ACP American College of Physicians℠
INTERNAL MEDICINE | Doctors for Adults

Improving FDA Regulation of Prescription Drugs

Summary of Position Paper Approved by the ACP Board of Regents, April 2009

What Does FDA Regulation of Prescription Drugs Entail?

Prescription drugs are vital to preventing and treating illness and helping to avoid costlier health problems. The Food and Drug Administration (FDA) is charged with the mammoth and complex task of regulating the safety and effectiveness of new and approved drugs. The FDA reviews proposals for conducting clinical drug trials, evaluates drug applications and proposed drug labeling, and monitors drugs once they are approved and marketed.

The current system of drug safety monitoring includes preclinical testing followed by three phases of clinical studies. To obtain approval for a marketing drug in the U.S., drug sponsors must submit a new drug application that details the completed clinical drug trials and includes data on safety and effectiveness, pharmacology, toxicology, chemistry, manufacturing information, and proposed labeling language. The applications are evaluated by FDA reviewers and other experts who help the FDA determine whether to approve a drug for marketing. The FDA Amendments Act of 2007 increased the FDA's regulatory authority for postmarketing surveillance activities, enabling the FDA to require postmarketing testing to identify or assess potential serious risks.

Why Is It Important to Improve FDA Regulation?

Unfortunately, over the years the FDA's ability to approve and monitor new drugs has been compromised by chronic underfunding, limited regulatory authority, and insufficient organizational structure. The demands on the FDA have increased exponentially because of scientific advancement, an increase in the complexity and number of new products submitted for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries regulated by the FDA. However, the agency's resources have not increased in proportion to the demands.

In 2005, an Institute of Medicine committee, in a study requested by the FDA, concluded that the FDA's ability to approve and monitor drug safety and efficacy has been impaired by a lack of regulatory authority, long-standing underfunding, organizational problems, and an alarming lack of postmarketing data on the effectiveness and safety of drugs.

Key Findings and Recommendations from the Paper

ACP recommends the following:

- Improve the FDA's ability to approve and monitor prescription drugs through increased funding.
- Increase the FDA's capacity to regulate drugs manufactured outside the U.S. through both appropriations and user fees.

- The FDA's regulatory authority should be expanded and more clearly exercised in the design of preapproval trials and studies. Design of preapproval trials should include at least the following:
  - A sample size large enough to reflect an appropriate distribution of age and comorbidity among subjects.
  - Similar priority given to evaluating both drug safety and efficacy.
  - Use of scientific and technological tools (such as pharmacogenetics and computer stimulations) to provide earlier warnings about drug toxicities and potential harm.
  - Mandatory registration and public reporting of all clinical trial results.
- Bundling of drugs to limit marketability and availability should be prohibited.
- Improve the adverse events reporting system.
- Grant the FDA the authority to require that newly approved drugs have a special symbol on their labels to help increase public awareness that they are new, and limit direct-to-consumer advertising for the first two years after approval.

For More Information

This issue brief is a summary of *Improving FDA Regulation of Prescription Drugs*. The full paper is available at http://www.acponline.org/advocacy/where_we_stand/policy/fda.pdf.