



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

April 30, 2012

The Honorable Margaret A. Hamburg, M.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Rm. 1061)
Rockville, MD 20852

Re: Using Innovative Technologies and Other Conditions of Safe Use to Expand Which
Drug Products Can Be Considered Nonprescription, Docket No. FDA-2012-N-017

Dear Commissioner Hamburg:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 100,300 family physicians and medical students nationwide, I am writing in response to the request for comments on "Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription", as [published](#) by the Food and Drug Administration (FDA) in the February 28, 2012 *Federal Register*. Under the *Federal Food, Drug, and Cosmetic Act*, the FDA currently approves drugs either as prescription or nonprescription. In the referenced publication, the FDA sought input on a new and third paradigm that would allow the agency to approve and for pharmacists to dispense certain drugs, which would have otherwise required a prescription, for nonprescription use under conditions of "safe use," which would be determined specific to the drug product.

The AAFP recognizes the important role of pharmacists in the provision of high quality health care; however, this proposed new paradigm would allow patients to receive powerful prescription drugs without the input of a physician. It is the AAFP's [policy](#) to oppose regulations and legislation that would allow pharmacists to dispense medication beyond the expiration of the original prescription for reasons other than emergency purposes.

At issue is the nature of the appropriate relationship between patients, physicians and pharmacy professionals. Only licensed doctors of medicine, osteopathy, dentistry, and podiatry have the statutory authority to prescribe drugs. The pharmacist dispenses the medication prescribed by the physician, or the physician's designated surrogate functioning under the appropriate level of supervision, to the patient. Allowing the pharmacist authority to dispense medication without consulting with the patients' physician first, could seriously compromise the physician's ability to coordinate the care of multiple problems of many patients.

The AAFP continues to strongly support maintaining the existing two classes of drug products, prescription and nonprescription, in the United States. Instead, of creating a new class of "safe use" drugs, pharmacy professionals and physicians can, and should, work in a collaborative

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environment where their combined expertise is used to optimize the therapeutic effect of pharmaceutical agents in patient care to achieve the desired outcomes while maintaining overall efficiency.

The role of the pharmacy professional in health care service and delivery is enormously significant. An estimated 250 million people walk into a pharmacy every week. As such, pharmacists play an essential role in providing direction to patients seeking advice on nonprescription and over-the-counter (OTC) medications. In instances where a patient is seeking information in the absence of direction from a physician, the pharmacy professional is the logical source to provide that information.

The AAFP recognizes the unique expertise of the pharmacist. Because of this expertise there are areas of professional activity where, by good practice and law, the pharmacist practices independently. However, other areas exist where that expertise is best exercised in an environment with physician supervision. While pharmacy professionals should not prescribe drugs or alter a prescription written by a physician, they have valuable contributions to make as part of a patient's medical team, especially in a predetermined collaborative practice arrangement

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Roland A. Goertz MD". The signature is fluid and cursive, with the letters "MD" clearly visible at the end.

Roland A. Goertz, MD, MBA, FAAFP
Board Chair