

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of)
)
TMJ IMPLANTS, INC.) ADMINISTRATIVE COMPLAINT
a corporation,) FOR CIVIL MONEY PENALTY
)
and)
)
ROBERT W. CHRISTENSEN, and)
MAUREEN K. MOONEY,)
Individuals.)
_____)

FDA Docket: 2005H-0271

INITIAL DECISION

On July 14, 2005, the Center for Devices and Radiological Health, Food and Drug Administration ("CDRH"), United States Department of Health and Human Services, filed this Complaint under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 3 333(g) seeking civil money penalties against Respondents, TMJI implants, Inc. ("TMJI"); Robert W. Christensen, President; and Maureen K. Mooney, Regulatory Affairs and Quality Assurance Manager (collectively, "Respondents"), for failing to submit to FDA 21 Medical Device Reports ("MDRs") for adverse events associated with their temporomandibular joint ("TMJ") implants and accessories. Respondents filed their answer on September 9, 2005.

Under 21 C.F.R. § 17.2, the amount of civil penalties assessed against any person for a device-related violation under 21 U.S.C. § 333(g)(1)(A) shall not exceed \$16,500 for each such violation, and \$1,100,000 for all such violations adjudicated in a single proceeding. In its Complaint, CDHR originally sought civil money penalties in the amount of \$210,000 against each Respondent based on their alleged failure to file MDRs for 21 events. Following discovery CDRH modified its position to reflect the fact that there were 17 events between October 22, 2002 and July 10, 2003, for which MDRs were not filed. CDRH now seeks penalties against each Respondent in the amount of \$10,000 for each of the 17 events at issue which amounts to a penalty of \$170,000 against each Respondents and a combined total penalty of \$630,000 for all violations adjudicated in this proceeding.

The history of this matter is extensively set out in the record and will be repeated here only where necessary. The basic facts are not in dispute. Absent disputed facts, both CDRH and Respondents moved for Partial Summary Decisions (styled Summary Judgement by Respondents). In support of their respective Motions, both relied on expert testimony. By Order of July 6, 2006, both motions were denied because the evidence

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concerning the issue of the reasonableness of Respondents' decision not to file the MDRs, could not be properly considered before providing an opportunity for cross examination. The hearing for the purposes of cross examination was held on April 16, 2007. Final briefs were filed on June 15, 2007.

Respondents' position with respect to this proceeding can be divided into three main areas which will be considered separately. These are:

- 1) The Complaint was issued prematurely because of Respondents' pending appeal to The Commissioner of The FDA for reconsideration of the denial of TMJI's interpretation of the MDR regulations had not been resolved.
- 2) None of the reports were of a nature which required the filing of an MDR, and
- 3) Civil Money penalties can only be assessed against TMJI and not against the individual Respondents in this proceeding.

Was The Complaint Prematurely Filed?

Respondents in their Final Brief again raise a claim of a violation of Due Process by reason of CDRH's filing of the instant Complaint while the issue of TMJI's interpretation of the MDR regulations was pending before the Commissioner. In line with this position TMJI maintains that it never refused to file the adverse events at issue as MDRs. Instead, it reserved the possibility of doing so depending on the ruling of the Commissioner on its appeal request. The Respondents' maintain that they were not required to file MDRs while a decision on their appeal was pending before the Commissioner. Also, they assert that absent a final determination on the interpretation of the MDR regulations in dispute, Respondent TMJ Implants, Inc. could not be deemed to be in knowing violation of the Regulations.

Correspondence between CDRH and TMJI regarding the 17 involved events included a Warning Letter and requests for submission of MDRs. On March 22, 2004, TMJI wrote a letter questioning FDA's application of the MDR regulation to the events described in the Warning Letter and offering its own interpretation of the MDR regulation. A series of ensuing correspondence (see Exs G-14,17,22,27 and31) culminated in a November 10, 2004 letter from CDRH's Director, Daniel G. Schultz, M.D., F.A.C.S., in which he reiterated that MDRs should have been filed. The letter indicated stated that CDRH was willing to process the events as incoming MDRs if TMJI notified CDRH of its desire to submit the events as MDRs within 10 days from the date of the letter. Dr. Schultz stated that CDRH's position on the issue was final. In closing, Dr. Schultz noted that TMJI could appeal CDRH's decision to the Commissioner, but indicated that pendency of such an appeal did not preclude the agency from taking action to enforce the requirements of the Act.

On November 16, 2004, TMJI requested that CDRH forward its decision to the Commissioner for review. The appeal request was forwarded to and reviewed by the Office of the Commissioner. After reviewing TMJI's appeal request, FDA denied the

request. In July 2005¹, FDA Commissioner for External Affairs, Sheila Walcoff, notified TMJI in writing that its appeal request was denied and that the agency planned to file this action.

In this CMP proceeding, Respondents also sought to stay or dismiss the Complaint while apparently seeking further reconsideration of their position from the Commissioner. By Orders dated July 16, 2006, and October 12, 2006, Respondents' requests to stay this proceeding pending further consideration by The Commissioner, were denied because it appeared highly unlikely, considering the history of this matter, that any further consideration by The Commissioner would result in a decision contrary to those previously rendered and that such a stay would only serve to unduly delay the proceeding.

Nevertheless, as late as March 7, 2007 Respondents filed a Petition for Stay of Action with the Commissioner of FDA. The Petition once again sought to stay this proceeding pending a dispositive ruling by The Commissioner on Respondents' latest appeal (included in the Petition) on the grounds that their prior appeal was "...heretofore ignored by the prior Commissioner, regarding the issue of whether Respondents['] or CDRH's position.....reflects the correct interpretation and application of FDA's MDR regulations." . Respondents' interpretation of the MDR regulations has been considered and rejected by the FDA on more than one occasion. The fact that the administrative process provides additional avenues for seeking reconsideration of rulings, does not justify the delay of a formal evidentiary proceeding. Under the circumstances, the CMP was not filed prematurely and Respondents have had (and continue to have) ample opportunities to have their interpretation of the MDR regulations considered.

Did The 17 Events Require MDR Filings?

21 U.S.C. 360i(a) provides in pertinent part that:

Every person who is a manufacturer or importer 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 (1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer 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 and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

¹The wording "...that the agency planned to file..." this action is somewhat inaccurate because it appears that this communication was actually sent after the CMP Complaint was filed.

- (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.

The FDA MDR regulations promulgated thereunder provide *inter alia that*: "If you are a user facility, importer, or 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....."(21 C.F.R. § 803.20(c)(2).

Relying on the above regulation, Respondent TMJI reviewed each of the adverse events involved in this CMP to determine if the event rose to the level of a death or serious injury as defined. For each event, Respondent TMJI concluded through a decision tree process that the device did not cause or contribute to a death or serious injury. Respondent TMJI claims extensive testing and publication of written articles to back up the decisions documented on the decision tree (see Exhibits R-52, R-52 and R-161 through R-221). Respondents therefore contend that should the 17 events ultimately be determined to have been reportable, their failure to submit the MDRs cannot be considered a knowing violation. A review of 17 events indicates otherwise.

The 17 events involve individuals who received devices to treat TMD. TMJI received information about these events between October 22, 2002 and July 10, 2003, but did not report them within 30 days, as required by 21 C.F.R. § 803.50(a). The available information as submitted by CDRH is as follows:

02-063 - TMJI was notified of this event through a MedWatch report (MW1026451), dated October 16, 2002. Ex. G-34. The report states that the patient received a TMJI "total jaw joint replacement" and that "[s]hortly after implantation of the device, patient experienced significant swelling, increased pain and eventually decreased mobility." The report also states that the patient "[h]as tried 6-7 different types of antibiotics." According to the report, the patient's "blood work show[ed] no sign of infection, but when taken off antibiotics, swelling and pain [got] worse." The report notes that the "[p]atient [is] concerned about long-term use of antibiotics." Additionally, the reporter indicated on the form that the event was both a "disability" and "required intervention to prevent permanent impairment/damage." *Id.* TMJI noted these injuries in its MDR Evaluation Checklist for this event, but concluded that the event was not a serious injury because "Implanting [TMJI's] fossa-eminence prostheses does not cause any change to the body structure." *Id.*

02-064 - combined three separate MedWatch reports into one complaint. TMJI concluded that the following events were not reportable because "There [was] no information . . . from a Health Professional . . ." Ex. G-35.

(a) MW1026641 - TMJI was notified of this event through a MedWatch report, dated November 5, 2002. Ex. G-35. The MedWatch report states that the patient "[r]eceived Christensen Fossa and Condyle and six months later they had to be removed due to bone growth and [the] jaw fusing shut." The report states that the patient subsequently received "an all-metal total joint Christensen device" and "[s]ince surgery, [the] patient is unable to touch face without pain. Jaw function has been impaired." The report also states that the patient experienced "sharp stabbing pain when biting down on food [and] constant swelling on [the] right side of [the] face/ear/cheek/nose region, which sometimes spreads to [the] entire face." The report notes that before the surgery, the patient was not taking any medication, but "[s]ince receiving implants, [the] patient is on Celebrex, Nexium, Neurotin, Flexeril and Morphine in order to control pain." The report also notes that the patient is "gradually losing hearing." The reporter indicated on the form that the event was both a "disability" and "required intervention to prevent permanent impairment/damage." Id.

(b) MW1026649 - TMJI was notified of this event through a MedWatch report, dated November 5, 2002. Ex. G-35. The report states that the patient received "a Christensen Fossa bilaterally." According to the report, one year after receiving the implants, the "patient began having grand mal seizures for the first time [and] now has persistent migraine and facial swelling, which has closed off the ear canal and causes black eyes." The report states that the "[s]crews from fossa have loosened and have penetrated through to the zygomatic arch [and the] patient . . . need[s] [to have] both fossas . . . removed." Additionally, the reporter indicated on the form that the event was both a "disability" and "required intervention to prevent permanent impairment/damage." Id.

(c) MW1026650 - TMJI was notified of this event through a MedWatch report, dated November 5, 2002. Ex. G-35. The MedWatch report states that the patient received two "Christensen fossa implants." According to the report, the patient then began experiencing headaches, pain when chewing, and constant pain in the jaw joint area. The report also states that the "implants are failing and [the] patient is now in extreme pain." The reporter indicated on the form that the event was both a "disability" and "required intervention to prevent permanent impairment/damage." Id.

02-065 - TMJI was notified of this event through a MedWatch report (MW1026765), dated November 15, 2002. Ex. G-36. The report states that the patient received an "all metal total joint Christensen prosthesis on the left side" and thereafter the patient's jaw deviated to the left. According to the report, the patient also experienced "a decrease in mouth opening [and the] [p]ain is at an incredible level 24 hours." The report also notes that the patient experienced "infections and migraine headaches." The reporter indicated on the form that the event was a "disability." Id.

03-010 - TMJI was notified of this event through a user facility MedWatch report, dated March 31, 2003. Ex. G-37. The report indicates that the patient received bilateral TJR prostheses which were surgically explanted. The report also states that the "patient has had several episodes of recurrent swelling involving the left temporal area near the left [TMJ]." It notes that the patient developed "marked limitations of opening along with left [TMJ] dysfunction and anklosing of the right and left [TMJs]." The report states that before the explant surgery, the surgeon noted that both the left fossa-eminence prosthesis and the left condylar prosthesis were "[s]everely displaced" and there was

"loose screw fixation" on the left fossa-eminence prosthesis. The report states that the surgery "revealed wear involving the acrylic heads of the left condylar prosthesis and hypertrophic bone formation on the left and right prostheses." The reporter indicated on the MedWatch form that the event "required intervention to prevent permanent impairment/damage." Id. TMJI concluded that this event was not reportable because "[t]he medical intervention was due to the patient's condition of [TMJ] disorders." Id.

03-011 - TMJI was notified of this event through a TMJ Registry report, dated March 30, 2003. Ex. G-38. The report states that fossa-eminence prostheses were explanted due to bilateral pain and later replaced with fossa and condyle prostheses. In a subsequent letter, the surgeon confirmed that the devices were explanted. TMJI's complaint file contained no additional documentation about the surgery. Id. TMJI concluded that this event was not reportable because "This was a revision surgery" and "many TMJI patients have chronic pain before implantation of the device." Id.

03-017 - TMJI was notified of this event through a TMJ Registry explant report, dated June 3, 2003. Ex. G-39. The report states that TMJI left fossa and condylar prostheses were explanted bilaterally due to "infection" and "perforation between external auditory canal and joint space." The surgical report states that approximately two and a half years after receiving TJR prostheses, "[the patient] developed chronic ear infection that [did not respond] to traditional antibiotic therapy" According to the report, the patient was diagnosed as having a "fistula" (perforation) between the external auditory canal and inner spaces of the joint. The report states that "The diagnosis was a foregone conclusion that [the patient] had infected hardware with draining fistula through the external auditory canal." Additionally, the report states that "The screws in the condylar portion of the right hand side were all loose except for the inferior two screws . . . one of the screws [was] completely lifted out of its hole in the condylar portion of the prosthesis." Id. TMJI concluded that this event was not reportable because "[t]he devices were removed due to the patient's condition (chronic ear infection)" and because "[t]he infection did not develop immediately after surgery." Id.

03-018 - TMJI was notified of this event through a TMJ Registry explant report, dated May 23, 2003. Ex. G-40. The report states that the patient received a "custom" right fossa-eminence prosthesis and a custom right condylar prosthesis. The reason listed for explantation was "loose hardware" and "infection." On the report, the surgeon noted that the "condylar prosthesis was quite thick, 12 mm screws were not long enough." The surgeon also indicated that the device caused or contributed to the reason for explantation. Id. TMJI concluded that this event was not reportable because "the devices were removed due to the patient's condition." Id.

03-019 - TMJI was notified of this event through a TMJ Registry explant report, dated April 15, 2003, and through a surgical report provided to TMJI. Ex. G-41. Both the TMJ Registry report and the surgical report indicate that the patient received TMJI prostheses which were surgically explanted. The explant report states that the prostheses on each side of the patient's jaw were explanted due to pain, limited opening, swelling, and malocclusion. The surgical report also states that during the explant surgery, the right fossa implant was found to be dislocated and had loose screws. It further states that the right and left condyle implants were also loose. The report also notes that tissue from the mandibular joints appeared to be chronically inflamed with

fibrosis, that there was a "cranial base defect . . . with suspected dural exposure," and that the "fossa area . . . had been eroded through changes due to mobility of the implant." Id.

On the explant report, the surgeon checked the box marked "unknown" as to whether the device caused or contributed to the reason for explantation and next to the box wrote, "abnormal anatomy device became unstable." However, in the pre-surgical report, the surgeon stated that the fact that three sets of total joint prostheses have failed "is of concern" and commented that "with a metal/metal prosthesis one must consider metallosis, one must consider inflammatory processes that led to prosthetic loosening and displacement." Id. TMJI concluded that this event was not reportable because "[t]he explant was due to the patient's [TMJ] condition." Id.

03-021 - TMJI was notified of this event through a TMJ Registry explant report, dated April 18, 2003. Ex. G-42. The report states that the left fossa-eminence prosthesis was explanted due to a "failed fossa" and "adhesions." The accompanying surgical report states that "the posterior and third screws were found to be loose and somewhat backed out." The report also notes that abnormal bone growth was observed and surgically removed. The report states that the fossa was reconstructed, and that there was a "fibrous capsule" on the prosthesis and the patient's glenoid fossa. On the explant report, the surgeon checked the box marked "unknown" as to whether the device caused or contributed to the reason for explanation. Id. TMJI concluded that this event was not reportable because the "medical intervention was due to the patient's condition of [TMJ] disorders." Id.

03-022 - This report involves three separate MedWatch reports. TMJI concluded that each of these three events were not reportable because "There [was] no information . . . from a Health Professional . . ." Ex. G-43.

(a) MW1027889 - TMJI was notified of this event through a MedWatch report, dated March 17, 2003. Ex. G-43. The report states that the patient "had total joint Christensen prosthesis implant" and then began experiencing migraine headaches, jaw pain, and limited jaw opening and was hospitalized. The report also states, "Pain is worse since [the] device was implanted," and notes that the patient's "Jaw doesn't open as much and it hurts when trying to do stretching exercises." Id. In addition, the reporter indicated on the form that the event was a "disability." Id.

(b) MW1027890 - TMJI was notified of this event through a MedWatch report, dated March 17, 2003. Ex. G-43. The MedWatch report states that the implants were removed after two and a half years "because [the] patient could barely open mouth and experienced terrible ear pain." According to the report, the surgeon stated that "the implants didn't take and had to come out." It further states that the implants were removed and that the condyles were reconstructed "because of huge bone spurs and masses of fibrosis." The reporter indicated on the MedWatch form that the event "required intervention to prevent permanent impairment/damage." Id.

(c) MW1027891 - TMJI was notified of this event through a MedWatch report, dated March 17, 2003. Ex. G-43. The report states that the patient received a "Christensen titanium fossa." It also states that, after receiving the device, the patient reported the "joint [was] sticking in [the] ear" and that the patient was "[i]n a lot of pain and experience[ing] migraine headaches." The report further states that surgery was performed to remove excess bone and that radiation treatment was given to

prevent additional bone growth. The reporter indicated on the form that the event "required intervention to prevent permanent impairment/damage." Id.

03-024 - TMJI was notified of this event through a MedWatch report (MW1028047), dated March 28, 2003. Ex. G-44. The report states that the patient received a TJR Implant bilaterally. The report states that after receiving the implant, the patient developed "severe (disabling) headaches, muscle pain in and around the implant and serious tenderness in and around the implant area." The patient also experienced "[d]izziness, nausea, and neck and shoulder pain accompanying the problem" and "[c]hewing, speaking, or any bump on the chin exacerbate the problems." The report further states that the patient is on anti-inflammatory and pain medications and that the "[s]ituation appears to be attributable to foreign body reaction or other problem with implant." The report states that the implant "[w]ill be removed and replaced." Additionally, the reporter indicated on the form that the event was both a "disability" and "required intervention to prevent permanent impairment/damage." Id. TMJI concluded that this event was not reportable because "There [was] no information . . . from a Health Professional . . ." Id.

03-025 - TMJI was notified of this event on June 3, 2003 through a letter from a surgeon accompanied by a TMJ Registry explant report. Ex. G-45. The explant report, dated May 29, 2003, states that a left condylar prosthesis and left fossa-eminence prosthesis were explanted due to pain and swelling. The June 3, 2003 letter states that during the explant operation, the surgeon noted that the acrylic condyle device appeared to be worn and flattened and surrounded by granulation tissue. The surgeon observed that some of the large submandibular nodes evidenced inflammatory reaction to the wear of the device. On the explant report, the surgeon checked the box indicating that the devices caused or contributed to the reason for explanation. Id. TMJI concluded that this event was not reportable because "the devices were revised due to the patient's condition." Id.

03-030 - TMJI was notified of this event through a TMJ Registry explant report, dated June 27, 2003. Ex. G-46. The complaint also includes a surgical report which states that after receiving TJR prostheses on both sides of the face, the patient had progressive restriction of the ability to open the mouth and a "persistent complaint of clicking and popping in the right TMJ." The report notes that the patient was unable to open more than 12-13 millimeters. According to the report, exploratory surgery was performed to determine the cause of these symptoms and during surgery, "it was noted that the head of the condyle prosthesis . . . had fractured away from the prosthesis arm." After the new device was implanted, the patient had a marked increase in mouth opening. The surgeon indicated on the explant report that the device caused or contributed to the reason for the explant. TMJI concluded that this event was not reportable because "the explant was due to the patient's condition."

One of, if not the primary purpose of the MDR regulations is to permit the FDA to act as a sort of clearing house with respect to health problems which may be related to the use of medical devices. This clearing-house approach allows the FDA to be better able to isolate the causes and determine whether they are related directly to the device or to some other factor such as improper implantation or user error. Therefore, CDRH contends that

the clear meaning of definition of serious injury contained in 21 U.S.C. § 360i(a)(2) should be applied strictly so as to insure the fulfilling of the statutory purpose.

Respondents contend that not only does such an absolute standard replace the MDR's reasonableness standard but it completely makes meaningless the MDR regulation provisions pertaining to FDA's complaint procedures for the good faith investigation and analysis imposed on manufacturers. They argue that, if the mere existence "intrinsically" of a manufacture's device is enough evidence that precludes absolutely ruling out that its device caused or may have contributed to the serious injury, then any good faith investigation and analysis by the manufacturer can never trump Complainant CDRH's determination to the contrary. Respondents may have a valid argument with respect to the investigation and analysis procedures imposed on manufacturers being rendered almost meaningless under given circumstances because of the definition of "serious injury" contained in the Statute. However, all events do not include serious injuries as defined by the Statute. When such injuries are present, there is little point in further investigation and analysis. The language of the Statute is abundantly clear and requires the reporting of all such injuries.

As set out above, the term "serious injury means an injury or illness that: (i) Is life-threatening; (ii) Results in permanent impairment of a body function or permanent damage to a body structure; or (iii) Necessitates medical or surgical intervention, to preclude permanent impairment of a body function or permanent damage to a body structure." 21 C.F.R. § 803.3(bb)(1); see also 21 U.S.C. § 360i(a)(2). A review of the 17 events clearly indicates that each falls within the definition of "serious injury." In each and every case, the necessity for medical intervention satisfies the statutory definition and reasonably indicates that devices may have caused or contributed to serious injuries. This conclusion was reached by Complainant's expert witnesses who testified that these events should have been reported as MDRs. As matter of law, the Statute leaves no room for a different conclusion. 21 U.S.C. 360i(a)(2)(c).

A manufacturer's reluctance to file MDRs, as here, apparently has its roots in potential economic impact. Being aware of this and general industry concerns with respect to product liability law suits, and in order to facilitate the reporting of device-related adverse events, the regulation specifies that the submission of a report to FDA does not constitute an admission that the medical device actually caused any injury. See 21 C.F.R. § 803.16; see also 60 Fed. Reg. at 63587 (Comment 25). Form 3500A, which is the standard form for submitting MDRs, also includes a disclaimer, stating that submission of a report does not constitute an admission that the user facility, manufacturer/distributor, product, or medical personnel caused or contributed to the event. See Ex. G-51 (sample Form 3500A).

As for those events where Respondents were unable to determine whether TMJI actually manufactured the devices included in Med Watch reports, it is argued that since it is impossible to prove a negative, the failure to file MDRs for these events cannot by

considered a knowing violation. The facts are that each of those MedWatch reports identifies TMJI as the manufacturer of the "suspect device." See Exs. G-34 -G-36; G-43 - G-44. Information was redacted in accordance with FDA regulations and statutory requirements prohibiting the disclosure of patient information, (See Hearing Tr. at 20-22), the report nevertheless suggests that TMJI's devices were involved. During the April 2007 hearing, Dr. Christensen (referring to the report of event 02-063), admitted that "It would appear from that description that a [TMJI] device could be involved." Hearing Tr. at 188-89.

21 C.F.R. § 803.22(a)(2) provides that "When [a manufacturer] receive[s] reportable event information in error, [the manufacturer] must forward this information to [FDA] with a cover letter explaining that [the manufacturer] did not manufacture . . . the device in question."). If TMJI had serious reservations as to whether certain of the events actually involved TMJI's devices, then at a minimum, Respondents should have filed the MDRs with a cover letter explaining their position.

Individual Respondents

In their Final Brief, Respondents revisit the Motions For Partial Summary Judgement (dismissal) Of Robert W. Christensen And Maureen K. Mooney, filed April 27, 2007, which were denied by ORDER of May 15, 2007. That Order relied, *Inter alia*, on the definition of any person as contained in 21 C.F. R. §17.3(b)².

Respondents focus on the last phrase of the Section, "...or as may be defined in the act or regulation pertinent to the civil penalty action being brought." Since the MDR regulations deal specifically with manufacturers, Respondents contend that TMJI and not he individuals are subject to this action for Civil Money Penalties. The argument is not convincing. As indicated in the Order of May 15:

Both "CMP" provisions of the FDCA, 21U.S.C. §333(g)(1)(A), and its implementing regulation 21 C.F.R. Part 17, make it abundantly clear that corporate officers and employees may be liable in their individual capacities for device-related violations. Under 21 U.S.C. § 333(g)(1)(A), "... any person who violates a requirement of [the FDCA] which relates to devices shall be liable to the United States for a civil penalty...."

21C.F.R. § 17.3 (b), relied on here by Respondents, in no way limits the CMP actions to manufacturers by reason of the inclusion of the phrase "or as may be defined in the act or regulation pertinent to the civil penalty action being brought. Respondents TMJI and

² 21 C.F. R. §17.3(b) Reads:

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

the individuals, Robert W. Christensen and Maureen K. Mooney are all liable for the CMPs to be imposed in this proceeding.

As indicated, Complainant is seeking Penalties amounting to \$630,000, \$170,000³ from each Respondent. 21 C.F.R. § 17.45(b)(3) requires the consideration of, and findings with respect to the appropriateness of the CPMs imposed including any mitigating or aggravating circumstances.

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.

CDRH has established by a preponderance of the evidence that Respondents TMJI, Robert W. Christensen, and Maureen K. Mooney are each liable for Civil Money Penalties for 17 violations. Respondents failed to accept FDA's determination that MDRs should have been filed for the events at issue. There is no evidence indicating that the events at issue do not meet the MDR requirements. Therefore, Civil Money Penalties will be imposed on the Respondents for their knowing and significant violations and to encourage future compliance with the MDR requirements in the interest of protecting the public health. Respondents violated the FDCA by failing to file MDRs for the 17 events at issue; Respondents' affirmative defenses are not meritorious; each Respondent is liable for Civil Money Penalties for all 17 violations.

While there appears to 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, the Respondents' ability to pay those penalties may be another matter. As late as June 19, 2007, Respondents submitted information (apparently with the consent of counsel for CDRH) indicating that Complainant's Ex.G-54 had seriously overstated TMJI's annual sales volume. Because of this change, the language of 21 C.F.R. § 17.45(b)(3) requires further consideration of Respondents' finances before determining the appropriate amount of the CMPs to be imposed⁴. To this end, 21 C.F.R. §17.45(d) will be suspended under the authority contained in 21 C.F.R. § 17.19(17) pending said further consideration.

³ This represents less than the maximum \$16,500 per violation authorized by Statute.

⁴ It appears that during discovery, limited information regarding the personal finances of Respondents Christensen and Mooney was made available. However, this was incomplete and may not have reflected Respondents' current financial situation.

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 CPMs after review of the Respondents' financial information. Respondents will then have fifteen (15) days to respond. Should the Respondents fail or refused to fully disclosure their financial information, the CMPs sought by Complainant will be imposed.

It is ORDERED that on or before August 8, 2007, Respondents are to submit a full disclosure of their financial information along with their position(s) on their ability to pay the CMPs;

It is Further ORDERED that on or before September 7, 2007, Complainant will submit is position with respect to the appropriate amount of the CMPs in this proceeding;

It is Further ORDERED that on or before September 24, 2007, Respondents will submit any response with respect to the appropriate amount of the CMPs;

It is Further ORDERED that 21 C.F.R. § 17.45(d) is suspended pending consideration of the appropriate CMPs and Respondents' ability to pay,

And it is Further ORDERED that should Respondents fail to fully disclose their financial information as ordered, Civil Money Penalties in the amount of \$630,000, \$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.

Dated this 6th day of July, 2007.

/s/ Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge