



## Adverse Drug Event Reporting: The Roles of Consumers and Health-Care Professionals: Workshop Summary

By Board on Health Sciences Policy, Institute of Medicine, Forum on Drug Discovery, Development, and Translation, Jeffrey M. Drazen, Jennifer Rainey

National Academies Press. Paperback. Book Condition: new. BRAND NEW, Adverse Drug Event Reporting: The Roles of Consumers and Health-Care Professionals: Workshop Summary, Board on Health Sciences Policy, Institute of Medicine, Forum on Drug Discovery, Development, and Translation, Jeffrey M. Drazen, Jennifer Rainey, Recent concerns about the unexpected adverse effects of marketed drugs, such as COX-2 (cyclooxygenase-2) inhibitors or specific statins, raise concerns not only about reporting these events during premarket studies, but also about the responsibility for ongoing surveillance of drugs once they are on the market. Sometimes serious adverse drug reactions are fully appreciated only after a drug has been on the market for years. Therefore, when a drug is approved and released to the market, large numbers of patients will be exposed before all the potential adverse effects have been identified and thoroughly studied. Currently, there is no clearly defined process for addressing safety questions about drugs after premarketing research has occurred. In November 2005, the Institute of Medicine's Forum on Drug Discovery, Development, and Translation convened a workshop to explore issues associated with the reporting of ADEs. The workshop addressed the following questions: How can ADEs be effectively identified, particularly when the adverse effects are rare? How...

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