Postmarketing Surveillance of Prescription Drugs

November 1982

NTIS order #PB83-173625
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
Health Program Advisory Committee

Sidney S. Lee, Chair
Michael Reese Hospital and Medical Center
Chicago, Ill.

Stuart H. Altman
Florence Heller School
Brandeis University
Waltham, Mass.

Kurt Deuschle
Mount Sinai School of Medicine
New York, N.Y.

Carroll Estes*
School of Nursing
University of California
San Francisco, Calif.

Rashi Fein
Center for Community Health and Medical Care
Harvard Medical School
Boston, Mass.

Melvin A. Glasser
Committee for National Health Insurance
Washington, D.C.

Patricia King
Georgetown Law Center
Washington, D.C.

Joyce C. Lashof
School of Public Health
University of California
Berkeley, Calif.

Mark Lepper
Rush-Presbyterian-St. Luke’s Medical Center
Chicago, Ill.

Margaret Mahoney
The Commonwealth Fund
New York, N.Y.

C. Frederick Mosteller
Department of Health Policy and Management
School of Public Health
Harvard University
Boston, Mass.

Mitchell Rabkin
Beth Israel Hospital
Boston, Mass.

Dorothy P. Rice*
Department of Social and Behavioral Sciences
School of Nursing
University of California
San Francisco, Calif.

Richard K. Riegloman’
School of Medicine
George Washington University
Washington, D.C.

Walter L. Robb*
Medical Systems Operations
General Electric
Milwaukee, Wis.

Frederick C. Robbins
Institute of Medicine
Washington, D.C.

Rosemary Stevens
Department of History and Sociology of Science
University of Pennsylvania

Kerr L. White
Rockefeller Foundation
New York, N.Y.

*Appointed summer of 1982