

Drug Labeling in Developing Countries

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Foreword

Pharmaceuticals developed in the latter part of this century have caused dramatic improvements in the quality of life for people around the globe. U.S. pharmaceutical companies can take credit for the largest number of new products and collectively maintain a share of the market larger than that of any other country. With this prominence comes the responsibility of informing the prescribers and consumers of pharmaceuticals of all the medically important information known about each one. In developing countries, where government resources to analyze and monitor drug labeling are severely constrained, companies operate with little oversight.

Prompted by the ethical imperative that U.S. pharmaceutical companies provide accurate and complete information with their products, and evidence from the past that they did not always do so, Congressman John Dingell, Chairman of the House Committee on Energy and Commerce; Congressman Henry Waxman, Chairman of its Subcommittee on Health and the Environment; and Senator Edward M. Kennedy, then Ranking Minority Member and now Chairman of the Senate Committee on Labor and Human Resources, asked OTA to examine the status of drug labeling by U.S.-based multinational pharmaceutical companies in developing countries.

OTA developed a method for analyzing drug labeling, using a sample of several hundred labels from four developing countries—Brazil, Kenya, Panama, and Thailand. Unfortunately, serious problems were found. The policy options identified by OTA present Congress with possible ways to improve the situation.

The success of this project depended on a great deal of assistance to OTA. An Expert Working Group, which spent many days working with OTA staff, was key to the analytic process. The advisory panel, chaired by Dr. Bernard Mirkin, Professor of Pediatrics at Northwestern University Medical School, helped to guide the project. The cooperation and interaction with OTA of the 18 companies whose product labeling was evaluated was essential. Numerous individuals and organizations also provided information and assistance, including meeting with project staff in Kenya and Thailand and reviewing drafts of the report.

OTA is grateful for the contribution of each of these individuals and groups. As with all OTA reports, the final responsibility for the content of the assessment rests with OTA.



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NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

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