



# **Challenges for the FDA: The Future of Drug Safety, Workshop Summary (Forum on Drug Discovery, Development, and Translation)**

*Institute of Medicine, Board on Health Sciences Policy, Development, and Translation Forum on Drug Discovery, Sally Robinson, Leslie Pray*

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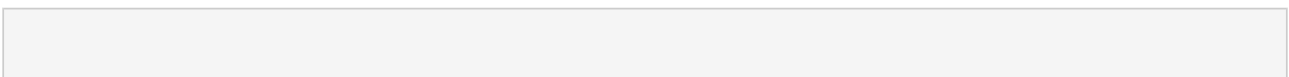
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As the principal agency regulating food, drugs, medical devices, and biological products used by Americans, the U.S. Food and Drug Administration (FDA) serves one of the most critical consumer protection functions of the federal government. The FDA's reach is enormous, regulating products that represent roughly 25 percent of all consumer spending in the United States. Since 1992, however, federal funding for the agency has diminished, and the FDA's Center for Drug Evaluation and Research (CDER) currently relies on the fees it receives from the industry it regulates to fund the majority of its drug regulation functions. Prescription drug safety is receiving heightened press coverage and congressional scrutiny as a result of recent, highly publicized events, such as the recall of Vioxx because of its link to heart attacks, and the link between certain antidepressants (selective serotonin reuptake inhibitors, or SSRIs) and an increased risk of suicidal ideation in children.

To address these concerns, the FDA in 2005 commissioned the Institute of Medicine (IOM) to conduct an independent assessment of the current U.S. drug safety system. In September 2006, the IOM committee released its report—The Future of Drug Safety: Promoting and Protecting the Health of the Public—which included 25 recommendations for improving the system for drug safety review. The committee identified four major vulnerabilities in the U.S. drug safety system: (1) chronic underfunding; (2) organization problems, particularly inadequate integration of pre- and postmarket data review; (3) a range of technical problems related to the insufficient quantity and quality of postmarket data and inadequate capability to systematically monitor the risks and benefits of drugs after marketing; and (4) unclear regulatory authority and insufficiently flexible regulatory tools. Since the IOM report was issued, the FDA has taken a number of steps toward implementing the recommended improvements. Like many government agencies, however, the FDA is financially strained by its existing responsibilities, and fully implementing the recommended improvements to the drug safety system would require significant financial commitments. The IOM report addressed some of the costs associated with its recommendations, but left many unanswered questions about the resources required to fully achieve the envisioned improvements. To better understand the types and magnitude of resources required to achieve the goals of the IOM report, the IOM's Forum on Drug Discovery, Development, and Translation convened a 1-day symposium in March 2007. Challenges for the FDA: The Future of Drug Safety, Workshop Summary explains the presentations and discussions in seven key areas: addressing the FDA's resource challenges; strengthening the scientific base of the agency; integrating pre- and postmarket review; enhancing postmarket safety monitoring; conducting confirmatory drug safety and efficacy studies; enhancing the value of clinical trial registration; and enhancing the FDA's postmarket regulation and enforcement.



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