 110 stat. 847 (1996). AR 600 at 12-15. We disagree. As FDA pointed out, it is not required to apply the SBREFA if it determines that a small entity's violations involve "willful or criminal conduct" or "the small entity does not make a good faith effort to comply with the law." The ALJ found that Respondents' violations were knowing. FDA could reasonably regard Respondents' continued failure to file MDRs after months of discussions as willful and as evidence of a lack of good faith for purposes of the benefits of the SBREFA. Finally, FDA points to the fact, which Respondents do not dispute, that TMJI previously filed MDRs for the very type of events at issue here. AR 587, at 6, citing AR 572, at ¶ 10. Respondents have articulated no good faith basis that would account for TMJI's changed practices in regard to filing MDRs or otherwise support its allegations of good faith.

The $10,000 per event CMP requested by FDA in its CMP Complaint (AR 1, at 15-16) reflects FDA's expertise with the MDR

requirements and its experience in setting enforcement penalties. The fact that FDA requested only two-thirds of the maximum CMP amount for these violations shows that FDA is not treating Respondents as harshly as it might for violating MDR requirements, further undercutting Respondents' claim that FDA's actions are punitive in nature, rather than remedial. Thus, as the above discussion of alleged mitigating factors demonstrates and as the ALJ concluded, none of Respondents' allegations persuasively support lowering the amount requested by FDA.

Conclusion

For the reasons discussed above, we reverse the ALJ's imposition of a CMP on Ms. Mooney and affirm the Initial Decision and the Final Order as to TMJI and Dr. Christensen.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member