New paper from internists calls for increased role for FDA

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A new policy paper that calls for broader authority and increased funding for the Food and Drug Administration (FDA) was released today by the American College of Physicians (ACP). Improving FDA Regulation of Prescription Drugs offers a half-dozen recommendations about how to improve the agency's ability to approve and monitor new drugs.

The paper notes that the FDA has been chronically underfunded, has limited regulatory authority, and insufficient organizational structure to effectively undertake the complex task of regulating the safety and effectiveness of new and approved drugs. This regulating includes reviewing proposals for conducting clinical drug trials, evaluating drug applications and proposed drug labeling, and monitoring drugs once they are approved and marketed.

"The FDA is critical in assuring the prescription drugs available in this country are safe and effective," said Joseph W. Stubbs, MD, FACP, president of ACP. "Unfortunately they have not historically been given the support and structure necessary to be optimally effective."

In 2005, the FDA requested that the Institute of Medicine put together a committee to assess the current state of the U.S. drug safety system and to make recommendations to improve that system. The committee found that FDA's ability to approve and monitor drug safety had been compromised by a lack of regulatory authority, long-standing underfunding, organizational problems, and a lack of postmarketing data

on the effectiveness and safety of drugs. Since the report was issued the agency has taken steps to improve, however problems still remain.

In order to effectively improve the agency's ability to regulate drugs, ACP recommends that the FDA:

- be given increased funding;
- increase their capacity to regulate drugs manufactured outside the U.S. through appropriations and user fees;
- be given expanded authority to exercise in the design of preapproval trials and studies;
- prohibit the bundling of drugs that limits marketability and availability;
- improve the adverse events reporting system; and,
- be given the authority to require new drugs be labeled with a symbol that indicates it is a new drug and that direct-to-consumer advertising be limited for the first two years after a drug's approval.

"Physicians and our patients expect that the medications we prescribe and use are beneficial and will not cause significant harm," concluded Dr. Stubbs. "I believe that using the recommendations we have provided today will allow us all to be more secure in that expectation."

Source: American College of Physicians