

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 79828 / January 18, 2017

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 3851 / January 18, 2017

ADMINISTRATIVE PROCEEDING
File No. 3-17800

In the Matter of

Orthofix International N.V.

Respondent.

ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING REMEDIAL SANCTIONS AND A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”) against Orthofix International N.V. (“Orthofix” or “Respondent”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (“Offer”) that the Commission has determined to accept. Respondent admits the facts set forth in Paragraphs 1 through 20 below, acknowledges that its conduct violated the federal securities laws, admits the Commission’s jurisdiction over it and the subject matter of these proceedings, and consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order (“Order”), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds¹ that:

SUMMARY

This matter concerns violations of the books and records and internal controls provisions of the Foreign Corrupt Practices Act of 1977 ("FCPA") by Orthofix International N.V., a medical device company organized under the laws of Curacao and headquartered in Lewisville, Texas, and its Brazilian subsidiary, Orthofix do Brasil LTDA. From at least 2011 to 2013 (hereinafter "the relevant period"), senior personnel at Orthofix Brazil employed at least four schemes, with third-party commercial representatives and distributors, to make improper payments to doctors employed at government-owned hospitals to induce them to use Orthofix's products, thereby increasing sales. The improper payments to doctors employed at government hospitals were improperly recorded as legitimate expenses and generated illicit profits to Orthofix of approximately \$2,928,000.

Orthofix also failed to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances to detect and prevent such payments by Orthofix Brazil, despite the fact that Orthofix had been charged by the Commission in 2012 with violating the books and records and internal controls provisions of the FCPA in connection with bribes paid to Mexican officials by its Mexican subsidiary.

By engaging in the foregoing conduct, Orthofix violated the books and records and internal controls provisions of the federal securities laws set forth in Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act.

RESPONDENT

Orthofix International N.V. ("Orthofix," "Respondent," or "Company") is a limited liability company formed under the laws of Curacao and headquartered in Lewisville, Texas. It is a diversified medical device company that develops and sells surgical and non-surgical medical products to medical professionals in various market sectors, including orthopedics. It distributes its products both domestically in the United States and internationally in multiple countries. Orthofix's common stock is registered with the Commission pursuant to Section 12(b) of the Exchange Act and currently trades on the Nasdaq Global Select Market under the symbol "OFIX."

¹ The findings herein are made pursuant to Respondent's Offer and are not binding on any other person or entity in this or any other proceeding.

RELEVANT ENTITY

Orthofix do Brasil LTDA (“Orthofix Brazil”) is a wholly-owned subsidiary of Orthofix headquartered in Sao Paulo, Brazil. Orthofix Brazil markets and sells extremity fixation products through direct and indirect sales to public and private sector customers. From 2011 to 2013, approximately 12.5 % of Orthofix Brazil’s sales were made to public sector customers, such as government-owned hospitals and associated doctors, and the remaining 87.5% to private customers, including non-government-owned hospitals and associated doctors. Orthofix consolidated Orthofix Brazil’s financial statements into its financials.

FACTS

A. Prior Commission Enforcement Action Against Orthofix

1. In 2012, the Commission filed a settled civil injunctive action in United States District Court for the Eastern District of Texas alleging that Orthofix had violated the books and records and internal controls provisions of the FCPA through its Mexican subsidiary, Promeca S.A. de C.V. (“Promeca”). From at least 2003 to 2010, Promeca made improper payments totaling approximately \$317,000 to employees of a government agency in Mexico. These improper payments, recorded as training and promotional expenses, generated illicit net profits to Orthofix of approximately \$4.9 million.

2. Orthofix settled the matter by consenting to the entry of a final judgment that (i) enjoined the company from violating Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act, (ii) ordered Orthofix to pay disgorgement and prejudgment interest of approximately \$5.2 million, and (iii) ordered Orthofix to undertake certain remedial measures concerning its FCPA compliance program, including self-reporting to the staff for a two-year term regarding its remediation efforts. In a parallel criminal investigation, Orthofix entered into a deferred-prosecution agreement in which it admitted, accepted, and acknowledged responsibility for specific conduct related to Promeca’s operations in Mexico, and paid a \$ 2,220,000 criminal fine.

B. Background

3. During the relevant period, Orthofix Brazil accounted for approximately 5-7% of Orthofix’s consolidated net sales. During the relevant period, Orthofix Brazil sold its products through either (i) direct sales to a customer through third-party commercial representative entities who provide assistance and receive a commission, or (ii) indirect sales through a third-party distributor that purchased the products from Orthofix Brazil, held the inventory, and resold them to an end customer.

4. During the relevant period, Orthofix Brazil engaged in direct sales with the assistance of third-party commercial representatives who helped to market and sell its products in Brazil. These commercial representatives also employed sales agents to make sales. Commercial representative sales comprised approximately two-thirds of the sales of the

subsidiary. In addition, Orthofix Brazil engaged sixteen distributors to conduct indirect sales. Orthofix Brazil sold its products to the distributors who in turn resold the products to health care providers, including private and government-owned hospitals, in various regions in Brazil. Indirect sales through distributors comprised about one-third of the sales of the subsidiary.

5. Orthofix provided budgets, financial targets, and guidance to Orthofix Brazil and approved certain actions and expenditures. Orthofix also received regular updates from Orthofix Brazil on many details regarding sales opportunities, numbers, and business developments. Orthofix set internal sales targets and management imposed pressure on subsidiaries to meet those targets. Orthofix's reporting structure and relationship with its subsidiaries was decentralized during the relevant time period, complicating parent oversight, compliance monitoring, and communication with U.S. executives. Orthofix lacked adequate training, policies, processes, and corporate culture that would have allowed employees at its subsidiaries to raise compliance concerns to the parent level.

C. Orthofix Brazil Made Improper Payments to Doctors Through Commercial Representatives

6. During the relevant period, Orthofix Brazil entered into agreements with third-party commercial representatives to directly sell its products to hospitals and doctors in Brazil, and it paid commissions to those commercial representatives as part of such agreements. Orthofix Brazil's commercial representatives in turn made improper payments to certain doctors at government owned hospitals in exchange for sales contracts.

7. The scheme involving commercial representatives worked in one of two ways. In the first scenario, commercial representatives made arrangements to pay doctors a specific amount, usually constituting 20-25% of the sales price, in exchange for using Orthofix products. After doctors performed a procedure using Orthofix's products, Orthofix Brazil typically billed the hospital for the products used. Orthofix Brazil then paid a commission of approximately 33-43% of the sales price to the commercial representative responsible for the sale, who then used a portion of that commission to make certain agreed upon payments to doctors.

8. In the second scenario, a company related to the commercial representative sent Orthofix Brazil false invoices for services such as marketing that were never provided. The former general manager of Orthofix Brazil approved these payments and the former finance director of Orthofix Brazil instructed Orthofix Brazil employees to classify the payments as "administrative expenses." The services were never rendered and the payments were not administrative expenses but rather provided funds that were intended to be used to make improper payments to certain doctors. The payments were intentionally improperly recorded as legitimate expenses to hide the true nature of the payments.

9. Certain Orthofix Brazil employees knew that commercial representatives were paying doctors and were involved in the schemes. The former general manager was responsible for negotiating the arrangements with the commercial representatives, and he instructed the former finance director and other lower level Orthofix Brazil employees to make the commission

payments to commercial representatives. Payments to commercial representatives were referred to by these employees as “doctors’ commissions.” Orthofix Brazil employees and commercial representatives openly discussed payment percentages, total amounts, and payment instructions for making direct deposits or in-person payments to doctors.

D. Orthofix Brazil Made Improper Payments to Doctors Through Distributors

10. Similar to the schemes involving commercial representatives, Orthofix Brazil used third-party distributors in two ways to make improper payments to doctors. In the first scenario, Orthofix Brazil provided a high discount ranging in certain instances of up to 70% to the distributors, who then used part of the profit generated by that discount to make improper payments to certain doctors. The high discounts were purportedly meant to allow distributors to make a sufficient profit while also covering their overhead costs. In reality, part of the discount was often used to make the improper payments to certain doctors at public hospitals. Employees of the distributors openly discussed the improper payment scheme in emails to certain Orthofix Brazil employees. For example, in 2011, one distributor emailed an Orthofix Brazil employee that “[t]he agreement with the physicians is to make the payment after using the material,” indicating a promise to pay doctors after they used Orthofix products. The four distributors that made improper payments to doctors on behalf of Orthofix Brazil openly discussed the improper payments in person with certain Orthofix Brazil employees and demanded higher discounts from the company to facilitate the payments.

11. In the second scenario involving distributors, Orthofix Brazil made payments for services that were never rendered. These payments were inaccurately described in the company’s books and records as “consulting for sales” payments made to a company related to one of the distributors, when, in fact, the payments to the distributor were made to facilitate improper payments to doctors.

12. The general manager, finance director, and certain other Orthofix Brazil employees no longer associated with Orthofix Brazil knew that distributors were using excessive discounts and making payments on false invoices to pay doctors. Nevertheless, Orthofix Brazil improperly recorded the payments as legitimate business expenses to hide the true nature of the payments.

E. Orthofix Failed to Maintain Accurate Books and Records

13. Orthofix Brazil improperly recorded certain payments to commercial representatives and discounts to third-party distributors, portions of which were used to make improper payments to doctors, as commissions, discounts, consulting fees, administrative expenses, and other legitimate business expenses in its books and records that were subsequently consolidated into Orthofix’s books and records, rendering them inaccurate.

F. Orthofix Lacked Adequate Internal Accounting Controls

14. Orthofix failed in a timely manner to devise and maintain an adequate system of internal accounting controls in Brazil, even after the company had been charged previously for internal controls failings in the Commission's earlier case against it for improper payments in Mexico. The controls in place during the relevant period were minimal and clearly deficient.

15. The internal accounting controls were deficient with respect to the setting, approval, and payment of commissions and discounts. Orthofix had no policies or processes in place to standardize or centrally approve and monitor the commissions and discounts that Orthofix Brazil was providing to third parties, which allowed Orthofix Brazil to push through high commissions and discounts that ultimately were used to facilitate improper payments. The decentralized nature of Orthofix's business in Brazil allowed Orthofix Brazil to easily evade the policies and controls that Orthofix did have in place when the conduct occurred. An indirect reporting structure created gaps in supervision that provided the opportunity to orchestrate and execute the bribery schemes without detection.

16. Furthermore, a lack of centralized global accounting and payment controls allowed Orthofix Brazil to record the improper payments as legitimate business expenses. Given the prior corruption and internal controls issues at its Mexican subsidiary, Orthofix was aware of deficiencies in its controls and the FCPA risks at its subsidiaries' operations. Despite these red flags, Orthofix failed to establish better controls and supervision over its subsidiaries in high risk countries.

COOPERATION AND REMEDIAL ACTION

17. Orthofix disclosed the Brazil allegations as part of its ongoing self-reporting obligations undertaken as part of its earlier settlement with the Commission for its conduct related to Mexico discussed above. Orthofix cooperated with the investigation by, among other things: (i) conducting a thorough and timely internal investigation; (ii) voluntarily producing documents and other information in a timely manner, identifying significant documents and translating documents from Portuguese; (iii) compiling financial data and analysis; (iv) providing detailed witness interview downloads, Power-Point presentations summarizing its findings, and timelines; and (v) assisting us in our efforts to coordinate witness interviews with current and former Orthofix and Orthofix Brazil employees.

18. Although the Company took remedial steps following the resolution of the Promeca allegations in 2012, Orthofix did not start fully implementing sufficient remedial steps until after the discovery of the Brazil conduct in late 2013. Though delayed, these efforts have been significant. Orthofix and Orthofix Brazil now have terminated problematic representatives and distributors; developed and implemented new global accounting policies to provide further structure and guidance to foreign subsidiaries; established an internal audit function and expanded Orthofix's compliance department; conducted extensive audits of third-party vendors used by subsidiaries; and revised existing trainings and implemented additional compliance training for employees.

LEGAL STANDARDS AND VIOLATIONS

19. As a result of the conduct described above, Orthofix violated Section 13(b)(2)(A) of the Exchange Act, which requires issuers to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflect their transactions and dispositions of the assets of the issuer.

20. In addition, as a result of the conduct described above, Orthofix violated Section 13(b)(2)(B) of the Exchange Act, which requires issuers to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 21C of the Exchange Act, Respondent cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

B. Respondent shall, within thirty days of the entry of this Order, pay disgorgement of \$2,928,000, prejudgment interest of \$263,375, and a civil money penalty in the amount of \$2,928,000 to the Securities and Exchange Commission. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717. Payment must be made in one of the following three ways:

1. Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
2. Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofin.htm>; or
3. Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Orthofix as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Kara N. Brockmeyer, Division of Enforcement, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549-5720.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent shall comply with the following undertakings:

1. Retain an independent consultant (the "Independent Consultant") not unacceptable to the Staff within sixty (60) calendar days after the issuance of this Order. Within thirty (30) calendar days after the issuance of this Order, Respondent shall recommend to the Staff three qualified candidates to serve as the Independent Consultant. The Staff shall provide feedback to Respondent within fifteen (15) calendar days of receiving Respondent's recommendations.
2. The Independent Consultant candidates shall have, at a minimum, the following qualifications: demonstrated expertise with respect to the FCPA, including experience counseling on FCPA issues; experience designing and/or reviewing corporate compliance policies, procedures, and internal controls, including FCPA-specific policies, procedures, and internal controls; ability to access and deploy resources as necessary to discharge the Independent Consultant's duties as described herein; and independence from Respondent

to ensure effective and impartial performance of the Independent Consultant's duties.

3. The Independent Consultant should not have provided legal, auditing, or other services to, or have had any affiliations with, the Respondent during the two years prior to the issuance of this Order.
4. Respondent shall retain the Independent Consultant for a period of one (1) year from the date of the engagement. Respondent shall exclusively bear all costs, including compensation and expenses, associated with the retention of the Independent Consultant.
5. To ensure the independence of the Independent Consultant, Respondent shall not have the authority to terminate the Independent Consultant without the prior written approval of the Staff.
6. The Independent Consultant's responsibility is to review and evaluate Respondent's internal controls, record-keeping and financial reporting policies and procedures as they relate to its compliance with the books and records, internal accounting controls, and anti-bribery provisions of the FCPA ("the Policies and Procedures") and to make recommendations designed to reasonably improve the Policies and Procedures. This review and evaluation shall include an assessment of the Policies and Procedures as actually implemented and how FCPA compliance fits within Respondent's ethics and compliance function. The Independent Consultant shall consider whether the ethics and compliance function has sufficient resources, authority, and independence, and provides sufficient training and guidance.
7. Respondent and the Independent Consultant shall agree that the Independent Consultant is an independent third-party and not an employee or agent of the Respondent. In addition, Respondent and the Independent Consultant agree that no attorney-client relationship shall be formed between them.
8. Respondent shall require the Independent Consultant to enter into an agreement with Respondent providing that, for the period of engagement and for a period of two years from completion of the engagement, the Independent Consultant shall not enter into any employment, consultant, attorney-client, auditing or other professional relationship with Respondent, or any of its present or former affiliates, directors, officers, employees, or agents acting in their capacity as such. Any firm with which the Independent Consultant is affiliated or of which he/she is a member, and any person engaged to assist the Independent Consultant in performance of his/her duties under this Order shall not, without prior written consent of the Staff enter into any employment, consultant, attorney-client, auditing or other professional relationship with Respondent, or any of its present or former affiliates, directors, officers,

employees, or agents acting in their capacity as such for the period of the engagement and for a period of two (2) years after the engagement.

9. Respondent shall require the Independent Consultant to prepare a written work plan and submit it to Respondent and the Staff for comment within thirty (30) calendar days of commencing the engagement. The Respondent's comments shall be provided to the Independent Consultant no more than fifteen (15) calendar days after receipt of the written work plan. In order to conduct an effective initial review and to understand fully any deficiencies in the Policies and Procedures, including how FCPA compliance fits within Respondent's ethics and compliance function, the Independent Consultant's initial work plan shall include such steps as are reasonably necessary to develop an understanding of the facts and circumstances surrounding any violations that may have occurred as reflected in this matter and to assess the effectiveness of Respondent's existing Policies and Procedures, and of Respondent's ethics and compliance program. Any dispute between Respondent and the Independent Consultant with respect to the work plan shall be decided by the Staff.
10. Respondent shall cooperate fully with the Independent Consultant, and the Independent Consultant shall have the authority to take such reasonable steps as, in his or her view, may be necessary to be fully informed about Respondent's Policies and Procedures in accordance with the principles set forth herein and applicable law, including data protection, blocking statutes, and labor laws and regulations applicable to Respondent. To that end Respondent shall provide the Independent Consultant with access to all information, documents, records, facilities and/or employees, as requested by the Independent Consultant, that fall within the scope of the Independent Consultant's responsibility, except as provided in this paragraph; and provide guidance on applicable laws (such as relevant data protection, blocking statutes, and labor laws).
11. In the event the Respondent seeks to withhold from the Independent Consultant access to information, documents, records, facilities and/or employees of Respondent that may be subject to a claim of attorney-client privilege or to the attorney work product doctrine, or where Respondent reasonably believes production would otherwise be inconsistent with applicable law or beyond the scope of these undertakings, Respondent shall work cooperatively with the Independent Consultant. If the matter cannot be resolved, at the request of the Independent Consultant, Respondent shall promptly provide written notice to the Independent Consultant and the Staff. Such notice shall include a general description of the nature of the information, documents, records, facilities and/or employees that are being withheld, as well as the basis for the claim. To the extent Respondent has provided information to the Staff in the course of the investigation leading to

this action pursuant to a non-waiver of privilege agreement, Respondent and the Independent Consultant may agree to production of such information to the Independent Consultant pursuant to a similar non-waiver agreement.

12. Respondent shall require the Independent Consultant to issue a written report (“Report”), within six (6) months after being retained to review Respondent’s Policies and Procedures: (a) summarizing its review and evaluation, and (b) if necessary, making recommendations based on its review and evaluation that are reasonably designed to improve Respondent’s Policies and Procedures. Respondent shall require that the Independent Consultant provide the Report to the Board of Directors of Respondent and simultaneously transmit a copy to the Staff at the following address: Ansu N. Banerjee, Assistant Regional Director, Division of Enforcement, Securities and Exchange Commission, 444 South Flower Street, Suite 900, Los Angeles, California 90071.
13. Respondent shall adopt all recommendations in the Report within sixty (60) days of the issuance of the Report; provided, however, that, as to any recommendations that Respondent considers to be unduly burdensome, impractical, or costly, Respondent need not adopt the recommendations at that time, but may submit in writing to the Staff, within thirty (30) days of receiving the Report, an alternative policy or procedure designed to achieve the same objective or purpose. Respondent and the Independent Consultant shall attempt in good faith to reach an agreement relating to each recommendation Respondent considers unduly burdensome, impractical, or costly. In the event that Respondent and the Independent Consultant are unable to agree on an alternative proposal within thirty (30) days, Respondent will abide by the determinations of the Staff.
14. Upon completion of the implementation, the Independent Consultant shall have thirty (30) calendar days to complete a follow-up review to confirm that Respondent has implemented the recommendations or agreed-upon alternatives and continued the application of the Policies and Procedures, and to deliver a supplemental report to the Board of Directors of Respondent and the Staff setting forth its conclusions and whether any further improvements should be implemented.
15. Respondent agrees that the Staff may extend any of the dates set forth above at its direction.
16. Respondent shall certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. Respondent shall submit the certification

and supporting material to Ansu N. Banerjee, Assistant Regional Director, Division of Enforcement, with a copy to the Office of Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

17. Respondent agrees that these undertakings shall be binding upon any successor in interest to Respondent or any acquirer of substantially all of Respondent's assets and liabilities or business.

By the Commission.

Brent J. Fields
Secretary