

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

In the Matter of )  
)  
)

TMJ IMPLANTS, INC., )  
a corporation, )

and )  
)

ROBERT W. CHRISTENSEN, and )  
MAUREEN K. MOONEY, )  
individuals. )  
\_\_\_\_\_ )

**ADMINISTRATIVE  
COMPLAINT FOR  
CIVIL MONEY PENALTIES**

FDA Docket No: 2005H-0271

Date: July 14, 2005

Complainant, the Center for Devices and Radiological Health ("CDRH"), Food and Drug Administration ("FDA"), United States Department of Health and Human Services, by Vernessa T. Pollard, attorney for Complainant, respectfully represents as follows:

**INTRODUCTION**

1. This action is brought by FDA on behalf of CDRH under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 333(g),<sup>1</sup> and its implementing regulations, 21 C.F.R. pt. 17, which authorize the imposition of civil money penalties against persons who violate the FDCA, 21 U.S.C. §§ 301-397, relating to medical devices, after the opportunity for a hearing provided in accordance with 5 U.S.C. § 554 and 21 U.S.C. § 333(g)(3)(A).

**JURISDICTION**

2. FDA has subject matter jurisdiction, as delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs, over this action and personal

<sup>1</sup> Until recently, this provision was codified in the United States Code as 21 U.S.C. § 333(f). The Office of the Law Revision Counsel of the United States House of Representatives, which is the Congressional entity solely responsible for the codification and publication of the United States Code, has redesignated subsection (f) as (g). Additional information is available at <http://uscode.house.gov/>.

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jurisdiction over the parties, pursuant to 21 U.S.C. § 333(g). Pursuant to 21 U.S.C. § 333(g)(3)(A) and the implementing regulations, 21 C.F.R. pt. 17, the authority to conduct an administrative civil money penalty (hereinafter "civil penalty") hearing and assess a civil penalty is vested in an administrative law judge, appointed in accordance with 5 U.S.C. § 3105.

3. Respondent, TMJ Implants, Inc. ("TMJ Implants") is a corporation organized and existing under the laws of the State of Colorado and at all times relevant to this action was doing business at 17301 W. Colfax Avenue, Suite 135, Golden, Colorado.

4. At all times relevant to this action, TMJ Implants was engaged in the interstate manufacture, labeling, promotion, holding for sale, sale, and distribution of medical devices.

5. At all times relevant to this action, Respondent, Robert W. Christensen, an individual, was the President of TMJ Implants. He was responsible for and had authority over all operations at TMJ Implants, including but not limited to, the acts of employees of TMJ Implants committed while acting within the scope of their employment.

6. At all times relevant to this action, Respondent, Maureen K. Mooney, an individual, was the Regulatory Affairs and Quality Assurance Manager of TMJ Implants. She was responsible for and had authority over the quality assurance program, including complaint handling and medical device reporting.

7. TMJ Implants, Robert W. Christensen, and Maureen K. Mooney (collectively "Respondents") manufacture and distribute class III temporomandibular joint ("TMJ") implants and accessories, the TMJ Metal-on-Metal Total Joint Replacement Prosthesis System™ and the Fossa-Eminence Prosthesis.™ These implants and accessories are medical devices within the meaning of 21 U.S.C. § 321(h).

8. Respondents' TMJ Metal-on-Metal Total Joint Replacement Prosthesis System™ is an implant approved for replacing the natural TMJ (i.e., the moving joint between the temporal and mandibular bones that attaches the jaw to the skull). Diseases involving this joint can cause extreme pain, permanent damage to the TMJ, and permanent impairment of jaw and other body functions, including the ability to open the mouth normally.

9. Respondents' Fossa-Eminence Prosthesis™ is an implant that lines the skull portion (called the glenoid fossa) of the TMJ and is approved for use in the reconstruction of the TMJ. The implant is indicated for use in the treatment of severe TMJ disease involving moderate to severe pain and/or disabling dysfunction of the TMJ that has not responded to less invasive conventional therapy.

#### **STATUTORY PROVISIONS**

10. The FDCA requires that "a manufacturer . . . of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, [as FDA] may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." 21 U.S.C. § 360i(a). These reports assist FDA in protecting the public health by helping to ensure that medical devices are not adulterated or misbranded and are safe and effective for their intended use.

11. FDA regulations, 21 C.F.R. pt. 803, require, among other things, that a medical device manufacturer file a medical device report ("MDR") whenever the manufacturer becomes aware of deaths and serious injuries which the manufacturer's device has caused or may have caused or to which the device has contributed or may have contributed. 21 C.F.R. § 803.1.

12. FDA regulations also require that a medical device manufacturer maintain adverse event files that contain information about the adverse event, including death and serious injury or

references to information related to the adverse event, including all documentation of the manufacturer's deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable. 21 C.F.R. § 803.18.

13. Medical "[d]evice manufacturers are required to [file MDR] report[s] 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." 21 C.F.R. § 803.50(a)(1) & (2).

14. Medical device manufacturers must file a "5-day report to FDA . . . within 5 workdays of: (a) Becoming aware that a reportable MDR event or events . . . necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or (b) Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report." 21 C.F.R. § 803.53.

15. The term "*[b]ecome aware*" means that an employee of the entity required to report has acquired information reasonably suggesting that a reportable adverse event has occurred." 21 C.F.R. § 803.3(c).

16. The term "*[c]aused or contributed*" means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error." 21 C.F.R. § 803(d).

17. The term "*[s]erious 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).

18. The FDCA prohibits "[t]he failure or refusal to . . . furnish any notification or other material or information required by or under [21 U.S.C. § 360i] . . . ." 21 U.S.C. § 331(q)(1)(B).

19. The "failure or refusal . . . to furnish any material or information required by or under [21 U.S.C. § 360i] respecting the device" also renders the medical device misbranded. 21 U.S.C. § 352(t)(2).

20. Under 21 U.S.C. § 333(g)(1)(A), any person who violates a requirement of the FDCA relating to medical devices, including the MDR requirements shall be liable to the United States for a civil penalty.

21. Under 21 C.F.R. § 17.2, which sets forth the maximum civil penalties for certain violations of the FDCA, any person against whom a civil penalty is assessed under 21 U.S.C. § 333(g)(1)(A) for device-related violations, shall be liable to the United States for a civil penalty in an amount not to exceed \$16,500 for each such violation, and not to exceed \$1,100,000 for all such violations adjudicated in a single proceeding.

### **VIOLATIONS**

22. Respondents failed and/or refused to furnish to FDA MDRs for complaints of serious injuries that Respondents received and/or became aware of between October 22, 2002 and July 10, 2003 as required by 21 U.S.C. § 360i(a)(1)(A).

23. FDA routinely inspects medical device manufacturers to determine their compliance with FDCA requirements and monitors adverse event reporting systems such as MedWatch, through which consumers and physicians report deaths, serious injuries, or other adverse events which a medical device has caused or may have caused or to which the device has contributed or may have contributed.

24. FDA conducted an inspection of Respondents' facility from July 29, 2003 to August 11, 2003. During this inspection, FDA collected complaint reports received by Respondents between October 22, 2002 and July 10, 2003. These complaint reports describe MDR reportable events which Respondents' medical devices have caused or may have caused or to which the devices have contributed or may have contributed.

25. The following describes MDR reportable events which Respondents' medical devices have caused or may have caused or to which the devices have contributed or may have contributed that Respondents either failed or refused to furnish to FDA as required by 21 U.S.C. § 360i(a)(1)(A):

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
02-063	12/9/02	MW1026451 TMJ Implants, Inc. device identified as "Total jaw joint replacement"	Shortly after device implantation, the patient experienced significant swelling, increased pain, and decreased mobility. Long-term use of antibiotics required to control swelling and pain.

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
02-064 (includes 3 separate MedWatch Reports)	12/12/02	MW1026641 Fossa & Condyle	Fossa and condyle were surgically removed. After replacement device implantation, the patient was unable to touch face without pain, experienced impaired jaw function, constant swelling, hearing loss, and pain when eating requiring the use of prescription pain medication.
	12/12/02	MW1026649 Fossa, bilaterally	One year after device implantation, the patient experienced seizures, persistent migraine headaches, and facial swelling that closed off the ear canal and caused black eyes. Device screws were loose and had penetrated the zygomatic arch. The report states: "Patient is in need of both fossas being removed."
	12/12/02	MW1026650 Fossa, bilaterally	The patient experienced headaches, pain when chewing, and constant jaw pain. The report states: "Six months after implant . . . more symptomatic problems are occurring. Implants are failing and patient is now in extreme pain."
02-065	12/18/02	MW1026765 Fossa & Condyle	After device implantation, the patient's jaw deviates to the left and the patient has decreased ability to open mouth. The report states: "Pain is at an incredible level 24 hours a day, not to mention frequent sinus infections and migraine headaches."

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
02-066	12/26/02	Fossa	The patient experienced ankylosis ( <u>i.e.</u> , stiffness, fixation, fused bones, or limited movement of a joint), decrease in range of motion, and heterotopic bone formation ( <u>i.e.</u> , occurring at an abnormal place in the body). The device was surgically removed and a metal fatigue fracture was observed on the left glenoid fossa. The firm's complaint documentation indicates that the surgeon opined that the device caused or contributed to the reason for device removal.
03-010	3/30/03	User Facility Report 3900280000-2003-0007 Fossa & Condyle, bilaterally	After device implantation, the patient experienced swelling of the left TMJ, limited opening of the jaw with left TMJ dysfunction, ankylosis of both the right and left TMJs, and a severely displaced left TMJ with loose screw fixation. The acrylic heads of the implant were worn and hypertrophic bone formation ( <u>i.e.</u> , excessive bone growth), inflammation and infection were noted. The device was surgically removed.
03-011	3/30/03	Fossa, bilaterally	The complaint indicates that the implants were surgically removed due to bilateral pain. Respondents concluded that the event was not reportable but the complaint file did not contain adequate information to exclude the implant as a cause or contributing factor to the reported injury or to support the

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
			conclusion that the event was not reportable.
03-012	4/3/03	Fossa	After device implantation, the patient experienced continuing pain, swelling, and restricted opening of mouth resulting in surgical removal of device.
03-017	3/10/03	Fossa & Condyle, bilaterally	After device implantation, the patient developed chronic ear infections, a perforation between the external canal and joint space, and loose screws. The device was surgically removed.
03-018	3/7/03	Condyle	After device implantation, the patient developed an infection. The physician reported loose hardware and screws that were not long enough. The device was surgically removed.
03-019	4/15/03	Fossa & Condyle, bilaterally	After device implantation, the patient experienced pain, limited opening of jaw, swelling and malocclusion (i.e., poor positioning or inappropriate contact between teeth on closure). The implants were loose, dislocated, and unstable. The device was surgically removed.
03-020	4/16/03	Fossa	After device implantation, surgery was performed to replace the implant screws due to improper screw fit.

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
03-021	4/18/03	Fossa	After device implantation, surgery was performed to replace the original implant, which was reported to have adhesions (i.e., tissues or parts abnormally joined or adhering to each other resulting from inflammation). The report also noted loose screws that were "somewhat backed out" and heterotopic bone formation.
03-022 (includes 3 separate MedWatch Reports)	4/25/03	MW1027889 Fossa & Condyle	After device implantation in 1999, the patient had limited jaw opening, experienced migraine headaches, and jaw pain. The patient was hospitalized. The report states: "Pain is now worse since device was implanted."
	4/25/03	MW1027890 Fossa & Condyle	After device implantation in 1999 (referenced in MW1027889), the report states that the patient "could barely open . . . mouth and experienced terrible ear pain." In 2002, the devices referenced in MW1027889 were surgically removed and replaced because of ear pain and fibrosis. After replacement device implantation, the patient was attending therapy and continued to experience headaches, ear pain, and ringing in ears.

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
	4/25/03	MW1027891 Fossa	During the replacement device implantation in 2002 (referenced in MW1027890), excessive bone growth was noted in the joint. The bone growth was surgically removed, and the patient received a one-time radiation treatment to prevent additional excess bone growth. After replacement device implantation, the patient experienced joint "sticking in ear," pain, and migraine headaches.
03-024	5/19/03	MW1028047 Fossa & Condyle, bilaterally	After device implantation in 1999 (referenced in MW1027889), the patient developed severe disabling headaches, muscle pain in and around the implant, serious tenderness in and around the implant areas, dizziness, nausea, and neck and shoulder pain. The report indicates that chewing, speaking, or any forceful contact with the chin exacerbate problems and states that surgical removal of device is planned.

<u>Event No.</u>	<u>Date Received</u>	<u>Product</u>	<u>Reported Event</u>
03-025	6/3/03	Condyle	After device implantation, the patient experienced swelling and pain. The devices were surgically removed and replaced. The acrylic condyle appeared to be worn and flattened and surrounded by a significant amount of granulation tissue (i.e., granules of new capillaries or tissue fibers that form on the surface of a wound). The firm's complaint documentation indicates that the surgeon opined that the device caused or contributed to the reason for device removal.
03-030	6/26/03	Fossa & Condyle	After device implantation, the patient experience ankylosis and could not open the jaw more than 12mm. The device was surgically removed.
03-035	7/9/03	Fossa & Condyle	A surgeon reported that two patients who received the implants experienced infections following the implant surgery. Respondents concluded that the event was not reportable but the complaint file did not contain adequate information to exclude the implant as a cause or contributing factor to the reported injury or to support the conclusion that the event was not reportable.

26. Respondents have violated 21 U.S.C. § 331(q)(1)(B) by failing to furnish to FDA the information described in the preceding paragraph as required by 21 U.S.C. § 360i(a)(1)(A).

27. The medical devices that have caused or may have caused or have contributed or may have contributed to the serious injuries described in paragraph 25 are also misbranded within the meaning of 21 U.S.C. § 352(t)(2) in that Respondents have failed to furnish the information described in paragraph 25 as required by 21 U.S.C. § 360i(a)(1)(A).

### **PRIOR VIOLATIONS**

28. TMJ Implants has a history of inadequate complaint handling and MDR reporting procedures dating back to 1992. Inadequate complaint handling and/or MDR reporting procedures were observed in at least eight FDA inspections of the firm conducted between 1992 and 2003.

29. FDA also has specifically notified Respondents in writing of their failure to comply with the MDR regulations. Warning Letters for inadequate complaint handling procedures and/or failure to file MDRs were issued to Respondents the on February 24, 2004, March 27, 2002, and January 27, 1992. Untitled letters for MDR reporting violations were issued on April 28, 2003, March 13, 2003, and October 23, 2002.

30. Additionally, on March 10, 2004, FDA met with Respondents Christensen and Mooney, and legal counsel for Respondent TMJ Implants to discuss Respondents' failure to comply with MDR requirements.

31. In spite of these warnings and FDA's efforts to obtain Respondents' voluntary compliance with the MDR requirements, to date, Respondents have failed to comply with the MDR requirements for the twenty-one (21) events described in paragraph 25 of this Complaint.

32. Respondents have asserted that their devices did not cause or contribute to the twenty-one (21) events described in paragraph 25 and/or that these events are not "serious injuries" as defined in 21 C.F.R. § 803.3(bb)(1), or are otherwise not reportable to FDA.

#### **AMOUNT OF CIVIL PENALTY**

33. Complainant seeks to impose upon each Respondent a civil penalty of \$10,000 for each MDR violation listed in paragraph 25. Thus, Complainant seeks to impose a total civil penalty of \$210,000 against TMJ, Implants and \$210,000 against each named individual.

#### **OPPORTUNITY FOR HEARING**

34. To obtain a hearing in this matter, Respondents must, within 30 days of service of this Complaint, file an answer pursuant to 21 C.F.R. § 17.9. The answer must be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852. The failure to file an answer within 30 days of service of the Complaint may result in the imposition of the proposed civil penalty and assessment, as provided by 21 C.F.R. § 17.11. Respondents may retain counsel to represent them in conjunction with this proceeding.

35. Pursuant to 21 C.F.R. § 17.9, Respondents' answer, if filed, must admit or deny each of the allegations made in this Complaint and must include the following: all defenses on which Respondents intend to rely; all reasons (if any) why Respondents contend that the civil penalty and assessment should be less than the amount requested by this Complaint; and the name(s), address(s), and telephone number(s) of Respondents' counsel (if any).

## PRAYER FOR RELIEF

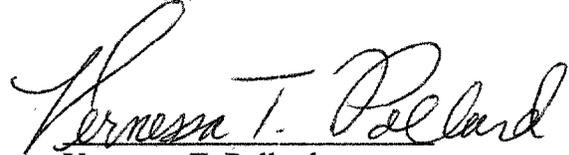
Based on the violations described in this Complaint,

COMPLAINANT PRAYS THAT:

1. The Presiding Officer enter a finding that each of the allegations in this Complaint are true;
2. The Presiding Officer enter a finding that Respondents violated 21 U.S.C. § 331 (q)(1)(B) by failing or refusing to furnish information for twenty-one (21) complaints of serious injuries that Respondents' devices have caused or may have caused or to which the devices have contributed or may have contributed as required under 21 U.S.C. § 360i(a)(1)(A);
3. The Presiding Officer enter a finding that the medical devices that have caused or may have caused or have contributed or may have contributed to the twenty-one (21) complaints of serious injuries described in paragraph 25 are misbranded within the meaning of 21 U.S.C. § 352(t)(2) in that Respondents failed or refused to furnish material and information for twenty-one (21) complaints as required by 21 U.S.C. § 360i(a)(1)(A);
4. The Presiding Officer enter a finding that each and every affirmative defense presented by each Respondent is not meritorious;
5. The Presiding Officer enter a finding that each Respondent is liable for civil money penalties pursuant to 21 U.S.C. § 333(g)(1)(A) and 21 C.F.R. § 17.2;
6. The Presiding Officer enter a finding that the appropriate amount of the civil penalty for which each of the Respondents is liable, considering all mitigating or aggravating factors, including the nature, circumstances, extent, and gravity of the violations, Respondents' ability to pay a civil penalty, the effect on their ability to continue to do business, their prior

violations, their degree of culpability, and such other matters as justice may require, is \$210,000 for each Respondent.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Vernessa T. Pollard". The signature is written in black ink and is positioned above the printed name.

Vernessa T. Pollard  
Attorney for Complainant  
U.S. Food and Drug Administration  
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