UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

EDRA CARVELL and GEORGE E CARVELL, her husband,	:	
Plaintiffs	:	**CIVIL ACTION**
v.	:	
STRYKER CORPORATION, HOWMEDICA OSTEONICS CORPORATION, OTISMED CORPORATION,	:	
Defendants	:	
	:	

COMPLAINT

Plaintiff Edra Carvell and George E. Carvell, her husband, by and through the undersigned attorneys and by way of Complaint against Defendants say:

I. PARTIES

1. Plaintiffs Edra Carvell and George Carvell, her husband are adult residents of Millersburg, Pennsylvania.

2. Defendant Stryker Corporation is a Michigan corporation with its principal place of business located at 2825 Airview Boulevard, Portage, Michigan.

3. Defendant Howmedica Osteonics Corporation is a New Jersey corporation with its principal place of business located at 325 Corporate Boulevard, Mahway, New Jersey. Upon information and belief, Defendant Howmedica Osteonics is a wholly owned subsidiary of Defendant Stryker Corporation.

4. Defendant OtisMed Corporation is a California corporation with its principal place of business at 1600 Harbor Bay Parkway, Alameda, California. Upon information and belief, OtisMed was acquired by Defendant Stryker Corporation in September 2009 and is operated as a wholly owned subsidiary of Defendant Howmedica Osteonics Corporation and/or Defendant Stryker Corporation.

5. At all relevant times, each Defendant was the representative, agent, employee or alter ego of the other Defendant, and in doing the things alleged herein was acting within the scope of its authority as such.

II. JURSIDICTION AND VENUE

6. Jurisdiction is based upon diversity of citizenship and jurisdictional amount pursuant to 28 U.S.C. §§ 1332 and 1333.

a. Plaintiffs are citizens of the Commonwealth of Pennsylvania

b. Defendant Stryker Corporation is a citizen of the State of Michigan

c. Defendant Howmedica Osteonics Corporation is a citizen of the State of New Jersey

d. Defendant OtisMed is a citizen of the State of California

7. Venue is proper pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events or omissions giving rise to this action occurred in this judicial district.

III. BACKGROUND

A. PLAINTIFF EDRA CARVEL

8. On May 13, 2008 Edra Carvel, then age 70, underwent right total knee replacement surgery for “right knee end stage degenerative joint disease – osteoarthritis.”

Surgery was performed by Raymond E. Dahl, D.O. at Holy Spirit Hospital in Camp Hill, Pennsylvania.

9. In that procedure, Dr. Dahl implanted a Howmedica #4 femoral component, a Howmedica 29 mm/9mm thickness pattelar button, a Howmedica Size 3 tibial component and a Howmedica 9 mm tibial bearing insert. Dr. Dahl also utilized Stryker Simplex bone cement.

10. Dr. Dahl described the procedure:

> [The] right lower extremity was prepped and draped in a sterile fashion using Esmarch dressing and I extended the right lower extremity and inflated the tourniquet to 250 millimeters of Mercury. I then made standard midline incision to gain access to the knee and that incision was carried down through skin to the subcutaneous tissues, identifying the retinaculum. Median parapatellar incision was made in the retinaculum. I first measure a 29 millimeter patella and then resected 9 millimeters of bone. I drilled the 3-peg pilot holes to accommodate the patella component. **I used the OtisMed technology.** I first positioned the OtisMed distal femoral block in place. I then made the distal femoral cut and I next used an all in one femoral cutting jig #4 size and I made anterior cuts, posterior cuts, anterior and posterior Chamfer cuts. Once that was completed, I subluxed the tibial fold. I released the anterior cruciate ligament. I also went ahead and removed the medial and laterial menisci. Once that was completed, I then at that point went ahead and positioned the tibial cutting jig in place. I made the tibial cut. At that point I trialed the #4 femoral component, 9 millimeter polyethylene component, #3 tibial component and the 29 millmeter patella. I had excellent flexion and extension on the table. No varus/valgus instability. I cemented those components in place. All excess cement was removed. I then went ahead and closed the reitinaculum with #1 PDS suture. I used 2-0 Vicryl suture in the subcutaneous tissues and then staples for the skin. Sterile dressings were applied.

11. Plaintiff was discharged on post-operative day 4 and saw Dr. Dahl for follow up on May 29, 2008 at which time he prescribed outpatient physical therapy and noted a plan to see her for follow up in 6-8 weeks or "sooner if needed." She was next seen on July 10, 2008 at which time it was noted that while she was improving overall "in terms of her motion[,] [s]he

does still have some pain." Dr. Dahl's plan was to continue physical therapy and to follow up with her in three months. Plaintiff presented next to Dr. Dahl less than one month later on August 7, 2008 at which time Dr. Dahl noted that "[s]he continues to have quite a bit of pain [and] is utilizing a combination of Darvocet as well as Ultram." Dr. Dahl recommended that she continue physical therapy and counseled her that maximum medical improvement could take up to a year. He also noted a plan to see her in follow up in three months or "sooner if needed." Approximately 8 weeks later, however, she again presented to Dr. Dahl reporting that she was continuing to use Ultram "because she is having a lot of pain." Dr. Dahl noted that "[s]he is quite frustrated at this time." Dr. Dahl again counseled her that maximum improvement could take up to a year and he encouraged her to continue a home exercise program. He planned to see her again in three months.

12. On December 11, 2008, a little less than three months later, Plaintiff again presented to Dr. Dahl with a chief complaint of "right knee pain," Dr. Dahl noted that

> This is a 71-year-old female who comes in today for evaluation of right knee pain. She underwent a right total knee replacement arthroplasty on May 13, 2008. She reports that she is still having a lot of pain. She denies any fever or chills. She currently uses Ultram to manage her pain. She reports numbness and tingling down the right leg.

On examination he observed that

> She is alert and oriented times three. She is in no acute distress. She is pleasant and cooperative with normal posture and gait. Her right lower extremity is neurovascularly intact with good sensation and good distal pulses. She has 0 to 90 degrees range of motion. She has no effusion. She reports pain with range of motion. No varus/valgus instability . . . She has no tenderness across the base of the lumbosacral spine. She has a negative straight-leg raise bilaterally. Her reflexes are intact. No clonus or myelopathy.

The diagnosis was "[p]ain status post right total knee replacement arthroplasty" and Dr. Dahl ordered "a CBC, CRP, Sed Rate, and a whole body scan to rule out infection versus loosening."

13. Bone scan on December 26, 2008 revealed "[f]ocal increase in tracer activity in the proximal tibia immediately beneath the tibial plateau component of the total knee replacement, raising the possibility of loosening." Following the scan, Plaintiff then saw Dr. Dahl again on January 8, 2009 who noted

> This is a 71-year-old female who is having severe pain involving her right knee. She is currently walking with a cane. She reports that she feels the pain is worsening. She did undergo a CBC, Sed Rate, and C-reactive protein which was essentially normal. I sent her for a bone scan and she comes in today to review the results of that.

On examination he observed that

> She is alert and oriented times three. She is in no acute distress. She is pleasant and cooperative with normal posture and an antalgic gait. Her right lower extremity is neurovascularly intact with good sensation and good distal pulses. She has pain with range of motion of the knee. She has no varus/valgus instability. No significant effusion.

Based upon the bone scan, which Dr. Dahl interpreted as demonstrating "loosening under the tibial component," the diagnosis was "aseptic loosening right total knee replacement arthroplasty." Because of an incidental finding a lesion on her lumbar spine on earlier MRI, however, Dr. Dahl planned to "put her knee on hold at this time" pending evaluation of the spinal lesion.

14. Plaintiff next saw Dr. Dahl on March 5, 2009 with a chief complaint of "severe right knee pain." It was noted that "[s]he currently walks with a cane" and on examination she demonstrated "gross tenderness to the knee[,] [and] [p]ain with range of motion of the knee."

The diagnosis was "aseptic loosening, right total knee replacement arthroplasty." The plan was a revision of the right total knee replacement.

15. On March 29, 2009, Plaintiff underwent revision of her right total knee arthroplasty secondary to aseptic loosening of the joint.

B. THE OTISMED OTISKNEE® DEVICE IS DEFECTIVE, UNSAFE AND WAS NEVER APPROVED BY THE FDA

16. On December 8, 2014 OtisMed, by then a subsidiary of Howmedica Osteonics Corporation and Stryker Corporation, pleaded guilty in federal court in New Jersey to a single count of unlawful "introduction into interstate commerce, with the intent to defraud and mislead, of medical devices that were adulterated (pursuant to 21 U.S.C. § 351(f) (1) (B)) in violation of the Federal Food Drug and Cosmetic Act ('FDCA'), 21 U.S.C. §§ 331(a) and 333(a)(2)." Exhibit 1.

17. As part of that plea, OtisMed and the United States stipulated to the following facts pertinent to the plea and sentencing:

a. Between May 2006 and November 2009, OtisMed distributed more than 18,000 OtisKnee Orthopedic Cutting Guides ("OtisKnee devices") to surgeons throughout the United States. From May 2006 to October 2008, OtisMed had not sought or received approval or clearance from the Food and Drug Administration ("FDA") to market or distribute the OtisKnee in interstate commerce and distributed the OtisKnee, taking the position that the OtisKnee was a Class I device and exempt from FDA premarket approval and clearance requirements.

b. On October 2, 2008, OtisMed submitted a premarket notification pursuant to 21 U.S.C. § 360(k) (known as a "510(k) notification") seeking FDA clearance to market the OtisKnee. On or about September 2, 2009, the FDA sent Otismed a

notice that its 510(k) submission had been denied. Specifically, the FDA notified OtisMed that the FDA had determined that the OtisKnee was not substantially equivalent to another approved Class I or Class II device, and OtisMed had not demonstrated the OtisKnee to be as safe and effective as other legally marketed devices (the "NSE Letter").

c. The NSE Letter informed OtisMed that "any commercial distribution of the OtisKnee 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 FDCA."

d. Between September 2, 2009, and September 9, 2009, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed received advice from legal and regulatory counsel confirming that, based on the NSE letter, it would be unlawful for OtisMed to continue distributing the OtisKnee.

e. Despite the NSE Letter and against the advice from legal counsel, on or about September 10, 2009, OtisMed's Chief Executive Officer Charlie Chi ordered OtisMed employees to distribute more than 200 OtisKnee devices to surgeons throughout the United States from OtisMed's facility in California. Because these devices did not have the required clearance or approval of the FDA, they were adulterated as a matter of law. Exhibit 1.

18. According to the FDA

> The OtisKnee was used by surgeons during total knee arthroplasty (TKA) commonly known as knee replacement surgery. OtisMed marketed the OtisKnee cutting guide as a tool to assist surgeons in making accurate bone cuts specific to the individual patient's anatomy based on magnetic resonance imaging (MRI) performed prior to surgery. None of OtisMed's claims regarding the

> OtisKnee device were evaluated by the FDA before the company made them in advertisements and promotional material.
>
> Between May 2006 and September 2009, OtisMed sold more than 18,000 OtisKnee devices generating revenue of approximately $27.1 million.
>
> On October 2, 2008, OtisMed submitted a pre-market notification to the FDA seeking clearance to market the OtisKnee. The company had not previously sought the FDA's clearance or approval, and had been falsely representing to physicians and other potential purchasers that the product was exempt from such pre-market requirements.

Exhibit 2.

19. According to the Justice Department

> The OtisKnee was used by surgeons during total knee arthroplasty (TKA) commonly known as knee replacement surgery. The surgical procedure requires a surgeon to remove the ends of the leg bones and to reshape the remaining bone to accommodate the implantation of an artificial knee prosthesis. The cuts to the bone must be made at precise angles because they are critical to the clinical result; failure to achieve the correct angle in TKA procedures can result in failure of the bones and/or the implanted prosthetic device.

Exhibit 3.

20. As part of the plea agreement with the United States, and in addition to various criminal and civil penalties, OtisMed was required to, within ninety (90) days of sentencing, provide notice of the plea agreement "to all customers to whom OtisMed distributed the OtisKnee," and specifically inform all health care providers to whom the devices were distributed that

> As you may be aware, in December 2009, Stryker Corporation acquired OtisMed Corporation. In September 2010, Stryker received a Civil Investigative Demand from the U.S. Department of Justice relating to OtisMed. In September 2014, OtisMed agreed to enter into a global resolution, including a criminal plea agreement and a civil settlement with the United States in

connection with OtisMed's marketing and distribution of OtisKnee Orthopedic Cutting Guides ("OtisKnee") between 2006 and 2009 – before Stryker acquired OtisMed. This letter provides you with additional information about the settlement

The resolution described in this letter **does <u>not</u> pertain** to the Stryker product known as the ShapeMatch Cutting Guide, a different device marketed and distributed by Stryker that received 510(k) clearance in May 2011. This settlement pertains to a device known as the OtisKnee, which was marketed and distributed by OtisMed from 2006 through September 2009, before OtisMed was acquired by Stryker.

In general terms, OtisMed has admitted that OtisMed illegally distributed the OtisKnee without the approval or clearance of the Food and Drug Administration ("FDA") in violation of the Federal Food, Drug and Cosmetic Act ("FDCA"). In the United State, the FDA regulated the sale of and monitors the safety of medical device products. Before certain medical devices may be legally sold in the United States, the manufacturer must request permission from the FDA, after presenting evidence that the device is reasonably safe and effective for the particular use for which it is intended. Because OtisMed did not obtain approval or clearance from the FDA prior to distributing the OtisKnee, the OtisKnee is considered to have been and "adulterated" medical device under the FDCA. OtisMed pleaded guilty to introduction of an adulterated medical device into interstate commerce with the intent to defraud and mislead in the United States District Court for the District of New Jersey. OtisMed has agreed to pay a fine and forfeiture of $39.56 million. In addition, OtisMed has entered into a civil settlement agreement to settle allegations that OtisMed violated the False Claims Act. Pursuant to this civil settlement agreement, OtisMed has agreed to pay an additional $40 million plus interest to the Federal Government. More information about this settlement, including OtisMed's plea agreement, the Information, and the civil settlement agreement, may be found at [OtisMed shall include a link to the USAO website in the letter.]

As part of the federal settlement, Stryker, which acquired OtisMed after the conduct that is the basis for this criminal charge, committed to maintaining its Compliance Program. Under this agreement, which is available at [OtisMed shall include a link to the USAO website in the letter], Stryker agreed to continue to undertake certain actions designed to promote compliance with Federal health care programs and FDCA requirements and make

> periodic certifications to the Department of Justice. Stryker also agreed to provide this notice to Health Care Providers.
>
> You may report and improper conduct associate with device marketing to the FDA's Center for Devices and Radiological Health (CDRH) Allegations of Regulatory Misconduct Branch and OCMedicalDeviceCO@FDA.hhs.gov.

Exhibit 1 (emphasis in original).

C. THE DEFECTIVE OTISKNEE® DEVICE AND THE DEFENDANTS' CONDUCT CAUSED INJURIES AND SUBSTANTIAL DAMAGES TO PLAINTIFF.

21. On or about May 13, 2008, Plaintiff Edra Carvell underwent a right total knee replacement surgery at Holy Spirit Hospital in Camp Hill, Pennsylvania for "end stage degenerative joint disease – osteoarthritis." Plaintiff's surgeon, Dr. Dahl, utilized an OtisKnee device to make measurements and to cut and reshape Plaintiff's leg bones in order to accommodate the implantation of an artificial knee prosthesis.

22. Following that surgery, Plaintiff Edra Carvell had progressively increasing pain in the joint and ultimately underwent revision surgery less than one year later because the joint failed due to, among other things, early loosening of the tibial component and failure of the joint.

23. On or about March 29, 2009, Plaintiff Edra Carvell underwent a painful, complex and risky surgery known as a "revision surgery" to correct the aseptic loosening of her prosthesis. Revision surgeries normally take longer than the original knee replacement surgery and the revision surgery has a higher rate of complications.

24. Had Plaintiff Edra Carvell or her physician known that the OtisKnee device had not been approved by the FDA at the time of surgery, the OtisKnee device would not have been used during Edra Carvell's initial knee replacement surgery and she would not have suffered early failure of the prosthesis necessitating revision surgery.

25. As a direct and proximate result of the failure of the defective OtisKnee device, Plaintiff Edra Carvell sustained and continues to suffer damages, including, but not limited to, past, present, and future pain and suffering, severe and possibly permanent injuries, emotional distress, disability, disfigurement, economic damages (including medical and hospital expenses) monitoring, rehabilitative and pharmaceutical costs, and lost wages and loss of future earnings capacity. Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

26. All of the injuries and complications suffered by Plaintiff Edra Carvell were caused by the defective design, warnings, construction and unreasonably dangerous character of the OtisKnee device utilized during her knee replacement surgery. Had Defendants not falsely claimed that the OtisKnee device was lawfully marketed and concealed the lack of FDA approval, the known defects, the known complications and the unreasonable risks associated with the use of the OtisKnee device, the OtisKnee device would not have been used during her knee replacement surgery.

IV. FRAUDULENT CONCEALMENT

27. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part. Plaintiffs could not reasonably have discovered the dangerous nature of and unreasonable adverse effects associated with the OtisKnee device prior to the filing of this Complaint.

28. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of their OtisKnee device to Plaintiff Edra Carvell, her physician and

the FDA. Because of Defendants' concealment of the true character, quality and nature of the OtisKnee device, the Defendants are estopped from relying on any statute of limitations defense.

IV. CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

29. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

30. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers and sellers of the OtisKnee device, which is defective and unreasonably dangerous.

31. The OtisKnee device is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The OtisKnee device is defective in design in that it lacks efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the OtisKnee device did not outweigh its risks.

32. The defective condition of the OtisKnee device rendered it unreasonably dangerous and/or not reasonably safe, and the OtisKnee device was in this defective condition at the time it left the hands of Defendants. The OtisKnee device was expected to and did reach Plaintiff Edra Carvell and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

33. Plaintiff Edra Carvell and her physician were unaware of the significant hazards and defects in the OtisKnee device and that it had not been approved by the FDA despite Defendants' false and misleading claims that it had. The OtisKnee device was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Plaintiff Edra Carvell's physician used the OtisKnee device, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff Edra Carvell's physician utilized the OtisKnee device in her total knee replacement surgery, it was represented to be safe and effective, FDA-approved and free from latent defects.

34. Defendants are liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce the OtisKnee device, which was unreasonably dangerous for its reasonably foreseeable uses because of its design defects.

35. Defendants knew or should have known of the danger associated with the use of the OtisKnee device, as well as the defective nature of the OtisKnee device, but continued to design, manufacture, sell, distribute, market, promote and/or supply the OtisKnee device so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the OtisKnee device.

36. As a foreseeable, direct and proximate result of Defendants' conduct, Plaintiff Edra Carvell has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiffs in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages

where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

37. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

38. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the OtisKnee devices.

39. The OtisKnee device utilized during Plaintiff Edra Carvell's right total knee replacement surgery was defective in its manufacture and/or was otherwise in a defective condition unreasonably dangerous when it left the hands of Defendants in that it deviated from product specifications and/or was not manufactured in accordance with Current Good Manufacturing Practices and/or otherwise in violation of FDA regulations and federal law, posing a serious risk that it could fail to assure or provide the precise measurements and/or bone cuts necessary in total knee replacement arthroplasty procedures therefore giving rise to failure of the bones, failure of the implanted prosthetic device, physical injury, pain and suffering, debilitation, and the need for early revision surgery to replace the prosthetic device with the attendant risks of complications and death from such further surgery.

40. As a direct and proximate result of Defendants' placement of the defective OtisKnee devices into the stream of commerce, Plaintiff Edra Carvell experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for an early revision surgery to replace her knee prosthesis

with the attendant risks of complications and death from such further surgery as well as the pain and recovery associated with the revisions surgery.

41. As a foreseeable, direct and proximate result of Defendants' conduct, as herein before set forth, Plaintiff Edra Carvell has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiffs in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III
STRICT PRODUCTS LIABILITY-FAILURE TO WARN

42. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

43. Defendants are manufacturers, distributors, sellers, and suppliers of the OtisKnee device.

44. The OtisKnee device was not accompanied by proper warnings and instructions to physicians and the public regarding the proper use of the device and/or potential adverse effects associated with the use of the OtisKnee device and the comparative severity and duration of such adverse effects.

45. The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the proper use or the symptoms, scope, or severity of potential adverse effects, specifically the risk of bone failure and the possibility of misalignment

and/or misplacement and/or mismeasurement and/or failure of the implanted prosthetic device measured and cut utilizing the OtisKnee device.

46. Defendants failed to perform adequate testing which would have demonstrated that the OtisKnee device had potentially serious adverse effects about which Defendants should have provided full and proper warnings.

47. The OtisKnee device was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential adverse effects.

48. As a direct result of Defendants' conduct, Plaintiff Edra Carvell has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiffs in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IV
NEGLIGENCE

49. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

50. At all material times, Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and/or distribution of the OtisKnee device into the stream of commerce, including a duty to assure that the device's use would not cause adverse harmful effects.

51. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and/or distribution of the OtisKnee device into interstate commerce in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous adverse effects, thereby breaching their duty to consumers, including Plaintiff.

52. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the OtisKnee device in a manner which was dangerous to those individuals whose physicians used the device during knee replacement surgery;

b. Designing, manufacturing, producing, creating and/or promoting the OtisKnee device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the OtisKnee device was safe for use;

d. Defendants herein knew or should have known that the OtisKnee device was unsafe and unfit for use by reason of the dangers to its users;

e. Promoting, selling and marketing the OtisKnee device without proper FDA approval;

f. Selling the OtisKnee device without making proper and sufficient tests to determine the danger to its users;

g. Negligently failing to adequately and correctly warn Plaintiff or her physicians, hospitals and/or healthcare providers of the dangers of the OtisKnee device;

h. Negligently failing to recall their dangerous and defective OtisKnee device at the earliest date that it became known that the device was, in fact, dangerous, defective, and not properly approved by the FDA;

i. Failing to provide adequate instructions regarding the safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, use the OtisKnee device during knee replacement surgeries with their patients;

j. Negligently advertising and recommending the use of the OtisKnee device despite the fact that Defendants knew or should have known of its dangerous propensities;

k. Negligently representing that the OtisKnee device was safe for use for its intended purpose, when, in fact, it was unsafe;

l. Negligently manufacturing the OtisKnee device in a manner which was dangerous to those individuals whose physicians used the device during knee replacement surgeries;

m. Negligently producing the OtisKnee device in a manner which was dangerous to those individuals who had it implanted;

n. Negligently assembling the OtisKnee device in a manner which was dangerous for use in total knee replacement surgeries;

o. Under-reporting, underestimating and downplaying the serious danger of the OtisKnee device; and

p. Negligently representing to the medical community, including Plaintiff Edra Carvell's treating physician, that the OtisKnee device was either exempt from FDA approval or indeed had FDA approval when it did not.

53. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting packaging, distributing, testing, advertising, warning, marketing and sale of the OtisKnee device in that they:

a. Failed to use due care in designing and manufacturing the OtisKnee device so as to avoid the aforementioned risks to individuals whose physicians used the device during knee replacement surgeries;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the OtisKnee device; and

e. Were otherwise careless and/or negligent.

54. Upon information and belief, Defendants continued to market, manufacture distribute and/or sell the OtisKnee devices despite the fact that Defendants knew or should have known that the OtisKnee device posed a risk of unreasonable, dangerous adverse effects when there were safer devices available for the purposes for the OtisKnee device was designed, manufactured, labeled and marketed.

55. Defendants knew or should have known that the OtisKnee, as designed, manufactured, labeled or marketed could pose a significant risk to patients but negligently failed to inform physicians and patients about these risks.

56. At all material times, Defendants knew of the defective nature of the OtisKnee device as set forth herein, and continued to design, manufacture, market and sell the device so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life; and further, upon information and belief, Defendants exhibited such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice and a conscious and deliberate disregard of foreseeable harm to Plaintiff Edra Carvell herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT V
NEGLIGENCE *PER SE*

57. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

58. The OtisKnee device supplied by Defendants is an adulterated and/or misbranded product as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a) and 333(a)(2) ("FD&C Act").

59. Plaintiff Edra Carvell is within the class of persons the FD&C Act and regulations promulgated pursuant to it by the FDA are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

60. Defendants were negligent *per se* in marketing and distributing the OtisKnee device because it is was never subjected to FDA approval and is therefore an adulterated and/or misbranded product. Moreover, Defendant OtisMed pleaded guilty to a one-count criminal Information of placing in the stream of commerce an "adulterated" and "misbranded" device in its sale and distribution of OtisKnee devices between 2006 and 2009. As a direct and proximate result of Defendants' violations of federal law, Plaintiff Edra Carvell has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VI
NEGLIGENT MISREPRESENTATION

61. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

62. At the time Defendants manufactured, designed, marketed, sold and distributed the OtisKnee device for use by Plaintiff Edra Carvell, Defendants knew or should have known of

the use for which the OtisKnee device was intended and the serious risks and dangers associated with such use of the OtisKnee device.

63. Defendants also knew that the device was not FDA approved but took the position that no such FDA approval was necessary when it knew or should have known that was not true.

64. Defendants owed a duty to treating physicians and Plaintiff Edra Carvell to accurately and truthfully represent the risks of the OtisKnee device and that it was not FDA-approved during the time in which it was marketed. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff Edra Carvell's physicians, the medical community, Plaintiff Edra Carvell and the public about the risks of the OtisKnee device and that the device was not FDA-approved despite representations to the contrary, which Defendants knew or in the exercise of diligence should have known.

65. As a direct result of Defendants' conduct, Plaintiff Edra Carvell has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VII
FRAUDULENT CONCEALMENT

66. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

67. Defendants fraudulently concealed information with respect to the OtisKnee device in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the OtisKnee device was FDA-approved.

b. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the OtisKnee device was safe and effective and fraudulently withheld and concealed information about the substantial risks of using the OtisKnee device; and

c. Defendants represented that the OtisKnee device was safer than other alternative devices and fraudulently concealed information which demonstrated that the OtisKnee device was not safer than alternatives available on the market.

68. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the OtisKnee device.

69. The concealment of information by Defendants about the risks of the OtisKnee device was intentional, and the representations made by Defendants were known by Defendants to be false.

70. The concealment of information and the misrepresentations about the OtisKnee device were made by Defendants with the intent that doctors and patients, including Plaintiff Edra Carvell, rely upon them.

71. Plaintiff Edra Carvell and her physicians relied upon the representations and were unaware of the substantial risks of the OtisKnee device which Defendants concealed from health care providers and the public, including Plaintiff Edra Carvell and her physicians.

72. Plaintiff Edra Carvell was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff Edra Carvell has incurred, and will continue to incur expenses as a result of the use of the OtisKnee device during her total right knee replacement surgery.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VIII
BREACH OF EXPRESS WARRANTY

73. Plaintiffs incorporate by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

74. Defendants expressly warranted to physicians and the public, by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff Edra Carvell, and the general public, that the OtisKnee device was safe, effective, fit and proper for its intended use and FDA-approved.

75. The OtisKnee device does not conform to those express representations because the OtisKnee device is not safe and effective, is adulterated and misbranded within the meaning of the federal Food Drug and Cosmetic Act and poses a risk of significant and serious, adverse effects.

76. In utilizing the OtisKnee device during Plaintiff Edra Carvell's knee replacement surgery, Plaintiff Edra Carvell and her physician relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the OtisKnee device was not safe and was unfit for the uses for which it was intended.

77. Defendants breached their warranty of the fitness, safety and efficacy of the OtisKnee device by continuing sales and marketing campaigns highlighting the safety and

efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries.

78. As a foreseeable, direct and proximate result of Defendants' conduct, as hereinbefore set forth, Plaintiff Edra Carvell has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiffs in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IX
BREACH OF IMPLIED WARRANTY

79. Plaintiffs incorporate by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

80. Defendants impliedly warranted to physicians and the public, including Plaintiff Edra Carvell, that the OtisKnee device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

81. Plaintiff Edra Carvell's surgeon, in selecting the device to utilize in Plaintiff Edra Carvell's knee replacement surgery, reasonably relied upon the skill and judgment of Defendants as to whether the OtisKnee device was of merchantable quality and safe and fit for its intended use.

82. Upon information and belief, and contrary to such implied warranties, the OtisKnee device was not of merchantable quality or safe and fit for its intended use, because the

product was adulterated and misbranded, not FDA-approved and is unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

83. As a direct and proximate result of the breach of implied warranties by Defendants, Plaintiff Edra Carvell suffered and will continue to suffer harm and economic loss as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT X
FRAUD

84. Plaintiffs incorporate by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

85. Defendants made representations to Plaintiff Edra Carvell and her physicians that their OtisKnee device is a high-quality, safe and effective knee replacement tool that either was not subject to FDA approval or was FDA-approved when in fact it never was.

86. Before they marketed the OtisKnee device that was utilized in Plaintiff Edra Carvell's knee replacement surgery, Defendants knew or should have known of the unreasonable dangers and serious health risks that the device posed to patients like Plaintiff Edra Carvell.

87. As specifically described in detail above, Defendants knew that the OtisKnee device was not FDA-approved but between 2006 and October 2008 sold as many as 18,000 devices without ever seeking FDA-approval, thereby subjecting patients to risks of early bone and prosthetic device failure, painful and harmful physical reactions, and the need for explantation of prostheses and revision surgery.

88. Defendants' representations to Plaintiff Edra Carvell and her physicians that their OtisKnee device is FDA-approved, high-quality, safe and effective were false.

89. Defendants concealed their knowledge of lack of FDA-approval and the unreasonable risks and dangers associated with the use of the OtisKnee device with the intent to induce Plaintiff Edra Carvell's physician and many thousands of others like him to utilize the device in total knee replacement surgeries.

90. Neither Plaintiff Edra Carvell nor her physicians knew of the falsity of Defendants' statements regarding the OtisKnee device.

91. Plaintiff Edra Carvell and her physicians relied upon and accepted as truthful Defendants' representations regarding the OtisKnee device.

92. Plaintiff Edra Carvell and her physician had a right to rely on Defendants' representations and in fact did rely upon such representations to their detriment

93. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and misrepresentations alleged here. Plaintiffs and others were kept in ignorance of vital information, without any fault or lack of diligence on their part, had no knowledge of the above facts and could not reasonably have discovered the fraudulent nature of Defendants' conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT XI
UNFAIR AND DECEPTIVE TRADE PRACTICES/CONSUMER FRAUD

94. Plaintiffs incorporate by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

95. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers and sellers of the OtisKnee device, which they represented as FDA-approved (or not subject to FDA approval), to be free from defects and fit for its intended or foreseeable purposes.

96. Defendants advertised, labeled, marketed and promoted their product, the OtisKnee device, representing the quality to health care professionals, the FDA, Plaintiff Edra Carvell, Plaintiff Edra Carvell's surgeon, and the public in such a way as to induce its purchase or use. More specifically, Defendants represented that the OtisKnee device was safe and effective for use by surgeons doing total knee arthroplasties.

97. Defendants knew or should have known that the OtisKnee device did not or would not conform to Defendants' representations and promises.

98. Defendants' concealed knowledge of the serious risks associated with the OtisKnee device, concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data, and concealed the fact that the OtisKnee device was not FDA-approved, or selectively and misleadingly indicated that it was FDA-approved.

99. Defendants' representations, actions and conduct regarding the OtisKnee device were in or affecting commerce.

100. Defendants' actions and conduct, as alleged in this Complaint, constitute deceptive trade practices in the course of Defendants' business in violation of the provisions of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-

1, *et seq.* and/or the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* and/or the Michigan Consumer Protection Act, Mich. Comp. Laws Serv. § 445.901, *et seq.* and/or the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud.

101. As a direct and proximate result of Defendants' unfair and/or deceptive conduct, in or affecting commerce, Plaintiffs are entitled to recover damages from Defendants, pursuant to the provisions of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et seq.* and/or the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* and/or the Michigan Consumer Protection Act, Mich. Comp. Laws Serv. § 445.901, *et seq.* and/or the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT XII
PUNITIVE DAMAGES

102. Plaintiffs incorporate by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

103. Plaintiffs are entitled to punitive damages because Defendants' wrongful acts and/or omissions were willful and wanton conduct and in conscious and intentional disregard of and indifference to the rights and safety of others. Defendants misled both the medical community and the public at large, including Plaintiffs, by making false representations about

the safety and efficacy of the OtisKnee device and by failing to provide adequate instructions and training concerning its use.

104. Defendants downplayed, understated, misstated or falsely stated and/or disregarded their knowledge of the serious and permanent adverse effects and risks associated with the use of the OtisKnee device despite available information demonstrating that the OtisKnee device was defectively designed, was not adequately tested, was never FDA-approved or that it could significantly compromise a total knee arthroplasty leading to early failure of the bone or implanted prosthetic device. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the OtisKnee device.

105. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the OtisKnee device, and its FDA-approval status.

106. Defendants were or should have been in possession of evidence demonstrating that the OtisKnee device caused serious adverse effects. Nevertheless, Defendants continued to market the OtisKnee device by providing false and misleading information with regard to its safety and efficacy.

107. Defendants failed to provide warnings that would have dissuaded health care professionals from using the OtisKnee device, thus preventing health care professionals, including Plaintiff Edra Carvell's surgeon, and consumers, including Plaintiff Edra Carvell, from weighing the true risks against any benefits of using the OtisKnee device.

108. Defendants failed to provide adequate training and instructions to surgeons, including Plaintiff Edra Carvell's surgeon, who could have prevented early failure of her total knee arthroplasty by utilizing another device or devices.

109. As a foreseeable, direct and proximate result of Defendants' willful, wanton conduct in reckless disregard for the safety and health of Plaintiffs and others similarly situated, Defendants are liable to Plaintiffs for punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT XIII
LOSS OF CONSORTIUM

110. Plaintiffs repeat and reallege each and every paragraph of this Complaint as if fully set forth herein.

111. At the times and places aforesaid and at all times material hereto, Plaintiff George E. Carvell was the husband of Plaintiff Edra Carvell and entitled to his wife's consortium, comfort, companionship, society, guidance, advice and counsel.

112. As a foreseeable, direct and proximate result of the tortious conduct of Defendants, and each of them as hereinbefore set forth, Plaintiff George E. Carvell has been, and will in the future be, deprived of his wife's consortium, comfort, companionship, society, guidance, advice and counsel.

WHEREFORE Plaintiff George E. Carvell demands judgment against Defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

PRAYER FOR RELIEF AS TO ALL COUNTS

WHEREFORE, Plaintiffs, Edra Carvel and George E. Carvell, her husband, pray for judgment against Defendants as follows:

1. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;
2. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, pain and suffering, mental anguish, emotional distress and loss of consortium in such amounts as may be proven at trial;
3. Punitive and/or exemplary damages in such amounts as may be proven at trial;
4. Attorneys' fees, expenses and costs of this action;
5. Pre- and post-judgment interest as provided by law; and
6. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: December 1, 2016

/s/ Kevin Haverty

Kevin Haverty, Esq.
Sarah T. Hansel, Esq. *(pending admission pro hac vice)*
Email: Khaverty@wcblegal.com
Shansel@wcblegal.com
WILLIAMS CUKER BEREZOFSKY, LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Telephone: (856) 667-0500
Facsimile: ((856) 667-5133
Attorneys for Plaintiff

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Edra Carvell and George E. Carvell, her husband

(b) County of Residence of First Listed Plaintiff Dauphin
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Williams Cuker Berezofsky, LLC
1515 Market Street, Suite 1300, Phila., PA 19102
215-557-0099

DEFENDANTS

Stryker Corporation, Howmedica Osteonics Corp., OtisMed Corporation

County of Residence of First Listed Defendant Kalamazoo County, Michigan
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ❒ 2 Removed from State Court
- ❒ 3 Remanded from Appellate Court
- ❒ 4 Reinstated or Reopened
- ❒ 5 Transferred from Another District *(specify)*
- ❒ 6 Multidistrict Litigation - Transfer
- ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. §§ 1332 and 1333

Brief description of cause:
Product Liability/Personal Injury

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 12/2/16

SIGNATURE OF ATTORNEY OF RECORD
/s/ Kevin Haverty

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

EXHIBIT 1

U.S. Department of Justice

United States Attorney
District of New Jersey

970 Broad Street, 7th floor
Newark, New Jersey 07102

973-645-2700

JTE/PL AQR
2011R00148

August 29, 2014

Brien T. O'Connor, Esq.
Joshua S. Levy, Esq.
Ropes & Gray LLP Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199

Re: Plea Agreement with OtisMed Corporation
14-CR-688(CCC)

Dear Messrs. O'Connor and Levy:

This letter sets forth the plea agreement between the United States Attorney for the District of New Jersey and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, the "United States") and your client, OtisMed Corporation ("OtisMed"), a subsidiary of Stryker Corporation ("Stryker").

Charge

Conditioned on the understandings specified below, the United States will accept a guilty plea from OtisMed to a one-count felony Information, which charges OtisMed with the introduction into interstate commerce, with the intent to defraud and mislead, of medical devices that were adulterated (pursuant to 21 U.S.C. § 351(f)(1)(B)) in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2). If OtisMed enters a guilty plea and a judgment of conviction is entered that is consistent with the terms of the agreed disposition included in this plea agreement under Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, and if OtisMed otherwise fully complies with all of the terms of this agreement, the United States will not initiate any further criminal charges against OtisMed with respect to its sales, marketing and distribution of the OtisKnee Orthopedic Cutting Guides (hereinafter "OtisKnee") medical device between

May 2006 and November 2009. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, OtisMed agrees that any dismissed charges and any other charges that were not time-barred by the applicable statute of limitations on the date this agreement is signed by OtisMed may be commenced against OtisMed, notwithstanding the expiration of the limitations period after OtisMed signs the agreement.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of OtisMed, in connection with the conduct encompassed by this plea agreement or known to the United States.

Sentencing

The violation of 21 U.S.C. §§ 331(a) and 333(a)(2) to which OtisMed agrees to plead guilty carries a statutory maximum term of probation of 5 years, and a statutory maximum fine equal to the greatest of: (1) $500,000; (2) twice the gross amount of any pecuniary gain derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(1), 3571(c)(3), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

Further, in addition to imposing any other penalty on OtisMed, the sentencing judge: (1) will order OtisMed to pay an assessment of $400 pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; and (2) may order OtisMed to pay restitution pursuant to 18 U.S.C. § 3563.

The parties agree that the fine agreed upon by the parties is consistent with the United States Sentencing Guidelines ("U.S.S.G.") and takes into account OtisMed's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

(1) The parties agree that the base fine is $34,400,000, in that such amount was the reasonably estimated pecuniary gain to OtisMed from the offense, see U.S.S.G. §§ 8C2.3, 8C2.4(a);

(2) Pursuant to U.S.S.G. § 8C2.5, the culpability score is five (5), which is determined as follows:

(i) Base culpability score of five (5) pursuant to U.S.S.G. § 8C2.5(a);

(ii) Add two (2) points pursuant to U.S.S.G. § 8C2.5(b)(4) because the organization had 50 or more employees, and an individual within substantial authority personnel of the organization participated in the offense;

and

(iii) Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) for OtisMed's full cooperation in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct after its acquisition by Stryker.

(3) Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of five (5) is 1.0 to 2.0; and

(4) Therefore, the advisory Guidelines Fine Range is $34,400,000 to $68,800,000.

Agreed Disposition

The United States and OtisMed agree that, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the appropriate disposition of the case is as follows, and will result in the imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, and taking into account that $40,000,000 plus interest will be paid to resolve the civil investigation arising out of the same course of conduct, pursuant to an agreement with the U.S. Attorney's Office for the District of New Jersey and the United States Department of Justice's Civil Division, Fraud Section, attached hereto as Exhibit 1, to settle related civil claims:

(1) OtisMed shall pay a criminal fine in the amount of $34,400,000 within seven (7) days after sentencing;

(2) OtisMed shall be subject to pay criminal forfeiture in the amount of $5,160,000 within seven (7) days after sentencing;

(3) OtisMed shall pay a special assessment of $400, which shall be paid to the Clerk of Court on or before the date of sentencing;

(4) The United States agrees that it will not seek a separate restitution order as to OtisMed as part of the resolution of the charge in the Information. The United States and OtisMed agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweigh the need to provide restitution to non-governmental victims, if any, in this case; and

(5) The United States further agrees that it will not seek a term of probation in light of: (i) the remedial measures undertaken by OtisMed after its acquisition by Stryker; (ii) the enhanced corporate rehabilitative compliance measures and certifications agreed to by Stryker as attached hereto as Exhibit 2; and (iii) OtisMed's agreement with the Office of Inspector General, U.S. Department of Health and Human Services to be excluded from participating in all Federal healthcare programs for a period of 20 years, see Exhibit 1.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the United States and OtisMed agree that no other sentence or fine is appropriate, beside those set forth above. If the Court accepts this plea agreement, OtisMed must be sentenced accordingly. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this agreement shall be null and void at the option of either the United States or OtisMed, except that OtisMed expressly waives, and agrees that it will not interpose, any defense to any charges brought against OtisMed which OtisMed might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act. If OtisMed fails to pay any amounts within the time frames specified in this plea agreement, this agreement shall be null and void at the sole option of the United States. See 18 U.S.C. § 3614.

Rights of the Parties Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any

misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of OtisMed's activities and relevant conduct with respect to this case.

Agreement Not to Prosecute

Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges or forfeiture action against OtisMed, its present and former parent companies, affiliates, divisions, and subsidiaries, or their predecessors, successors, and assigns, for conduct which (1) falls within the scope of the investigation in the District of New Jersey relating to the OtisKnee, or (2) was known to the United States Attorney's Office for the District of New Jersey or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the OtisKnee in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the District of New Jersey, the Consumer Protection Branch, Civil Division, of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions in this paragraph are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of OtisMed, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of OtisMed's products to foreign customers, which investigations are specifically excluded from the release in this paragraph. Attached as Exhibit 3 to this agreement is a copy of the letter to United States Attorney Paul J. Fishman from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

OtisMed understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in this agreement. Further, OtisMed understands that the United States takes no position as to the proper tax treatment of any of the payments made by OtisMed pursuant to this plea agreement, any

civil settlement agreement, or any agreement with the Department of Health and Human Services.

Waiver of Appeal and Post-Sentencing Rights

OtisMed knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the conviction or sentence imposed by the Court if the plea is accepted and the sentence is imposed in accordance with the terms of this agreement.

The United States will not file any appeal, motion or writ which challenges the conviction or sentence imposed by the Court if that sentence is imposed in accordance with the terms of this agreement. Furthermore, if the Court accepts the terms of this plea agreement, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the Court erred in doing so.

Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraphs.

Forfeiture

OtisMed agrees that as part of its acceptance of responsibility, OtisMed will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c). OtisMed admits that the value of the quantities of the OtisKnee that were distributed in violation of 21 U.S.C. § 331 totaled approximately $5,160,000 in United States currency.

OtisMed acknowledges and agrees that the quantities of the OtisKnee that were distributed in violation of 21 U.S.C. § 331 cannot be located upon the exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property that cannot be divided without difficulty. Accordingly, OtisMed agrees that the United States is entitled to forfeit as "substitute assets" any other assets of OtisMed up to the value of the now-missing directly forfeitable assets.

OtisMed agrees that, within seven (7) days after sentencing, it shall remit the amount of $5,160,000 in United States currency to the United States Marshals Service. Payment

shall be made by certified or bank check payable to the United States Marshals Service. Within seven (7) days after sentencing, OtisMed shall cause said check to be hand-delivered to Assistant United States Attorney Jacob T. Elberg, United States Attorney's Office, District of New Jersey, 970 Broad Street, Newark, New Jersey 07102. OtisMed and the United States agree that this payment shall satisfy any and all forfeiture obligations that OtisMed may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of OtisMed's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon OtisMed, nor shall the forfeiture be used to offset OtisMed's tax liability or any other debt owed to the United States.

OtisMed agrees to consent to the entry of an order of forfeiture for $5,160,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. OtisMed acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the Court to advise it of this, pursuant to Federal Rule of Criminal Procedure 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this agreement, OtisMed hereby waives any and all claims arising from or relating to the forfeiture set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, or any other provision of state or federal law. The United States District Court for the District of New Jersey shall retain jurisdiction to enforce the provisions of this section.

Notification to Healthcare Providers

Within ninety (90) days after OtisMed is sentenced pursuant to this agreement, OtisMed will provide notice of the Information and this agreement to all customers to whom OtisMed distributed the OtisKnee. Specifically, OtisMed shall send, by first class mail, postage prepaid, a notice containing the

language set forth below to all Health Care Providers to whom OtisMed distributed the OtisKnee:

> "As you may be aware, in December 2009, Stryker Corporation acquired OtisMed Corporation. In September 2010, Stryker received a Civil Investigative Demand from the U.S. Department of Justice relating to OtisMed. In September 2014, OtisMed agreed to enter into a global resolution, including a criminal plea agreement and a civil settlement with the United States in connection with OtisMed's marketing and distribution of OtisKnee Orthopedic Cutting Guides ("OtisKnee") between 2006-2009 - before Stryker acquired OtisMed. This letter provides you with additional information about the settlement.
>
> The resolution described in this letter **does not pertain** to the Stryker product known as the ShapeMatch Cutting Guide, a different device marketed and distributed by Stryker that received 510(k) clearance in May 2011. This settlement pertains to a device known as the OtisKnee, which was marketed and distributed by OtisMed from 2006 through September 2009, before OtisMed was acquired by Stryker.
>
> In general terms, OtisMed has admitted that OtisMed illegally distributed the OtisKnee without the approval or clearance of the Food and Drug Administration ("FDA") in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the United States, the FDA regulates the sale of and monitors the safety of medical device products. Before certain medical devices can be legally sold in the United States, the manufacturer must request permission from the FDA, after presenting evidence that the device is reasonably safe and effective for the particular use for which it is intended. Because OtisMed did not obtain approval or clearance from the FDA prior to distributing the OtisKnee, the OtisKnee is considered to have been an "adulterated" medical device under the FDCA. OtisMed pleaded guilty to introduction of an adulterated medical device into interstate commerce with the intent to defraud and mislead in the United States District Court for the District of New Jersey. OtisMed has agreed to pay a fine and forfeiture of $39.56 million. In addition, OtisMed has entered into a civil settlement agreement to settle allegations that OtisMed violated the False Claims Act. Pursuant

to this civil settlement agreement, OtisMed has agreed to pay an additional $40 million plus interest to the Federal Government. More information about this settlement, including OtisMed's plea agreement, the Information, and the civil settlement agreement, may be found at [OtisMed shall include a link to the USAO website in the letter].

As part of the federal settlement, Stryker, which acquired OtisMed after the conduct that is the basis for this criminal charge, committed to maintaining its Compliance Program. Under this agreement, which is available at [OtisMed shall include a link to the USAO website in the letter], Stryker agreed to continue to undertake certain actions designed to promote compliance with Federal health care program and FDCA requirements and make periodic certifications to the Department of Justice. Stryker also agreed to provide this notice to Health Care Providers.

You may report any improper conduct associated with device marketing to the FDA's Center for Devices and Radiological Health (CDRH) Allegations of Regulatory Misconduct Branch at OCMedicalDeviceCO@fda.hhs.gov."

Cooperation

OtisMed shall cooperate completely and truthfully in any trial or other proceeding arising out of any civil, criminal or administrative investigation of its current and former officers, agents, employees and customers in connection with matters described in the Information. OtisMed shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. OtisMed shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, OtisMed shall promptly furnish to any federal agency, upon its request, all non-privileged documents and records in its possession, custody, or control relating to the conduct that are within the scope of any investigation,

proceeding, or trial, in connection with the matters described in the Information.

Notwithstanding any provision of this agreement, (1) OtisMed is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney or that they act contrary to that advice; (2) OtisMed is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) OtisMed is not required to waive any privilege or claim of work product protection.

Other Provisions

OtisMed agrees that it is authorized to enter into this agreement, that it has authorized the undersigned corporate representative, Michael Cartier, to take this action, and that all corporate formalities for such authorization have been observed. By entering this guilty plea, OtisMed hereby waives all objections to the form of the charging document and admits that it is in fact guilty of the offense charged in the Information.

Corporate Authorization

OtisMed's corporate acknowledgment of: (a) this agreement; and (b) the corporate resolution authorizing entry into and execution of this agreement, is attached as Exhibit 4. OtisMed has provided to the United States a certified copy of a resolution of the governing body of OtisMed, affirming that it has authority to enter into this agreement and has (1) reviewed this plea agreement and the Information in this case; (2) consulted with legal counsel in this matter; (3) authorized execution of this agreement; (4) authorized OtisMed to plead guilty to the Information; and (5) authorized Michael Cartier to execute this agreement and all other documents necessary to carry out the provisions of this agreement. A copy of this resolution is attached hereto as Exhibit 5.

No Other Promises

This agreement and the Exhibits hereto constitute the plea agreement between OtisMed and the United States and together their terms supersede any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Very truly yours,

PAUL J. FISHMAN
United States Attorney

JACOB T. ELBERG
Chief
Health Care & Government Fraud Unit
U.S. Attorney's Office
District of New Jersey

ROSS S. GOLDSTEIN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice

APPROVED:

THOMAS J. EICHER
Chief
Criminal Division
U.S. Attorney's Office
District of New Jersey

I am the authorized corporate representative for OtisMed Corporation ("OtisMed"). I have received this letter from Brien T. O'Connor, Esq. and Joshua S. Levy, Esq., who are the attorneys for OtisMed. I have read the letter, and Mr. O'Connor, Mr. Levy and I have discussed it and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. I understand this letter fully. On behalf of and with the express authorization of OtisMed, I hereby accept its terms and conditions and acknowledge that it constitutes the plea agreement between the parties. OtisMed understands that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. OtisMed wants to plead guilty pursuant to this plea agreement.

AGREED AND ACCEPTED:

Michael Cartier Date: September 12, 2014
Michael Cartier
As Authorized Corporate Representative
for OtisMed Corporation

I am counsel for OtisMed Corporation ("OtisMed"). I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. Further, I have fully advised the authorized corporate representative, Michael Cartier, of OtisMed's rights regarding this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. My client, OtisMed, understands this plea agreement fully and wants to plead guilty pursuant to it.

Date: September 15, 2014
BRIEN T. O'CONNOR, Esq.
JOSHUA S. LEVY, Esq.

Schedule A

1. The United States and OtisMed agree to stipulate to the following facts:

(a) Between May 2006 and November 2009, OtisMed distributed more than 18,000 OtisKnee devices to surgeons throughout the United States. From May 2006 to October 2008, OtisMed had not sought or received approval or clearance from the Food and Drug Administration (FDA) to market or distribute the OtisKnee in interstate commerce and distributed the OtisKnee, taking the position that the OtisKnee was a Class I device and exempt from FDA premarket approval and clearance requirements.

(b) On October 2, 2008, OtisMed submitted a premarket notification pursuant to 21 U.S.C. § 360(k) (known as a "510(k) notification") seeking FDA clearance to market the OtisKnee. On or about September 2, 2009, the FDA sent OtisMed a notice that its 510(k) submission had been denied. Specifically, the FDA notified OtisMed that the FDA had determined that the OtisKnee was not substantially equivalent to another approved Class I or Class II device, and OtisMed had not demonstrated the OtisKnee to be as safe and effective as other legally marketed devices (the "NSE Letter").

(c) The NSE Letter informed OtisMed that "[a]ny commercial distribution of [the OtisKnee] 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]."

(d) Between September 2, 2009, and September 9, 2009, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed received advice from legal and regulatory counsel confirming that, based on the NSE Letter, it would be unlawful for OtisMed to continue distributing the OtisKnee.

(e) Despite the NSE Letter and against the advice from legal counsel, on or about September 10, 2009, OtisMed's Chief Executive Officer Charlie Chi ordered OtisMed employees to distribute more than 200 OtisKnee devices to surgeons throughout the United States from OtisMed's facility in California. Because these medical devices did not have the required clearance or approval of the FDA, they were adulterated as a matter of law.

(f) OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed took steps to conceal these shipments from the FDA. Among other things, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed kept the shipments secret from OtisMed's Board of Directors and OtisMed's attorneys who were communicating with the FDA. In addition, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed did not inform surgeons at the time of the September 10, 2009, shipments that the FDA had determined that the OtisKnee had not been demonstrated to be safe and effective for its intended use, and that the device could therefore not be lawfully introduced into interstate commerce. OtisMed distributed the devices despite knowledge that surgeons relied on OtisMed's prior representations that the OtisKnee was legally marketed. As such, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed distributed these OtisKnee devices with the intent to defraud or mislead.

2. In accordance with the above, and pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the parties agree that the following sentence (hereinafter the "Stipulated Sentence") is reasonable, taking into account all of the factors under 18 U.S.C. §§ 3553(a) and 3572:

(a) OtisMed shall pay a criminal fine in the amount of $34,400,000;

(b) OtisMed shall pay forfeiture in the amount of $5,160,000;

(c) OtisMed shall pay a special assessment of $400;

(d) OtisMed shall not be ordered to pay restitution; and

(e) OtisMed shall not be subject to a term of probation.

3. The parties further agree that neither party will argue for a sentence that varies from any of the terms of the Stipulated Sentence.

Exhibit 1

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"); the Defense Health Agency, acting on behalf of the TRICARE Program ("DHA"), through its General Counsel (collectively the "United States"); OtisMed Corporation, Stryker Corporation, Howmedica Osteonics Corporation (collectively "Defendants"), and Richard Adrian ("Relator"), (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. OtisMed Corporation ("OtisMed") is a biotechnology corporation based in Alameda, California. During the time period from January 2006 to September 2009, OtisMed developed, manufactured, and sold "OtisKnee Orthopedic Cutting Guides." The OtisKnee was intended for use as an aid in positioning orthopedic implants and guiding the marking of osseous tissue before initial cuts during a total knee replacement surgery. In November 2009, Stryker Corporation ("Stryker") acquired OtisMed and OtisMed now operates as a wholly-owned subsidiary within Stryker's Orthopaedics Division, Howmedica Osteonics Corporation ("Howmedica").

B. On October 2, 2009, Richard Adrian filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States ex rel. Adrian v. OtisMedCorp. et al.*, Civil No. 09-cv-5083, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action").

C. On such date as may be determined by the Court, OtisMed will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information filed in United States of America v. OtisMed Corp., Criminal Action No. [to be assigned] (District of New Jersey) (the "Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B), namely, the introduction into interstate commerce, with the intent to defraud or mislead, of an adulterated medical device, the OtisKnee Orthopedic Cutting Guide, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA").

D. Defendants have entered or will be entering into separate settlement agreements, described in Paragraph 1.b. below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Defendants execute a Medicaid State Settlement Agreement in the form to which Defendants and the National Association of Medicaid Fraud Control Units ("NAMFCU") have agreed, or in a form otherwise agreed to by Defendants and an individual state, are referred to herein as "Medicaid Participating States."

E. The United States contends that OtisMed submitted or caused to be submitted claims for payment for total knee replacement surgeries that used the OtisKnee to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the FEHBP, 5 U.S.C. §§ 8901-8914; the TRICARE Program, 10 U.S.C. §§ 1071-1110a; and the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396- 1396w-5 (collectively, the "Federal Health Care Programs"); between January 2006 and November 2009.

F. The United States contends that it and the Medicaid Participating States have certain civil claims against Defendants, relating to the period from January 2006 through November 2009, arising from the marketing and distribution of the OtisKnee Orthopedic Cutting

Guide, a medical device, without receiving approval or clearance from the FDA for the device. Specifically, in May 2006, OtisMed, through co-promotion activities with Stryker, began commercially distributing the OtisKnee without having received clearance or approval from the FDA for the device. In October 2008, OtisMed submitted a 510(k) application to the FDA, but continued to distribute the device while the 510(k) was under FDA review. On September 2, 2009, the FDA informed OtisMed that it had not demonstrated that the OtisKnee was as safe and effective as legally marketed devices and thus could not be lawfully distributed until FDA approved the device. Even after receiving this letter, OtisMed continued to distribute the OtisKnee.

In addition, the United States also contends that OtisMed encouraged health care providers to submit claims for magnetic resonance imaging (MRIs) that were not reimbursable because they were not performed for diagnostic use, but rather were only performed to provide data for the creation of the OtisKnee.

As a result of the foregoing conduct, the United States contends that Defendants knowingly caused the submission of false and fraudulent claims for procedures using the OtisKnee to Federal Health Care Programs and Defendants obtained proceeds and profits to which they were not entitled, from January 2006 through November 2009.

The conduct described in Paragraph F is referred to herein as the Covered Conduct.

G. This Agreement is made in compromise of disputed claims. Defendants deny the United States' allegations in Paragraph F and the Relator's allegations in the Civil Action, except to the extent admitted in OtisMed's guilty plea. This Settlement Agreement is neither an admission of liability by Defendants, nor a concession by the United States that its claims are not well founded.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants shall pay to the United States and the Medicaid Participating States, collectively, the sum of $40,000,000 plus interest at a rate of 2.14% per annum accruing from May 17, 2013 (the "Settlement Amount"), as set forth below:

a. Defendants shall pay to the United States the amount of $40,781,532, including accrued interest (the "Federal Settlement Amount"). If the Federal Settlement Amount is not paid by September 22, 2014, Defendants shall pay additional interest at a rate of 2.14% per annum from September 22, 2014, until the date of payment. The Federal Settlement Amount shall be paid pursuant to written instructions to be provided by the Department of Justice, by electronic funds transfer, no later than seven (7) days after (i) the Effective Date of this Agreement; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

b. Defendants shall pay to the Medicaid Participating States the amount of $376,700, including accrued interest (the "Medicaid State Settlement Amount"). If the Medicaid State Settlement Amount is not paid by September 22, 2014, Defendants shall pay additional interest at a rate of

2.14% per annum from September 22, 2014, until the date of payment. The Medicaid State Settlement Amount shall be paid pursuant to the terms of the Medicaid State Settlement Agreements or otherwise agreed to by Defendants and the National Association of Medicaid Fraud Control Units.

c. If OtisMed's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Defendants. If either the United States or Defendants exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Defendants will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within 90 calendar days of rescission, except to the extent such defenses were available on the day on which the Civil Action listed in Preamble Paragraph B, above, was filed.

2. On or about the Effective Date of this Agreement, Defendants and Relator will enter into a separate agreement with respect to the payment by Defendants of Relator's attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

3. Conditioned upon the United States receiving the Settlement Amount from Defendants and as soon as feasible after receipt, the United States shall pay $7,013,477 to Relator by electronic funds transfer.

4. Subject to the exceptions in Paragraph 9 (concerning excluded claims) below, and conditioned upon the full payment of the Settlement Amount, the United States releases Defendants from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 2 above and Paragraph 9 below, and conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendants from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. a. In compromise and settlement of the rights of OIG HIS to exclude OtisMed pursuant to 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7(a)(3) for the conduct described in Paragraphs C and F, OtisMed agrees to be excluded under these statutory provision from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f), for twenty (20) years. Such exclusion shall have national effect. Federal health care programs shall not pay OtisMed or anyone else for items or services, including administrative and management services, furnished, ordered, or prescribed by OtisMed in any capacity while

OtisMed is excluded. This payment prohibition applies to OtisMed and all other individuals and entities (including, for example, anyone who employs or contracts with OtisMed, and any hospital or other provider where OtisMed provides services). The exclusion applies regardless of who submits the claims or other request for payment.

b. OtisMed further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. OtisMed waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court.

c. OtisMed understands that violations of the conditions of exclusion may subject it to criminal prosecution, the imposition of civil money penalties and assessments, and an additional period of exclusion (see 42 U.S.C. §§ 1320a-7b and 1320a-7a).

d. Reinstatement to program participation is not automatic. If OtisMed wishes to be reinstated, OtisMed must submit a written request for reinstatement to the OIG HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Such request may be made to OIG HHS no earlier than 120 days prior to the expiration of the period of exclusion reflected in Paragraph 6.a. Reinstatement becomes effective only upon notice of reinstatement by OIG HHS after OIG HHS approval of the

application by OtisMed. Obtaining another license, moving to another state, or obtaining a provider number from a Medicare contractor, a state agency, or a Federal health care program does not reinstate OtisMed's eligibility to participate in these programs.

e. OtisMed shall not contest, in any manner, the terms or provisions of Paragraph 6 of this Agreement, nor shall OtisMed seek any remedy or relief for any matter, cause of action, or claim arising from implementation of Paragraph 6 of this Agreement. OtisMed expressly waives all procedural rights granted under the OIG HHS's exclusion authority and regulations, section 1128 of the Act, 42 U.S.C. § 1320a- 7, and 42 C.F.R. Part 1001, including, but not limited to any notice, hearing, or appeal with respect to its exclusion.

7. DHA expressly reserves authority to exclude Stryker and Howmedica from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(l)(i)(A), (f)(l)(i)(B), and (f)(l)(lii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below. The exclusion of OtisMed described in Paragraph 6, which includes "all other Federal Health care programs, as defined in 42 U.S.C. 1320A-7B(F)," includes the TRICARE program.

8. OPM expressly reserves all rights to institute, direct or to maintain any administrative action seeking debarment against Stryker and Howmedica and/or their officers, directors, and employees from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment). Nothing in this Paragraph precludes OPM from taking action

against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below. For the purposes of this settlement agreement, the term "Federal health care program" in Paragraph 6 above shall include the FEHBP authorized under 5 U.S.C. Chapter 89. OtisMed expressly waives all procedural rights granted under the U.S. Office of Personnel Management's authority and regulations, 5 U.S.C § 8902a and 5 C.F.R. Part 890, Subpart I, including, but not limited to any notice, hearing, or appeal with respect to its debarment.

9. Notwithstanding the releases given in Paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

i. Any liability of individuals.

10. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 3, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

11. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Defendants, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action. Defendants and its officers, agents, and employees, release Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns from any liability arising from the filing of the Civil Action.

12. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

13. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier); TRICARE fiscal intermediary, carrier; and/or contractor, FEHBP carrier or payer; or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare carrier or intermediary; TRICARE fiscal intermediary, carrier, and/or contractor; FEHBP fiscal agent; or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, its present or former officers, directors, employees, shareholders, and agents in connection with:

1) the matters covered by this Agreement and any related plea agreement;

2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

4) The negotiation and performance of this Agreement and any plea agreement; and

5) the payment Defendants make to the United States pursuant to this Agreement and any payments that Defendants may make to Relator, including costs and attorney's fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendants or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Defendants or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendants shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

18. Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). Such dismissal shall be with prejudice to Relator and the

United States as to the Covered Conduct; and with prejudice to Relator and without prejudice to the United States as to all other claims in the Complaint.

20. Except as set forth in Paragraph 2 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

22. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

27. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 9.16.14

BY: _____
CHARLES J. BIRO
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
CHARLES GRAYBOW
Assistant U.S. Attorney
Office of the United States Attorney
for the District of New Jersey

DATED: _____

BY: _____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the
Inspector General Office of Inspector General
United States Department of
Health and Human Services

DATED: _____

BY: _____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: _____

BY: _____
ALAN P. SPIELMAN
Assistant Director of Federal Employee
Insurance Operations
United States Office of Personnel
Management

THE UNITED STATES OF AMERICA

DATED:_____

BY:_____
CHARLES J. BIRO
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: Sept. 15, 2014

BY: Charles Graybow
CHARLES GRAYBOW
Assistant U.S. Attorney
Office of the United States Attorney
for the District of New Jersey

DATED:_____

BY:_____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the
Inspector General Office of Inspector General
United States Department of
Health and Human Services

DATED:_____

BY:_____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____

BY:_____
ALAN P. SPIELMAN
Assistant Director of Federal Employee Insurance Operations
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED:_____ BY:_____
CHARLES J. BIRO
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ BY:_____
CHARLES GRAYBOW
Assistant U.S. Attorney
Office of the United States Attorney
for the District of New Jersey

DATED: 9/15/14 BY: Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY:_____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY:_____
ALAN P. SPIELMAN
Assistant Director of Federal Employee Insurance Operations
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED:_____

BY:_____
CHARLES J. BIRO
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____

BY:_____
CHARLES GRAYBOW
Assistant U.S. Attorney
Office of the United States Attorney
for the District of New Jersey

DATED:_____

BY:_____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General Office of Inspector General
United States Department of Health and Human Services

DATED: 9/12/2014

BY:_____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____

BY:_____
ALAN P. SPIELMAN
Assistant Director of Federal Employee Insurance Operations
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED:_____ BY:_____
CHARLES J. BIRO
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ BY:_____
CHARLES GRAYBOW
Assistant U.S. Attorney
Office of the United States Attorney
for the District of New Jersey

DATED:_____ BY:_____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY:_____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 9/12/14 BY: Alan P. Spielman
ALAN P. SPIELMAN
Assistant Director of Federal Employee Insurance Operations
United States Office of Personnel Management

OTISMED CORP., STRYKER CORP., HOWMEDICA OSTEONICS - DEFENDANTS

DATED: September 12, 2014

BY: _____
MICHAEL CARTIER
As Authorized Corporate Representative for
OtisMed Corp., Stryker Corp., and
Howmedica Osteonics Corp.

DATED: September 15, 2014

BY: _____
BRIEN T. O'CONNOR
JOSHUA S. LEVY
Counsel for OtisMed Corp., Stryker Corp.,
and Howmedica Osteonics, Corp.

RICHARD ADRIAN - Relator

DATED: _____

BY: _____
RICHARD ADRIAN

DATED: _____

BY: _____
JOSEPH M. CALLOW, JR
KEATING, MUETHING & KLEKAMP PLL
Counsel for Richard Adrian

OTISMED CORP., STRYKER CORP., HOWMEDICA OSTEONICS - DEFENDANTS

DATED:_____ BY:_____
MICHAEL CARTIER
As Authorized Corporate Representative for
OtisMed Corp., Stryker Corp., and
Howmedica Osteonics Corp.

DATED:_____ BY:_____
BRIEN T. O'CONNOR
JOSHUA S. LEVY
Counsel for OtisMed Corp., Stryker Corp.,
and Howmedica Osteonics, Corp.

RICHARD ADRIAN - Relator

DATED: 9/12/2014 BY:_____
RICHARD ADRIAN

DATED: 9/14/2014 BY:_____
JOSEPH M. CALLOW, JR
KEATING, MUETHING & KLEKAMP PLL
Counsel for Richard Adrian

Exhibit 2

U.S. Department of Justice

United States Attorney
District of New Jersey

970 Broad Street, 7th floor
Newark, New Jersey 07102

973-645-2700

August 29, 2014

Mr. Brien T. O'Connor
Mr. Joshua S. Levy
Ropes & Gray
One International Place
Boston, Massachusetts 02110

Re: *United States v. OtisMed*; Side Letter Agreement with Stryker Corporation

Dear Messrs. O'Connor and Levy:

This letter ("Side Letter Agreement" or "Agreement") sets forth the terms of the agreement between your client, Stryker Corporation ("Stryker"), and the United States of America, acting through the United States Attorney for the District of New Jersey and the Consumer Protection Branch of the U.S. Department of Justice (collectively, "the United States"). In exchange for Stryker's full performance of the terms contained within this Side Letter Agreement and the Plea Agreement entered into by OtisMed Corporation (attached hereto as Exhibit A), the United States and Stryker Corporation ("Stryker") hereby agree as follows:

Charge and Plea Agreement with OtisMed Corporation

On or about September 17, 2014, the United States will file an Information in the United States District Court for the District of New Jersey charging OtisMed with the introduction into interstate commerce, with the intent to defraud and mislead, of medical devices that were adulterated (pursuant to 21 U.S.C. § 351(f)(1)(B)), in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2). Stryker Corporation acquired OtisMed Corporation ("OtisMed") on November 10, 2009. Since that date, Stryker Corporation has operated OtisMed as a wholly-owned subsidiary within Stryker's Orthopaedics division. The United States acknowledges that the conduct that forms the basis of the criminal charge occurred prior to Stryker's acquisition of OtisMed and without Stryker's prior knowledge or acquiescence.

Pursuant to the Plea Agreement attached as Exhibit A, entered into between OtisMed and the United States, OtisMed will plead guilty to the Information and agrees to comply with all terms of the Plea Agreement, provided that the district court accepts OtisMed's guilty plea and agrees to enter a judgment of conviction consistent with the agreed-upon disposition pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure.

No Criminal Prosecution of Stryker Corporation

Conditioned upon the performance of terms set forth below in the section entitled "Cooperation by Stryker," the United States hereby agrees to decline prosecution of Stryker or any of its subsidiaries (except for OtisMed as set forth in the Information) for conduct by or attributable to Stryker or any of its subsidiaries that:

- Falls within the scope of the Information to which OtisMed is pleading guilty;

- Was a subject of the investigation regarding the "Custom Fit Total Knee Replacement with OtisKnee" (hereinafter "OtisKnee") medical devices; or

- Was otherwise known to the U.S. Attorney for the District of New Jersey and the Consumer Protection Branch of the U.S. Department of Justice prior to December 8, 2014, in connection with any allegations that Stryker may have:

1. Promoted, marketed, and sold the OtisKnee for use in orthopedic surgeries without marketing approval or clearance from the Food and Drug Administration ("FDA");

2. Conspired with others to introduce or deliver or cause the introduction or delivery into interstate commerce of the OtisKnee while adulterated;

3. Aided or abetted OtisMed in violating the FDCA with regard to the OtisKnee; or

4. Carried out any acts that resulted in Stryker's Triathlon Total Knee Replacement System becoming adulterated or misbranded when used, or intended by Stryker to be used, in conjunction with the OtisKnee.

This Side Letter Agreement is not intended to, and does not, affect any criminal liability of any natural person. It is understood and agreed among the parties to this Side Letter

Agreement that the promise of the United States not to prosecute Stryker is contingent upon and subject to OtisMed fulfilling its obligations as set forth in the Plea Agreement.

Who is Bound By Agreement

This Side Letter Agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys and the Criminal Division, and the Consumer Protection Branch in the Civil Division (United States), except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of Treasury. **The non-prosecution provisions of this Side Letter Agreement are binding on the United States, with the exception of any investigations of Stryker, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division of the United States Department of Justice regarding possible violation of the Foreign Corrupt Practices Act and related offenses, in connection with the sales and marketing of Stryker's products to foreign customers, which investigations are specifically excluded from the release in this Side Letter Agreement.**

Term of Agreement

This Side Letter Agreement is effective for a period beginning on the date on which the United States District Court

for the District of New Jersey enters a Judgment of Conviction against OtisMed pursuant to the Plea Agreement attached as Exhibit A (the "Effective Date") and shall be binding for a period of three years from the Effective Date.

Notice to Stryker Employees

Within ten (10) days of the Effective Date of this Side Letter Agreement, Stryker will communicate to all employees of the Knee Business Unit within the Reconstructive Division of the Orthopaedics Group within Howmedica Osteonics or any subsequently named business unit that encompasses knee products within Howmedica Osteonics (the "Knee Business Unit") that OtisMed pleaded guilty to the Information and that Stryker entered into this Side Letter Agreement. Stryker will distribute the OtisMed Information, this Agreement, and the Statement of Facts to all such employees. Within ninety (90) days after OtisMed is sentenced pursuant to the Plea Agreement, Stryker will ensure that OtisMed fulfills its obligations under the Plea Agreement with regard to providing the required Notice to Healthcare Providers as set forth therein.

Compliance Measures

After the conduct giving rise to the criminal prosecution of OtisMed and prior to entering into this Side Letter Agreement, OtisMed was acquired by Stryker. As the current

owner of OtisMed, Stryker agrees to the following Compliance provisions and obligations.

Stryker's Compliance Program

Stryker has in place and will maintain a Compliance Program, which governs all Stryker divisions, including the Knee Business Unit. The Compliance Program consists of

- A Chief compliance Officer;
- A Corporate Compliance Committee;
- Divisional Compliance Officers;
- Divisional Compliance Committees;
- Policies and Procedures governing Stryker employee conduct;
- Education and training programs for Stryker employees regarding applicable laws, policies, and procedures.
- A Compliance Hotline to allow Stryker employees to report conduct or activity they believe may be illegal, improper, or unethical;
- An Ethics Hotline Committee; and
- An anti-retaliation policy.

Stryker agrees to continue to establish and maintain policies and procedures designed to prevent violations of the FDCA regarding the sale, marketing, and promotion of medical devices.

The Stryker Board of Directors will establish compliance oversight responsibilities for its Governance and Nominating Committee (the "Governance Committee"). The Committee will be

appointed annually by the Board of Directors and will consist of at least two directors, each of whom has been affirmatively determined by the Board of Directors to be independent of Stryker. The Governance Committee will report issues to the full Board of Directors as the Governance Committee deems appropriate.

The Governance Committee's oversight responsibilities shall include issues regarding Stryker's compliance with applicable law and regulations, including processes and procedures for management's monitoring of compliance. The Stryker Group President of Global Quality and Operations will report on regulatory affairs and quality assurance issues to the Governance Committee at least annually. An independent expert on the FDCA and FDA regulations will be retained by the Board and will report on trends on regulatory and compliance issues to the Governance Committee at least annually.

Clinical Trial Data Bank Requirements

A. Within 180 days of the Effective Date of this Side Letter Agreement, Stryker will conduct an audit of its records regarding any "ongoing" (as that term is defined by 42 U.S.C. § 282(j)) "clinical investigations" (as that term is defined by 21 C.F.R. § 50.3) in which the test article is a device marketed by the Reconstructive Division of the Orthopedics Group of which

Stryker is a "responsible party" (as that term is defined by 42 U.S.C. § 282(j)). With regard to each clinical investigation, Stryker will determine whether there has been compliance with the requirements of Section 282 of Title 42, United States Code. A written report of the results of this audit will be provided to the Government at the addresses below no later than sixty (60) days following the audit's completion. For any clinical investigation in which the audit reveals that there has been less than full compliance, Stryker will achieve compliance within 120 days of the audit's completion.

B. Beginning on December 31, 2014, and continuing on an annual basis for two years, Stryker will include in its annual certifications (as described below) that, to the best of its knowledge, all ongoing clinical investigations studying health outcomes for which Stryker is a "responsible party" (including uncontrolled studies, but excepting small feasibility studies and pediatric postmarket surveillance studies) in which the test article is a medical device (subject to 21 U.S.C. §§ 360(k), 360e, or 360j(m)) and is manufactured, distributed, or marketed by the Reconstructive Division of the Stryker Orthopaedics Group have been registered in the national clinical trial registry data bank in accordance with Section 282 of Title 42, United States Code.

Device Classification & Market Pathway Review

Stryker shall conduct a review and audit of all Letters to File for all marketed devices within the Knee Business Unit (including any marketed devices subject to co-promotion by the Knee Business Unit with or on behalf of a non-Stryker entity) from April 9, 2009 to present to assess and evaluate the devices' classification and regulatory status. As part of the review, Stryker will evaluate its systems, processes, policies, and procedures relating to the classification, pathway to market, and regulatory status of these devices, including evaluating any decisions whether or not to file premarket approval applications and/or premarket notifications.

Stryker will report the results of this audit to the United States and the FDA Center for Devices and Radiological Health ("CDRH") no later than sixty (60) days following its completion. However, nothing with regard to this requirement is intended to relieve Stryker of any of its obligations under the FDCA or FDA regulations, including with regard to violative devices.

Corrective and Preventative Action & Medical Device Reporting Review

Stryker has in place, and will continue to maintain, policies and procedures within the Knee Business Unit for documenting Corrective and Preventative Actions and for complying with adverse event data reporting to the FDA. In

addition, Stryker will continue to conduct periodic assessments to evaluate and ensure that its adverse event and complaint reporting systems, processes, policies, and procedures are fully implemented and effective in the Knee Business Unit.

Annual Management Certification

The President of Stryker's Orthopaedics Group shall conduct a review of Stryker's Compliance Program as it relates to the marketing, promotion, and sale of medical devices within the Knee Business Unit during the preceding year. The first review period shall run from the date of the sentencing of OtisMed through December 31, 2014. Thereafter, the reviews will be conducted on an annual basis for two years.

The Group President, Orthopaedics, shall submit to the United States a signed certification stating that based on his or her review and to the best of his or her knowledge, during the period [insert time period]: (1) Stryker's Compliance Program in the Knee Business Unit continued to include the policies and procedures set forth in this Side Letter Agreement; (2) the Compliance Program was effective in preventing, detecting, and/or remediating, where necessary, violations of the FDCA regarding sales, marketing, and promotion of medical devices within the Knee Business Unit; and (3) the

certifications described with regard to the registration of clinical investigations described above.

The Group President's certification shall summarize the review described above that he or she conducted to provide the required certification. If the Group President is unable to certify that the Compliance Program was effective in preventing, detecting, and/or remediating, where necessary, violations of the FDCA regarding sales, marketing, and promotion of medical devices within the Knee Business Unit, he or she shall explain the steps Stryker is taking to ensure the future effectiveness of the Compliance Program. This explanation will satisfy the certification requirement above with regard to the Compliance Program. If the Group President is unable to provide the certifications associated with the registration of clinical investigations, he or she shall similarly explain the steps Stryker is taking to register the clinical investigations. This explanation will satisfy the certification requirement above with regard to the clinical investigation registry.

Annual Board of Directors Resolution

The Board of Directors of Stryker, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of Stryker's Compliance Program as it relates to the marketing, promotion, and sale of medical devices. This

review shall be conducted on an annual basis and shall include, but not be limited to, updates and reports by Stryker's Chief Compliance Officer and other compliance personnel. The review shall evaluate the Compliance Program, including, among other means, by receiving updates about the activities of the Chief Compliance Officer and other company personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with applicable FDCA requirements.

The first review will cover the time period from the date of the sentencing of OtisMed through December 31, 2014. Thereafter the reviews will be conducted on an annual basis for two years. Based on its review, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of Stryker's Compliance Program and, at a minimum, includes the following language:

> The Board of Directors has made a reasonable inquiry into the content and operations of Stryker's Compliance Program for the time period *[insert time period]*, including the performance of the Chief Compliance Officer and other compliance personnel employed by Stryker. The Board has concluded that, to the best of its knowledge, Stryker has implemented a Compliance Program designed to exercise due diligence to prevent, detect, and remediate misconduct, including violations of the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and is promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Stryker's Compliance Program continued to include the policies and procedures set forth in Stryker's Side Letter Agreement with the United States, dated August 29, 2014.

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about Stryker's Compliance Program.

Stryker shall provide the Certification and Board Resolution to the United States on an annual basis for the term of the Agreement. Stryker shall provide the Certification and Board Resolution to the United States within 60 calendar days following the end of each review period as follows:

Chief, Health Care & Government Fraud Unit
United States Attorney's Office,
District of New Jersey
970 Broad Street, 7th Floor
Newark, NJ 07102

Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044

In addition to providing the results of the audit described in the paragraph entitled "Clinical Trial Data Bank Requirements" to the addresses above, Stryker will also provide the results of the audit to FDA at:

Chief Counsel for Enforcement
Food & Drug Division, OGC
White Oak Bldg. 31, Room 4418
10903 New Hampshire Avenue
Silver Spring, MD 20993

Cooperation by Stryker

Stryker shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal, or administrative investigation of any current or former officers, agents, employees, or customers of Stryker or OtisMed in connection with the matters described in the paragraph entitled "No Criminal Prosecution of Stryker Corporation" (hereinafter "Relevant Matters"). Stryker shall make all reasonable efforts to facilitate access to, and to encourage the cooperation of, any current or former officers, agents, and employees of Stryker or OtisMed for interviews sought by law enforcement officers or agencies, upon request and reasonable notice in connection with the Relevant Matters. Stryker shall also make all reasonable efforts to encourage current and former officers, agents, and employees of Stryker or OtisMed to testify truthfully and completely before any grand jury, tribunal, or hearing, at which they are requested to do so by any federal agency in connection with the Relevant Matters. In addition, Stryker shall promptly furnish to any federal agency, upon its request, all non-privileged documents and records in its possession, custody, or control relating to the conduct that are within the scope of any investigation, proceeding, or trial, in connection with the Relevant Matters.

Stryker agrees to waive any defenses regarding pre-indictment delay, statutes of limitations, or Speedy Trial Act with respect to any and all criminal charges as set forth above that could have been timely brought or pursued as of the date of this letter, for any part of the term of this Side Letter Agreement during which Stryker fails to fulfill its cooperation obligations, as described herein.

Notwithstanding any provision of this Side Letter Agreement:

- Stryker is not required to request of current or former officer, agents, or employees of Stryker or OtisMed that they forego seeking the advice of an attorney or that they act contrary to any such advice;
- Stryker is not required to take any action against its officers, agents, or employees for acting in accordance with his or her attorney's advice; and
- Stryker is not required to waive any claim of privilege or work product protection.

Remedies for Breach

Stryker and the United States agree that the only remedy for failure to comply with the obligations set forth in this Side Letter Agreement (other than those dealing with Stryker's cooperation obligations, above) is the imposition of the following monetary penalties in accordance with the following provisions:

A. A stipulated penalty of $20,000 per day for each day Stryker: (1) fails to maintain a Compliance Program as set

forth in this Side Letter Agreement, or (2) fails to timely supply the Certification or Board Resolution required in this Side Letter Agreement. With regard to the Certification and Board Resolution, the Stipulated Penalty will begin to accrue on the day after the date the obligation was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

B. Stryker may submit a timely written request for an extension of time to provide any Certification or Board Resolution required in this Side Letter Agreement. A written request is timely if received by the U.S. Attorney's Office for the District of New Jersey and the U.S. Department of Justice's Consumer Protection Branch at least five business days prior to the date by which the Certification or Board Resolution is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after Stryker fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after Stryker receives the United States'

written denial of such request, or the original due date, whichever is later.

C. Upon the United States' reasonable determination that Stryker has failed to comply with any of the obligations described herein, the United States shall notify Stryker in writing of Stryker's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (i) the provision breached; (ii) the date of the breach; (iii) a description of the breach sufficient to permit Stryker to cure (as described below); and (iv) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter.

D. Within thirty (30) days after receipt of a Demand Letter, or such other period as the United States and Stryker may agree in writing, Stryker shall have the opportunity to cure the breach to the United States' reasonable satisfaction ("Cure Period"). If Stryker cures the breach within the Cure Period, no Stipulated Penalties shall be due. Alternatively, Stryker shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the United States in writing to explain the nature and circumstances of such breach, including why

Stryker believes whether a breach occurred, whether such breach was material, and whether such breach was knowingly or willfully committed. The United States agrees to consider any such explanation in determining whether to assess a Stipulated Penalty. If Stryker fails to cure the breach during the Cure Period or to provide a satisfactory explanation regarding the breach, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by the United States Attorney for the District of New Jersey and the Assistant Attorney General for the Civil Division regarding Stryker's failure to comply with any of the obligations described herein will be final and non-appealable. Stryker agrees that the United States District Court for the District of New Jersey shall have jurisdiction over any action to impose such a penalty.

Complete Agreement

This Side Letter Agreement sets forth all the terms of the agreement between Stryker and the United States. No amendments, modifications, or additions to this Side Letter Agreement shall

be valid unless they are in writing signed by the United States, the attorneys for Stryker, and a representative of Stryker duly authorized by Stryker's Board of Directors.

If the foregoing accurately reflects the agreement entered into between the United States and Stryker, and Stryker's Board of Directors has authorized you to enter into this agreement, please sign below and return the original to AUSA Jacob T. Elberg or DOJ Trial Attorney Ross S. Goldstein.

Very truly yours,

PAUL J. FISHMAN
United States Attorney

JACOB T. ELBERG
Chief
Health Care & Government Fraud Unit
U.S. Attorney's Office
District of New Jersey

ROSS S. GOLDSTEIN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice

APPROVED:

THOMAS J. EICHER
Chief
Criminal Division
U.S. Attorney's Office
District of New Jersey

AGREED AND ACCEPTED:

Michael Cartier
As Authorized Corporate Representative for Stryker Corporation

Date: September 12, 2014

BRIEN T. O'CONNOR, Esq.
JOSHUA S. LEVY, Esq.
Counsel for Stryker Corporation

Date: September 15, 2014

Exhibit 3

U.S. Department of Justice

Criminal Division

Assistant Attorney General

Washington, D.C. 20530

FEB 03 2014

The Honorable Paul J. Fishman
United States Attorney
District of New Jersey
970 Broad Street, 7th Floor
Newark, New Jersey 07102

Attention: Jacob T. Elberg
Assistant United States Attorney

Re: Global Plea Agreement for OtisMed Corporation and Side Letter Agreement for Stryker Corporation

Dear Mr. Fishman:

This is in response to your request for authorization to enter into global agreements with OtisMed Corporation (OtisMed) and Stryker Corporation (Stryker).

I hereby approve the terms of the Plea Agreement with OtisMed, including the provisions on pp. 5-6, through which the United States agrees not to initiate further criminal proceedings against OtisMed for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Plea Agreement. I also approve the terms of the Side Letter Agreement with Stryker Corporation, including the provisions on pp. 2-3, through which the United States agrees not to initiate criminal proceedings against Stryker for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Side Letter Agreement.

You are authorized to make these approvals a matter of record in this proceeding.

Sincerely,

Mythili Raman
Acting Assistant Attorney General

/s/ Paul M. O'Brien

PAUL M O'BRIEN
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION

Exhibit 4

ACKNOWLEDGEMENT OF PLEA AGREEMENT

The Board of Directors ("Board") of OtisMed Corporation ("OtisMed") has authorized me to execute this Plea Agreement on behalf of OtisMed, and to take all such action as may be necessary to effectuate this Plea Agreement. The Board has read this Plea Agreement, the related criminal Information, and the related Civil Settlement Agreement, including all attachments, in their entirety, and has discussed them fully in consultation with OtisMed's attorneys. I am further authorized to acknowledge on behalf of OtisMed that these documents fully set forth OtisMed's agreement with the United States, and that no additional promises or representations have been made to OtisMed by any officials of the United States in connection with the disposition of this matter, other than those set forth in these documents.

Dated: September 12, 2014

Michael Cartier
As Authorized Corporate Representative for
OtisMed Corporation

Dated: September 15, 2014

Brien T. O'Connor, Esq.
Joshua S. Levy, Esq.
Ropes & Gray LLP
Counsel for OtisMed Corporation

Exhibit 5

OTISMED CORPORATION

UNANIMOUS WRITTEN CONSENT OF THE BOARD OF DIRECTORS

The undersigned, being all the directors of OtisMed Corporation (the "Company"), a wholly-owned subsidiary of Stryker Corporation, hereby waive all notice of the time, place, or purpose of a meeting and consent to, approve, and adopt the following resolutions without a meeting:

WHEREAS, the United States Attorney's Office for the District of New Jersey and the United States Department of Justice have been conducting an investigation into the Company's conduct relating to the OtisKnee device;

WHEREAS, the Board of Directors has consulted with legal counsel in connection with this matter;

WHEREAS, the Company's legal counsel has been negotiating a resolution of this matter;

WHEREAS, the Company's legal counsel has reported to the Board the terms and conditions of a proposed resolution of this matter;

WHEREAS, the Board of Directors has reviewed, with counsel, the contents of the Information, proposed Plea Agreement, and proposed Civil Settlement Agreement in this matter;

NOW THEREFORE, BE IT:

RESOLVED, that the Company is hereby authorized to enter into the Plea Agreement dated August 29, 2014, between the United States Attorney for the District of New Jersey, the Department of Justice, and OtisMed Corporation (the "Agreement").

FURTHER RESOLVED, that the Company is authorized to plead guilty to the charge specified in the Information.

FURTHER RESOLVED, that Michael Cartier, Deputy General Counsel of Stryker Corporation, or any other Officer of the Company or legal counsel to the Company, are hereby authorized and directed to take all actions and deliver any agreements, certificates, documents, and instruments with respect to or contemplated by the Agreement and matters set forth above, including, without limitation, the payment of all amounts, fees, costs, and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby.

This Written Consent may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned Directors of the Company have executed this consent as of the 10th of September, 2014.

David Floyd
Director, OtisMed Corporation

Mark Mania
Director, OtisMed Corporation

EXHIBIT 2

FDA News Release

OtisMed Corporation, former CEO plead guilty for distributing FDA-rejected cutting guides for knee replacement surgeries

Corporation to pay more than $80 million to resolve criminal and civil investigations

For Immediate Release

December 8, 2014

Release

OtisMed Corporation (OtisMed) and its former chief executive officer, Charlie Chi, admitted today to intentionally distributing knee replacement surgery cutting guides after their application for marketing clearance had been rejected by the U.S. Food and Drug Administration. OtisMed also agreed to pay more than $80 million to resolve related criminal and civil liability.

Chi, 45, of San Francisco, and OtisMed entered guilty pleas in Newark federal court. OtisMed pleaded guilty before U.S. District Judge Claire C. Cecchi to distributing, with the intent to defraud and mislead, adulterated medical devices into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Chi pleaded guilty before U.S. Magistrate Judge Mark Falk to three counts of introducing adulterated medical devices into interstate commerce. Judge Cecchi also sentenced the company today, fining OtisMed $34.4 million and ordering $5.16 million in criminal forfeiture. In a separate civil settlement, OtisMed agreed to pay $40 million plus interest to resolve its civil liability.

The office of U.S. Attorney Paul J. Fishman, District of New Jersey, prosecuted this case.

The guilty pleas and civil settlement are the culmination of a long-term investigation conducted jointly by special agents from the FDA's Office of Criminal Investigations and from the Department of Health and Human Services' Office of the Inspector General.

"Companies and individuals put the public health at risk by not complying with FDA regulatory requirements for the pre-market review of medical devices," said Philip J. Walsky, acting director of the FDA's Office of Criminal Investigations. "We will continue to investigate and bring to justice those who potentially endanger patient safety by distributing unapproved medical devices."

The OtisKnee was used by surgeons during total knee arthroplasty (TKA), commonly known as knee replacement surgery. OtisMed marketed the OtisKnee cutting guide as a tool to assist surgeons in making accurate bone cuts specific to individual patients' anatomy based on magnetic resonance imaging (MRI) performed prior to surgery. None of OtisMed's claims regarding the OtisKnee device were evaluated by the FDA before the company made them in advertisements and promotional material.

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

On Oct. 2, 2008, OtisMed submitted a pre-market notification to the FDA seeking clearance to market the OtisKnee. The company had not previously sought the FDA's clearance or approval, and had been falsely representing to physicians and other potential purchasers that the product was exempt from such pre-market requirements.

On Sept. 2, 2009, the FDA sent OtisMed a notice that its submission had been denied, noting that the company had failed to demonstrate the OtisKnee was as safe and effective as other legally marketed devices. One week after the FDA denied OtisMed's request for clearance, the company shipped approximately 218 OtisKnee guides from California to surgeons throughout the U.S.

"Americans must be able to trust that they are treated with medical devices that have been shown to be safe and effective," said Deputy Assistant Attorney General Jonathan Olin for the Justice Department's Civil Division. "The Department of Justice will not tolerate companies and individuals that cut corners when it comes to the public's health."

On each of the three counts, Chi faces a maximum potential penalty of one year in prison and a $100,000 fine, or twice the gain or loss from the offense.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Christopher Kelly (mailto:Christopher.Kelly@fda.hhs.gov)
301-796-4676

Consumers

888-INFO-FDA

Related Information

- Department of Justice news release (http://www.justice.gov/usao/nj/Press/files/Otismed%20News%20Release.html)

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More in Press Announcements (/NewsEvents/Newsroom/PressAnnouncements/default.htm)

2015 (/NewsEvents/Newsroom/PressAnnouncements/2015/default.htm)

2014 (/NewsEvents/Newsroom/PressAnnouncements/2014/default.htm)

2013 (/NewsEvents/Newsroom/PressAnnouncements/2013/default.htm)

EXHIBIT 3

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, December 8, 2014

OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries

Corporation to Pay More than $80 Million to Resolve Criminal and Civil Investigations

OtisMed Corp. and its former chief executive officer (CEO) admitted today to intentionally distributing knee replacement surgery cutting guides after their application for marketing clearance had been rejected by the Food and Drug Administration (FDA), and the corporation agreed to pay more than $80 million to resolve its related criminal and civil liability, the Justice Department announced today.

OtisMed and its CEO, Charlie Chi, 45, of San Francisco, pleaded guilty in federal court in Newark, New Jersey. OtisMed pleaded guilty before U.S. District Judge Claire C. Cecchi to an information charging it with distributing, with the intent to defraud and mislead, adulterated medical devices into interstate commerce in violation of the Food, Drug, and Cosmetic Act (FDCA). Judge Cecchi also sentenced the company today, fining OtisMed $34.4 million and ordering $5.16 million in criminal forfeiture. In a separate civil settlement, OtisMed agreed to pay $40 million plus interest to resolve its civil liability. Chi pleaded guilty before U.S. Magistrate Judge Mark Falk to three counts of introducing adulterated medical devices in interstate commerce. Chi will be sentenced by Judge Cecchi on March 18, 2015.

"Americans must be able to trust that they are treated with medical devices that have been shown to be safe and effective," said Deputy Assistant Attorney General Jonathan Olin for the Justice Department's Civil Division. "The Department of Justice will not tolerate companies and individuals that cut corners when it comes to the public's health."

"It is vital that products like the OtisKnee are subjected to the appropriate level of scrutiny," said U.S. Attorney Paul J. Fishman for the District of New Jersey. "Patients seeking medical care are vulnerable; they are often afraid, and in pain. They should be able to trust their doctors. And they should be entitled to trust that the devices their doctors are using are safe, effective, tested and approved. OtisMed and Charlie Chi betrayed that trust."

The civil settlement resolves claims filed under the whistleblower provisions of the False Claims Act, which permit private parties to file suit on behalf of the United States and obtain a portion of the government's recovery. The civil lawsuit was filed in the District of New Jersey and is captioned *U.S. ex rel. Adrian v. OtisMed Corp., et al.*

OtisMed was a privately held company when OtisMed and Chi committed the criminal conduct, and was later acquired by Stryker Corp., a medical technology company based in Michigan, in November 2009. At the time the shipments were made in September 2009, Stryker executives were not aware that OtisMed and Chi had shipped cutting guides after the FDA had rejected the company's application for marketing clearance for the

device. Stryker, OtisMed's parent corporation, cooperated with the government with regard to Otismed's pre-acquisition conduct throughout the investigation. In addition to the criminal pleas and civil resolution, OtisMed also agreed to be excluded from participating in all federal health care programs for a period of 20 years and Stryker separately agreed to a series of compliance measures aimed at preventing future misconduct.

According to documents filed in this case and statements made in court:

Chi was among the founders of OtisMed in August 2005, and conceived of the OtisKnee orthopedic cutting guide, its primary product. Chi acted as OtisMed's president, CEO and board of directors' chairman until OtisMed was acquired by Stryker in November 2009. The OtisKnee was used by surgeons during total knee arthroplasty (TKA), commonly known as knee replacement surgery. The surgical procedure requires a surgeon to remove the ends of the leg bones and to reshape the remaining bone to accommodate the implantation of an artificial knee prosthesis. The cuts to the bone must be made at precise angles because they are critical to the clinical result; failure to achieve the correct angle in TKA procedures can result in failure of the bones and/or the implanted prosthetic joint.

OtisMed marketed the OtisKnee cutting guide as a tool to assist surgeons in making accurate bone cuts specific to individual patients' anatomy based on magnetic resonance imaging (MRI) performed prior to surgery. None of OtisMed's claims regarding the OtisKnee device were evaluated by the FDA before the company used them in advertisements and promotional material.

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

On Oct. 2, 2008, OtisMed submitted a pre-market notification to the FDA seeking clearance to market the OtisKnee. The company had not previously sought the FDA's clearance or approval and had been falsely representing to physicians and other potential purchasers that the product was exempt from such pre-market requirements.

On Sept. 2, 2009, the FDA sent OtisMed a notice that its submission had been denied, noting that the company had failed to demonstrate that the OtisKnee was as safe and effective as other legally marketed devices. The letter warned OtisMed that distribution of the OtisKnee prior to approval would be an FDCA violation, and indicated the FDA viewed the product as a "significant risk device system," which is defined as presenting a potential for serious risk to the health, safety or welfare of a subject. Chi and others at OtisMed received advice from legal and regulatory counsel confirming it would be unlawful for OtisMed to continue distributing the OtisKnee.

Though the board of directors unanimously decided to stop further shipments of the devices, Chi and others at OtisMed were concerned that inconveniencing surgeons planning to use the OtisKnee in scheduled surgeries would exacerbate the negative impact of the FDA letter on the reputation of OtisMed and the device. Chi directed OtisMed employees to organize a mass shipment of all OtisKnee devices that had been manufactured but had not yet been shipped and suggested ways for the employees to hide the shipments from FDA regulators.

At Chi's direction, OtisMed shipped approximately 218 OtisKnee guides from California to surgeons throughout the United States, including 16 to surgeons in New Jersey. Both Chi and OtisMed admitted that Chi ordered the distribution a week after the FDA denied OtisMed's request for clearance.

"Companies and individuals put the public health at risk by not complying with FDA regulatory requirements for the pre-market review of medical devices," said Acting Director Philip J. Walsky for the FDA's Office of Criminal Investigations. "We will continue to assure consumer confidence in FDA-regulated products by

investigating and bringing to justice those who endanger patient safety by distributing unapproved surgical devices." "When OtisMed and its CEO, Charlie Chi, distributed medical devices that were not FDA-approved, they violated the trust that patients extend to health care professionals," said Special Agent in Charge Thomas O'Donnell of the New York Regional Office of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). "This outrageous behavior triggered our agency to exclude OtisMed from participating in Medicare and Medicaid for 20 years. We will continue to work with our law enforcement partners to protect federally funded health care programs and the patients who rely on those programs."

The civil settlement resolves allegations arising from the marketing and distribution of the OtisKnee without receiving approval or clearance from the FDA for the device. Specifically, the settlement alleged that in May 2006, OtisMed, through co-promotion activities with Stryker Corporation, began commercially distributing the OtisKnee without having received clearance or approval from the FDA for the device. OtisMed continued to distribute the device while its application was pending and even after the FDA informed OtisMed that the product could not be lawfully distributed until FDA approved the device.

The settlement also alleged that OtisMed encouraged health care providers to submit claims for MRIs that were not reimbursable because they were not performed for diagnostic use, but rather solely to provide data for the creation of the OtisKnee. Except as admitted in the plea agreement, the claims settled by the civil settlement agreement are allegations only, and there has been no determination of liability as to those claims.

The company will pay approximately $41.2 million, including interest, to resolve its civil liability for submitting false claims to the Medicare, TRICARE, Federal Employees Health Benefits and Medicaid programs. Of that amount, approximately $41 million will be paid to the federal government. Medicaid is funded jointly by the states and the federal government and participating Medicaid states will receive approximately $376,700 of the settlement amount. As part of today's resolution, the relator will receive approximately $7 million.

In addition to agreeing to continue to cooperate with the government's investigation and maintain a compliance program, Stryker agreed to conduct a review and audit regarding whether other marketed devices have the appropriate FDA approvals and share the results of that audit with the government. Stryker also agreed to annual certifications from the president of Stryker's orthopedics group and from Stryker's board of directors regarding the effectiveness of the compliance program.

Chi faces a statutory maximum sentence of one year in prison and a $100,000 fine, or twice the gain or loss from the offense, for each of the three counts of introducing adulterated medical devices in interstate commerce.

The guilty pleas and civil settlement are the culmination of a long-term investigation conducted jointly by the FDA's Office of Criminal Investigations, under the direction of Special Agent in Charge Antoinette V. Henry, and HHS-OIG, under the direction of Special Agent in Charge O'Donnell. Counsel to the HHS-OIG and FDA's Office of Chief Counsel to the FDA also assisted. The National Association of Medicaid Fraud Control Units, along with the Medicaid Fraud Control Unit of the Massachusetts Attorney General's Office, assisted in coordinating the settlements with the various states.

Additional assistance was provided by the Defense Health Agency and the Office of Personnel Management–Office of the Inspector General.

This resolution illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims

Act. Since January 2009, the Justice Department has recovered a total of more than $23.2 billion through False Claims Act cases, with more than $14.9 billion of that amount recovered in cases involving fraud against federal health care programs.

The government is represented in the criminal case by Chief Jacob T. Elberg of the U.S. Attorney's Office Health Care and Government Fraud Unit and Trial Attorney Ross S. Goldstein of the Civil Division's Consumer Protection Branch, and in the civil settlement by Assistant U.S. Attorney Charles Graybow of the District of New Jersey's Health Care and Government Fraud Unit and Trial Attorney Charles Biro of the Civil Division.

U.S. Attorney Fishman reorganized the health care fraud practice at the U.S. Attorney's Office for the District of New Jersey shortly after taking office, including creating the stand-alone Health Care and Government Fraud Unit to handle both criminal and civil investigations and prosecutions of health care fraud offenses. Since 2010, the office has recovered more than $620 million in health care fraud and government fraud settlements, judgments, fines, restitution and forfeiture under the False Claims Act, the FDCA and other statutes.

OtisMed Documents

14-1369

Topic:
Consumer Protection

Civil Division

Updated December 9, 2014