

The Future of Drug Safety: Promoting and Protecting the Health of the Public

Alina Baciu, Kathleen Stratton, Sheila P. Burke

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In the wake of publicity and congressional attention to drug safety issues, the Food and Drug Administration (FDA) requested the Institute of Medicine assess the drug safety system. The committee reported that a lack of clear regulatory authority, chronic underfunding, organizational problems, and a scarcity of post-approval data about drugs' risks and benefits have hampered the FDA's ability to evaluate and address the safety of prescription drugs after they have reached the market. Noting that resources and therefore efforts to monitor medications' risk-benefit profiles taper off after approval, The Future of Drug Safety offers a broad set of recommendations to ensure that consideration of safety extends from before product approval through the entire time the product is marketed and used.



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