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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. ZIMMER BIOMET HOLDINGS, INC., Defendant.	CRIMINAL NO. 12-CR-00080 RBW VIOLATIONS: 15 U.S.C. §§ 78m (Foreign Corrupt Practices Act)

SUPERSEDING INFORMATION

The United States Department of Justice, Criminal Division, Fraud Section, charges as follows:

At all times material to this Information (unless specified otherwise):

GENERAL ALLEGATIONS

Relevant Statutory Background

1. The Foreign Corrupt Practices Act of 1977, as amended, Title 15, United States Code, Sections 78dd-1, et seq. ("FCPA"), was enacted by Congress for the purpose of, among other things, making it unlawful to act corruptly in furtherance of an offer, promise, authorization, or payment of money or anything of value, directly or indirectly, to a foreign official for the purpose of obtaining or retaining business for, or directing business to, any person. The FCPA's accounting provisions, among other things, require that any issuer make and keep books, records, and accounts that accurately and fairly reflect the transactions and disposition of the company's assets, prohibit the knowing and willful falsification of an issuer's

books, records, or accounts, and prohibit the knowing and willful failure to implement an adequate system of internal accounting controls. 15 U.S.C. §§ 78m(b)(2), 78m(b)(5), and 78ff(a).

Relevant Entities and Individuals

2. Defendant ZIMMER BIOMET HOLDINGS, INC. ("ZIMMER BIOMET") was an orthopedic medical and dental device manufacturer incorporated in Delaware with its headquarters in Warsaw, Indiana.

3. Biomet, Inc. ("Biomet") was an orthopedic medical and dental device manufacturer incorporated in Indiana. Biomet sold its products worldwide. At all times material to this Statement of Facts, Biomet was an "issuer" within the meaning of the FCPA, 15 U.S.C. §§ 78dd-1 and 78m.

4. On or about March 26, 2012, Biomet entered into a deferred prosecution agreement with the Fraud Section (the "2012 DPA") arising out of Biomet's FCPA violations in Brazil, China, and Argentina. The FCPA violations in Brazil included bribes carried out by the "Brazilian Distributor" described below.

5. In June 2015, Zimmer Holdings, Inc. ("Zimmer") acquired LVB Acquisition, Inc., which owned all of Biomet, Inc. ("Biomet"). The combined entities and their subsidiaries became defendant ZIMMER BIOMET, headquartered in Warsaw, Indiana and incorporated in Delaware. Thus, ZIMMER BIOMET knowingly assumed all the rights and obligations of Biomet under the 2012 DPA, including under the compliance monitorship that was part of the 2012 DPA.

6. As the result of the acquisition that occurred in June 2015, ZIMMER BIOMET assumed the obligations of Biomet under the 2012 DPA and became Biomet's successor-in-interest for purposes of the 2012 DPA and Biomet's conduct described below.

7. Biomet International, Ltd. ("Biomet International"), a wholly-owned subsidiary of Biomet, was incorporated in Delaware. Prior to May 2008, Biomet sold its products through Biomet International using "Brazilian Distributor." Biomet International's financial statements were consolidated into Biomet's financial statements.

8. Implant Innovations Holdings, LLC ("IIH"), a wholly-owned subsidiary of Biomet, owned several subsidiaries, including Biomet 3i, LLC ("Biomet 3i"), which was incorporated in Florida. Biomet 3i marketed and sold dental implants and related products. Biomet 3i was Biomet's fourth-largest subsidiary by revenues. Biomet 3i's financial statements were consolidated into IIH's financial statements, which were consolidated into Biomet's financial statements.

9. Biomet 3i Mexico S.A. de C.V. ("3i Mexico"), which was incorporated in Mexico, was owned by JERDS Luxembourg Holding S.àr.l. ("JERDS"), a wholly-owned subsidiary of IIH. 3i Mexico marketed and sold Biomet 3i's products in Mexico. 3i Mexico's financial statements were consolidated into JERDS's financial statements, which were eventually consolidated into Biomet's financial statements.

10. "Brazilian Distributor Company A," a Brazilian company whose identity is known to the United States and ZIMMER BIOMET, had exclusive distribution rights for certain Biomet products in Brazil prior to May 2008.

11. "Brazilian Distributor Company B," a company whose identity is known to the United States and ZIMMER BIOMET, distributed Biomet's products in Brazil.

12. "Brazilian Distributor," an individual whose identity is known to the United States and ZIMMER BIOMET, was the principal owner of Brazilian Distributor Company A and at relevant times controlled Brazilian Distributor Company B.

13. "Mexico Customs Broker," a company whose identity is known to the United States and ZIMMER BIOMET, is a customs broker that 3i Mexico hired to import products from the United States to Mexico.

14. "Shipping Company," a company whose identity is known to the United States and ZIMMER BIOMET, is a shipping company in Texas that worked with Mexico Customs Broker to export Biomet 3i's products from the United States to Mexico.

15. "Biomet Executive," an individual whose identity is known to the United States and ZIMMER BIOMET, was an attorney at Biomet and Biomet International during the relevant period and became a high-level attorney during that period. Biomet Executive's responsibilities included ensuring that Biomet had effective internal accounting controls, such as third-party due diligence, and implementing Biomet's internal accounting controls. Biomet Executive was also responsible for addressing the requirements of Biomet's FCPA monitor with respect to Biomet International.

16. "3i Mexico Managing Director," an individual whose identity is known to the United States and ZIMMER BIOMET, was an employee of 3i Mexico.

17. "Biomet International Managing Director," an individual whose identity is known to the United States and ZIMMER BIOMET, was Biomet International's Managing Director for South America.

18. "3i Mexico Employee," an individual whose identity is known to the United States and ZIMMER BIOMET, was an employee of 3i Mexico.

The Unlawful Schemes

19. At all relevant times, Biomet exported products to, and sold those products in, countries with a high risk for corruption, including Mexico and Brazil. Despite being aware of red flags and prior corruption-related misconduct at Biomet's subsidiaries in Mexico and Brazil, and despite entering into the 2012 DPA both in connection with corruption in Brazil and other countries relating to Biomet's distributors, and as a consequence of its failure to implement internal accounting controls, Biomet knowingly failed to implement and maintain an adequate system of internal accounting controls designed to detect and prevent bribery by its agents and business partners. As a result, Biomet's subsidiary in Mexico paid bribes to customs officials through an agent and its sub-agents. Biomet further did not conduct appropriate due diligence on proposed agents and business partners or require adequate controls for payments to third parties, which also resulted in bribes being paid in Mexico, as well as the use of a distributor in Brazil whom Biomet knew had previously paid bribes on its behalf.

20. Specifically, in connection with the 2012 DPA, Biomet knew that Brazilian Distributor previously had paid bribes to win business for Biomet through Brazilian Distributor Company A, and as a result, Biomet had prohibited its employees from using all companies affiliated with Brazilian Distributor. Despite knowing this, Biomet, through its employees and agents, including Biomet Executive, allowed Brazilian Distributor to sell, import, and market its products through Brazilian Distributor Company B and took steps to conceal Brazilian Distributor's relationship with Brazilian Distributor Company B.

21. In Mexico, despite being aware of red flags and issues concerning due diligence, and its obligations under the 2012 DPA, Biomet's employees failed to implement due diligence procedures or payment authorization controls to ensure that payments were made in accordance with Biomet's policies. As a result, Biomet's subsidiaries used a customs broker whose

subagents bribed Mexican customs officials to allow Biomet to export mislabeled products to Mexico. Between in or around 2010 and 2013, 3i Mexico paid approximately $980,774 to the customs broker's subagents knowing that at least part of this amount would be passed on to customs officials, and falsified corporate records to disguise the bribe payments.

Brazil

22. Brazil has a public healthcare system that provides universal health care to all Brazilian citizens, and the majority of hospitals in Brazil are government instrumentalities. Health care providers ("HCPs") who work in Brazil's public sector are government employees who provide health care services in their official capacities, and are "foreign officials" as that term is used in the FCPA. Biomet and its subsidiaries sold Biomet's medical devices in Brazil through distributors.

23. Prior to May 2008, Biomet used Brazilian Distributor Company A and its owner, Brazilian Distributor, to distribute its products in Brazil. In or around April 2008, Biomet was considering acquiring Brazilian Distributor Company A and sent accountants and outside counsel to Brazil to conduct due diligence as part of the acquisition. During Biomet's due diligence, Biomet Executive and others at Biomet discovered that Brazilian Distributor Company A and Brazilian Distributor had been bribing HCPs to use Biomet's products. Indeed, during a meeting in or around April 2008, Brazilian Distributor admitted to Biomet Executive and others at Biomet that he had bribed HCPs so that they would use Biomet's products.

24. On or about May 2, 2008, Biomet notified Brazilian Distributor that Biomet had "uncovered highly disconcerting information regarding [Brazilian Distributor]'s business practices" and that Biomet was "immediately terminating its business relationship with [Brazilian Distributor Company A]." At or about the same time, Biomet International's senior

leadership was advised that Biomet could not do any further business with Brazilian Distributor. Biomet, through Biomet International, then suspended its operations in Brazil until it could contract with new distributors who would be subject to new due diligence procedures.

25. In or around June 2009, Biomet signed an agreement with Brazilian Distributor and Brazilian Distributor Company A terminating their relationship to ensure that bribes were not paid to sell its products. The agreement prohibited Brazilian Distributor from "directly or indirectly . . . importing, storing, promoting, distributing or in any way marketing in Brazil the products made by Biomet."

26. Despite this prohibition, from in or around 2009 until in or around 2013, Biomet continued to use Brazilian Distributor and one of his affiliated companies, Brazilian Distributor Company B, and knowingly and willfully failed to implement additional controls to ensure that Brazilian Distributor and Brazilian Distributor Company B would not pay bribes or maintain its affiliation with Brazilian Distributor.

27. In or around 2009, Biomet, through Biomet International, began using Brazilian Distributor Company B to distribute its products in Brazil. On or about December 17, 2009, one of Biomet's internal auditors sent an email to Biomet Executive stating that "I am working on a draft report [regarding Brazilian Distributor Company B and two other companies] . . . The relationship between [Brazilian Distributor Company A] and [Brazilian Distributor Company B] is unclear and did not leave us with a high level of comfort." At or around the same time, the internal auditor in charge of the review prepared a draft internal audit memorandum summarizing his findings and recommendations. That memorandum noted that Brazilian Distributor was a "main shareholder" of Brazilian Distributor Company A and was responsible for paying bribes to sell Biomet's products in the past. The memorandum recommended that

Brazilian Distributor Company B terminate its relationship with Brazilian Distributor Company A.

28. Biomet executives involved in developing, approving, and implementing Biomet's internal accounting controls and anti-corruption program, including Biomet Executive, knew that Biomet was not implementing the internal accounting controls, policies, and procedures that Biomet approved to prevent or detect bribery of foreign officials.

29. For example, on or about January 7, 2010, Biomet Executive received a draft version of the memorandum discussed above in Paragraph 27, which recommended that Biomet ensure that "the relationship between [Brazilian Distributor Company A and Brazilian Distributor Company B] is separated completely." Biomet Executive deleted that recommendation from the memorandum and, as a result, the final version of the memorandum, did not include the recommendation that Brazilian Distributor Company A and Brazilian Distributor Company B separate their relationship.

30. On or about April 30, 2010, Biomet learned that Brazilian Distributor was not only affiliated with Brazilian Distributor Company B, but had control of Brazilian Distributor Company B, which marketed and sold Biomet's products. On that day, an attorney representing a co-owner of Brazilian Distributor Company B contacted Biomet Executive and other Biomet International executives and reported that the co-owner had lost control of Brazilian Distributor Company B to Brazilian Distributor. As a result of learning this, Biomet Executive contacted an attorney representing Brazilian Distributor and asked for more information about Brazilian Distributor's relationship with Brazilian Distributor Company B. Brazilian Distributor's attorney told Biomet Executive that Brazilian Distributor was not involved in Brazilian Distributor Company B's operations or with the sale of Biomet's products. Biomet Executive

did not take any other actions to determine whether Brazilian Distributor had a role in Brazilian Distributor Company B.

31. On or about May 12, 2010, Biomet International Managing Director sent a PowerPoint presentation to another Biomet executive in Indiana which stated: "[Brazilian Distributor Company B] = [Brazilian Distributor]."

32. On or about June 10, 2010, Brazilian Distributor sent an email to Biomet International Managing Director in which Brazilian Distributor requested a personal meeting in Argentina to discuss, as translated from Spanish, "registers, price policy, tours, Warsaw[, Indiana, the city where Biomet was headquartered,] meeting, etc.," and cautioned that, "I think that some things would be better to discuss in person." Biomet International Managing Director agreed to meet with Brazilian Distributor.

33. On or about June 24, 2010, Brazilian Distributor Company B and Brazilian Distributor executed a contract for the provision of "Business Consulting Services" under which Brazilian Distributor would: train Brazilian Distributor Company B's sales team about Biomet's products; develop a sales plan, quotas, and market projections for Brazilian Distributor Company B's sales of Biomet products; and perform orientation on the logistics, storage, and delivery of Biomet products. Brazilian Distributor received a flat rate of 5,000 Brazilian Reals per month and a 1% commission on monthly sales increases. In an amendment to the consulting agreement, Brazilian Distributor Company B agreed to provide Brazilian Distributor with a residence in São Paolo, Brazil.

34. On or about June 27, 2010, Brazilian Distributor and Biomet International Managing Director met to discuss Biomet's marketing, sales, and distribution strategies in

Brazil. Notes taken by a Biomet International employee during that meeting, as translated from Spanish, identified Brazilian Distributor as an "advisor" to Brazilian Distributor Company B.

35. On or about June 29, 2010, Biomet International Managing Director sent an email to other Biomet employees, including Biomet Executive, with the subject line "[Brazilian Distributor Company B] Second Amendment to Distribution Agreement." Biomet International Managing Director gave the following instructions: "[P]lease reduce the total invoices of [Brazilian Distributor Company B's] account from the agreement . . . When you have the final agreement please send it to [Brazilian Distributor's attorney] for [Brazilian Distributor's] signature."

36. Beginning in or around July 2010, Brazilian Distributor Company B placed product orders with Biomet International, and Brazilian Distributor wired funds from his personal bank account to Biomet International to pay for some of those products. Biomet International shipped those products to Brazilian Distributor Company B in Brazil using a freight forwarder in Miami, and Brazilian Distributor Company B paid Brazilian Distributor cash to cover customs, duties, and the cost of the products. Brazilian Distributor or his agent, with Biomet's knowledge, imported the products at the São Paolo, Brazil airport, paid customs and duties, and deposited the remainder of the cash into Brazilian Distributor's personal bank account.

37. On or about July 5, 2010, Brazilian Distributor Company B contacted Biomet International Managing Director and requested permission to sell Biomet's products to Brazilian Distributor Company A. Biomet International Managing Director notified Biomet Executive and the President of Biomet International.

38. On or about July 8, 2010, an attorney representing both Brazilian Distributor and Brazilian Distributor Company B contacted Biomet Executive and two other Biomet International executives by email. The attorney reported that Brazilian Distributor Company B faced an import restriction because Brazilian Distributor Company B was a "new product registration user" under Brazilian law and, consequently, could import only $150,000 worth of products every six months. The attorney representing both Brazilian Distributor and Brazilian Distributor Company B proposed to overcome this restriction by having Brazilian Distributor Company A import Biomet products directly on behalf of Brazilian Distributor Company B.

39. In response to the email referenced in Paragraph 38 above, Biomet Executive, knowing that Biomet was prohibited from using Brazilian Distributor Company A and Brazilian Distributor, and that Brazilian Distributor owned Brazilian Distributor Company A, replied to all of the recipients on the email in Paragraph 38 and stated: "Yes- We are fine with the solution and believe it is covered in our current [June 2009] agreement."

40. On or about November 8, 2011, Biomet Executive received an email message from Brazilian Distributor's attorney requesting permission for Brazilian Distributor to attend a cadaver lab event at Biomet's headquarters in Indiana. Brazilian Distributor's attorney cited Brazilian Distributor's consulting agreement with Brazilian Distributor Company B as grounds for Brazilian Distributor's attendance.

41. On or about March 26, 2012, Biomet entered into the 2012 DPA.

42. On or about May 23, 2012, Brazilian Distributor wired approximately $38,400 from his personal bank account to Biomet's bank account in Indiana for the purchase of Biomet products to be shipped to Brazil.

43. Between on or about June 13, 2013, and on or about June 15, 2013, Brazilian Distributor attended a two-day launch meeting in Brazil, prior to which he had dinner with Biomet employees and HCP consultants to Biomet.

44. Between in or around 2009 and 2013, Biomet earned approximately $3,168,000 in profits from sales of its products in Brazil through Brazilian Distributor and Brazilian Distributor Company B, some of which Brazilian Distributor Company A had imported for Brazilian Distributor Company B.

Mexico

45. Beginning in or around no later than April 2008, Biomet became aware that certain of its third-party distributors, including a third-party distributor in Latin America, were making corrupt payments to HCPs to secure sales of Biomet products. Nevertheless, Biomet did not implement internal accounting controls to prevent future corrupt payments in Mexico, among other places. From in or around 2010 to in or around 2013, Biomet's knowing and willful failure to implement internal accounting controls sufficient to detect and prevent bribes from being paid at 3i Mexico resulted in 3i Mexico's using Mexico Customs Broker and its subagents to bribe Mexican customs officials to smuggle unregistered and improperly-labeled dental products into Mexico.

46. 3i Mexico sold Biomet 3i's dental products in Mexico, which were regulated under Mexican law; Mexican law required proper labeling, identification of the product's country of origin, and a valid product registration issued by Mexican regulatory authorities.

47. In or about January 2009, 3i Mexico began having difficulty importing some of Biomet 3i's membrane products into Mexico because of problems with their product

registrations. At one point, customs authorities at the Mexico City Airport detained shipments destined for 3i Mexico due to product registration problems.

48. On or about January 7, 2009, several individuals at Biomet 3i's headquarters in Florida received an email from the then-general manager of 3i Mexico who proposed that 3i Mexico use a Texas-based customs agent to bring unregistered membrane products into Mexico through Texas.

49. On or about January 19, 2009, soon after 3i Mexico learned that the registration for a specific type of membrane was not current, a senior manager in Biomet 3i's regulatory affairs department – the head of Latin American regulatory affairs – requested that all shipments of membranes to Mexico be placed on hold until further notice.

50. On or about January 28, 2009, the managing director of a Biomet subsidiary in Mexico advised the senior manager and head of Biomet 3i's regulatory affairs department for Latin America in an email message that importing dental implants without a valid registration from Mexico's Secretary of Health was a crime.

51. In or around February 2009, Biomet Executive undertook a compliance assessment of another Biomet subsidiary in Mexico. One of the findings in that compliance assessment was that the subsidiary had used a third-party "consultant" to expedite customs shipments at the border. The subsidiary had used the consultant to import products that would have been delayed in customs due to problems with the products' licenses if they had been shipped via the Mexico City Airport. The consultant did not have the requisite credentials to carry out import and export activities. The assessment stated that using the consultant was a risk and noted that Biomet Corporate had labelled the consultant "higher risk." In response to the assessment, the subsidiary terminated its relationship with the consultant, but Biomet did not

implement controls to ensure that 3i Mexico did not use third parties who engaged in similar high risk activities. Prior to this time, both Biomet's subsidiary and 3i Mexico had used the consultant to import products.

52. In or around 2010, 3i Mexico began having difficulty importing its products into Mexico from the United States via the airport in Mexico City. Some of the shipments were stopped by Mexican customs officials because the products were mislabeled, lacked proper country of origin markings, and did not have valid product registrations with the Mexican government.

53. In response to these issues, 3i Mexico's agents and employees developed a scheme to avoid those problems: first, Biomet 3i would ship certain Biomet 3i products to an address in Texas provided by Mexico Customs Broker; second, Mexico Customs Broker would segregate the products into two sets of products – those products that were properly labeled and registered under Mexican law, and those products that were not properly labeled and registered and thus contraband; third, Mexico Customs Broker would transport all of the compliant products across the border to Mexico, but one of Mexico Customs Broker's subagents would bribe Mexican customs officials so that the contraband dental products could cross the border illegally.

54. 3i Mexico did not have a written contract with Mexico Customs Broker or its subagents even though they were providing services in a country and industry with high corruption risks. 3i Mexico also did not receive anticorruption representations from Mexico Customs Broker or its subagents.

55. Biomet did not implement internal accounting controls to ensure that 3i Mexico would undertake those tasks. In addition, 3i Mexico knew that Mexico Customs Broker's

subagents would pay bribes and that there was no legitimate reason to use subagents when it had retained Mexico Customs Broker as its customs broker.

56. On or about March 17, 2010, an employee at Mexico Customs Broker sent an email message to 3i Mexico Managing Director and 3i Mexico Employee which read as follows: "here is the procedure that will be followed to release shipments through [Texas] customs: Deliver the shipment to [Shipping Company's address], Attn: [an employee at Shipping Company]. The person responsible for carrying out this step, will go to our warehouse and afterwards will send us the quotation." 3i Mexico Employee knew that Mexico Customs Broker's subagents would bribe Mexican customs officials to ensure that the mislabeled products would be imported into Mexico.

57. On or about April 8, 2010, 3i Mexico Managing Director wrote an email to five other Biomet 3i and 3i Mexico employees and stated that they had problems getting shipments through customs at Mexico City's airport because some product labels indicated that they were manufactured in countries other than the United States, while the product registrations stated that they were manufactured in the United States. 3i Mexico Managing Director recommended that Biomet 3i ship the products to Shipping Company's office because at "the border they have more flexibility to access and import the products according to the right procedures. The details of the broker are: [Shipping Company's address], Attn: [an employee at Shipping Company]."

58. On or about April 9, 2010, 3i Mexico Managing Director wrote the following in an email to a 3i Mexico employee and two other Biomet 3i employees: "Ok lets [*sic*] do the following . . . lets [*sic*] return all previous shipment[s] to [Biomet 3i's office] and you send us 1 new shipment with all the [back order items] to Texas, then we normalize the inventory and return to weekly shipments using only items made in USA and the rest special shipments using

[Texas]." The 3i Mexico employee knew that Mexico Customs Broker's subagents were being paid large amounts of money to smuggle the mislabeled products into Mexico.

59. On or about April 9, 2010, 3i Mexico Managing Director sent an email to the senior manager who was the head of Biomet 3i's regulatory affairs department for Latin America, stating, as translated from Spanish to English, that because of problems with illegal drugs being smuggled into Mexico City's airport, Mexican authorities had reinforced border controls over health products. 3i Mexico Managing Director wrote that customs agents had recommended "that we use the border and in this case [Texas] because at this entry point the authorities are not as strict since from the US to Mexico there is no problem with prohibited substances, indeed it is the reverse."

60. On or about April 9, 2010, the senior manager who was the head of Biomet 3i's regulatory affairs department for Latin America, responded to 3i Mexico Managing Director by email and stated, as translated from Spanish to English: "I understand completely—how do we set this up so that the product enters through [Texas]?"

61. On or about April 9, 2010, 3i Mexico Managing Director responded to the senior manager who was the head of Biomet 3i's regulatory department for Latin America by email, stating, as translated from Spanish to English: "[two employees] are already working to send this Friday's shipment to [Texas]."

62. On or about March 26, 2012, Biomet entered into the 2012 DPA.

63. On or about April 27, 2012, an employee in Biomet 3i's regulatory department sent 3i Mexico Managing Director an email message and said that Biomet 3i could not import a particular ceramic dental cement into Mexico because it did not have the necessary importation license. 3i Mexico Managing Director responded that customs officials at Mexico City's airport

would require the importation license, so Biomet 3i was instead using Mexico Customs Broker to ship the products through the border at Texas.

64. On or about July 27, 2012, an employee at Mexico Customs Broker sent an email to 3i Mexico Employee and another employee at Mexico Customs Broker and stated, as translated from Spanish to English: "I attached the prepayment request and proforma of this week's shipment. Taxes on models with registry [MX]$26,900.00. American account, deliver, digitization and fees MX$18,009.00 (vat included). Taxes on models without registry MX$115860.00 (vat included)."

65. On or about July 30, 2012, one of Mexico Customs Broker's subagents sent an invoice to 3i Mexico requesting payment of approximately MX$115,860 for "servicios profesionales" with no further description of the services provided.

66. On or about July 30, 2012, 3i Mexico Managing Director caused a wire transfer in the amount of approximately MX$44,909 (the amount of the taxes and fees in the prepayment request identified in Paragraph 64) to be made from a 3i Mexico bank account in Mexico to Mexico Customs Broker's bank account in Mexico. That same day, 3i Mexico Managing Director caused a wire transfer in the amount of approximately MX$115,860 (the same amount as one of the prepayment requests identified in Paragraph 64 and the invoice identified in Paragraph 65 that one of Mexico Customs Broker's subagents sent to 3i Mexico) to be made from the same 3i Mexico bank account in Mexico to the bank account of Mexico Customs Broker's subagent in Mexico.

67. On or about July 30, 2012, 3i Mexico Employee sent an email to an employee at Mexico Customs Broker, stating, as translated from Spanish to English: "I attach copies of the deposits, will you know [*sic*] something about the merchandise." Wire transfer records

reflecting the two wire transfers authorized that same day by 3i Mexico Managing Director were attached to that email.

68. On or about July 31, 2012, Mexico Customs Broker sent an invoice to 3i Mexico requesting payment of approximately MX$44,909 for Mexico Customs Broker's services in transporting a shipment of dental implants to 3i Mexico's address in Mexico City, Mexico. The invoice was supported by a shipping record explaining the items that Mexico Customs Broker had imported on behalf of 3i Mexico.

69. On or about July 31, 2012, 3i Mexico Employee recorded the two wire transfers from the previous day in 3i Mexico's accounting system as three payments to Mexico Customs Broker totaling approximately MX$160,769, which was equal to the combined amount of the invoices sent on July 30, 2012 and July 31, 2012. 3i Mexico Employee recorded each of the wire transfers as payments to Mexico Customs Broker even though 3i Mexico made one of those payments to Mexico Customs Broker's subagent instead of Mexico Customs Broker. 3i Mexico Employee made no separate record of any payment to Mexico Customs Broker's subagent. The payments were then recorded in the general ledger for 3i Mexico as payments to Mexico Customs Broker for customs services and later consolidated into JERDS's financial statements, which were consolidated into Biomet's financial statements.

70. Between in or around 2010 and 2013, 3i Mexico paid approximately $980,774 to Mexico Customs Broker in connection with clearing Biomet 3i products.

71. Between in or around 2010 and 2013, 3i Mexico and Biomet's Mexican subsidiary earned approximately $2,652,100 in profits from sales of products in Mexico that were shipped through Texas.

Biomet's Internal Accounting Controls

72. During the relevant period, even though Biomet was aware of high corruption risks and having entered into the 2012 DPA based in part on corruption in Argentina and Brazil relating to its distributors and its failure to implement internal accounting controls, Biomet knowingly and willfully failed to devise and maintain an adequate system of internal accounting controls. In particular, and as relevant here, Biomet had inadequate internal accounting controls to, among other things: (a) ensure that the company would conduct adequate due diligence for the retention of third-party consultants and agents; (b) ensure that Biomet not continue to contract with or use directly or indirectly third-party consultants and agents who Biomet determined had engaged in corrupt practices and were prohibited from importing, storing, promoting, distributing, or marketing its products; (c) implement oversight of the payment process to ensure that payments were made pursuant to appropriate controls, including those that verified that payments were made only when invoices accurately described the goods or services rendered in exchange for the payment and the party rendering the goods or services; (d) ensure that standard contracts were used when retaining third parties who interacted with government officials; and (e) ensure that third parties did not retain subagents without Biomet's approval, especially in high-risk areas where the third parties interacted with foreign government officials.

73. For example, in connection with the Brazil scheme, senior Biomet employees allowed Brazilian Distributor to purchase, import, and market Biomet's products in Brazil even after Brazilian Distributor had admitted to bribing HCPs and after Biomet terminated its relationship with Brazilian Distributor and prohibited its employees from working with Brazilian Distributor.

74. Furthermore, Biomet's inadequate due diligence on Brazilian Distributor Company B failed to identify that Brazilian Distributor used Brazilian Distributor Company B to hide Brazilian Distributor's continued marketing of Biomet's products.

75. In addition, when Biomet's internal audit team learned that Brazilian Distributor controlled Brazilian Distributor Company B, Biomet did not terminate its relationship with Brazilian Distributor Company B until several years later and failed to implement controls to ensure that Brazilian Distributor was not paying bribes on behalf of Biomet.

76. Further, in connection with the Mexico scheme, Biomet did not require 3i Mexico to conduct adequate due diligence on third parties, especially those that worked in high-risk areas, such as third parties that interacted with customs officials in Mexico.

77. Biomet also did not prohibit third parties, including its customs brokers in Mexico, who interacted with Mexican government officials from hiring subagents to perform work for Biomet without Biomet's approval or without Biomet's ability to conduct due diligence.

78. Moreover, Biomet did not implement controls to ensure that 3i Mexico made payments only when invoices accurately described the goods or services rendered in exchange for the payment and the entity that performed the service.

COUNT ONE
(Violation of the Internal Controls Provisions of the FCPA)

79. Paragraphs 1 through 78 are realleged and incorporated by reference as though fully set forth herein.

80. From in or around 2009, and continuing through in or around 2013, the defendant,

ZIMMER BIOMET HOLDINGS, INC.,

knowingly and willfully failed to implement a system of internal accounting 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 and willfully failed to implement, among other internal accounting controls, controls that: (a) required adequate due diligence for the retention of third-party consultants and agents; (b) required a fully executed contract with a third-party before payment could be made to it; (c) required documentation or other proof that services had been rendered by a third-party before payment could be made to it; or (d) implemented oversight

of the payment process to ensure that payments were made pursuant to appropriate controls, including those described above, in violation of Title 15, United States Code, Section 78m(b)(2)(B), 78m(b)(5), and 78ff(a).

ANDREW WEISSMANN
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BY: _____

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