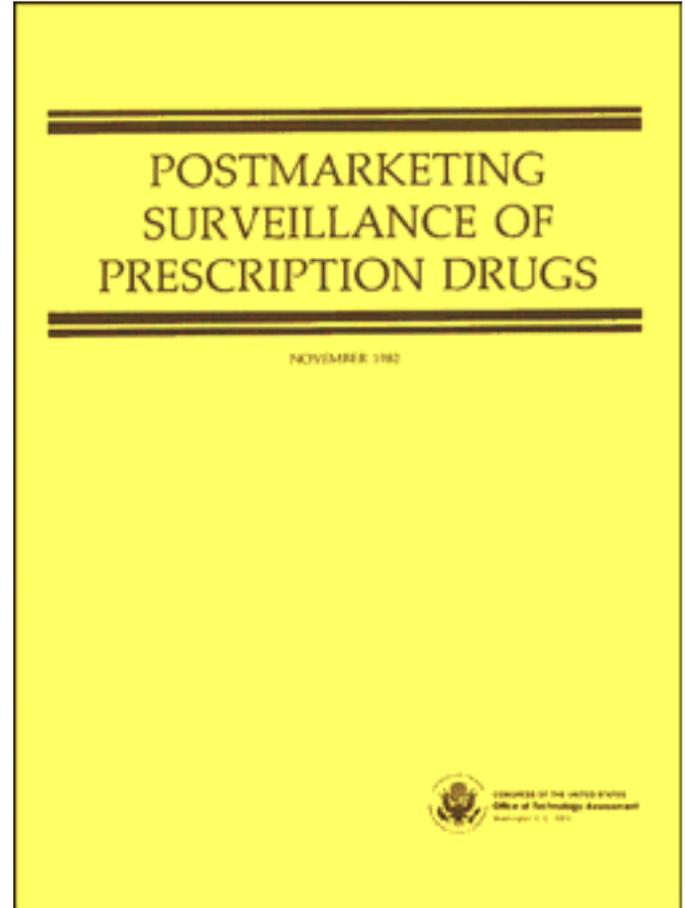


*Postmarketing Surveillance of Prescription
Drugs*

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Foreword

Before a drug can be prescribed for use in the United States, it must meet minimum statutory requirements for proof of its efficacy and safety as these have been established by the U.S. Food and Drug Administration (FDA). In premarketing testing, the numbers and types of patients exposed to a drug are necessarily limited compared with the numbers and types of patients who will eventually be prescribed the drug after it is marketed. New uses, contraindications, and side effects of drugs will then inevitably be discovered. Thus, various kinds of postmarketing surveillance have been proposed over the past decade.

A background paper on postmarketing surveillance of prescription drugs was originally being prepared by the Office of Technology Assessment for the project on strategies for medical technology assessment, as requested by the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment. At the further request of that committee and its subcommittee, that background paper was expanded into this full report, *Postmarketing Surveillance of Prescription Drugs*.

Current interest in drug regulation is also focused on the premarketing approval process, because the process has been criticized as unnecessarily delaying the release of valuable drugs in this country. As a result of such criticism, efforts are underway to shorten the approval process through administrative changes within FDA's Office of Drugs, and through revisions of the regulatory interpretations of the statutory requirements for "adequate tests" of a drug's safety and "substantial evidence" of its effectiveness.

This report describes the drug approval process, the history and objectives of postmarketing surveillance, the methods employed to accomplish it, and current activities in postmarketing surveillance. The report provides guidelines to determine whether shortening the drug approval process by various means would diminish its ability to detect adverse drug reactions prior to a drug's release for marketing. The report also identifies oversight issues and options for increased postmarketing surveillance both in the case that Congress decides to relax premarket approval requirements and in the case that it does not.



JOHN H. GIBBONS
Director

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OTA Postmarketing Surveillance of Prescription Drugs Project Staff

H. David Banta, *Assistant Director, OTA
Health and Life Sciences Division*

Clyde J. Behney, *Health Program Manager*

Lawrence H. Miike, *Project Director*

Kerry Britten Kemp, *Editor*

Mary E. Harvey, *Secretary*

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