Ethical and Scientific Issues in Studying the Safety of Approved Drugs

Institute of Medicine, Board on Population Health and Public Health Practice, Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs

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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). Not all risks associated with a drug are known at the time of approval, because safety data are collected from studies that involve a relatively small number of human subjects during a relatively short period.

Written in response to a request by the FDA, *Ethical and Scientific Issues in Studying the Safety of Approved Drugs* discusses ethical and informed consent issues in conducting studies in the postmarketing setting. It 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. The book provides guidance to the FDA on how it should factor in different kinds of evidence in its regulatory decisions.

Ethical and Scientific Issues in Studying the Safety of Approved Drugs will be of interest to the pharmaceutical industry, patient advocates, researchers, and consumer groups.

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