2011R00148/JTE

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	Crim. No. 14-
v.	:	
CHARLIE CHI	:	21 U.S.C. §§ 331(a) and 333(a)(1)

I N F O R M A T I O N

The United States Attorney for the District of New Jersey charges:

BACKGROUND

At all times relevant to this Information, unless otherwise alleged:

Defendant Charlie Chi, OtisMed Corporation, the OtisKnee, and Total Knee Arthroplasty

1. OtisMed Corporation was founded in or around August 2005 as a privately-held corporation, organized under the laws of the State of California. By September 2009, OtisMed Corporation, based in Alameda, California, had grown to more than 50 employees following substantial private equity financing and increased revenues.

2. In or around November 2009, OtisMed Corporation was acquired by Stryker Corporation, a publicly-traded

manufacturer of orthopedic implant devices and supplies. OtisMed Corporation then became a wholly-owned subsidiary of Stryker Corporation.

3. OtisMed Corporation's primary product was the OtisKnee device - a cutting guide introduced by OtisMed Corporation to the commercial market in May 2006 and designed for use in knee replacement surgery, known as "total knee arthroplasty" or "TKA."

4. TKA was a surgical procedure that replaced the weight-bearing surfaces of the knee joint to relieve often debilitating pain and improve stability. TKA was one of the most common orthopedic procedures performed in the United States. Americans underwent approximately 686,000 TKAs in 2009 alone.

5. TKA was most commonly performed due to severe osteoarthritis, the second most common chronic condition in the United States. Osteoarthritis was a disease of the joints characterized by a disruption and potential loss of joint cartilage along with other joint changes. Symptoms included gradually developing pain aggravated or triggered by activity, stiffness on awakening and after inactivity, and occasional joint swelling.

6. During TKA, metal and plastic parts were used to cap the ends of the bones that form the knee joint, with the

goal being to resurface the parts of the knee joint that have been damaged to relieve pain, improve stability, and restore joint function. The procedure required the orthopedic surgeon to remove the ends of the bones and to reshape the remaining bone to accommodate the artificial knee prosthesis. The bone cuts must be made with precision, as the angles formed by the bone cuts directly impacted the "alignment" of the leg. This was critical for a good clinical result, since poor alignment in TKA could result in failure of the bone and/or the implant.

7. Cutting guides such as the OtisKnee device were not themselves implanted during knee replacement surgery. Rather, the OtisKnee device was used during surgery to assist the surgeon in making accurate bone cuts that were specific to the individual patient.

8. Between May 2006 and September 2009, approximately 75% of OtisKnee devices were sold in conjunction with sales of Stryker Corporation's Triathlon Total Knee Replacement System, with marketing for the OtisKnee done by both representatives of OtisMed Corporation and representatives of Stryker Corporation. Other OtisKnee devices were sold in conjunction with sales of Biomet Orthopedics, LLC's Vanguard Complete Knee System. The Triathlon Knee System and the

Vanguard Complete Knee System were permanent joint prostheses implanted into the patient during knee replacement surgery.

9. The OtisKnee device purportedly matched the size and placement of a knee implant (the Triathlon Knee System or the Vanguard Complete Knee System) to the patient's unique and normal (non-diseased) knee anatomy using data from magnetic resonance imaging ("MRI") of the patient's knee prior to surgery and OtisMed Corporation's 3-D software. (OtisMed Corporation had configured its software to create OtisKnee devices for use with the Triathlon Knee System or for use with the Vanguard Complete Knee System, but had not configured its software to create OtisKnee devices for use with other permanent implants.)

10. This patient-specific, "custom fit" approach was promoted by OtisMed Corporation as enabling surgeons to preserve more of the patient's own bone and ligaments, which in turn would allow for better implant fit, alignment, and longevity. OtisMed Corporation's marketing materials claimed that when surgeons elected to use the OtisKnee device, "[the patient] would receive a knee replacement tailor made for [their] own normal (non-diseased) anatomy, and no one else's." OtisMed Corporation's marketing materials also claimed that TKAs performed with the OtisKnee device were accomplished "with less intra-operative decision-making required from the surgeon … the custom fit technology is all that is needed to ensure proper

alignment. In addition, less bone cut and all ligaments are spared, preserving the feel of a more 'natural' feeling knee based on the patient's normal knee function." OtisMed Corporation also claimed that TKAs performed with the OtisKnee device were safer than those performed using traditional instruments and resulted in less post-operative pain for patients.

11. None of OtisMed Corporation's claims regarding the OtisKnee device were evaluated by the United States Food and Drug Administration before OtisMed Corporation used them in its advertisements and promotional material.

12. Between May 2006 and September 2009, OtisMed Corporation sold more than 18,000 OtisKnee devices, generating revenue of approximately $27.1 million.

Defendant Charlie Chi

13. Defendant Charlie W. Chi, Ph.D. (CHARLIE CHI) was among the founders of OtisMed Corporation in or around August 2005. CHARLIE CHI and others conceived of the OtisKnee device and CHARLIE CHI acted as OtisMed Corporation's president, chief executive officer, and chairman of the Board of Directors until OtisMed Corporation was acquired by Stryker Corporation in November 2009.

14. In his capacity as OtisMed Corporation's president, chief executive officer, and chairman of the Board of

Directors, CHARLIE CHI was responsible for the day-to-day operations of OtisMed Corporation.

The FDA and FDCA

15. The United States Food and Drug Administration ("FDA"), an agency within the United States Department of Health and Human Services, was the agency of the United States government responsible for protecting the health and safety of the American public by assuring, among other things, that medical devices intended for use in the treatment of human beings are safe and effective for their intended uses. Pursuant to its statutory mandate, FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

16. The Federal Food, Drug, and Cosmetic Act ("FDCA"), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at Title 21, United States Code, Section 301 *et seq.*

17. Under the FDCA and its implementing regulations, all medical devices were classified into one of three regulatory classes - Class I, II, or III, based on the level of controls necessary to provide reasonable assurance of the device's safety and effectiveness for the general and specific uses for which it was intended. Classification was largely risk-based, that is, the risk the device posed to the patient and/or the user was a

major factor in determining the class to which a device was assigned.

18. Class I devices were deemed to present minimal potential for harm to the user and were often simpler in design than Class II or Class III devices. They were therefore subject to the least regulatory controls. For example, dental floss, enema kits, and elastic bandages were classified as a Class I devices.

19. Class II devices were higher risk devices than Class I and required greater regulatory controls to provide reasonable assurance of their safety and effectiveness. For example, powered wheelchairs and some pregnancy test kits were classified as Class II devices.

20. Class III devices were generally the highest risk devices and were therefore subject to the highest level of regulatory controls. For example, replacement heart valves and pacemakers were classified as Class III devices. Class III devices included devices that were intended for use in supporting or sustaining life, were of substantial importance in preventing impairment of health, or presented a potential unreasonable risk of illness or injury. These devices were subject to the highest level of regulatory controls in order to provide reasonable assurance of safety and effectiveness for their intended use.

21. The class to which a device was assigned generally determined whether and the type of pre-market submission/application to FDA was required before the device could be lawfully marketed. Most Class I and some Class II devices (but no Class III devices) were classified as exempt from pre-market review, but remained subject to the "general controls" applicable to all medical devices and were subject to specific limitations on the exemption found within FDA regulations.

22. Devices that were not in commercial distribution prior to May 28, 1976, when the Medical Device Amendments to the FDCA became effective, were automatically assigned to Class III by operation of law. Such Class III devices could not legally be marketed in the United States until the manufacturer submitted to FDA an application for pre-market approval ("PMA") and FDA approved that application, or, alternatively, the manufacturer obtained a different classification and marketing authorization through a different regulatory pathway. FDA would not grant PMA approval unless the information in the PMA application provided FDA with reasonable assurance that the device was safe and effective when used according to its labeling.

23. A manufacturer could remove a device from automatic assignment to Class III, and thereby bypass the PMA

process, by obtaining either an order from FDA classifying or reclassifying the device into Class I or Class II, or a finding by FDA that the device was substantially equivalent to a legally marketed device (called a "predicate device") for which PMA approval was not required.

24. A manufacturer that sought a determination of "substantial equivalence" was required to submit to FDA "pre-market notification" (also known as a "510(k) submission") no later than ninety days before the manufacturer intended to introduce the device into interstate commerce. If FDA found the device to be "substantially equivalent" based on the manufacturer's pre-market notification, the device was then "cleared" for marketing and could be distributed in interstate commerce for the FDA-cleared indications for use so as long as the manufacturer complied with all other applicable requirements.

25. A determination of "substantial equivalence" required that a manufacturer demonstrate that a particular device had the same intended use as a legally marketed predicate device, and that the device had either the same technological characteristics as the predicate device, or had different technological characteristics but the information submitted by the manufacturer, including appropriate clinical or scientific data if necessary, demonstrated that the device was as safe and

effective as a legally marketed predicate device and did not raise different questions of safety and effectiveness than the predicate.

26. Some new devices could not be cleared through the 510(k) process because their manufacturers could not demonstrate that such devices were substantially equivalent to a legally marketed predicate device. Manufacturers of such devices could also seek classification and marketing authorization through the "de novo" process. A manufacturer could file a de novo petition which, if granted, provided a route to market for a medical device that was low to moderate risk, but was originally classified into Class III because FDA found it to be "not substantially equivalent" (NSE) to any legally marketed predicate device.

27. Approval of a PMA application, clearance of a 510(k) submission, and granting of a de novo petition were different regulatory routes for obtaining FDA's authorization to market a medical device. Until a device obtained one of these forms of authorization, or was subject to an exemption not applicable in this case, it could not legally be distributed in interstate commerce.

28. A Class III device was "adulterated" under 21 U.S.C. 351(f)(1)(B) if it was required to have, but did not have, PMA approval for its intended use. The FDCA prohibited

the introduction of adulterated medical devices into interstate commerce.

OtisMed Corporation's 510(k) Submission

29. Between May 2006 and November 2009, OtisMed Corporation distributed more than 18,000 OtisKnee devices to surgeons throughout the United States. From May 2006 to October 2008, OtisMed Corporation had not sought or received PMA approval, 510(k) clearance, or the grant of a de novo petition from FDA to market or distribute the OtisKnee device in interstate commerce. During this time, OtisMed Corporation took the position with physicians who inquired and with the companies with which OtisMed Corporation co-marketed the OtisKnee device, that the OtisKnee was classified as a Class I device (a template for clinical use) and exempt by regulation from FDA premarket approval and clearance requirements. However, OtisMed Corporation never sought a statement from FDA confirming that the agency agreed that its new device should be classified as a Class I exempt device.

30. On October 2, 2008, OtisMed Corporation submitted a 510(k) notification to FDA seeking clearance to market the OtisKnee device.

The NSE Letter

31. On or about September 2, 2009, FDA sent OtisMed Corporation a notice that its 510(k) submission had been denied.

32. Specifically, FDA notified OtisMed Corporation that FDA had determined that the OtisKnee device was not substantially equivalent to another legally marketed device not subject to a PMA, and OtisMed Corporation had not demonstrated the OtisKnee device to be as safe and effective as other legally marketed devices (the "NSE Letter").

33. Among other things, the NSE Letter noted several deficiencies in the data provided by OtisMed Corporation which OtisMed Corporation claimed established the OtisKnee device to be safe and effective. For example, the NSE Letter noted that the 510(k) submission included insufficient preoperative information regarding patients included in the data, which was "important to identify whether or not there are certain Triathlon patients who would be contraindicated for the OtisKnee or at higher risk for poor results," and that missing data regarding follow-up was sufficient "to raise concerns about the failure rate of the Stryker Triathlon when implanted with the OtisKnee Orthopedic Cutting Guides, if some of these missing patients have experienced revisions or failures." The NSE letter also observed OtisMed Corporation did not provide FDA with information about whether and how frequently surgeons

judged the cutting angles prescribed by the OtisKnee to be flawed such that the surgeons found it necessary to forgo using the OtisKnee guides during the surgical procedure.

34. The NSE Letter informed OtisMed Corporation that the OtisKnee device was classified by statute into "Class III (Premarket Approval)." The letter further warned that "[a]ny commercial distribution of [the OtisKnee device] prior to approval of a [premarket approval application], or the effective date of any order by the Food and Drug Administration re-classifying [the OtisKnee] into Class I or Class II would be a violation of the [Federal Food, Drug, and Cosmetic Act]."

35. The NSE Letter also informed OtisMed Corporation that FDA viewed the OtisKnee device to be part of a "significant risk device system under [21 CFR § 812.3]." By definition, a "significant risk device" is one that "presents a potential for serious risk to the health, safety, or welfare of a subject." 21 C.F.R. § 812.3(m).

36. To date, OtisMed Corporation has never sought nor obtained PMA approval for the OtisKnee. Nor has it obtained FDA marketing authorization through the 510(k) or de novo processes.

37. Between September 2, 2009, and September 9, 2009, OtisMed Corporation's Chief Executive Officer CHARLIE CHI and others at OtisMed Corporation received advice from legal and regulatory counsel confirming that, based on the NSE Letter, it

would be unlawful for OtisMed Corporation to continue distributing OtisKnee devices in interstate commerce.

38. For example, on or about September 4, 2009, OtisMed Corporation's Board of Directors, including CHARLIE CHI, participated in a conference call to discuss OtisMed Corporation's response to the NSE Letter. In addition to the Board of Directors, a regulatory expert retained as outside counsel by OtisMed Corporation ("outside regulatory counsel") participated in the conference call. The outside regulatory counsel made clear to the Board of Directors that it would be against the law to continue to ship OtisKnee devices without permission from FDA. During that conference call, OtisMed Corporation's Board of Directors unanimously decided to stop further shipments of OtisKnee devices.

39. Following the September 4, 2009, Board of Directors conference call, CHARLIE CHI and others at OtisMed Corporation were concerned that the consequences of the NSE Letter - in particular the sudden ceasing of shipments of the OtisKnee - would have a negative impact on the brand, image, reputation, and value of OtisMed Corporation and the OtisKnee device. This concern was exacerbated by the fact that, at the time, OtisMed Corporation was set to be acquired by Stryker Corporation for as much as $100 Million (including potential milestone payments) on the condition that FDA clear OtisMed

Corporation's 510(k) submission for the OtisKnee device prior to closing of the acquisition.

40. In response to those concerns, CHARLIE CHI and others at OtisMed Corporation sought to develop a communications plan to reach out to, among others, OtisMed Corporation's surgeon customers and hospital customers to inform them of the fact that the OtisKnee device would not be available until FDA granted approval. The plan was to notify surgeon customers and hospital customers on September 14, 2009, and to develop between September 4, 2009, and September 14, 2009, the messaging that would be used on September 14, 2009.

41. CHARLIE CHI and others at OtisMed Corporation were concerned that causing surgeons who had patients scheduled for surgeries within weeks of the NSE Letter to make last minute changes would exacerbate the negative impact of the NSE Letter on the reputation of OtisMed Corporation and the OtisKnee device.

42. On or about September 9, 2009, at approximately 4:30 p.m. Pacific Time, OtisMed Corporation's Board of Directors, including CHARLIE CHI, participated in another conference call. During this conference call, the Board of Directors discussed, among other things, the advice from the outside regulatory counsel that OtisMed Corporation could not lawfully continue to ship the OtisKnee without permission from

FDA. The Board of Directors conference call concluded at approximately 5:18 p.m. Pacific Time.

Post-NSE Shipments

43. Approximately one hour after the September 9, 2009, Board of Directors conference call, CHARLIE CHI entered the office of OtisMed Corporation's Director of Strategic Financial Planning and Analysis (OtisMed Employee # 1), and directed OtisMed Employee # 1 to work with OtisMed Corporation's Director of Operations (OtisMed Employee # 2) to organize a mass shipment of all OtisKnee devices which had been manufactured but had not yet been shipped due to the hold on shipping placed following receipt of the NSE Letter.

44. During this conversation, CHARLIE CHI suggested to OtisMed Employee # 1 that they could hide the shipments from regulators (FDA) through a number of potential means, including by: taking the packages to an off-site shipping location instead of having them picked up by Federal Express at OtisMed Corporation's facility; utilizing CHARLIE CHI's personal Federal Express shipping account; hand-writing the Federal Express airbills and backdating the shipment dates to September 4, 2009; or utilizing a temporary employee, rather than regular employees, to hand-write the airbills. At the end of the conversation, as CHARLIE CHI left OtisMed Employee # 1's office,

CHARLIE CHI stated, in substance and in part, "this conversation did not happen."

45. Following the conversation in OtisMed Employee # 1's office, CHARLIE CHI reiterated his instruction to OtisMed Employee # 1 by sending a Blackberry messenger instant message stating: "We are shipping everything out tomorrow. One Shot."

46. On or about September 10, 2009, after OtisMed Employee # 1 had shared with OtisMed Employee # 2 the direction from CHARLIE CHI, OtisMed Employee # 2 met with CHARLIE CHI and informed CHARLIE CHI that, given the NSE Letter, OtisMed Employee # 2 objected to the ordered shipment of OtisKnee devices. CHARLIE CHI informed OtisMed Employee # 2 that despite OtisMed Employee # 2's objections, CHARLIE CHI was directing that the OtisKnee devices be shipped and directing OtisMed Employee # 2 to carry out that directive.

47. Because of, and in accordance with the directives issued by CHARLIE CHI, acting for the benefit of OtisMed Corporation and within the scope of his employment as its president and chief executive officer, on or about September 10, 2009, OtisMed Corporation shipped approximately 218 OtisKnee devices from California to surgeons throughout the United States, including approximately 16 OtisKnee devices shipped to approximately 6 surgeons within the District of New Jersey.

48. OtisMed Employee # 1 and OtisMed Employee # 2 decided not to utilize the means of avoiding detection suggested by CHARLIE CHI, referenced in paragraph 44, above. However, neither CHARLIE CHI nor any other OtisMed Corporation employee informed those individuals they knew to be communicating with FDA on OtisMed Corporation's behalf regarding the OtisKnee device of the September 10, 2009, shipments.

49. Neither CHARLIE CHI nor any other OtisMed Corporation employee informed surgeons receiving the September 10, 2009, shipments that those shipments had been made in violation of law, nor did they inform such surgeons of the NSE letter or that the FDCA prohibited commercial distribution of the OtisKnee device because the OtisKnee device had not been demonstrated to be as safe or effective as other legally marketed devices. CHARLIE CHI and other OtisMed Corporation employees were aware that many surgeons had relied on prior representations from CHARLIE CHI and other OtisMed Corporation employees that the OtisKnee device was a Class I device and exempt from FDA premarket review.

Counts One-Three

(Introduction of Adulterated Medical Devices into Interstate Commerce, 21 U.S.C. §§ 331(a) and 333(a)(1))

50. The allegations contained in paragraphs 1 through 49 are realleged and incorporated herein as if set forth in full.

51. On or about September 10, 2009, in the District of New Jersey and elsewhere, defendant

CHARLIE CHI

did introduce and deliver for introduction, and cause the introduction or delivery for introduction, into interstate commerce, adulterated (pursuant to 21 U.S.C. § 351(f)(1)(B)) medical devices, namely approximately 218 OtisKnee devices, which were required to have, and lacked, FDA clearance or approval, including the following shipments, among others, to physicians in New Jersey:

COUNT	PHYSICIAN
1	Physician # 1
2	Physician # 2
3	Physician # 3

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(1).

Paul J. Fishman

PAUL J. FISHMAN
UNITED STATES ATTORNEY

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UNITED STATES OF AMERICA

v.

CHARLIE CHI

INFORMATION

21 U.S.C. §§ 331(A) and 333(a)(1)

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