



DECLARATION OF COMPLIANCE AND DESCRIPTION OF COMPLIANCE PROGRAM

Introduction

Our ambition is to continue as a strong, growing and innovative business long into the future. Our business values are performance, innovation and trust. We respect the rights of all our stakeholders and seek to build open, honest and constructive relationships. We take into account ethical, social, environmental, legal and financial considerations in our planning and business decisions, and are committed to high standards of ethical practice. We aim to be honest and fair in all aspects of our business and we expect the same in our relationships with all those with whom we do business. We do not give or receive improper financial inducements either directly or indirectly, for business or financial gain. As part of our continued efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations of our business principles.

Our Primary Business is the Design, Manufacture and Sale of Medical Devices.

The AdvaMed Code of Ethics on Interactions with Healthcare Professionals recognizes that the medical device industry is significantly different from the pharmaceutical industry. Consistent with the HHS-OIG Guidance, we have tailored our Compliance Program to the nature of our business as a medical device manufacturer.

While the California law makes reference to compliance with the PhRMA Code, we design, manufacture, distribute and sell medical devices rather than pharmaceutical products, and have adopted the AdvaMed Code policies and procedures for compliance which are substantially similar to the PhRMA Code.

Description of Compliance Program

To the best of our knowledge, and based on our good faith understanding of the statutory requirements, we have established a Comprehensive Compliance Program (CCP) compliant with requirements of Chapter 8 to Part 15 of Division 105 of California's Health and Safety Code. We have developed a CCP tailored to the size, organizational structure and resources of the company, and implemented our CCP to meet the compliance goals set forth by the State of California. The description of our CCP, provided below, reflects the plan we have implemented. To our knowledge, we are, in all material respects, in compliance with our CCP as described, meaning that we have established the elements outlined, and where procedures are described, we have set up programs to initiate these procedures.

Compliance Program Changes and Limitations

We are constantly reassessing the program to improve it, and it is possible (and likely) that we will make further adjustments aimed at improving the effectiveness of our CCP in the coming year. We recognize that compliance is a dynamic concept that must be adapted to the characteristics of a particular company. Government standards on compliance programs, including the U.S. Sentencing Guidelines and the HHS-OIG Compliance Program Guidance,

recognize that no program can completely prevent individual employees or agents from improper conduct. While we are not making a representation that every employee and agent will always fully comply with our business values, our program is reasonably designed to prevent and detect violations. We are committed to monitoring our conduct and acting swiftly to discipline any employee or agent or take appropriate action with an agent that violates our ethics standards.

This declaration is made as of, May 1, 2009, and as noted above, it is possible and likely that we will update our program on an ongoing basis. In addition to the continual refinement process that we expect to occur for this CCP, Smith & Nephew will assess its program prior to July 1 of each year.

DESCRIPTION OF COMPREHENSIVE COMPLIANCE PROGRAM

I. INTRODUCTION

Smith & Nephew, Inc., is committed to establishing and maintaining an effective compliance program in accordance with “Compliance Program Guidance” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”). Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to increase the likelihood of preventing, detecting and correcting violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee or agent conduct will be entirely eliminated. Nonetheless, it is Smith & Nephew’s expectation that employees and agents will comply with our Code of Conduct and Business Principles, Global Standard Operating Procedures and other codes and policies established in support of such a Code.

In the event that Smith & Nephew becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations. For purposes of our Compliance Program, the term “agent” means persons under contract to act on behalf of Smith & Nephew as sales representatives or independent distributors to sell, or facilitate the sale of, goods or services that may be reimbursed under US Federal healthcare programs.

Smith & Nephew has described below the fundamental elements of its Compliance Program. In accordance with the voluntary standards established by the HHS-OIG Guidance and as explicitly recognized in the Guidance, we have tailored our Compliance Program to fit the unique environment, size and product range of our company. Further, Smith & Nephew’s business in the United States is organized into four autonomous operating divisions (Global Business Units or GBUs): Advanced Wound Management, with principal offices in St. Petersburg, Florida; Endoscopy, with principal offices in Andover, Massachusetts; Orthopaedics, with principal offices in Memphis, Tennessee, and Biologics & Spine, with principal offices in Raleigh, North Carolina.

Our Compliance Program applies to each GBU; however, each GBU independently implements and administers the Compliance Program according to its specific business characteristics. A Compliance Program is dynamic, involving not only multiple policies, procedures, and programmatic activities, but also the commitment of senior management, and the support of all

employees and agents to make the program effective.

We will regularly review and enhance our Compliance Program to meet our evolving compliance needs. For a written copy of this Declaration and Description of Comprehensive Compliance Program, please call (800) 490-3461.

II. Overview of Compliance Program

1. Written standards.

Smith & Nephew's Code of Conduct and Business Principles, together with our Global Standard Operating Procedures and each GBU's Standard Operation Procedures (collectively our "Code") is our statement of ethical and compliance principles, policies and procedures that guide our daily operations. The Code establishes that we expect management, employees and agents of the company to act in accordance with law and applicable company policy. The Code articulates our fundamental principles, values and framework for action within our organization. Smith & Nephew also adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals. We are committed to train on and comply with the AdvaMed Code's standards and guidance.

To comply with a specific California law, and subject to the provisions of this section, we have established an annual spending limit for each GBU of \$2,500 for certain promotional materials, items and/or promotional activities provided to California licensed healthcare professionals. This amount is an upper limit that represents the most we reasonably anticipate any GBU will spend on any one licensed health care professional in a year's time. This annual spending limit is dynamic and may change. It is important to note that we expect to spend considerably less, and may never spend to the limit on any one licensed health care professional.

Medical devices such as those we design, license, manufacture, distribute and/or sell (e.g., SPINECATH® Intradiscal Catheter for IntraDiscal ElectroThermal* Therapy (IDET); and knee or hip replacement implants using our proprietary advanced bearing material OXINIUM®), require specialized training for health care practitioners to obtain the best possible clinical outcomes. Smith & Nephew goes to significant lengths and expense to provide such training and education.

Often, such training occurs in a central location, in special purpose-built labs where clinical faculty can most efficiently teach new or improved techniques. Due to the regulatory approval cycle for certain medical devices, some training may require company-sponsored travel. We will continue to abide by our Code and the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

The spending limit stated above does not include the value of certain education and product training activities that we may provide to California licensed healthcare professionals. Such activities may include travel expenses when travel is necessary to accomplish educational and training objectives. The spending limit also excludes those amounts exempted by California Health and Safety Code Sec. 119402.

2. Leadership and Structure.

Compliance Officer. For each Global Business Unit we designate a senior level officer to serve as the Compliance Officer. We are committed to ensuring that each Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent

judgment. Each Compliance Officer is charged with ensuring a comprehensive and effective compliance program is implemented.

Compliance Committee. Smith & Nephew has established a Group Compliance Council comprised of the Compliance Officers of each GBU, and there is a Compliance Committee in each GBU to advise and assist each Compliance Officer in the implementation of the Compliance Program within the GBU. Each GBU Compliance Committee has senior executive members from the key functional areas within each GBU, this may include Legal, Sales, Marketing, Finance, Professional Affairs, Regulatory Affairs and Human Resources.

3. Education and Training.

A critical element of our Compliance Program is the education and training of our employees and agents on their legal and ethical obligations under applicable federal health care program requirements. Smith & Nephew is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Our training activities may include a combination of in-person seminar presentations, on-line web modules, printed material, third-party seminars and individualized sessions. Smith & Nephew will regularly review and update its training programs, as well as identify additional areas of training on an “as needed” basis.

4. Internal Lines of Communication.

Smith & Nephew is committed to fostering dialogue between management and employees and agents. Our goal is that all employees and agents, when seeking answers to questions or reporting potential instances of misconduct, should know who to turn to for a meaningful response and should be able to do so without fear of retribution. In order to encourage open lines of communication regarding potential ethical or legal violations, we adopted open-door policies, as well as confidentiality and non-retaliation policies.

Anyone with compliance questions, concerns, or who suspects a potential violation of our Code may call Smith & Nephew’s compliance helpline at 877-874-8416. Callers may choose to remain anonymous, and information provided will be treated as confidential as far as possible. We will ensure that no action is taken against anyone who reports, in good faith, actual or suspected misconduct.

5. Auditing and Monitoring.

Smith & Nephew’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with our Code, related policies and procedures, including efforts to monitor the activities of sales personnel. We note that in accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. We will utilize ongoing assessment of compliance programs to identify new and emerging risk areas and address these risks.

6. Responding to Past and Potential Violations.

Smith & Nephew’s Compliance Program includes reasonable procedures to screen potential employees, vendors, and agents, and Smith & Nephew will not knowingly do business with

persons or organizations that have been excluded, debarred, suspended, or are otherwise ineligible to participate in Federal healthcare programs. Smith & Nephew's Compliance Program also includes clear disciplinary policies that set out the consequences if current employees or agents violate the law or company policy. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

7. Corrective Action Procedures.

A Compliance Program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, our Compliance Program requires the company to respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations. To that end we have established Corrective and Preventive Action procedures for noncompliance and ethics complaints.

©2009 Smith & Nephew, Inc. All rights reserved.