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Guidance for Industry

Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
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Center for Drug Evaluation and Research (CDER)
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GUIDANCE FOR INDUSTRY¹

**Promoting Medical Products in a Changing Healthcare Environment;
I. Medical Product Promotion by Healthcare Organizations or Pharmacy
Benefits Management Companies (PBMs)**

I. INTRODUCTION

During the past few years, several medical product sponsors² have acquired or entered into agreements with healthcare organizations or pharmacy benefits management companies (PBMs). Medical product sponsors often use such healthcare organizations/PBMs to promote their products, including the dissemination of promotional labeling and advertising. FDA generally does not exercise jurisdiction over materials disseminated by individuals or entities that are not in any way affiliated with a medical product sponsor. However, when a medical product sponsor is involved in promotional activities performed by healthcare organizations/PBMs, the sponsor should not be permitted to avoid regulation by changing the form through which their communications are accomplished. Accordingly, this document provides guidance to medical

¹ This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER), the Promotion and Advertising Policy Staff in the Center for Devices and Radiological Health (CDRH), and the Office of Establishment Licensing and Product Surveillance in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on promotional activities that are the responsibility of the medical product sponsor even though performed by healthcare organizations or PBMs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Additional copies of this draft guidance document are available from the Drug Information Branch, Division of Communications Management, HFD-210, CDER, FDA, 5600 Fishers Lane, Rockville, MD 20857, (Tel) 301-827-4573, (Internet) <http://www.fda.gov/cder/guidance.htm>.

² A medical product sponsor, as used in this document, is any individual or entity that is the holder of an application to market a human drug, medical device, or biological product.

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product sponsors by describing circumstances in which they may be held responsible for promotional activities performed by healthcare organizations/PBMs that violate the Federal Food, Drug, and Cosmetic Act (the Act) and regulations promulgated thereunder.

Under the Act, FDA has responsibility for regulating the labeling and, in many cases, the advertising of medical products (human and animal drugs, biologics, and medical devices). Section 301 of the Act (21 U.S.C. § 331) prohibits the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug or device and of an unapproved new drug; the adulteration or misbranding of a drug or device in interstate commerce; and the doing of any act that results in the adulteration or misbranding of a drug or device while such article is held for sale after shipment in interstate commerce. A drug or device is misbranded if its labeling is false or misleading (section 502(a) of the Act, 21 U.S.C. § 352(a)) or if its labeling fails to bear adequate directions for use (section 502(f) of the Act, 21 U.S.C. § 352(f)). A change or modification in the intended use of a device may cause the device to be adulterated (section 501(f) (1) (B) of the Act, 21 U.S.C. § 351 (f) (1) (B)) and misbranded (section 502 (o) of the Act, 21 U.S.C. § 352 (o)).

FDA's determination that medical product sponsors are responsible, under certain circumstances, for promotional activities performed by healthcare organizations/PBMs on their behalf is consistent with longstanding agency policy and finds support in the Act, regulations, and legal precedent. The introductory phrase of section 301 of the Act provides that the "causing" of any prohibited act, as well as the act itself, is prohibited. In addition, 21 C.F.R. § 1.1 (a) provides that the provisions of regulations promulgated under the Act, "with respect to the doing of any act shall be applicable also to the causing of such act to be done."

This broad theory of liability, which is based on FDA's responsibility to protect the public health, has been upheld in several FDA enforcement actions. See, e.g., United States v. Dotterweich, 320 U.S. 277 (1943) ("The offense is committed...by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws"); United States

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v. Industrial Laboratories Co., 456 F.2d 908 (10th Cir. 1972) (contract testing laboratory that failed to perform proper tests caused the introduction into interstate commerce of adulterated drugs); United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947) (“one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law”), cert. denied, 332 U.S. 851 (1948). Additional support is found in the law of agency, doctrine of respondeat superior, see, e.g., Taylor v. Phelan, 912 F.2d 429 (10th Cir. 1990) (principal is liable for acts of agent when those acts are committed in course of or within scope of agent’s employment), cert. denied, 111 S.Ct. 786 (1991), and 21 C.F.R. §§ 202.1 (l) (1) and (2), which provide that labeling and advertising include promotional information that is disseminated by a sponsor or by other persons on behalf of the sponsor.

II. MEDICAL PRODUCT PROMOTION BY A HEALTHCARE ORGANIZATION/PBM SUBSIDIARY³ OF A MEDICAL PRODUCT SPONSOR

Generally, a medical product sponsor will be held responsible for promotional activities performed by its healthcare organization or PBM subsidiary that violate the Act or regulations (e.g., the dissemination of false or misleading labeling or advertising). Promotional labeling and advertising disseminated by the subsidiary are subject to the existing postmarketing reporting requirements (see section IV).

III. MEDICAL PRODUCT PROMOTION BY A NON SUBSIDIARY HEALTHCARE ORGANIZATION/PBM ON BEHALF OF THE MEDICAL PRODUCT SPONSOR

Under certain circumstances, a medical product sponsor may be held responsible for

³ “Subsidiary” used herein is to be interpreted in its broadest sense to include any corporate relationship, in whole or in part, and a company unit, division, subsidiary company, or any other entity within or attached to a corporation.

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promotional activities performed by other persons (other than subsidiaries) that violate the Act or regulations. In determining whether violative promotional activities performed by non subsidiary healthcare organizations or PBMs are attributable to a medical product sponsor, the agency will consider a number of factors, including, among others, the relationship between the sponsor and the healthcare organization/PBM, and whether the sponsor has control of or influence over the activities of the healthcare organization/PBM or the content of the violative material disseminated by the healthcare organization/PBM. These factors are described below:

1. Relationship

The agency will consider the nature of the sponsor's relationship with the healthcare organization/PBM (e.g., whether that relationship is defined by a contract or other agreement). For example, if a contract between the sponsor and the healthcare organization/PBM to promote the sponsor's product(s) exists, the sponsor will generally be responsible for promotional activities performed by the healthcare organization/PBM that are violative.

2. Control and Influence of Information Content and Distribution

The agency will consider whether the sponsor has control of or influence over the promotional activities of the healthcare organization/PBM. For example, the agency will examine whether the sponsor scripted the disseminated information, targeted points for emphasis, or otherwise acted to control or influence the content of the information; whether individuals involved in designing or disseminating promotional materials are also involved in advising or otherwise assisting the sponsor with respect to sales or marketing of the sponsor's product; whether similar messages are contained in promotional materials disseminated by the sponsor directly; whether the targeted audience was determined by the sponsor's sales or marketing department; and whether any complaints have been raised regarding attempts by the sponsor to influence the content of disseminated information.

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The foregoing factors are not intended to be exhaustive and other factors may be appropriate for consideration in a particular case. Promotional labeling and advertising disseminated by healthcare organizations/PBMs under the circumstances described in this section are subject to the existing postmarketing reporting requirements (see section IV).

IV. POSTMARKETING REPORTING REQUIREMENTS FOR PROMOTIONAL LABELING AND ADVERTISING

Promotional labeling and advertising materials disseminated or published by a medical product sponsor, a sponsor's subsidiary, or by a healthcare organization/PBM under the circumstances described in section III above, are subject to the existing postmarketing reporting requirements set forth in 21 CFR § 314.81 (b) (3) (i) for drugs, 21 CFR § 601.12 (f) (4) for biologics, and 21 CFR §§ 814.39 and 814.82 for devices reviewed under the premarket approval regulations, and the requirement to maintain historical files for labeling and advertising for all devices set forth in 21 CFR § 807.31. The medical product sponsor is responsible for ensuring compliance with these reporting requirements.

FDA recognizes that, on occasion, duplicative materials are often distributed by or on behalf of medical product sponsors in the managed care environment (e.g., mass mailings in which only the addressee changes). To satisfy the postmarketing reporting requirements listed above, only a representative sample of such duplicative material need be submitted. The submitted representative sample (e.g., a formulary kit) should be accompanied by a list of recipients or other description of the variation in the material.