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FDA Considers A New Prescription Drug Paradigm

Under Section 503(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act, a drug must be dispensed by prescription if safe use of the drug requires supervision by a licensed health care professional. The need for professional supervision can be due to the drug's toxicity or other potential harmful effects, its method of use or collateral measures necessary to its use. But on February 28, 2012, the U.S. Food and Drug Administration ("FDA" or "the Agency"), announced that it believes the prescription drug paradigm has contributed to the undertreatment of certain common diseases, and it therefore is considering a new paradigm under which it would approve certain drugs that ordinarily would require a prescription to be sold over the counter under "conditions of safe use."[1] On March 22–23, 2012, the Agency will hold a public hearing to obtain comments about the new paradigm's feasibility, as well as its potential costs and benefits.

The New Paradigm

According to FDA, the undertreatment of common medical conditions is a well-recognized public health problem in the U.S. FDA believes the requirement to obtain a prescription for certain medications may contribute to undertreatment of common medical conditions such as high cholesterol, high blood pressure, migraine headaches and asthma. In FDA's view, the temporal and financial costs associated with obtaining initial prescriptions and prescription refills impede access to necessary treatments. FDA's proposed solution to the plight of undertreatment is a new paradigm under which certain drugs ordinarily requiring a prescription would instead be made available over the counter, under conditions of safe use.

FDA poses a number of ways in which the new paradigm could be implemented. For some drugs, a prescription might never be necessary, so long as the drug can be made available over the counter subject to conditions of safe use. For other drugs, an initial prescription might be necessary, but a certain number of refills would be authorized beyond those normally authorized, subject again to conditions of safe use. And in some cases, a drug might have "dual availability," meaning it could be dispensed over the counter under conditions of safe use, or alternatively by prescription.

FDA cites rescue medicines, such as inhalers and epinephrine shots, as products potentially subject to the new paradigm. According to FDA, the new paradigm would eliminate or reduce routine doctor visits, thereby allowing practitioners to spend more time with seriously ill patients, and would reduce health care costs.

FDA does not define "conditions of safe use," but rather discusses a number of examples that could qualify. These examples include:

- Assisting patients in self-selection of an appropriate medication through use of kiosks or other technological aids;

[1] Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Products can be Considered Nonprescription; Notice of Public Hearing; Request for Comments; 77 Fed. Reg. 12059 (Feb. 28, 2012).

- Monitoring of patients during continued use;
- Requiring pharmacist intervention to ensure appropriate nonprescription use; and
- Using diagnostic technologies in the pharmacy setting.

Public Hearing

FDA lists numerous topics on which it will seek input at the public hearing. These topics include:

- The types of evidence needed to demonstrate that a drug could be used safely and effectively without a prescription under conditions of safe use;
- Specific medical conditions for which the new paradigm would particularly benefit consumers;
- Types of conditions of safe use;
- Types of diagnostic aids that could be used either with or without the aid of a pharmacist;
- Whether the new paradigm would increase consumer access to necessary medical care;
- The financial impact of the new paradigm on consumers;
- The impact of the new paradigm on pharmacy business operations and pharmacist training; and
- The potential effect on insurance coverage of pharmaceutical products.

Anyone who wishes to make an oral presentation at the public hearing should submit a written or electronic request by March 9, 2012. Comments to the FDA announcement should be submitted by the same date.

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