

EDITORIALS



Blueprint for a Stronger Food and Drug Administration

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Over the past 5 years, a series of recalls of high-profile prescription medications has aroused serious concern about the safety of the nation's drug supply. Faced with a crisis of confidence, the Food and Drug Administration (FDA) in 2004 called on the Institute of Medicine (IOM) of the National Academies to conduct a comprehensive review of the safety of prescription drugs. The IOM assembled a distinguished review committee, and after nearly a year and a half of deliberations, a draft of the committee report became public on September 21, 2006 (www.iom.edu/CMS/3793/26341/37329.aspx). The committee recommends a number of specific reforms that we believe should serve as a blueprint for a stronger system of drug regulation. The reforms are discussed by Psaty and Burke in this issue of the *Journal*.¹

The committee emphasizes the need for improved monitoring of the safety of drugs after they have been approved and introduced into the marketplace. It points out that the FDA Center for Drug Evaluation and Research (CDER) devotes considerably more resources to the drug-approval process than to post-marketing surveillance. This imbalance must be corrected. Over half of CDER's financial resources are derived from user fees paid by the pharmaceutical industry, and these fees are earmarked for speedy drug approval. The committee recommends that more of CDER's financial resources come from general appropriations and that user fees also support post-marketing surveillance of drug safety. CDER, which has been chronically underfunded, needs sufficient financial resources to strengthen its drug-safety staff. The FDA must have the authority to require pharmaceutical companies to conduct fol-

low-up clinical studies on newly detected adverse effects of drugs, as well as the authority to enforce the completion of such studies and their submission to the agency.

The committee calls for greater transparency in communicating adverse drug effects to physicians and patients. It agrees with the International Committee of Medical Journal Editors that all clinical trials beyond phase 1 must be registered in a public database. The committee also proposes that the packaging materials for each newly approved drug carry a black triangle as an indication to consumers that the drug has been approved only recently and that the information about its safety is incomplete. Notably, the committee calls for a 2-year moratorium on direct-to-consumer advertising after a new prescription drug has been approved.

In recent years we have witnessed a growing politicization of the FDA. To strengthen the agency's leadership, this trend must be stopped. The decisions that the FDA commissioner and staff make about the nation's drug supply should be based solely on scientific evidence and should be independent of political considerations.

We face a mounting public health crisis in drug safety, and definitive action must be taken. The critical issues of financing, transparency, and independence must be addressed. The IOM committee's report is a crucial starting point, and we urge Congress to implement its recommendations and give them the highest priority.

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1. Psaty BM, Burke SP. Institute of Medicine on drug safety. *N Engl J Med* 2006;355:1753-5.

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