

1. Record Nr.	UNINA9911143028903321
Titolo	Understanding the benefits and risks of pharmaceuticals : workshop summary, Forum on Drug Discovery, Development, and Translation, Board on Health Sciences Policy / / Leslie Pray, rapporteur ; Institute of Medicine of the National Academies
Pubbl/distr/stampa	Washington, D.C., : National Academies Press, c2007
ISBN	0-309-17976-9 1-280-94146-4 9786610941469 0-309-10739-3
Edizione	[1st ed.]
Descrizione fisica	1 online resource (97 p.)
Altri autori (Persone)	PrayLeslie A
Disciplina	615
Soggetti	Drugs Drugs - Side effects Chemotherapy Chemotherapy - Side effects
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references.
Nota di contenuto	""Front Matter""; ""Reviewers""; ""Contents""; ""Summary""; ""1 Introduction""; ""2 Regulatory Assessment""; ""3 The Challenge of Communication""; ""4 The Importance of Context in Healthcare Decision Making""; ""5 Patient Experience with Drugs over Time""; ""6 Next Steps""; ""References""; ""Appendixes""; ""A Workshop Agenda""; ""B Discussion Leader and Speaker Biographies""
Sommario/riassunto	All pharmaceutical products have inherent risks, and their use involves trade-offs between their therapeutic benefits and their risks. However, the public has a limited understanding of the benefits and risks of drugs, and many individuals believe that drugs approved by the U.S. Food and Drug Administration (FDA) carry no risks. The FDA is responsible for evaluating and balancing the potential risks of drugs with their potential benefits. Assessing, managing, and communicating the benefit-risk profile of a pharmaceutical product is a complex and nuanced scientific, political, and sociological challenge. Once the

assessment is made, the FDA is then responsible for managing how to communicate these risks and make healthcare decisions based on them. To explore these issues, the Forum on Drug Discovery, Development, and Translation conducted a public workshop entitled Understanding the Benefits and Risks of Pharmaceuticals, with the broad goals of gaining a better understanding of the current system used to evaluate benefit and risk, and to identify opportunities for improvement. This workshop was held in Washington, D.C., on May 30-31, 2006. The benefit-risk profiles of pharmaceuticals are constantly evolving as new data are collected throughout the life cycle of a drug. Discussions during the workshop focused on the following: (1) premarket assessment, during which clinical trial data are used to assess benefit and risk; (2) communication of that information to prescribing physicians and their patients; (3) healthcare decisions made by prescribing physicians and their patients; and (4) the accumulation of benefit-risk information from postmarketing experience, which feeds back into the other phases. Understanding the Benefits and Risks of Pharmaceuticals: Workshop Summary explains in detail the discussions during this workshop.
