

accounting principles or any other criteria applicable to such statements, and (B) maintain accountability for assets; (iii) access to assets was permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets was compared with the existing assets at reasonable intervals, and appropriate action was taken with respect to any differences. 15 U.S.C. § 78m(b)(2)(B).

Introduction

At all times material to this Information, unless otherwise stated:

The Defendant and Defendant's Subsidiaries

3. Defendant **Orthofix International, N.V.** ("**Orthofix N.V.**"), was a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical devices, and was incorporated in Curaçao. **Orthofix N.V.** sold and distributed its products around the world from facilities in the United States, the United Kingdom, Italy, Mexico, and elsewhere. **Orthofix N.V.** employed over 1,500 people and currently maintained its corporate administrative offices in Lewisville, Texas.

4. **Orthofix N.V.** had a class of securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934 (15 U.S.C. § 78) and was required to file reports with the United States Securities and Exchange Commission under Section 15(d) of the Exchange Act, 15 U.S.C. § 78o(d). **Orthofix N.V.** was publicly traded on the NASDAQ stock exchange under the ticker symbol "OFIX." **Orthofix N.V.** was an "issuer" within the meaning of the FCPA.

5. Orthofix Inc. was incorporated in Minnesota and was an indirectly wholly owned subsidiary of **Orthofix N.V.** Orthofix Inc. was responsible for overseeing **Orthofix N.V.**'s business operations in Latin America, including Mexico, and for fulfilling **Orthofix N.V.**'s administrative and managerial functions in connection with **Orthofix N.V.**'s operations around

the world. Over 400 **Orthofix N.V.** employees were employed at Orthofix Inc.

6. **Orthofix N.V.**'s products included medical devices that physicians surgically implanted in patients, including fixators and bone nails that physicians used to stabilize bones in patients that had suffered serious trauma. **Orthofix N.V.**'s medical devices were sufficiently complex that personnel from **Orthofix N.V.** or one of its subsidiaries typically worked with surgeons during surgery to ensure that **Orthofix N.V.**'s products were used correctly.

7. Promeca S.A. de C.V. ("Promeca") was incorporated in Mexico and headquartered in Mexico City. Promeca was an indirectly wholly owned subsidiary of **Orthofix N.V.** that distributed **Orthofix N.V.**'s medical nails and fixators in Mexico. Promeca employed more than 50 employees, and its financial results were consolidated with **Orthofix N.V.**'s corporate financial statements, books, and records. **Orthofix N.V.** was responsible for ensuring Promeca's continued solvency, and **Orthofix N.V.** periodically infused Promeca with additional capital. **Orthofix N.V.** and Orthofix Inc. personnel based in the United States oversaw Promeca's activities, reviewed and approved Promeca's annual budgets, and had the authority to hire and fire Promeca's officers.

Defendant's Employees and Agents

8. "Orthofix Executive A," a citizen of Peru and legal permanent resident in the United States, was a senior manager of Orthofix Inc. who worked in the Eastern District of Texas, and elsewhere, and was responsible for **Orthofix N.V.**'s sales operations in Latin America from in or around 1991 until in or around 2008. Orthofix Executive A was a consultant to **Orthofix N.V.**, through its Italian subsidiary, Orthofix SRL, from in or around 1991 until in or around March 2004. Beginning in or around March 2004 and continuing until in or around October 2006, Orthofix Executive A served as Orthofix Inc.'s Vice President of Sales, Latin America. Orthofix Executive A then worked as a consultant to Orthofix Inc. until in or around

2008. Irrespective of Orthofix Executive A's title, Orthofix Executive A reported to other executives of **Orthofix N.V.** and Orthofix Inc. and was viewed within **Orthofix N.V.** and Orthofix Inc. as the individual responsible for developing **Orthofix N.V.**'s sales in Latin America.

9. "Orthofix Executive B," a citizen of the United States, was an Orthofix Inc. finance executive who worked in the Eastern District of Texas and elsewhere. Orthofix Executive B began working for **Orthofix N.V.** in or around 2001 and became a financial manager within **Orthofix N.V.** in or around 2003. Beginning in or around January 2008, Orthofix Executive B became an officer of Orthofix Inc. At various times between in or around 2001 and in or around 2010, Orthofix Executive B's responsibilities included consolidating Promeca's revenues into **Orthofix N.V.**'s financial statements, reviewing Promeca's profit and loss figures, reviewing individual **Orthofix N.V.** journal entries, reporting financial results to **Orthofix N.V.**'s Board of Directors, and assisting in reporting **Orthofix N.V.**'s financial data to the United States Securities & Exchange Commission. In or around January 2007, Orthofix Executive B also visited Promeca's offices in Mexico City to review Promeca's financial statements.

10. "Orthofix Executive C," a citizen of the United States, was an Orthofix Inc. finance executive who worked in the Eastern District of Texas and elsewhere. From in or around 2004 until in or around 2006 and again from in or around 2007 to present, Orthofix Executive C was the Orthofix Inc. executive responsible for overseeing Promeca's financial performance.

11. At various times between in or around 2001 and in or around 2010, Orthofix Executive B and Orthofix Executive C were responsible for monitoring the financial operations and results of **Orthofix N.V.**'s subsidiaries in Latin America, including Promeca.

12. “Promeca Executive A,” a citizen of Mexico and former owner of Promeca, was Promeca’s Commercial Director. Promeca Executive A reported directly to Orthofix Inc.’s President of the Americas and to Orthofix Executive A.

13. “Promeca Executive B,” a citizen of Mexico and licensed accountant, was Promeca’s Finance Manager. Promeca Executive B was responsible for Promeca’s payroll, purchasing, bookkeeping, inventory controls, and taxes. Promeca Executive B reported directly to Promeca Executive A and to Orthofix Inc.’s Chief Financial Officer.

Defendant’s Customers

14. Instituto Mexicano del Seguro Social (“IMSS”) was a social-service agency of the Mexican government that provided public services to Mexican workers and their families. IMSS was created in 1943 by order of the Mexican president, who continued to select IMSS’s head, and subsequent changes to IMSS programs were made by acts of Mexico’s legislature. IMSS provided health care services to tens of millions of people, including workers, their families, and pensioners, at hospitals that IMSS owned and operated throughout Mexico. Mexico’s government funded IMSS through taxation and compulsory contributions.

15. Hospital de Traumatología y Ortopedia Magdalena de las Salinas (“Magdalena de las Salinas”) was a hospital in Mexico City, Mexico, that IMSS owned and controlled.

16. Hospital de Traumatología y Ortopedia Lomas Verdes (“Lomas Verdes”) was a hospital in the State of Mexico that IMSS owned and controlled.

17. “Mexican Official 1” was a deputy administrator of Magdalena de las Salinas.

18. “Mexican Official 2” was purchasing director of Magdalena de las Salinas.

19. “Mexican Official 3” was purchasing director of Lomas Verdes.

20. “Mexican Official 4” was a sub-director of IMSS.

21. Promeca generated approximately 65 percent of its revenues through sales to IMSS and its hospitals, including sales to Magdalena de las Salinas and Lomas Verdes. **Orthofix N.V.** and Orthofix Inc. executives were aware that Promeca's revenues relied heavily upon sales to Mexican government customers.

Corrupt Conduct

22. From in or around 2003 through in or around March 2010, with the knowledge of Orthofix Executive A, Promeca and its employees paid approximately \$300,000 to Mexican officials, in return for agreements with IMSS and its hospitals to purchase millions of dollars in **Orthofix N.V.** products.

23. Promeca personnel colloquially referred to the illicit payments as "chocolates," a term commonly understood within Promeca and by Orthofix Executive A to describe a supplier's improper payments to purchasers of medical supplies and devices in exchange for an agreement to buy the supplier's goods.

24. In or around 2003, Promeca Executive A won the right to sell **Orthofix N.V.** products to Magdalena de las Salinas and Lomas Verdes by agreeing to pay to Mexican Official 1 and Mexican Official 2, respectively, a percentage of collected sales revenue generated through sales to the hospitals.

25. To implement this agreement, Promeca Executive B periodically reviewed a report of sales revenue collected from Magdalena de Las Salinas and Lomas Verdes. Promeca Executive B submitted requests for expense advancements payable to Promeca Executive B, cashed the resulting checks with the assistance of Promeca's office messenger, and delivered the cash to Promeca Executive A.

26. From in or around 2003 until in or around 2006, Promeca Executive A and additional Promeca employees delivered to Mexican Official 1 cash payments equal to as much as 10 percent of Promeca's collected sales to Magdalena de las Salinas.

27. From in or around 2006 until in or around 2007, Promeca Executive A and additional Promeca employees delivered to Mexican Official 2 cash payments equal to as much as 6 percent of Promeca's collected sales to Magdalena de las Salinas.

28. From in or around 2003 until in or around 2007, Promeca Executive A and additional Promeca employees delivered to Mexican Official 3 cash payments equal to as much as 5 percent of Promeca's collected sales to Lomas Verdes. Beginning in or around July 2007, Promeca stopped making cash payments to Mexican Official 3 and instead leased a vehicle for Mexican Official 3 to drive. Mexican Official 3 drove that leased car until in or around September 2010.

29. In or around 2008, IMSS began holding national tenders for medical-device contracts with hospitals that IMSS owned and controlled. To obtain contracts under the national tenders in or around 2008 and 2009, Promeca Executive A agreed to pay certain IMSS officials, including Mexican Official 4, a percentage of Promeca's sales revenue collected under the contracts that IMSS awarded to Promeca. To accomplish this agreement, Promeca Executive B regularly reported to IMSS officials the amount of collected sales revenue from the national tender contracts. IMSS officials then used fictitious companies to issue to Promeca invoices for medical equipment or training in an amount equal to the payments due to the IMSS officials plus a value-added tax to make the invoices appear to be legitimate. Promeca then paid the invoiced amounts to the front companies incorporated by the IMSS officials.

30. Promeca recorded the bribe-related expenses on its books and records as “promotional expenses,” payments for medical equipment, and training-related expenses, none of which reflected the true purpose for which the expenditures were made. Promeca consistently overspent in these categories the budget that it had communicated to **Orthofix N.V.** and Orthofix Inc.

31. Orthofix Executive A knew of the payments and things of value outlined above, but failed to stop the scheme or to report the scheme to **Orthofix N.V.** or Orthofix Inc.’s compliance department.

Defendant’s Internal Controls

32. **Orthofix N.V.**, which grew its direct distribution footprint in part by purchasing existing companies, often in high-risk markets, failed to engage in any serious form of corruption-related diligence before it purchased Promeca.

33. Although **Orthofix N.V.** promulgated its own anti-corruption policy, that policy was neither translated into Spanish nor implemented at Promeca. **Orthofix N.V.** failed to provide any FCPA-related training to many of its own personnel, including Orthofix Executive A. **Orthofix N.V.** also failed to train Promeca personnel for years on the FCPA, to test regularly or audit particular transactions, or to ensure that its subsidiary maintained controls sufficient to detect, deter, or prevent illicit payments to government officials.

34. **Orthofix N.V.**’s financial controls pertaining to Promeca were also inadequate. In addition to permitting unexplained variances from Promeca’s budget, **Orthofix N.V.** discovered in 2003 that Promeca Executive A had charged in 2002 and 2003 approximately \$100,000 in cash advances against Promeca Executive A’s corporate credit card. **Orthofix N.V.** eventually wrote off the expenses, which Promeca Executive A claimed were travel-related,

because Promeca could not provide sufficient receipts. Despite **Orthofix N.V.**'s inability to substantiate approximately \$100,000 in cash advances, until 2010, **Orthofix N.V.** failed to implement any policy changes to prohibit such cash advances.

35. From in or around 2003 until March 2010, **Orthofix N.V.**'s finance personnel, including Orthofix Executive B and Orthofix Executive C, required Promeca to submit to **Orthofix N.V.** monthly reports concerning Promeca's financial performance. Among other things, Promeca was required to report its budget and to compare its actual expenditures to its budget. Promeca's monthly reports showed that Promeca's expenditures regularly far exceeded the budgeted amounts in several categories, including promotional expenses, travel expenses, and meetings for doctors. Those categories were all high risk, received no extra scrutiny, and were in fact budgeted funds from which Promeca made bribe payments over a multi-year period. Despite imposing the monthly reporting requirement upon Promeca, neither Orthofix Executive B nor Orthofix Executive C reviewed Promeca's monthly reports in detail. Instead, Orthofix Executive B and Orthofix Executive C viewed the reports only as a way to encourage Promeca to operate within its budget. As a result, **Orthofix N.V.** failed to identify Promeca's persistent cost overruns or to endeavor to determine the reason for those overruns, and Promeca continued its bribery scheme for approximately seven years after being acquired by **Orthofix N.V.**

36. In or around June 2006 and again in or around December 2008, **Orthofix N.V.** executives summoned Promeca's executives, including Promeca Executive A and Promeca Executive B, to meetings in Boston, during which **Orthofix N.V.** reviewed Promeca's operations, revenues, and costs. Although Promeca's books accurately reflected significant cost overruns in categories in which Promeca disguised illicit payments, **Orthofix N.V.** personnel failed to discover those illicit payments.

37. On one occasion, Orthofix Executive B heard Orthofix Executive A and Promeca's executives refer to the payment of "chocolates" as a common feature in Mexico's medical-device market. When Orthofix Executive B discussed the payment of "chocolates" with Orthofix Executive A, Orthofix Executive A stated that Promeca's competitors in Mexico were paying "chocolates," and that most companies disguised the "chocolates" on their books as training, promotional, and other sales-related expenses. When Orthofix Executive B told Orthofix Executive A that standard audits of Promeca would detect such payments, Orthofix Executive A responded only that Orthofix Inc.'s finance department and auditors would be unable to detect whether Promeca was paying "chocolates." Orthofix Executive B failed to follow up on Orthofix Executive B's conversation with Orthofix Executive A or to report the conversation to **Orthofix N.V.** or Orthofix Inc.'s compliance personnel. **Orthofix N.V.**'s audits of Promeca consisted only of standard audits mandated by Mexican statute and did not include within the scope of the audit an anti-corruption review.

VIOLATION OF THE FOREIGN CORRUPT PRACTICES ACT

38. From in or about 2003 through in or about March 2010, within the Eastern District of Texas and elsewhere, **Orthofix N.V.**, knowingly and willfully failed to maintain a system of internal controls sufficient to provide reasonable assurances that: (i) transactions were executed in accordance with management's general or specific authorization; (ii) transactions were recorded as necessary to (A) permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (B) maintain accountability for assets; (iii) access to assets was permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for

assets was compared with the existing assets at reasonable intervals, and appropriate action was taken with respect to any differences, *to wit*: the defendant knowingly: (a) failed to adequately train key personnel to implement internal accounting controls meant to detect and avoid illegal payments and to identify and deter violations of those controls; (b) failed to identify and address obvious risks associated with **Orthofix N.V.**'s sales in Mexico and the operations of its subsidiary; (c) failed to monitor and control the financial transactions of its

Mexican subsidiary in a manner that provided reasonable assurances that its Mexican subsidiary's transactions were executed in accordance with management's general or specific authorization; and (d) failed to monitor and control the financial transactions of its Mexican subsidiary in a manner that provided reasonable assurances that its Mexican subsidiary's transactions were recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and any other criteria applicable to such statements.

In violation of 15 U.S.C. § 78m(b)(2)(B).

Respectfully submitted,

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Date:

July 10, 2012

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