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FOR ENGINEERING AND SCIENCE

Ethical and Scientific Issues in Studying the Safety of Approved Drugs

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Body

An estimated 48 percent of the population takes at least one prescription drug in a given month. Drugs provide great benefits to society by saving or improving lives. Many drugs are also associated with side effects or adverse events, some serious and some discovered only after the drug is on the market.

The discovery of new adverse events in the postmarketing setting is part of the normal natural history of approved drugs, and timely identification and warning about drug risks are central to the mission of the Food and Drug Administration (FDA). This report [evaluates the strengths and weaknesses of various approaches to generate evidence about safety questions, and makes recommendations for appropriate followup studies and randomized clinical trials](#). It provides guidance to the FDA on how it should factor in different kinds of evidence in its regulatory decisions.

[Read *Ethical and Scientific Issues in Studying the Safety of Approved Drugs*.](#)

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