UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

-vs-

Case No. 6:06-cv-1281-Orl-18KRS

ENDOTEC, INC.,
MICHAEL J. PAPPAS,
FREDERICK F. BUECHEL,
Defendants.

ORDER

This action was tried before the Court from March 17 to March 19, 2008. Plaintiff United States of America ("the Government") initiated this injunction action against Defendants Endotec, Inc. ("Endotec"), Michael J. Pappas, and Frederick F. Beuchel (collectively, "Defendants") alleging that Defendants were manufacturing and distributing adulterated and misbranded medical devices in violation of the Federal Food, Drug and Cosmetic Act ("the FDCA").

The FDCA provides consumers with the assurance that the safety and efficacy of the food, drugs, and cosmetics purchased via interstate commerce are being monitored by the Food and Drug Administration ("FDA"). In 1976, Congress enacted the Medical Device Amendments ("the Amendments") to the FDCA which imposed a regime of detailed federal oversight for medical devices. 21 U.S.C. §§ 360c-360k. Congress "charged the FDA with the task of implementing the Amendments, and thus of essaying judgments appropriate to ensure

safe and effective medical devices without stifling innovative technology." Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 594 (D.C. Cir. 1985).

The Amendments establish three device classes. Class I devices are subject to general controls, such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class I devices include elastic bandages and medical gloves. Class II devices are subject to special controls, such as performance standards and postmarket surveillance measures. 21 U.S.C. § 360c(a)(1)(B). Class II devices include x-ray machines and laparoscopes. Class III devices are the most regulated and are subject to premarket approval ("PMA") to provide reasonable assurance of their safety and effectiveness before release for commercial distribution. 21 U.S.C. § 360c(a)(1)(C). Class III devices include replacement heart valves and pacemakers. Premarket approval requires extensive clinical study of the device and a detailed application submitted by manufacturers including full reports of the studies and investigations of the device's safety and effectiveness. However, a new device does not require premarket approval if the FDA finds it is "substantially equivalent" to another device that is already exempt from premarket approval. 21 U.S.C. § 360c(f)(1)(A). FDA's review of devices for substantial equivalence is known as the § 510(k) process.

The PMA process does not apply to "custom devices" as defined in 21 U.S.C. § 360j. It provides that a custom device

> necessarily deviates from an otherwise applicable . . . [PMA] requirement . . . if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device–

> (A)(i) is intended for use by an individual patient named in such order of such physician or dentist . . . and is to be made in a specific form for such patient, or
>
> (ii) is intended to meet the special needs of such physician or dentist . . . in the course of the professional practice of such physician or dentist . . ., and
>
> (B) is not generally available to or generally used by other physicians or dentists.

21 U.S.C. § 360j(b). The FDCA also allows a Class III device to be distributed as part of a clinical investigation conducted pursuant to an approved investigational device exemption ("IDE"). 21 U.S.C. § 360j(g). Furthermore, the practice of medicine doctrine provides that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396.

I. FINDINGS OF FACT

Endotec is a Florida corporation engaged in the business of manufacturing and distributing medical devices. Dr. Michael J. Pappas is Endotec's President and co-owner and has had authority over Endotec's operations since 1989. Dr. Frederick F. Buechel is Endotec's Vice President, Medical Director, and co-owner. Dr. Beuchel is a joint replacement surgeon who implants knee. hip, and ankle joint replacements.

The Government initiated this injunction action on behalf of the FDA, alleging that Defendants are manufacturing and distributing adulterated and misbranded medical devices in violation of the FDCA. The Government seeks a permanent injunction preventing Defendants from manufacturing and distributing the devices at issue and an order of disgorgement. The

devices at issue include ankle replacement implants with mobile bearings, two types of mobile bearings used with knee replacement implants, and temporomandibular joint ("TMJ") implants.

At trial, the Government presented six witnesses from the FDA. Robert R. Gatling, Jr. is the Director of the Program Operations Staff at the Office of Device Evaluation for the Center for Devices and Radiological Health ("CDRH"). Gatling provided testimony regarding FDA's classification of medical devices, the PMA process, and exemptions. Gatling also testified specifically about the devices at issue. Barbara Maulfair is an FDA investigator with the New Jersey District Office who conducted three inspections of Endotec's New Jersey facility from 2001 to 2004. Richard K. Vogel is an FDA investigator and a medical device specialist with the Florida District Office. Vogel conducted two inspections of Endotec's Orlando facility from 2004 to 2005. Mark Melkerson is the Director of the Division of General Restorative and Neurological Devices at the Office of Device Evaluation for the CDRH. Melkerson reviews products to allow marketing of products either through the 510(k) application or PMA process. Casper Uldriks is the Associate Director for Regulatory Guidance and Government Affairs in the Center Director's Office at the CDRH. Uldriks has provided guidance and training on the custom device exemption and the practice of medicine doctrine. Dr. Mary Susan Runner is Chief of the Dental Devices Branch at the Office of Device Evaluation for the CDRH and provided testimony regarding FDA's regulations governing TMJ devices.

A. Ankle Devices

The specific ankle devices at issue are all the ankle devices that are distributed for use in patients beyond the 109 patients enrolled in an approved IDE clinical study and all ankle

devices Defendants describe as "custom" or "surgeon specials." The Government contends that by manufacturing and distributing these ankle devices, Defendants are violating 21 U.S.C. § 331(a), which prohibits the introduction into interstate commerce of any adulterated device, and 21 U.S.C. § 331(k), which prohibits causing a device to become adulterated while being held for sale after shipment in interstate commerce. Additionally, the Government contends that Defendants failed to comply with FDA's IDE regulations in their clinical study of the ankle device in violation of 21 U.S.C. §§ 351(i) and 331(q)(1). Defendants contend that the ankle devices are exempt from premarket approval as custom devices under 21 U.S.C. § 360j(b) and that Dr. Beuchel is protected by the practice of medicine doctrine under 21 U.S.C. § 396.

Gatling testified that the ankle devices at issue in this case are Class III devices. Gatling's diligent search of FDA's records revealed that Endotec had submitted six 510(k) submissions for ankle devices that had either been withdrawn by Endotec or found by FDA to be not substantially equivalent to a predicate device. A seventh 510(k) submission initiated in February is currently under review. (Govt.'s Ex. 37.) Additionally, there is an IDE submitted in 1997 for the Beuchel-Pappas Ankle ("B-P Ankle") that received full approval, but reached its maximum patient enrollment in September 2001. (Govt.'s Ex. 37.)

Maulfair testified that she was first directed to inspect Endotec's New Jersey facility to collect information on the B-P Ankle clinical trials being conducted by Endotec under the approved IDE. During Maulfair's 2001 inspection, she prepared an establishment inspection

report ("EIR") and an FDA form 483.[1] (Govt.'s Ex. 5.) The FDA form 483 lists seventeen observations which were significant deviations from the regulations. Maulfair testified that Endotec's level of accountability was the worst she had ever seen and violated FDA's regulations governing clinical trials. Maulfair observed that Endotec's database identified about 4,000 ankle units, but the patient enrollment was only approved for 109 patients. Endotec personnel were unable to explain to Maulfair which of the 4,000 units in the database were part of the clinical trial and which units had been exported. Dr. Feldman, one of the clinical investigators, had implanted seventeen B-P Ankles into seventeen new patients, but had never notified Endotec of these additional patients. Dr. Feldman had also implanted ten additional devices as "surgeon specials" and Dr. Beuchel, who was not a clinical investigator for this clinical trial, had implanted 218 ankle devices as "surgeon specials."

As a result of Maulfair's 2001 inspection, FDA applied the provisions of the Application Integrity Policy ("AIP") to Endotec because it determined there had been a "system-wide failure by Endotec to ensure the integrity of data and that data submitted to FDA regarding this study [was] unreliable." (Govt.'s Ex. 6.) The application of the AIP meant that FDA would "defer scientific review of any pending submission, and any new submission or supplemental submission filed after this notice." (Id.) FDA had to "assess the validity of the data and information in all of Endotec's affected submissions" and that assessment had "priority over scientific data review until questions regarding data integrity [were] resolved." (Id.) FDA also

[1] An FDA form 483 is issued to the most responsible person at the firm at the close of an inspection, if applicable, and lists citable objectionable observations. Citable observations include violations involving quality system regulations, reporting regulations, and medical device tracking.

issued a warning letter to Endotec on March 15, 2002. (Govt.'s Ex. 7.) The warning letter explained that the approved IDE did not cover the ten devices shipped to Dr. Feldman and the 218 devices shipped to Dr. Beuchel and that the devices did not meet the criteria for a custom device. (Id.)

Maulfair testified that she conducted a second inspection of Endotec's New Jersey facility in 2002 and determined that Endotec continued to ship numerous ankles under its position that they were custom ankles. Maulfair observed that some of the ankle components being shipped to Dr. Beuchel had serial numbers beginning with both "05" and "95." Endotec's personnel had previously explained to Maulfair that the "05" numbers were used for B-P Ankle components and that the "95" numbers were used for custom components. According to Maulfair, the "05" ankle components should not have been manufactured at this point because the IDE enrollment had already been completed, no more patients could be enrolled, and no more B-P Ankles could be shipped.

During Maulfair's third inspection in 2004, she found that Endotec continued to ship ankle devices. Endotec's manufacturing and shipping documents indicated to Maulfair that Endotec was shipping both custom and standard B-P Ankle components. (Govt.'s Ex. 25-28, 31-33.)

Vogel testified that he was directed to inspect Endotec's Orlando facility in August 2004 to collect documents regarding Endotec's shipment of ankle devices to two specific patients.[2]

[2]The initial August 2004 inspection was delayed because a manager at Endotec's Orlando facility informed Vogel that Endotec was in the process of moving its New Jersey facility operations to the Florida location and it would take several days to determine the location of the shipping

The focus of that investigation eventually changed to the collection of documentation of the manufacturing and shipment in interstate commerce of ankle devices manufactured between September 2004 and January 2005. Personnel at Endotec explained to Vogel that the B-P Ankle consists of three components: a tibial component, a talar component, and an ankle bearing component. The personnel further explained that when the components are sent as an ankle system, they ship one tibial, one talar, and three ankle bearings. At the time of surgery, the surgeon determines which of the three bearings fits best. Vogel made observations and collected documents regarding the manufacture and shipment of an ankle device for a patient Shaw. Endotec personnel explained to Vogel that these were custom components. (Govt.'s Ex. 23, 29.) At the conclusion of his inspection, Vogel explained to Jared Pappas, Endotec's director of regulatory affairs, that the continued distribution of the B-P Ankle was a violation of the law. Jared Pappas claimed that the ankles were custom devices and exempt from the PMA requirement. Vogel explained that the CDRH did not consider these devices to be custom devices and that Endotec could no longer distribute the B-P Ankle under the IDE because they had already reached the maximum patient enrollment. Vogel expressed that the FDA could take several regulatory actions if Endotec did not come into compliance.

Vogel was directed to conduct a second inspection of Endotec's Orlando facility in November 2005. Endotec supplied documentation of shipment of the B-P Ankle to George Makris, the distributor in New Jersey, in September 2005. Vogel observed that one shipment originally had an ankle bearing with a serial number with the last name Zych, indicating it was

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documents. FDA directed Vogel to conclude the inspection in January 2005.

to be implanted in a patient Zych. However, this particular ankle bearing was not needed for patient Zych and was sent back to Endotec's Orlando facility where it was repackaged and relabeled with a serial number including the last name Golding, indicating it was to be used for a patient Golding. (Govt.'s Ex. 24.) The B-P Ankle with components with serial numbers including the last name Golding were shipped to Makris who hand delivered the B-P Ankle to Dr. Beuchel in New Jersey for implantation into patient Golding. (Govt's Ex. 24.) Endotec did not have a compassionate use approval from FDA for patient Golding.

Melkerson testified that he had signed letters giving compassionate use approval to Endotec for specific patients requiring revisions of existing ankles, most recently on February 29, 2008. Melkerson testified that the compassionate use program is not equivalent to PMA or 510(k) clearance. Rather, approval is granted on a case-by-case basis as Endotec petitions the FDA. It is allowed during periods when the IDE is under review and moving towards a marketing application.

Uldriks testified that the ankle devices manufactured and distributed by Endotec outside the IDE did not meet any of the criteria of the custom device exemption. The ankle devices are used on a number of different patients, there are clear specifications and drawings of the basic device, there is a different device available to treat the patients, and the ankle devices can be studied as part of a clinical trial. According to Uldriks, since the B-P Ankle did receive an IDE, the ankle devices can be studied under clinical trials. Uldriks also testified that any differences between each ankle device are for tailoring or sizing, so each one does not necessarily deviate from devices that are generally available. Additionally, since Endotec has distributed over 200

ankles, they cannot be considered one-of-a-kind. Uldriks reviewed Endotec invoices which indicated that devices meant for one patient were being used on a different patient. (Govt.'s Ex. 14.) Since certain ankle components were interchangeable between patients, they could not have been made in a specific form for an individual patient. Additionally, the invoices listed components according to size and Uldriks testified that if a device is available in different sizes, it cannot be a custom device. (Id.)

Dr. Pappas testified at trial that after receiving FDA's March 2002 warning letter, Endotec limited its manufacture of ankle devices for Dr. Beuchel to custom designs. Dr. Pappas explained that all of the ankle devices at issue have a mobile bearing which is often referred to as a three-piece design. According to his testimony, mobile bearing ankle devices are not available in the United States. Only fixed bearing, two-part devices are available in the United States.

Dr. Pappas testified that while the ankle devices at issue were similar to the standardized B-P Ankle that was being studied under the IDE, each had differences because each was designed for an individual patient, according to that patient's physiology and pathology. For example, some ankles required a custom talus to account for bone loss, some required side walls on the tibial component, and some required flanges on the talar component.

Dr. Pappas testified that both the custom ankles manufactured by Endotec and the B-P Ankles use a mobile bearing. Pappas also testified that the custom ankle components listed in patient records indicated sizes. Additionally, Pappas admitted that custom components

manufactured by Endotec intended for one patient had been implanted in other patients and that at least one patient received a combination of standard and made to order components.

Dr. Beuchel testified that there are no mobile bearing ankles generally available in the United States. According to Dr. Beuchel, the only ankle devices currently available are overloaded and over-constrained fixed bearings. Mobile bearing ankles are only available in the United States through a clinical study. Dr. Beuchel testified that the B-P Ankle that had an approved IDE was a standardized device available in numerous sizes. It did not have any sidewalls or flanges.

Dr. Beuchel testified that during the clinical study of the B-P Ankle, one of the clinical investigators was an outlier that did not follow up on his data. The other nine clinical investigators followed the protocol and recorded their data. Once the FDA issued the AIP, Endotec could no longer move forward with its applications to the FDA. Dr. Beuchel testified that the ankle devices that are the subject of Defendant's Exhibits 203-208 were designed and manufactured for purposes of treating the particular patients because there were no devices generally available that would have provided a satisfactory outcome to those patients. He also testified that the ankle devices were not generally used by any other physicians, were not generally available in finished form for purchase or dispensing, and were not offered for commercial distribution through labeling or advertising. Additionally, Dr. Beuchel testified that each of these ankle devices was intended to be used by an individual patient named in the order of the physician, in accordance with the definition of "custom device."

Dr. Beuchel explained that Endotec manufactured several bearings when manufacturing a custom ankle so that they would have the right one for the patient at the time of surgery. If one of the leftover bearings was the size needed for another patient, then it could be repackaged for that patient. According to Dr. Beuchel, the ankle devices in Defendants' Exhibits 203-208 were different from the B-P Ankle because some had flanges, some had extensions, and some had a longer stem. Dr. Beuchel considered these to be modifications or feature changes from the B-P Ankle. It was Dr. Beuchel's impression that each of the ankle devices deviated from the B-P Ankle because they had different geometries, shapes, and extensions based on the anatomical requirements of the particular patients. The alternative treatment that is available in the United States for ankle replacements is fusion. Fusion involves using pins and bone grafts to make the tibia and talus into one piece and the result greatly inhibits mobility.

Dr. Beuchel acknowledged at trial that there is one mobile bearing ankle, known as the STAR ankle, that the FDA panel has reviewed and recommended for approval for PMA. There is another mobile bearing ankle that is currently the subject of a clinical study which is still open for patient enrollment. Dr. Beuchel also acknowledged that the website for his private practice, South Mountain Orthopaedic Associates, states that Dr. Beuchel offers total ankle replacement with the B-P Ankle, but also clarifies that the B-P Ankle is only available in the United States through the FDA's compassionate use program. (Govt.'s Ex. 11.) Dr. Beuchel admitted that he is not a clinical investigator for the B-P Ankle and that means he cannot implant B-P Ankles pursuant to the approved IDE. However, Dr. Beuchel implanted B-P Ankles as surgeon specials until 2002 when FDA issued its warning letter to Endotec. Since 2002, Dr. Beuchel has only

implanted what he describes as custom ankle devices. Dr. Beuchel admitted that in April 2007, he implanted an ankle device in which all the component numbers began with "05," indicating it was the standard B-P Ankle. (Govt.'s Ex. 15 at 69.) Dr. Beuchel offered that the particular situation must have been an emergency situation. In other situations, Dr. Beuchel used components that had been originally manufactured for another patient because it offered the patient the best fit.

Dr. Beuchel also testified that the B-P Ankle could be clinically studied, but the customized ankles that had side walls, flanges, or an extended tibial, could not be clinically studied because they are custom devices. However, during his deposition, Dr. Beuchel testified that he personally thought a clinical study "would be okay" because the concepts are similar.

B. Knee Devices

The specific knee devices at issue are the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing. The Government contends that these are adulterated devices that have been manufactured and distributed in violation of 21 U.S.C. §§ 331(a) and 331(k). Defendants contend that the knee devices are custom devices under 21 U.S.C. § 360j(b). Additionally, Defendants argue that the Fenning Modular Bearing is an allowable variation of a knee device that has a 510(k) clearance.

Gatling testified that the knee devices at issue are Class III devices. Gatling's diligent search of FDA's records revealed that Endotec had submitted three IDE applications that had been conditionally approved, but were later either withdrawn or terminated by Endotec. (Govt.'s Ex. 37.) Additionally, four 510(k) applications had been submitted. (Govt.'s Ex. 37.)

One of those devices was found to be substantially equivalent to a predicate device and is not at issue in this case. (Govt.'s Ex. 37.) One other 510(k) application was withdrawn by Endotec and the other two were deleted for nonresponsiveness after FDA requested additional information.

The 510(k) cleared knee device is known as the Beuchel-Pappas Fixed Bearing New Jersey Total Knee Replacement System ("B-P Knee") and was determined to be substantially equivalent to legally marketed predicate devices on January 30, 2002. (Govt.'s Ex. 39.) The 510(k) clearance allowed Endotec to commercially market that device. Melkerson testified that the cleared bearing component has a one-piece tibial insert and is made out of polyethylene. The Fenning Modular Bearing, however, is a two-piece design made of polyethylene plus a metal track and Melkerson considers it to be a significant change from the cleared knee device. Melkerson testified that "[i]f there's a significant change that could affect safety and effectiveness, [manufacturers] are required to submit a new 510(k) for a product if they're going to introduce it into the market for the first time or they are first-time manufacturer." (Trial Tr.133:21-25, March 17, 2008.) FDA's website offers guidance to help manufacturers understand when they need to submit a new 510(k) for their product. Melkerson also testified that there was no PMA allowing Endotec to use the FlexGlide Knee Bearing with Anterior Stop in conjunction with an approved knee device. According to Melkerson, the custom device exemption does not apply to products that are reproduced over and over.

Uldriks testified that the FlexGlide Knee Bearing with Anterior Stop does not satisfy the elements of a custom device. The device is similar enough to other devices that it can be

clinically studied. Additionally, it is offered for distribution through labeling and is available in finished form. Uldriks also testified that the ball bearing is not designed for the anatomical needs of Dr. Fenning.

Dr. Pappas testified that the FlexGlide Knee Bearing with Anterior Stop was manufactured to replace a bearing on an LCS knee device which is manufactured by DePuy of Johnson and Johnson. Dr. Pappas testified that it was manufactured to meet the needs Dr. John Fenning, a seventy-five year old surgeon. Dr. Fenning was concerned about performing revisions on the LCS knee because revisions required stretching the tibia and it was very awkward and difficult for him. Dr. Fenning was also worried about causing ligament damage to the patient. The FlexGlide Knee Bearing with Anterior Stop was designed to meet the needs of Dr. Fenning because it did not require stretching of the tibia and Dr. Pappas considered it to be a surgeon's special. Dr. Papps testified that the FlexGlide Knee Bearing with Anterior Stop was never used by any other physician, was not available to anyone else, and was never offered for commercial distribution. Endotec ceased its manufacture of the FlexGlide Knee Bearing with Anterior Stop several years ago.

Dr. Pappas testified that the Fenning Modular Bearing was a one-part bearing[3] that was sold only to Dr. Fenning. He testified that it was not generally available to or used by other physicians and that it was not available in finished form for purchase or for dispensing prior to the time Endotec manufactured it for Dr. Fenning. Dr. Pappas did acknowledge that the

[3] Dr. Pappas emphasizes that he believes the Fenning Modular Bearing is a one-piece part because the parts are fixed together so that they cannot move.

Fenning Modular Bearing was advertised on a one-sheet flyer which was published on Endotec's website. Once they learned that there was no interest in the Fenning Modular Bearing, they removed the advertisement from their website. At the time, Endotec did not consider this to be a custom device, but rather an allowable variation of the approved B-P Knee. Dr. Pappas testified that the Fenning Modular Bearing behaves exactly the same way and uses the same materials as the B-P Knee and he determined that it did not require a new 510(k) submission.

C. TMJ Devices

The specific TMJ devices at issue are the Hoffman-Pappas TMJ Device ("H-P TMJ") components used for revision surgeries in patients Edgerton and Entler and the Hemi TMJ used for surgery in patient Robinson. The Government contends that these are adulterated devices that have been manufactured and distributed in violation of 21 U.S.C. §§ 331(a) and 331(k). Defendants contend that H-P TMJ components implanted as revisions in patients Edgerton and Entler did not require separate FDA approval because the patients were enrolled in the approved IDE. Defendants contend that Hemi TMJ implanted in patient Robinson was a custom device under 21 U.S.C. § 360j(b).

Gatling testified that the TMJ devices at issue in this case are Class III devices by statute. Gatling's diligent search of FDA's records revealed that Endotec has had a fully approved IDE since 1997 that is open and available for further enrollment of patients. (Govt.'s Ex. 37.) Maulfair testified at trial that during the 2004 inspection of Endotec's New Jersey facility, she collected documents related to Endotec's manufacturing and shipping of TMJ devices. There

was one request for an individual custom device for patient Robinson from Dr. Stephens. Dr. Stephens was not a clinical investigator and patient Robinson was not enrolled in the clinical trial. The component that was shipped for patient Robinson was a right fossa. Maulfair also observed that two devices had been shipped for revisions in two patients that had been part of the IDE study.

During Vogel's November 2005 inspection of Endotec's Orlando facility, he documented shipment in interstate commerce of TMJ devices. Vogel learned that one component of an H-P TMJ, a left fossa, had been implanted by Dr. Hoffman as a revision in a patient Edgerton. There was no compassionate use approval for patient Edgerton because Jared Pappas believed they did not need one because patient Edgerton had been enrolled in the IDE and it was a revision surgery. (Govt.'s Ex. 24.)

Uldriks testified that the Hemi TMJ implanted in patient Robinson does not satisfy the custom device exemption because it is a finished device. It is the same basic design as other TMJ devices. Uldriks acknowledged that Endotec's website states that the H-P TMJ is "[a]vailable only under clinical investigation in the United States." (Govt.'s Ex. 10.)

Dr. Runner testified that TMJ implants are Class III devices and are governed by four regulations: 21 C.F.R §§ 872.3940, 872.3950, 872.3960, and 872.3970. Runner testified that Endotec had a valid IDE for its H-P TMJ and that the clinical investigator, Dr. Hoffman, could implant the devices within the scope of the IDE. Runner testified that the two revisions performed on patients initially approved for implantation of the total joint was a deviation from the study protocol. 21 C.F.R. 812.35 regulates how clinical investigators can deviate from a

study protocol and they must inform FDA in a supplemental application. Endotec would have had to follow the regulation to perform the revision procedures. Endotec could have requested compassionate use approval from FDA. but never did so. Dr. Runner acknowledged that there is nothing in the investigational plan that tells Endotec that it must obtain prior approval from the FDA before performing a revision.

Dr. Runner explained that the Hemi TMJ is either a condyle or fossa component that would be implanted separately, so it is governed by a regulation. There was no IDE for the Hemi TMJ which, according to Dr. Runner, is essentially a partial joint implant. Dr. Runner testified that there is a Hemi device that is legally available. Dr. Runner acknowledged that she does not know the specific medical history of the patient who received the Hemi TMJ manufactured by Endotec.

Dr. Pappas testified at trial that Endotec manufactured the Hemi TMJ specifically for patient Robinson who had a tumor and was missing bone. The device was different from a regular fossa component because it did not have a plastic barrier. Dr. Pappas testified that there was no device available off-the-shelf that would have fit patient Robinson. An IDE would not have been appropriate in this case because it was only one device and it is impossible to study only one device. Additionally, Dr. Pappas testified that Endotec did not offer the device for commercial distribution through labeling or advertising.

Dr. Pappas testified that the revisions performed on patients that were part of the TMJ IDE were reported to FDA in Endotec's annual reports. According to Dr. Pappas, there were more than just two patients who underwent revision surgeries, but he does not recall the FDA

ever complaining that Endotec had committed a violation. Dr. Pappas testified that there is nothing in the investigational protocol that required that Endotec obtain prior approval before performing a revision. (Defs.' Ex. 226.)

D. Custom Device Exemption

Uldriks testified that "[t]he burden [of demonstrating that the custom device exemption applies] rests upon the manufacturer who's going to be making this new thing, this new unique device. They have to demonstrate to [the FDA] why it is a custom device." (Trial Tr. 151:5-8, March 17, 2008.) Uldriks explained how the FDA has interpreted each of the elements of the custom device exemption codified at 21 U.S.C. § 360j(b).

The first element requires that the device must necessarily deviate from devices generally available or from a PMA. Uldriks testified that the device must be unusual and its unique nature means it cannot go through the approval process of a PMA. The second element of the exemption requires that the device not be generally available to, or generally used by, other physicians or dentists. Uldriks testified that the FDA has interpreted that element to mean that if the device has a basic characteristic or if a physician can contact a manufacturer to get a basic device and it is available for purchasing or for dispensing on a prescription, then the device is available in finished form. The availability of a finished device is not that it is in physical existence and in inventory, but rather that the manufacturer can or is able to manufacture what is requested in terms of a basic device type. The third element requires that the device not be offered through labeling or advertising for commercial distribution. Uldriks testified that the FDA interprets labeling in very broad terms and focuses on whether there is

any information in the public domain about the particular device. Any information in print, graphic, or on the Internet is going to be considered labeling. The next element requires that the device be manufactured to meet the specific needs of an individual patient or of an individual physician. Uldriks testified that if the device is for an individual patient, the device itself must be manufactured specifically for that patient in a specific form for use by that patient. If there is a group of patients with the same pathology or a particular condition that reappears in the patient population, that would be considered a commonality. If the same kind of device is used to treat that commonality, the device is not a custom device. Uldriks testified that if the device is intended to meet the special needs of a physician, it must be limited to meet the anatomical needs for that particular physician. Finally, the device must not be generally available to or generally used by other physicians or dentists. Uldriks explained that if other physicians know about the device and can access it or know where to obtain it, then it is available to them and the device does not come within the bounds of the exemption.

Uldriks testified that Endotec announced on its website that it would attend the 2007 American Association of Orthopedic Surgeons. (Govt.'s Ex. 10.) Uldriks explained that attendance at a professional trade show constitutes labeling or advertising activities if Endotec was making information available about the device through presentation, description, or hard-copy labeling. Uldriks also testified about an advertisement in *Orthopaedic Product News*, a trade journal, describing Endotec's custom devices. (Govt.'s Ex. 13.) Uldriks testified that such an advertisement in a professional journal constitutes labeling or advertising.

D. Practice of Medicine

Uldriks testified that the practice of medicine doctrine, codified at 21 U.S.C. § 396 allows a physician to use a legally marketed device for use on a patient in a different way than indicated. Uldriks explained that a legally marketed device means that it is either exempt from premarket criteria. has received 510(k) clearance. or has a PMA.

II. CONCLUSIONS OF LAW

The Court emphasizes that the mission of the FDA is to protect the public from dangerous and harmful products. However, that mission should not run contrary to technological progress and advancement that can provide the most up-to-date benefits to consumers. The FDA should ensure the safety and effectiveness of the devices it regulates, without stymying progress and technological advancement. It is noteworthy that throughout the duration of these proceedings, the FDA has not alleged that Defendants have harmed any individual by manufacturing or distributing medical devices and has not alleged that any of Defendants' devices are dangerous or that their use poses any risk.

A. Ankle Devices

Defendants are conversant with 21 U.S.C. §§ 360j(b) and the Court finds that since the March 2002 warning letter, Defendants have been in substantial compliance regarding the B-P Ankle. Defendants contend that the ankle devices at issue are custom devices and thus, exempt from the premarket approval requirement. In Contact Lens Mfrs. Ass'n v. FDA, the court concluded that the FDA acted reasonably in determining that the contact lenses at issue were not custom devices, even though individual lenses were ground to a particular doctor's

specifications, because the lenses could be rationally regarded as generally available to or generally used by other physicians." 766 F.2d 592, 600 (D.C. Cir. 1985). The court stated that "prescriptions for all but the most pathological eyes are likely to be replicated again and again and thus to be 'generally used.'" Id. Moreover, the court was concerned with the risks presented by "devices designed for prolonged contact with so delicate and vital an organ as the living eye." Id. at 603. Specifically, the FDA was concerned because the lenses at issue combined features of "hard" lenses and "soft" lenses. At the time, "soft" lenses were a recent development and the FDA was "concerned that the use of these contact lenses may result in serious eye damage if the new material of which they [were] composed [was] unsafe for use in the eye, if the user [could not] feasibly care for the lenses, or if the highly complex procedures for the manufacture of these lenses [was] not carefully controlled to assure a product of uniform quality." Id. at 595. In the present case, however, the Government did not present any evidence to indicate that the ankle devices were potentially dangerous, as was the case with the lenses in Contact Lens.

The court in Contact Lens, however, noted that the definition for a custom device "reflect[s] a commonsense congressional judgment that the design and composition of certain medical devices are so individualized that subjecting them to the usual regulatory controls would be impractical (and a complementary judgment that such particularly constructed devices are so closely monitored by the prescribing physician that stringent regulation might well be excessive)." Id. at 599. In the present case, Endotec manufactured and distributed ankle devices according to a particular patient's unique needs. While there may have been different sizes of the three components, each ankle device was designed with custom features according to the

particular patient's pathology. Some patients needed ankle devices with a custom talus and others needed sidewalls, flanges or fins. This is not a case where there was a standard deviation from a basic design because each patient had unique needs according to his or her pathology and each ankle device was manufactured according to the doctor's order for that patient. These ankle devices were not "merely a variation" within a range of sizes as was the case in Contact Lens. Thus, the Court finds that the ankle devices were not generally available or generally used by other physicians and each was manufactured to meet the needs of a specific patient.

Defendants also presented sufficient evidence to satisfy the other elements of the custom device exemption. Each ankle device is sufficiently unique that clinical investigations would be impractical and there are no other approved mobile bearing ankle devices currently available in the United States. The ankle devices were not available in finished form because each was manufactured on a case-by-case basis and included particular features to accommodate the particular patient's physiological needs. Finally, Defendants did not offer the custom ankle devices for commercial distribution through advertising or labeling. Any references to ankle devices on Endotec's website or on Dr. Beuchel's private practice website refer to the B-P Ankle, and not the unique ankle devices at issue in this case. The Court finds that the ankle devices at issue are custom devices.

Accordingly, the Court finds that the ankle devices are not adulterated and Defendants did not violate 21 U.S.C. §§ 331(a) and 331(k) by manufacturing and distributing the custom ankle devices. Uldriks' interpretation of "custom device" is so narrow as to make the definition

useless. The Court cautions, however, that Defendants must scrutinize their website and other marketing materials carefully to avoid the unlawful advertising or marketing of these devices.

The Government also contends that Defendants violated 21 U.S.C. §§ 351(i) and 331(q)(1) by failing to comply with the FDA's IDE regulations and with the terms and conditions of the B-P Ankle IDE during the clinical study. While the Court agrees that Endotec had faulty record-keeping, the Government has neither alleged that the B-P Ankle is unsafe or dangerous nor that Defendants' actions have caused harm to any patient. FDA's stringent regulations and strict interpretation of procedural requirements are resulting in technological innovation being stymied, rather than advanced. Indeed, the evidence presented at trial showed that the B-P Ankle provided greater benefits to patients than the alternatives available in the United States.

Accordingly, the Court finds that Defendants have not violated 21 U.S.C. §§ 351(i) and 331(q)(1). However, in the future, Defendants must maintain better records and Endotec must monitor its clinical trials more carefully in order to ensure the integrity of data it collects. Proper record-keeping is mandatory if Defendants hope to seek FDA approval. Unless Defendants comply with FDA requirements, they will be relegated to manufacturing ankle devices for custom use only, and the general population who needs ankle replacements will be unable to benefit.

B. Knee Devices

Defendants argue that the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing are custom devices that are exempt from the PMA requirement. Alternatively,

Defendants argue that the Fenning Modular Bearing is an allowable variation of the approved B-P Knee.

While Dr. Pappas testified that the FlexGlide Knee Bearing with Anterior Stop was manufactured only for use by Dr. Fenning, Defendants have been unable to identify any "special need" of Dr. Fenning that would bring the device within the custom device exemption. Additionally, the same bearing was implanted repeatedly in different patients. The Court finds that the FlexGlide Knee Bearing with Anterior Stop is not a custom device and therefore is not exempt from the PMA requirements.

Accordingly, the FlexGlide Bearing with Anterior Stop is an adulterated device that was manufactured and distributed in violation of 21 U.S.C. §§ 331(a) and 331(k).

Dr. Pappas testified that he also considered the Fenning Modular Bearing to be a custom device. However, Defendants did not present any evidence to show that each bearing was unique and manufactured according to a particular patient's needs. Defendants also failed to present evidence of any "special need" of Dr. Fenning that required the use of this bearing. Additionally, Dr. Pappas admitted that Endotec advertised the Fenning Modular Bearing on a flyer which was posted on Endotec's website. Since it was not manufactured for the specific needs of an individual patient and it was advertised for commercial distribution, the Court finds that the Fenning Modular Bearing is not a custom device.

Defendants' claim that the Fenning Modular Bearing is an allowable variation of the approved B-P Knee also fails. A new 510(k) application is required if a device is "significantly changed or modified in design, components, method of manufacture, or intended use." 21

C.F.R. §§ 807.81(a)(3). The bearing on the B-P Knee is a one-piece component made of polyethylene. The Fenning Modular Bearing, however, is a two-piece component made of polyethylene and metal. Despite Dr. Pappas' testimony that the Fenning Modular Bearing should be considered a one-piece bearing because the two pieces are fixed together, the Court finds that the Fenning Modular Bearing constitutes a significant change from the approved bearing component in the B-P Knee and Defendants were required to submit a new 510(k) application to the FDA.

Accordingly, the Court finds that the Fenning Modular Bearing is an adulterated device that was manufactured and distributed in violation of 21 U.S.C. §§ 331(a) and 331(k).

C. TMJ Devices

Defendants contend that Endotec did not need prior approval from the FDA to distribute the two H-P TMJ devices used for revision surgeries in patients that were already enrolled in the clinical study.

There is no dispute that patients Edgerton and Entler were enrolled in the approved IDE clinical study. The Government, however, claims that the revision surgeries went beyond the scope of the IDE protocol. Dr. Runner testified that 21 C.F.R. § 812.35 requires that a study sponsor obtain prior approval when implementing a change to an investigational plan. Defendants, however, assert that they never deviated from the approved investigational plan. Dr. Runner testified that there was nothing in the approved investigational plan which required Defendants to obtain prior approval before providing H-P TMJ devices for revision surgeries in patients already enrolled in the clinical study. Dr. Pappas testified that the inclusion criteria

of the investigational plan included patients who required revisions. Additionally, Dr. Pappas testified that Endotec listed the revision surgeries in its annual reports to FDA. Therefore, the Court finds that the two H-P TMJ devices used for revision surgeries did not constitute deviations from the study protocol, did not require prior approval from the FDA, and were exempt from PMA requirements.

Accordingly, the Court finds that the two H-P TMJ devices were not adulterated and Defendants did not violate 21 U.S.C. §§ 331(a) and 331(k) by manufacturing and distributing the two H-P TMJ devices for patients Edgerton and Entler.

The Government also claims that the Hemi TMJ manufactured for patient Robinson was an adulterated device. Defendants claim the Hemi TMJ was a custom device.

Patient Robinson was not enrolled in the clinical trial and Dr. Stephens was not a clinical investigator. Patient Robinson suffered from a tumor and was missing a large piece of bone in her jaw. The Hemi TMJ necessarily deviates from the PMA requirement because it is so unique that a clinical study would be impracticable. Indeed, as Dr. Pappas testified, this device was manufactured only once for this individual patient and it is impossible to perform a clinical study of just one unit. The Hemi TMJ was unique because unlike regular fossas that were part of the H-P TMJ devices, it did not have a plastic barrier, but rather it had a socket to compensate for the bone removal. The Hemi TMJ was not available in finished form because it was not available at all until it was designed for patient Robinson. Defendants did not offer the Hemi TMJ device for commercial distribution through labeling or advertising. The Hemi TMJ was manufactured specifically to account for the bone loss suffered by patient Robinson as a result

of a tumor and thus, it was intended to meet the patient's specific needs. Indeed, the Hemi TMJ was ordered in its specific form by Dr. Stephens for patient Robinson. Finally, the Hemi TMJ that was used for patient Robinson was not generally available to or used by other physicians. The Court finds that the Hemi TMJ was a custom device.

Accordingly, the Court finds that the Hemi TMJ was not adulterated and Defendants did not violate 21 U.S.C. §§ 331(a) and 331(k) by manufacturing and distributing the Hemi TMJ.

III. CONCLUSION

Federal courts may only interpret acts of Congress. However, in the field of medical devices, the FDA might ask Congress to revise 21 U.S.C. §§ 360a-360k to speed up procedures, so that citizens of the United States can benefit sooner from the fast-moving technology of the twenty-first century.

For the foregoing reasons, the Court orders as follows:

1. Defendants did not violate 21 U.S.C. §§ 331(a) and 331(k) by distributing the ankle devices which are the subject of this action. The ankle devices were each a custom device and exempt from PMA requirements. Defendants are enjoined from advertising the B-P Ankle or any custom ankle devices through websites, in professional journals, at professional conferences, or through any other means and the ankle devices may be used by prescription only.

2. Defendants did not violate 21 U.S.C. §§ 351(i) and 331(q)(1) in their clinical study of the B-P Ankle. However, Defendants must improve their record-keeping practices in order to strictly adhere to the FDA's requirements for monitoring clinical studies.

3. Defendants violated 21 U.S.C. §§ 331(a) and 331(k) by distributing the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing because both bearings are adulterated devices. Defendants are enjoined pursuant to 21 U.S.C. § 332(a) from manufacturing, packing, labeling, and distributing the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing, unless and until Defendants obtain an approved IDE, PMA, or 510(k) clearance.

4. Defendants did not violate 21 U.S.C. §§ 331(a) and 331(k) by distributing two H-P TMJ devices as revisions in patients enrolled in the approved IDE clinical study and one Hemi TMJ. The distribution of the two H-P TMJ devices does not constitute a deviation from the approved investigational plan and the Hemi TMJ is a custom device.

5. Approved export devices must be properly labeled as intended for export and Defendants shall not sell or advertise in domestic commerce without FDA approval.

6. The Government's request for an order of disgorgement is **DENIED.**

7. Each party is responsible for its own costs and attorney's fees.

8. The Clerk of the Court is directed to enter judgment accordingly and **CLOSE THE CASE.**

DONE and **ORDERED** in Orlando, Florida on this 30 day of April, 2008.

G. KENDALL SHARP
SENIOR UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record
Unrepresented Parties