

SkinMedica Pharmaceuticals, Inc.
Comprehensive Compliance Program
(CCP)
Effective January, 2010
(Revision to November 2005 Policy)

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INTRODUCTION--ESTABLISHING A COMPREHENSIVE COMPLIANCE PROGRAM

SkinMedica Pharmaceuticals, Inc. (SkinMedica Pharmaceuticals), a wholly-owned subsidiary of SkinMedica, Inc., hereby adopts this voluntary Comprehensive Compliance Program (CCP) to comply with the law in its interactions with healthcare customers. SkinMedica Pharmaceuticals has modeled its Compliance Program after the “Compliance Program Guidance for Pharmaceutical Manufacturers” issued by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) on April 2003. SkinMedica Pharmaceuticals has also followed the spirit of the PhRMA Code on Interactions with Healthcare Professionals in establishing this Policy. SkinMedica Pharmaceuticals is adopting its own Compliance Program in response to the complex issues and the responsibilities involved in interacting with healthcare customers. This compliance program is internal to SkinMedica Pharmaceuticals and is not intended to convey any legal rights upon any customer, shareholder or other third party. It is solely a statement of intention and aspiration for SkinMedica Pharmaceuticals.

The OIG Guidance focuses on three potential risk areas for manufacturers. They are as follows: (1) the integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration, and (3) in the case of pharmaceutical companies, compliance with laws regulating drug samples. The compliance measures SkinMedica Pharmaceuticals has and will adopt are unique to its business and the unique environment and size of the company. The ultimate responsibility for compliance lies not with SkinMedica Pharmaceuticals’ designated Compliance Officer, but with SkinMedica Pharmaceuticals’ Executive Committee.

This CCP policy incorporates the following elements:

- 1) This written CCP which articulates the company’s commitment to compliance in the pharmaceutical industry;
- 2) Other written internal standard operating procedures that may be adopted from time to time addressing specific areas of concern with and susceptibility to potential violations of the law in the interaction with healthcare professionals and other customers;
- 3) The designation of a Compliance Officer whose job will be to develop, operate and monitor the compliance program. Given the size of SkinMedica Pharmaceuticals, this will be an additional and part time responsibility for an existing employee. This person will be a member of and report directly to the Executive Committee;
- 4) The development of a regular, effective education and training program for all affected employees and subcontractors;
- 5) An annual review of the compliance program by management to identify problem areas and to address gaps and opportunities for improvement; and
- 6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs and addressing

appropriate disciplinary action against employees and subcontractors who have violated company policies and procedures and applicable federal health care program requirements.

LAWS APPLICABLE TO INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND SKINMEDICA PHARMACEUTICALS POLICY

There are four primary federal laws which govern the interaction between health care professionals and pharmaceutical companies. These include FDA's advertising and promotion regulations and guidance promulgated under and pursuant to the Food, Drug and Cosmetic Act (FDCA), the Anti-kickback Statute, the False Claims Act and the Prescription Drug Marketing Act (PDMA). These statutes are intertwined and sometimes all apply to the myriad of advertising and promotional programs that companies conduct as well as in the many other ways that companies interface with health care professionals. Some examples of how companies interact with health care professionals are in conducting market research or using advisory boards, providing reimbursement advice and drug samples, in providing grants for medical education and symposia, in consulting with physicians, and in supporting physician-initiated clinical trials. The regulatory environment in this arena is complex and this Policy will not cover every conceivable program or circumstance, but it provides some operating principles and a framework for analyzing issues.

FDA Advertising and Promotion Regulations--FDA's advertising and promotion laws and regulations address the claims a company can lawfully make about its products. To implement the law, we must be truthful, not misleading and fairly balanced in the claims we make about our products. This requires that claims must be substantiated. The claims we make about our products can be direct, indirect, express or implied. The FDA looks to the claims we make about our products to determine the true "intended use(s)" we claim for our products. Often the claims we make about our products are subtle and not direct or expressed. The company in its advertising and promotion of products can indirectly or impliedly expand the claims made about those products beyond the approved labeling. This can make our advertising or promotion unlawful.

The promotional arena has been impacted by some court cases, the most notable of which is the Washington Legal Foundation (WLF), in which WLF challenged three FDA Guidance documents which WLF alleged limited First Amendment commercial free speech. The FDA, in large measure, lost that case. This case and others have limited the way FDA regulates such things as a) the dissemination of information about off-label uses of a company's products, b) a company's ability to sponsor continuing medical education courses on off-label uses, and c) a company's ability to provide financial support for physician-initiated clinical trials on off-label uses.

In complying with FDA's advertising and promotional law, SkinMedica Pharmaceuticals shall promote based upon the approved claims for its products. SkinMedica Pharmaceuticals shall be truthful, not misleading and fairly balanced in the claims it makes about its products. If off-label information is shared with health care professionals, it will be done appropriately and lawfully given the current state of the law.

Anti-kickback Statute--Federal and some state laws impose criminal and civil penalties for offering or receiving any form of improper "inducement" to purchase, order or recommend a

healthcare item or service. The major purpose of these laws (often referred to as “anti-kickback” laws) is to ensure that the purchase or prescription of a product reimbursed by the government is based upon patient benefit, price, quality, service and similar considerations. A purchase or prescription should not be based upon providing personal benefit to a customer which could compromise the purchase or prescription from being made in the best interest of the patient. These laws are also intended to discourage the ordering or purchasing of medically unnecessary items or services. In addition, the federal government has become concerned that the increasing costs associated with sales “inducements” have an inflationary, and therefore harmful, effect on the nation’s healthcare budget.

The Anti-kickback Statute is designed to address paying “remuneration” to induce the purchase, prescription, or referrals to do the same, of goods or services reimbursed by the federal or a state government under Medicare, Medicaid or a similar state or federal program. In addition to preventing improper inducements, here are some of the other principal purposes behind the statute: a) to prevent the over-utilization of goods and services reimbursed by the government, b) to level the competitive playing field to prevent distortions in the marketplace by competitors who do not abide by the law, and c) to ensure the government pays the true acquisition cost for goods and services and is the beneficiary of all discounts, whether explicitly disclosed or hidden. See 42 USC 1320a-7b(b).

--Safe Harbors under the Anti-kickback Statute--The Anti-kickback Statute does have “safe harbors” that protect certain types of conduct that actually fall under the scope of the statute and, but for the safe harbor, would be considered a violation of the law. The safe harbors, if followed, ensure that the conduct in question will not be the subject of a prosecution, hence the term “safe harbor.”

SkinMedica Pharmaceuticals shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement, i.e. remuneration, to induce the purchase, prescription, or referrals to do the same, of goods or services reimbursed by the federal or a state government under Medicare, Medicaid or a similar state or federal program.

False Claims Act--The False Claims Act is designed to insure the integrity of information provided to the government for the reimbursement of products. The statute applies when health care professionals submit claims for reimbursement to the government for products they have prescribed. A manufacturer is deemed liable for a False Claims Act violation if it somehow participates in a false claim for reimbursement being made by a health care professional where, for example, the health care professional miscodes, “makes the AWP spread,” sells drug samples or otherwise seeks government reimbursement where no payment or a lower payment for reimbursement is due. In addition to inappropriate reimbursement payments, the False Claims act is triggered if there is an anti-kickback violation. The theory is that a party seeking reimbursement impliedly certifies that they are in compliance with all laws, such as the Anti-kickback statute, and if they are not, they are not entitled to reimbursement.

SkinMedica Pharmaceuticals shall ensure that its role in providing reimbursement advice to health care professionals is in compliance with the law and does not encourage inappropriate reimbursement for its products.

Prescription Drug Marketing Act (PDMA)--The PDMA governs the provision of drug samples by a pharmaceutical company to a physician or other health care professional. The statute was enacted to prevent, among other things, the sale of free samples to purchasers who would then bill the government for them at full price. The PDMA has very specific requirements for the handling of drug samples.

SkinMedica Pharmaceuticals shall ensure that in providing free drug samples to health care professionals, it is in compliance with the law, and it has policies and systems in place to comply with the PDMA.

INTERACTIONS WITH HEALTHCARE PROFESSIONALS

A. AN OVERVIEW

This portion of the CCP addresses the company's interactions with U.S. health care professionals and other customers and is intended to provide guidance about appropriate interactions with customers to all employees of SkinMedica Pharmaceuticals (or any subsidiary) conducting business within the United States to enable the Company to remain in compliance with the four laws discussed above. Contractors conducting business on behalf of SkinMedica Pharmaceuticals must also comply with this Policy. Employees and contractors interacting with customers outside of the United States should refer to the SkinMedica Pharmaceuticals policy applicable to their country for guidance on conducting business in their respective jurisdiction. These policies apply to any expenditure by SkinMedica Pharmaceuticals employees or contractors, regardless of whether the expenditure is reimbursed by the Company. In other words, any "personal" money given to or spent for the benefit of a SkinMedica Pharmaceuticals customer is considered money given or spent by the Company.

Definition of "Customer"--As used in this Policy, the term "customer" means any individual or organization that purchases, recommends, uses, or prescribes products manufactured or distributed by SkinMedica Pharmaceuticals, or an individual who is in a position to determine whether a SkinMedica Pharmaceuticals product is purchased, recommended, used, or prescribed, if any of those products are reimbursed under a federal or state healthcare program. This can include physicians, nurses, physician assistants, medical assistants, office administrators, pharmacists, purchasing agents, hospitals, clinical practices, MCOs, HMOs, PBMs, GPOs, etc.

The following general standards and principles should at all times guide our interactions with customers:

- SkinMedica Pharmaceuticals will encourage ethical business practices and socially responsible industry conduct, and will not use any unlawful inducement in order to sell, lease, recommend or arrange the sale, lease, or prescription of its products.
- SkinMedica Pharmaceuticals believes that enduring customer relationships are based on integrity and trust. We seek to gain advantage over competitors through superior products, research, manufacturing, marketing and service, never through improper business practices.
- SkinMedica Pharmaceuticals' relationships with customers are intended to benefit patient care and enhance the practice of medicine. Interactions should be focused on informing customers and prospective customers about products, providing scientific and educational information, and supporting medical research and education and should not, at any time, entice representatives of customers to place their own personal interests above those of the organizations they represent or the patients who will use or need the Company's products.

- SkinMedica Pharmaceuticals will not, directly or indirectly, offer or solicit any kind of payments or contributions for the purpose of obtaining, giving, keeping or rewarding business.

B. GIFTS, EDUCATIONAL AND PRACTICE-RELATED ITEMS.

Subject to California law, SkinMedica Pharmaceuticals has determined that the annual aggregate limit on covered promotional expenditures is set at \$3,000 per health care professional for annual periods commencing on January 1, 2010. This limit may be revised by SkinMedica Pharmaceuticals from time to time. The foregoing limit does not represent a usual, customary, average or typical amount for medical or health care professionals.

Items primarily for the benefit of patients may be offered to customers or prospective customers if they are not of substantial value. For example, an anatomical model for use in an examination room is primarily for the medical education of the patient, whereas a VCR or CD player is not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Special laws related to gifts, educational and practice-related items apply in California, Minnesota, Vermont and Massachusetts. SkinMedica Pharmaceuticals and its CCP are in compliance with these laws.

C. ENTERTAINMENT AND RECREATION

SkinMedica Pharmaceuticals may not offer entertainment and recreation to healthcare professionals who are licensed to practice medicine in the States of California, Vermont, Massachusetts; and Minnesota (under certain conditions) and who prescribe any of SkinMedica Pharmaceuticals' pharmaceutical products that are reimbursed by the federal government. SkinMedica Pharmaceuticals requires that any entertainment or recreation, for physicians not in the states described above, be approved in advance by management subject to the principles contained within this CCP.

EXCEPTIONS TO THE CCP

Exceptions to this Corporate Policy should be infrequent. All exceptions must be approved by a Vice-President, must be supported by written justification for the deviation, and must comply with applicable law.

CONSEQUENCES FOR NON-COMPLIANCE

Any employee who violates this CCP and any manager who knowingly permits or directs a subordinate to do so, will be disciplined accordingly, up to and including termination of employment. Any employee who suspects a violation of this policy is encouraged to discuss the

matter with his or her supervisor. Employees may also contact the Healthcare Compliance Officer.

Copies of the Compliance Program and our Annual Declaration of Compliance can be obtained by calling our Customer Service Department at 1-866-867-0110 or from our Web site at www.skinmedica.com. The Company has also established an Ethics Hotline that is available 24 hours a day, 7 days a week at 1-800-958-0188 for making anonymous reports. All reports shall be documented and reported to the Compliance Officer.