

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon. Madeline Cox Arleo  
v. :  
SMITH & NEPHEW, INC. : Mag No. 07-8132 (MCA)

ORDER FOR CONTINUANCE

This matter having come before the Court on the application of Christopher J. Christie, United States Attorney for the District of New Jersey (by Kevin M. O'Dowd, Assistant U.S. Attorney), with the consent of David Vicinanza, Esq., attorney for defendant SMITH & NEPHEW, INC., ("SMITH & NEPHEW"), for an order granting a continuance of the proceedings in the above-captioned matter for a period of eighteen (18) months pursuant to a Deferred Prosecution Agreement executed by the U.S. Attorney's Office and SMITH & NEPHEW and attached hereto as Exhibit A, and SMITH & NEPHEW being aware that it has the right to have the matter submitted to a grand jury within thirty days of the date of service of summons pursuant to Title 18 of the United States Code, Section 3161(b), and SMITH & NEPHEW having consented to the continuance in the above-captioned matter, and it appearing that SMITH & NEPHEW waives such right, and for good cause shown,

IT IS THE FINDING OF THIS COURT that this action should be continued for the following reasons:

(1) The United States and SMITH & NEPHEW have entered into, and desire additional time to allow the implementation of, the Deferred Prosecution Agreement for the purpose of allowing SMITH & NEPHEW to demonstrate its good conduct, successful completion of which would render any grand jury proceedings and any subsequent trial of this matter unnecessary;

(2) Pursuant to Title 18 of the United States Code, Section 3161(h)(2) and (8), the ends of justice served by granting the continuance outweigh the best interest of the public and SMITH & NEPHEW in a speedy trial.

WHEREFORE, IT IS on this 28 day of September, 2007,

ORDERED that this action be, and it hereby is, continued for a period of eighteen (18) months from September 27, 2007; and it is

FURTHER ORDERED that the period between September 27, 2007 and March 27, 2009, shall be excludable in computing time under the Speedy Trial Act of 1974.

  
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HON. MADELINE COX ARLEO  
United States Magistrate Judge

Exhibit A

**Deferred Prosecution Agreement**

1. Smith & Nephew, Inc., a wholly owned subsidiary of Smith & Nephew plc, by its undersigned attorneys, pursuant to authority granted by the Board of Directors of Smith & Nephew, Inc. and Smith & Nephew plc, and the United States Attorney's Office for the District of New Jersey (the "Office"), enter into this Deferred Prosecution Agreement (the "DPA") relative to the conduct of Smith & Nephew, Inc.'s unincorporated Orthopedic Reconstruction Global Business Unit (the "Company"). Except as specifically provided below, the DPA shall be in effect for a period of eighteen (18) months from the date it is fully executed (the "Effective Date").

2. The Office has informed the Company that it will file, on or shortly after the Effective Date of this DPA, a criminal complaint in the United States District Court for the District of New Jersey charging the Company with conspiracy to commit violations of the Federal Anti-Kickback Statute, contrary to Title 42, United States Code, Sections 1320a - 7b, in violation of Title 18, United States Code, Section 371, during the years 2002 through 2006 (the "Criminal Complaint"). This Office acknowledges that neither this DPA nor the Criminal Complaint alleges the Company's conduct adversely affected patient health or patient care.

3. The Company and the Office agree that, upon filing of the Criminal Complaint in accordance with the preceding paragraph, this DPA shall be publicly filed in the United States District Court for the District of New Jersey, and the Company agrees to post the DPA prominently on the Company website for the duration of the DPA.

4. In light of the Company's remedial actions to date and its willingness to (a) undertake additional remediation as necessary; (b) acknowledge responsibility for its behavior; (c) continue its cooperation with the Office and other government agencies; and (d) demonstrate its good faith and commitment to full compliance with federal health care laws, the Office shall recommend to the Court that prosecution of the Company on the Criminal Complaint be deferred for a period of eighteen (18) months from the filing date of such Criminal Complaint. If the Court declines to defer prosecution for any reason, this DPA shall be null and void, and the parties will revert to their pre-DPA positions.

5. The Office acknowledges that, to date, the Company has taken actions to develop a robust compliance program to protect against violations of federal health care laws. These actions include: the appointment of key personnel with enforcement responsibilities; the development of policies and procedures governing R&D project/program approval and selection and engagement of potential service providers; the requirement of consistent, accurate reporting of services performed on behalf of the Company; and ongoing monitoring and management of payment processes. The Company continues to commit to these compliance measures, as it strives to foster innovation in medical technology and promote exemplary, cost-effective patient care. The Office agrees with these goals and seeks to ensure that the Company and the

Orthopedic industry at large comply with applicable law in the course of achieving these goals.

**General Commitment to Compliance and Remedial Actions**

6. The Company commits itself to exemplary corporate citizenship, best practices of effective corporate governance, the highest principles of honesty and professionalism, the integrity of the operation of federal health care programs including Medicare and Medicaid, the sanctity of the doctor-patient relationship, and a culture of openness, accountability, and compliance throughout the Company. The Company also commits not to attempt to influence medical practitioners and institutions to use the Company's products through the use of unlawful inducements. To advance and underscore this commitment, the Company agrees to take, or has acknowledged that it has taken, the remedial and compliance measures set forth herein.

7. In matters relating to federal health care laws, the Company will cooperate fully with all federal law enforcement and regulatory agencies, including but not limited to: the Criminal and Civil Divisions of the Office; the United States Department of Justice, Criminal and Civil Divisions; the United States Department of Health and Human Services, Office of Inspector General ("HHS-OIG"); the Federal Bureau of Investigation ("FBI"); and the United States Postal Inspection Service ("USPIS"); provided, however, that such cooperation shall not require the Company's waiver of attorney-client and work product protections or any other applicable legal privileges. Nothing in this DPA shall be construed as a waiver of any applicable attorney-client or work product privileges (hereafter "privilege").

8. The Company shall communicate to its employees and distributors that Company personnel and agents are required to report to the Company any suspected violations of any federal laws, regulations, federal health care program requirements, or internal policies and procedures.

9. The Company shall implement or continue its operation of an effective corporate compliance program and function to ensure that internal controls are in place to prevent recurrence of the activities that resulted in this DPA. The Company shall also develop and implement policies, procedures, and practices designed to ensure compliance with federal health care program requirements, including the Anti-Kickback Statute, with respect to all its dealings with Consultants, as defined herein, and others who cause the purchase of Company orthopedic products in the United States.

10. The Company shall adhere to the AdvaMed Code of Ethics on Interactions with Health Care Professionals. The AdvaMed Code can be found at [www.advamed.org](http://www.advamed.org). The principles set forth in the AdvaMed Code are expressly incorporated as compliance requirements under this DPA.

11. The Company agrees that the Company President, Chief Compliance Officer ("Compliance Officer"), Chief Legal Officer, and appropriate Company executives will meet

quarterly with the Office and the Monitor, in conjunction with the Monitor's quarterly reports described in paragraph 19 herein.

### Definitions

12. "Consultant" is defined as any United States-based orthopedic surgeon, PhD, health care professional, non-physician practitioner, medical fellow, resident or student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for or in anticipation of personal or professional services relating to hip and knee reconstruction and replacement. The term Consultant shall not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or any other types of non-physician professionals or entities excluded from this definition by the Monitor upon recommendation by the Company.

13. "Consulting Agreement" includes all contracts with Consultants for services to be performed on behalf of the Company. This includes, but is not limited to, agreements for compensation, payments, remuneration, honoraria, fellowships, professional meetings, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research, and professional services agreements. The term "Consulting Agreement" also includes agreements to provide grants, donations, sponsorships and other forms of payment to medical educational organizations, medical societies and training institutions.

14. "Consulting Services" or "Services" include any and all professional services provided by a Consultant to or on behalf of the Company.

15. "Payment" shall include any and all compensation or remuneration paid to or for the benefit of Consultants, including but not limited to payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (c.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property. Unless otherwise approved by the Monitor, the Company shall only compensate or remunerate Consultants through direct Payments made pursuant to a Consulting Agreement. The Company shall not knowingly make any Payments to Consultants indirectly, such as through distributors.

### **Retention and Obligations of a Monitor**

16. The Company agrees that until the expiration of this DPA, it will retain an outside, independent individual (the "Monitor") selected by the Office, after consultation with

the Company, to evaluate and monitor the Company's compliance with the DPA. Among the conditions of the Monitor's retention are that the Monitor is independent of the Company, the Monitor works exclusively for and at the direction of the Office, and no attorney-client relationship shall be formed between the Monitor and the Company.

17. The Monitor shall have access to all non-privileged Company documents and information the Monitor determines are reasonably necessary to assist in the execution of his or her duties. The Monitor shall have the authority to meet with any officer, employee, or agent of the Company. The Company shall use its best efforts to have its independent distributors for hip and knee reconstruction and replacement products and their employees and agents fully cooperate and meet with the Monitor as requested. For all distributor agreements for hip and knee reconstruction and replacement products and renewals executed after the Effective Date, the Company shall require provisions allowing the Monitor access to non-privileged relevant documents and information relating to Consulting Agreements and Services, and compliance with all applicable provisions of the DPA.

18. The Monitor shall conduct a review and evaluation of all Company policies, practices, and procedures relating to compliance with the DPA and the following subjects, and report and make written recommendations as necessary ("Recommendations") to the Company and the Office concerning same:

- a. The corporate structure and governance of the Company relative to selecting, engaging, and paying Consultants;
- b. The effectiveness of the procedures and practices at the Company to select, engage, and pay Consultants in exchange for the provision of Services to the Company, as well as the related legal, compliance, research and development, marketing, sales, internal controls, and finance functions;
- c. The effectiveness of the training and education programs in the following areas: federal health care laws concerning relationships between the Company and Consultants; Medicare, Medicaid and other health care benefit programs; ethics; and compliance and corporate governance issues relating to federal health care laws;
- d. The structure and content of agreements memorializing arrangements to engage and pay Consultants in exchange for the provision of Services to the Company, and the Company's payments to Consultants made thereunder. The Monitor shall have access to and may review all previously entered agreements to the extent he or she reasonably deems necessary; and
- e. The influence, actual or potential, over Consultants' selection of Company

products as a result of the financial relationships between the Company and those Consultants.

19. The Monitor shall, *inter alia*:
- a. Monitor and review the Company's compliance with this DPA and all applicable federal health care laws, statutes, regulations, and programs, including the Anti-Kickback Statute, relating to the sale and marketing of hip and knee reconstruction and replacement products;
  - b. As requested by the Office, cooperate with the Criminal and Civil Divisions of the Office, the United States Department of Justice, Criminal and Civil Divisions, HHS-OIG, the FBI and the USPIS, and, as requested by the Office, provide information about the Company's compliance with the terms of this DPA;
  - c. Provide written reports to the Office, on at least a quarterly basis, concerning the Company's compliance with this DPA. In these reports or at other times the Monitor deems appropriate, the Monitor shall make Recommendations to the Company to take any steps he or she reasonably believes are necessary for the Company to comply with the terms of this DPA and enhance future compliance with federal health care laws as related to the sale and marketing of hip and knee reconstruction and replacement products; and, as agreed by the Company or mandated by the Office pursuant to paragraph 47, require the Company to take such steps when it is agreed that such steps are reasonable and necessary for compliance with the DPA. The first report to the Office shall be due three months after the Effective Date, and subsequent reports shall be made quarterly thereafter;
  - d. After consultation with the Company and the Office, and allowing reasonable time for the Company or the Office to object, the Monitor may retain, at the Company's expense, consultants, accountants or other professionals the Monitor reasonably deems necessary to assist the Monitor in the execution of the Monitor's duties. Before retention, these consultants, accountants or other professionals shall provide to the Monitor and the Company a proposed budget. If the Company believes the costs to be unreasonable, the Company may bring the matter to the Office's attention for dispute resolution by the Office;
  - e. Monitor the preparation of and approve the Needs Assessment and any Modifications thereto described in paragraphs 27-29 herein;
  - f. Review and approve all new or renewed Consulting Agreements executed between the Effective Date and the date the Needs Assessment is approved;

- g. Review in his or her discretion any requests for Consulting Services made between the Effective Date and the date the Needs Assessment is approved;
- h. Review in his or her discretion any Payments made to Consultants between the Effective Date and the date the Needs Assessment is approved;
- i. Review and approve in his or her discretion all Consulting Agreements with new Consultants executed after the Needs Assessment is approved;
- j. Review in his or her discretion any Consulting Agreement renewals executed after the Needs Assessment is approved;
- k. Review in his or her discretion any requests for Consulting Services made after the Needs Assessment is approved;
- l. Review in his or her discretion any Payments made to Consultants after the Needs Assessment is approved;
- m. Review in his or her discretion any payments made to CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or other excluded consultants as described in paragraph 12;
- n. Review in his or her discretion any payments made to Consultants as honoraria, fellowships, gifts, donations, charitable contributions and other non-Service payments as described in paragraph 27;
- o. Review and approve any new or substitute Consultants as described in paragraphs 33 and 34 herein;
- p. Approve any changes to the Hourly Rate or any Payments made at a rate other than the Hourly Rate, as described in paragraphs 35-37 herein;
- q. Monitor the Consultant disclosure obligations as described in paragraphs 40-41 herein; and
- r. Monitor the information received by the confidential hotline and e-mail address as described in paragraph 43 herein.

In the event the Monitor opposes any Consulting Agreement, request for Consulting Services, or request for Payment, the Monitor will promptly meet with the Company to discuss his or her concerns. The Consulting Agreement shall not be executed, the Consulting Services shall not be rendered, or the Payment shall not be made unless and until the Monitor's objections



are remedied. All actions of the Monitor in this regard shall be subject to review by the Office and shall not require the Company to breach any existing contractual requirements so long as they comply with all applicable laws. The Office will act promptly to resolve any issues on a good faith and reasonable basis.

20. The Company shall promptly notify the Monitor and the Office in writing of any credible evidence of criminal corporate conduct as well as of any known criminal investigations of any type of the corporation or any of its officers or directors that becomes known to the Company after the Effective Date. In addition, the Company shall promptly notify the Monitor and the Office in writing of any credible evidence of criminal conduct or serious wrongdoing relating to federal health care laws by the Company, its officers, employees and agents. The Company shall provide the Monitor and the Office with all relevant non-privileged documents and information concerning such allegations, including but not limited to internal audit reports, letters threatening litigation, "whistleblower" complaints, civil complaints, and documents produced in civil litigation. In addition, the Company shall report to the Monitor and the Office concerning its planned investigative measures and any resulting remedial measures, internal and external. The Monitor in his or her discretion may conduct an investigation into any such matters; and nothing in this paragraph shall be construed as limiting the ability of the Monitor to investigate and report to the Company and the Office concerning such matters.

### Remedial Measures

#### Responsibilities of Compliance Office

21. The Office of Ethics and Compliance ("Compliance Office") and Compliance Officer of the Company shall be responsible for monitoring the day-to-day compliance activities of the Company. The Compliance Officer shall report directly to the Company President and the Chief Compliance Officer of Smith & Nephew plc and shall not be a subordinate to the Chief Legal Officer, the Chief Financial Officer, or any sales or marketing officers. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters to the Company President and the Chief Compliance Officer of Smith & Nephew plc, who is authorized to report on such matters directly to the Smith & Nephew plc Board of Directors at any time.

22. The Compliance Officer shall have the authority to meet with, and require reports and certifications on any subject from, any officer or employee of the Company.

23. The Compliance Office shall be responsible for oversight, evaluation, and approval of the Company's Needs Assessments (described more fully at paragraphs 27-29), and shall evaluate and approve requests for Consulting Agreements, Services, and Payments, subject to review and approval by the Monitor as set forth in paragraph 19.

24. The Compliance Office shall be responsible for approving the Consulting Services

budget. All requests for Consulting Services and Payments must be made to and approved by the Compliance Office. Any Payments to or for the benefit of a Consultant must be approved by the Compliance Office, subject to review of the Monitor as set forth in paragraph 19.

25. Consulting Agreements shall be managed by Company employees who have no sales responsibilities and who report to the Compliance Office on Consulting issues. These employees shall interface directly with the Consultants on the terms of their Consulting Agreements and on issues relating to Payments.

26. From the Effective Date until the Needs Assessment is approved, all requests for Consulting Services and Payments shall be pre-approved by the Compliance Office. In considering these requests, the Compliance Office and any other Company personnel with knowledge of the request shall evaluate the bona fides of the activity for which the Services or Payments are requested, subject to review of the Monitor. No Consulting Services may be approved unless the Compliance Office verifies that the Company has a bona fide commercial need for such services. No Payments may be made without appropriate documentation and verification of services rendered on a standard form to be developed by the Compliance Office and approved by the Monitor.

#### Needs Assessment

27. The Company shall complete a Needs Assessment no later than December 31, 2007, and annually thereafter. The Needs Assessment may be modified if bona fide, commercially reasonable, unexpected business needs arise ("Modification"). The Needs Assessment must reflect the Company's expected, commercially reasonable needs for all Consulting Services to fulfill its medical, clinical, training, educational, and research and development needs. The Needs Assessment shall also contain a budget for the total amount of honoraria, fellowships, gifts, donations, charitable contributions, and any other payments contemplated to be made to Consultants for which no Consulting Services are provided. The Needs Assessment and any Modifications as defined herein shall be prepared in consultation with those areas of the Company that have bona fide needs for the services to be performed. The Needs Assessment and any Modifications must be approved by the Compliance Officer and the Monitor before they are finalized. As of January 1, 2008, the Needs Assessment and any Modifications shall be used as a basis for Consultant selection and all Consulting Agreements, Services and Payments. The Compliance Officer shall attest to the best of his or her knowledge, after conducting reasonable due diligence, that the Needs Assessment and any Modifications reflect the bona fide, commercially reasonable consulting needs of the Company.

28. The Needs Assessment shall establish or incorporate by reference detailed protocols or procedures that must be followed before a Consulting Agreement will be authorized. The Needs Assessment must identify and quantify the services needed within each discrete service category (e.g., operating room training, speaking engagements, clinical studies, product development groups), and provide written support for the needs. The Needs Assessment must set

forth the nature of the services needed, the range of hours or other quantitative measure needed to complete the services, the number of Consultants needed, and the maximum fair market value compensation to be paid for each consulting service. The Needs Assessment shall also identify the qualifications and expertise required to perform the services. The Needs Assessment shall ensure that Services are distributed appropriately to all regions of the country.

29. The Needs Assessment and any approved Modifications shall be used to define and limit all Consulting Services performed for the Company for the ensuing year. All Consulting Agreements entered into by the Company shall be for services specified and enumerated by the Needs Assessment and any approved Modifications. No Consulting Agreement shall be entered into with any Consultant for services outside those specified in the Needs Assessment and any approved Modifications, or for services exceeding the number of services specified in the Needs Assessment and any approved Modifications. For example, if the Needs Assessment specifies that the Company will require Consultants to conduct 50 speaking engagements on a particular topic, once the total number of contracted-for speaking engagements reaches 50, the Company may not engage any additional Consultants for such speaking engagements unless it obtains an approved Modification.

30. The Company shall maintain a record of all Consulting Services provided under the Needs Assessment and any Modification. Monthly reports will be issued by the Compliance Office to the Monitor and to senior executives in the areas in which services are provided summarizing the Consulting Services provided or submitted for Payment, by Consultant, by region, and by total, with a list of services left to be provided during the calendar year in fulfillment of the Needs Assessment.

### **Consulting Agreements**

31. All Consulting Agreements shall be in writing and executed by the Compliance Officer, the President, the Chief Legal Counsel, the Vice President, Global Research and Innovation for product development and research agreements, and the Chief Medical Officer for clinical services agreements (including clinical trials, clinical studies, follow-up visits). On an annual basis, the Compliance Officer, the Vice President, Global Research and Innovation, for product development and research agreements, and the Chief Medical Officer, for clinical services agreements, shall attest and certify in writing that, based on their reasonable inquiry and knowledge, all Consulting Agreements and all Consulting Services performed thereunder were bona fide, commercially reasonable, and compliant with all federal health care programs. The Company shall not enter into Consulting Agreements with Consultants through any third parties, including distributors.

32. All Consulting Agreements for Consulting Services to be rendered in 2008 and thereafter shall be for a term of the calendar year, with the exception of product development agreements that could result in the payment of royalties, clinical agreements, and external research agreements, which may be for a length appropriate to the type of Service being rendered,

upon approval of the Monitor. All Consulting Agreements shall identify the specific Services to be provided as defined by the Needs Assessment and any Modification thereto, and specify the rate to be paid for each Service. The Company may not enter into Consulting Agreements for Services exceeding the total number of Services set forth in the Needs Assessment and any Modification thereto. Consultants shall be paid only for the actual time expended in providing Consulting Services, in hourly billing increments or other reasonable quantitative measure as identified in the Needs Assessment, without regard to the total amount of consulting services permissible under their Consulting Agreements.

**New and Substitute Consultants**

33. The Compliance Office, in consultation with the Monitor and appropriate Company employees, shall conduct an evaluation of each new Consultant to be considered for a Consulting Agreement. This evaluation shall ensure the proposed Consultant's qualifications and experience are commensurate with those required by the Needs Assessment and any Modification thereto, and that any new relationship meets an unfilled bona fide commercial need of the Company.

34. In the event a Consultant is unable to provide service to the Company under a Consulting Agreement in any given year, the Company may substitute another Consultant or retain a new Consultant to perform the specified yet unfulfilled Consulting Services of the Consulting Agreement. The substitute Consultant must be authorized by the Compliance Officer and approved by the Monitor after conducting a substantive review of the Consultant's qualifications and expertise.

**Payments to Consultants**

35. A Company employee or representative must be present for every Consulting Service, except that the Monitor, upon application by the Compliance Office, may exempt certain Services from this requirement (such as collection of clinical study data, travel or preparation time). Upon completion of the Consulting Service, both the Company employee (or representative) in attendance and the Consultant must independently verify in writing that the Service took place, identify the participants present and length of service, and summarize the Service provided. These verifications must be certified, made under penalty of perjury, and submitted to the Compliance Office within ninety (90) calendar days of the date of the Service and as a condition precedent to any Payments being issued under a Consulting Agreement.

36. For all Consulting Agreements entered into after the Effective Date of this DPA, the Company agrees to make Payments to Consultants at a fair market value hourly rate ("Hourly Rate") of no more than \$500 per hour for time actually expended by a Consultant performing Consulting Services. In the event the Company wishes to make Payments to a Consultant at a higher Hourly Rate or at a different rate because of the Consultant's special expertise or the nature of the service (such as a per patient rate for clinical studies), the Company must obtain or

have obtained a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the Monitor. Any changes to the Hourly Rate or Payments other than the Hourly Rate must be approved by the Monitor.

37. With respect to product development agreements and renewals entered into after the Effective Date and for all Services to be rendered after January 1, 2008, the Company shall pay a Consultant on a product development team for the actual time spent providing Services to the Company, at no more than the Hourly Rate. In addition to the Hourly Rate payments, the Company may pay each member of a product development team royalties on any product the team may develop. The number of Consultants serving on a product development team must not exceed the number reasonably necessary to achieve the identified design and development needs of the project. The aggregate royalties paid per project to all Consultants shall not exceed fair market value expressed as a certain percentage of all domestic and international product sales of the product or products that are the subject of the product development agreement as proposed by the Company and approved by the Monitor. These royalty payments and Hourly Rate payments shall be the only compensation a Consultant may receive for participation on a product design team; that is, the Company shall not make any flat rate payments or minimum guaranteed payments in lieu of or in addition to Hourly Rate payments and royalty payments. The Company may offset royalty payments to a Consultant with Hourly Rate payments for Services the Consultant appropriately performed. The Company may pay royalties to a Consultant only for Intellectual Property received by the Company for products that have actually been sold. (Products may be considered to have been sold when the products are transferred to an unrelated third-party or to a Company affiliate located outside the United States.) If the Intellectual Property has been patented in the United States, royalty payments may not extend beyond the life of the U.S. patent. If the Intellectual Property has not been patented, royalties may not extend beyond a reasonable period (in light of factors such as the life cycle and commercial advantages of the products and Intellectual Property and the burden of administering the royalty arrangement). As used herein, "Intellectual Property" includes patents, trade secrets and know-how received by the Company from the Consultant or product development team under a product development agreement. The Company shall establish processes for reviewing individual Consultant contributions to determine whether Intellectual Property has been provided to the Company, such processes shall be approved by the Monitor. The persons responsible for deciding whether Intellectual Property has been provided shall not be involved in sales functions, and their decision is subject to Monitor approval. The identity of royalty-bearing products must be reasonable (in light of factors such as the scope of Intellectual Property transferred, the relationship of the Intellectual Property to the products and the burden of administering the royalty arrangement) and is subject to Monitor approval. Royalties must not be paid in advance or in anticipation of product development that might result in a royalty. No royalty may be paid to a Consultant that is earned by virtue of the use of the product in question by the Consultant or by any member of a practice group of which the Consultant is a member. In lieu of royalties, a fixed amount may be paid for Intellectual Property provided to the Company, provided the amount is commercially reasonable and subject to Monitor approval. For patents and patent applications that are not assigned or licensed to the Company under a product development

agreement, royalties, patent fees, patent costs, and/or a fixed amount may be paid for the acquisition or licensing of such patents and patent applications, subject to Monitor approval.

38. All Consultants on product design teams shall submit invoices, at least quarterly, and supporting documentation for services rendered to the Company's design team project manager for approval, prior to any Payments being made. A Company employee shall be present at all meetings of product development teams. That employee shall report the date, the participants, and a summary of the meeting to the project manager. The project manager must certify in writing that the invoices reflect bona fide services provided by the Consultant. These invoices, supporting documentation, and certification must be submitted to the Compliance Office for Payment.

39. In addition, the following practices have been or shall be implemented no later than sixty (60) calendar days after the Effective Date:

- a. The Company may not make Payments to Consultants for collection of clinical data unless there is a written agreement defining the required procedures and protocol and the amount of clinical data to be collected by the Consultant, pre-approved by the Chief Medical Officer.
- b. The Company may not make Payments to Consultants for research unless there is a written agreement defining the required procedures and protocol, pre-approved by the Vice President, Global Research and Innovation. The Company may not provide unrestricted grants to Consultants.
- c. The Company may not fund any fellowships for fellows who work with any Consultant, with the exception of fellowship funding to legitimate medical education foundations or institutions so long as that funding is approved in advance by the Compliance Office and the Monitor;
- d. The Company may not make charitable contributions to 501(c)(3) organizations that are, to the best of the Company's knowledge after reasonable due diligence is conducted, controlled by a Consultant or an immediate family member of a Consultant, or at which an immediate family member of a Consultant is employed. All charitable contributions must be approved in advance by the Compliance Office in consultation with the Monitor. The Monitor has the discretion to make exceptions to the above standard;
- e. Other than Consulting Agreements, the sale of products and associated equipment and instruments and the purchase of Intellectual Property, the Company may have no commercial dealings with any Consultant or any entity or organization that the Company has reason to believe, after

reasonable due diligence is conducted, is controlled by the Consultant or an immediate family member of the Consultant. The Monitor has the discretion to make exceptions to the above standard;

- f. The Company shall not hire or engage as an agent or distributor anyone in order to induce a Consultant to use or purchase Company products; and
- g. The Compliance Office shall notify the Monitor of any employees or independent distributors who are known to bear an immediate family relationship to any Consultant. In such cases, the Monitor may recommend changes in assignment or case coverage to avoid actual or perceived conflict of interest.

### **Disclosure**

40. All new Consulting Agreements and renewals shall require Consultants to disclose their financial engagement with the Company to their patients, as well as affiliated hospitals.

41. Within thirty (30) calendar days of the Effective Date of this DPA, the Company shall prominently feature on its web site the name, city, and state of residence for each of the Company's Consultants who were retained at any time in 2007, who provided Consulting Services to the Company at any time in 2007, or who received any Payments from the Company in 2007. The Company shall also there disclose the Payments made to each Consultant to date in 2007 within \$25,000 increments, and, within sixty (60) calendar days of the Effective Date, all other Payments made in other than dollar form. Within ten (10) calendar days after a new Consulting Agreement or renewal is executed, the Company shall post the name of the Consultant on its web site. If the Company has or does enter into a Consulting Agreement with an entity rather than an individual, the Company shall post both the name of the entity and the individual providing Services to the Company under the Consulting Agreement. Payment information shall be updated quarterly during the term of this DPA to reflect the total Payments made to each Consultant within \$25,000 increments, and all other Payments made in other than dollar form. The Company must also disclose this information to the Consultant's affiliated hospitals.

### **Compliance, Training, Hotline**

42. The Company agrees to enhance, support, and maintain its existing training and education programs, including any programs recommended by the Monitor pursuant to paragraph 18, above. The programs, which shall be reviewed and approved by the Company President, Compliance Officer, Chief Legal Officer, and the Monitor, shall be designed to advance and underscore the Company's commitment to exemplary corporate citizenship, to best practices of effective corporate governance and the highest principles of integrity and professionalism, and to fostering a culture of openness, accountability and compliance with federal health care laws

throughout the Company. Completion of such training shall be mandatory for all Company officers, executives, and employees who are involved in Sales, Marketing, Legal, Compliance, and other senior executives at the Company as proposed by the Company and approved by the Monitor (collectively the "Mandatory Participants"). Such training and education shall cover, at a minimum, all relevant federal health care laws and regulations, internal controls in place concerning Consultants and their Consulting Agreements with the Company, and the obligations assumed by, and responses expected of, the Mandatory Participants upon learning of improper, illegal, or potentially illegal acts relating to the Company's sales and marketing of hip and knee reconstruction and replacement products. The Company President and the Board of Directors of Smith & Nephew plc shall communicate to the Mandatory Participants, in writing or by video, their review and endorsement of the training and education programs. The Company shall commence providing this training within ninety (90) calendar days after the Effective Date of this DPA.

43. The Company agrees to establish and/or maintain a confidential hotline and e-mail address, of which Company employees, agents, and customers are informed and can use to notify the Company of any concerns about unlawful conduct, other wrongdoing, or evidence that Company practices do not conform to the requirements of this Agreement. This hotline and e-mail address shall be reviewed by the Monitor. The Company shall post information about this hotline on its website and shall inform all those who avail themselves of the hotline of the Company's commitment to non-retaliation and to maintain confidentiality and anonymity with respect to such reports.

44. [this paragraph left blank intentionally]

#### **Disclosure of Monitor Reports**

45. The Company agrees that the Monitor may disclose his or her written reports, as directed by the Office, to any other federal law enforcement or regulatory agency in furtherance of an investigation of any other matters discovered by, or brought to the attention of, the Office in connection with the Office's investigation of the Company or the implementation of this DPA. The Company may identify any trade secret or proprietary information contained in any report, and request that the Monitor redact such information prior to disclosure.

#### **Replacement of Monitor**

46. The Company agrees that if the Monitor resigns or is unable to serve the balance of his or her term, a successor shall be selected by the Office, in consultation with the Company, within forty-five (45) calendar days. The Company agrees that all provisions in this DPA that apply to the Monitor shall apply to any successor Monitor. The Company shall be given the opportunity to meet the successor Monitor before he or she is retained and to submit any



objections to the Office.

**Adopting Recommendations of Monitor**

47. The Company shall adopt all Recommendations contained in each report submitted by the Monitor to the Office, unless the Company objects to the Recommendation and the Office agrees that adoption of the Recommendation should not be required. The Monitor's reports to the Office shall not be received or reviewed by the Company prior to submission to the Office; such reports will be preliminary until the Company is given the opportunity, within ten (10) calendar days after the submission of the report to the Office, to comment to the Monitor and the Office in writing upon such reports, and the Monitor has reviewed and provided to the Office responses to such comments, upon which such reports shall be considered final. In the event the Company disagrees with any Recommendation of the Monitor, the Company and the Monitor may present the issue to the United States Attorney for his consideration and final decision, which is non-appealable.

**Meeting with the U.S. Attorney**

48. Within thirty (30) calendar days of the Effective Date of this DPA, the Company agrees to call a meeting, on a date mutually agreed upon by the Company and the Office, of Company senior compliance, sales, and marketing executives, and any other Company employees who the Company desires to attend, such meeting to be attended by the United States Attorney and other representatives of the Office for the purpose of communicating the goals and expected effect of this DPA.

**Cooperation**

49. The Company agrees that its continuing cooperation during the term of this DPA shall include, but shall not be limited to, the following:

- a. Not engaging in or attempting to engage in any criminal conduct;
- b. Completely, truthfully and promptly disclosing all non-privileged information concerning all matters about which the Office and other government agencies designated by the Office may inquire with respect to the Company's compliance with health care laws, and continuing to provide the Office, upon request, all non-privileged documents and other materials relating to such inquiries;
- c. Consenting to any order sought by the Office permitting disclosure to the Civil Division of the United States Department of Justice of any materials relating to compliance with federal health care laws that constitute "matters occurring before the grand jury" within the meaning of Rule 6(e) of the Federal Rules of Criminal Procedure. If the Company asserts that

any such any material contains trade secrets or other proprietary information, the Company shall propose redactions to the Office prior to disclosure to any other governmental entity, or the material shall be accompanied by a prominent warning notifying the agency of the protected status of the material;

- d. Making available current Company officers and employees and using its best efforts to make available former Company officers and employees to provide information and/or testimony at all reasonable times as requested by the Office, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities as may relate to matters involving compliance with health care laws. The Company is not required to request of its current or former officers and employees that they forego seeking the advice of an attorney nor that they act contrary to that advice. Cooperation under this paragraph shall include, upon request, identification of witnesses who, to the Company's knowledge, may have material non-privileged information regarding the matters under investigation;
- e. Providing testimony, certifications, and other non-privileged information deemed necessary by the Office or a court to identify or establish the original location, authenticity, or other evidentiary foundation necessary to admit into evidence documents in any criminal or other proceeding relating to compliance with health care laws as requested by the Office;
- f. The Company acknowledges and understands that its future cooperation is an important factor in the decision of the Office to enter into this DPA, and the Company agrees to continue to cooperate fully with the Office, and with any other government agency designated by the Office, regarding any issue about which the Company has knowledge or information with respect to compliance with health care laws;
- g. This agreement to cooperate does not apply to any information provided by the Company to legal counsel in connection with the provision of legal advice and the legal advice itself, or to information or documents prepared in anticipation of litigation, and nothing in this DPA shall be construed to require the Company to provide any such information or advice to the Office or any other government agency; and
- h. The cooperation provisions in this paragraph shall not apply in the event that the Office pursues a criminal prosecution against the Company.

**Breach of Agreement**

50. Should the Office determine, in good faith and in its sole discretion, during the term of this DPA that the Company has committed any criminal conduct relating to compliance with health care laws subsequent to the Effective Date of this DPA, the Company shall, in the discretion of the Office, thereafter be subject to prosecution for any federal crimes of which the Office has knowledge.

51. Should the Office determine in good faith and in its sole discretion that the Company has knowingly and willfully breached any material provision of this DPA, the Office shall provide written notice to the Company of the alleged breach and provide the Company with a two-week period from receipt of such notice in which to make a presentation to the Office to demonstrate that no breach occurred, or, to the extent applicable, that the breach was not material or knowingly and willfully committed or has been cured. The parties understand and agree that should the Company fail to make a presentation to the Office within the two-week period after receiving written notice of an alleged breach, it shall be conclusively presumed that the Company is in breach of this DPA. In the event the Office determines, in good faith and in its sole discretion, that a second material breach has occurred, or that the first material breach has not been adequately cured, the Office shall provide written notice to the Company of the breach, and the breach may result, in the sole discretion of the Office, in the prosecution of the Company relating to the allegations set forth in the criminal complaint described in paragraph 2 above. In the event of any breach of this DPA that results in a prosecution of the Company, such prosecution may be premised upon any information provided by or on behalf of the Company to the Office at any time, unless otherwise agreed when the information was provided. The parties further understand and agree that the determination whether the Company has breached this DPA rests solely in the discretion of the Office, and the exercise of discretion by the Office under this paragraph is not subject to review in any court or tribunal outside the Department of Justice.

52. In the event of breach of this DPA as defined in paragraph 50 or 51 above, the Company may be subject to exclusion by OIG-HHS from participation in all federal health care programs. Such exclusion shall have national effect and shall also apply to all other federal procurement and non-procurement programs. Federal health care programs shall not pay anyone for services or items manufactured, furnished, or distributed by the Company in any capacity while the Company is excluded. This payment prohibition applies to the Company and all other individuals and entities (including, for example, anyone who employs or contracts with the Company, and any hospital or other provider where the Company provides services). The exclusion applies regardless of who submits the claim or other request for payment. The Company shall not submit or cause to be submitted to any federal health care program any claim or request for payment for services or items manufactured, furnished, or distributed by the Company during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. The Company further agrees to hold the federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for services or items manufactured, furnished or distributed to such providers, beneficiaries or sponsors after the effective date of the exclusion. The Company waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such

exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion the Company wishes to apply for reinstatement, the Company must submit a written request for reinstatement to the OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. The Company will not be reinstated unless and until the OIG approves such request for reinstatement.

*Waivers and Limitations*

53. The Company shall expressly waive all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the District of New Jersey, for the period that this DPA is in effect for any prosecution of the Company relating to the allegations set forth in the criminal complaint described in paragraph 2 above.

54. In case of a knowing and willful material breach of this DPA, any prosecution of the Company relating to the allegations set forth in the criminal complaint described in paragraph 2 above that is not time-barred by the applicable statute of limitations as of the Effective Date of this DPA may be commenced against the Company notwithstanding the expiration of any applicable statute of limitations during the term of the DPA. The Company agrees to waive any claims of improper venue with respect to any prosecution of the Company relating to the allegations set forth in the criminal complaint described in paragraph 2 above. This waiver is knowing and voluntary and in express reliance on the advice of counsel. Any such waiver shall terminate upon final expiration of this DPA.

55. The Company agrees that, if after the Effective Date, it sells all or substantially all of the Company's business operations as they exist as of the Effective Date to a single purchaser or group of affiliated purchasers during the term of this DPA, or merges with a third party in a transaction in which the Company is not the surviving entity, the Company shall include in any contract for such sale or merger a provision binding the purchaser, successor, or surviving entity to the obligations contained in this DPA.

56. The Company is simultaneously entering into an agreement with the Office's Civil Division (the "Civil Settlement Agreement") regarding the payment of money to settle certain civil claims. The Company is also simultaneously entering into a Corporate Integrity Agreement ("CIA") with HHS-OIG to implement certain specified compliance measures. Failure by the Company to comply fully with those material terms of the Civil Settlement Agreement called to occur during the Effective Period of this DPA may constitute a breach of this DPA; provided, however, that a breach of the CIA referenced in the Civil Settlement Agreement does not constitute a breach of this DPA. Any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA.

57. Nothing in this DPA restricts in any way the ability of the Office to investigate and prosecute any current or former Company officer, employee, agent or attorney.

58. It is understood that this DPA is limited to the Company and the Office, and it cannot bind other federal, state or local authorities. However, the Office will bring this DPA, the Department of Justice Petite Policy, and the cooperation of the Company and its compliance with its other obligations under this DPA to the attention of other prosecuting offices, if requested to do so.

**Dismissal of Complaint**

59. The Office agrees that if the Company is in full compliance with all of its obligations under this DPA, the Office, within ten (10) calendar days of the expiration of the term of this DPA, will seek dismissal with prejudice of the criminal complaint described in paragraph 2 above. Except as otherwise provided herein, during and upon the conclusion of the term of this DPA, the Office agrees that it will not prosecute the Company further for the matters that have been the subject of the Office's investigation relating to this DPA, including but not limited to Payments that the Company made to Consultants between 2002 and 2006.

**The Full Agreement**

60. This DPA constitutes the full and complete agreement between the Company and the Office and supersedes any previous agreement between them. No additional promises, agreements, or conditions have been entered into other than those set forth in this DPA, and none will be entered into unless in writing and signed by the Office, Company counsel, and a duly authorized representative of the Company. It is understood that the Office may permit exceptions to or excuse particular requirements set forth in this DPA at the written request of the Company or the Monitor, but any such permission shall be in writing.

AGREED TO:

Smith & Nephew, Inc.

By \_\_\_\_\_  
Joseph DeVivo  
President, Orthopaedic Reconstruction  
Global Business Unit ("Recon")  
For Recon and Smith & Nephew, Inc.

\_\_\_\_\_  
Christopher J. Christie  
United States Attorney  
District of New Jersey

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

DIRECTOR'S CERTIFICATE

The Board of Directors of Smith & Nephew plc (the "plc Board") has reviewed this agreement with counsel for the Company. Counsel for the Company fully advised the plc Board of the Company's rights, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this agreement. The plc Board states that, so far as it is aware, no promises or inducements have been made by any official of the United States Government in relation to the subject matter of this agreement (other than those contained in this agreement, the related Civil Settlement Agreement and/or the related Corporate Integrity Agreement). I certify that I am a director of Smith & Nephew plc, and that I have been duly authorized by the plc Board to execute this certificate on its behalf.

Smith & Nephew plc

By \_\_\_\_\_  
Director

\_\_\_\_\_ Date

DIRECTOR'S CERTIFICATE

The Board of Directors of Smith & Nephew, Inc. (the "Inc. Board") has reviewed this agreement with counsel for the Company. Counsel for the Company fully advised the Inc. Board of the Company's rights, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this agreement. The Inc. Board states that, so far as it is aware, no promises or inducements have been made by any official of the United States Government in relation to the subject matter of this agreement (other than those contained in this agreement, the related Civil Settlement Agreement and/or the related Corporate Integrity Agreement). I certify that I am a director of Smith & Nephew, Inc., and that I have been duly authorized by the Inc. Board to execute this certificate on its behalf.

Smith & Nephew, Inc.

By \_\_\_\_\_  
James A. Ralston  
Director

\_\_\_\_\_  
Date

CERTIFICATE OF COUNSEL

We are external counsel for Smith & Nephew, Inc., including its Orthopaedic Reconstruction Global Business Unit, which is called the Company in this agreement. We have reviewed this agreement with the Board of Smith & Nephew plc and the Board of Smith & Nephew, Inc., and have fully advised the Boards of both Smith & Nephew plc and Smith & Nephew, Inc of their rights, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this agreement.

\_\_\_\_\_  
Attorneys for the Company

\_\_\_\_\_  
Date



SECRETARY'S CERTIFICATION

I, Paul Chambers, the duly elected Secretary of Smith & Nephew plc (the "Parent Company") a corporation duly organized under the laws of England and Wales, hereby certify that the following is a true and exact copy of a resolution approved by the Board of Directors of the Parent Company at a meeting held at Newbury, Berkshire, United Kingdom on the 27<sup>th</sup> day of September, 2007;

"The Chief Legal Officer updated the Board on Smith & Nephew, Inc.'s discussions with the United States Attorney's Office for the District of New Jersey (the "Office") in connection with an investigation being conducted by the Office into activities of the Orthopaedic Reconstruction Global Business Unit ("Recon") relating to certain payments to Consultants who have selected orthopaedic hip and knee replacement products manufactured by Recon in surgeries performed by them."

"Counsel from Nixon Peabody explained to the Board the contents of (i) a draft deferred prosecution agreement relating to a criminal complaint to be filed in the U.S. District Court for the District of New Jersey charging Recon with conspiracy to commit violations of the federal anti-kickback statute (the "Deferred Prosecution Agreement"), (ii) a draft civil settlement agreement relating to the same and related matters, and (iii) a draft corporate integrity agreement relating to the same and related matters."

"Counsel from Nixon Peabody also fully advised the Board of the Company's rights, of possible defences, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Deferred Prosecution Agreement."

"IT WAS RESOLVED that (a) the draft Deferred Prosecution Agreement provided to the meeting be and is hereby approved for execution by Smith & Nephew plc's subsidiary, Smith & Nephew, Inc., and its unincorporated division, the Orthopaedic Reconstruction Global Business Unit (subject to such amendments as any one Director may approve); and (b) the President of the Orthopaedic Reconstruction Global Business Unit be, and is hereby authorized to execute the Deferred Prosecution Agreement (subject to such amendments as any one Director may approve); (c) any one Director of Smith & Nephew plc is authorized to execute the Director's Certificate for Smith & Nephew plc attached to the Deferred Prosecution Agreement (subject to such amendments as any one Director may approve)"

IN WITNESS WHEREOF, I have hereunto signed my name as Secretary and affixed the Seal of said Corporation this 27th day of September, 2007.

\_\_\_\_\_  
Paul Chambers  
Secretary

SEAL

SECRETARY'S CERTIFICATION

I, James A. Ralston, the duly elected Secretary of Smith & Nephew, Inc. (the "Subsidiary Company") a corporation duly organized under the laws of Delaware, hereby certify that the following is a true and exact copy of a resolution approved by the Board of Directors of the Subsidiary Company by unanimous written consent on the 27<sup>th</sup> day of September, 2007;

"The Chief Legal Officer updated the Inc. Board on Smith & Nephew, Inc.'s discussions with the United States Attorney's Office for the District of New Jersey (the "Office") in connection with an investigation being conducted by the Office into activities of the Orthopaedic Reconstruction Global Business Unit ("Recon") relating to certain payments to Consultants who have selected orthopaedic hip and knee replacement products manufactured by Recon in surgeries performed by them."

"Counsel from Nixon Peabody explained to the Inc. Board the contents of (i) a draft deferred prosecution agreement relating to a criminal complaint to be filed in the U.S. District Court for the District of New Jersey charging Recon with conspiracy to commit violations of the federal anti-kickback statute (the "Deferred Prosecution Agreement"), (ii) a draft civil settlement agreement relating to the same and related matters, and (iii) a draft corporate integrity agreement relating to the same and related matters."

"Counsel from Nixon Peabody also fully advised the Inc. Board of the Company's rights, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Deferred Prosecution Agreement."

"IT WAS RESOLVED that (a) the draft Deferred Prosecution Agreement provided to the meeting be and is hereby approved for execution by Smith & Nephew, Inc., and its unincorporated division, the Orthopaedic Reconstruction Global Business Unit (subject to such amendments as any one Director may approve); and (b) the President of the Orthopaedic Reconstruction Global Business Unit be, and is hereby authorized to execute the Deferred Prosecution Agreement (subject to such amendments as any one Director may approve); (c) any one Director of Smith & Nephew, Inc. is authorized to execute the Director's Certificate for Smith & Nephew, Inc. attached to the Deferred Prosecution Agreement (subject to such amendments as any one Director may approve)"

IN WITNESS WHEREOF, I have hereunto signed my name as Secretary and affixed the Seal of said Corporation this 27th day of September, 2007.

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James A. Ralston  
Secretary

SEAL

