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 A. Cartier

Date: September 12, 2014

Michael Cartier
As Authorized Corporate Representative
for Stryker Corporation

Brien T. O'C

Date: September 15, 2014

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