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James E. Wise, Jr., Scott Baron

**Characterizing and Communicating Uncertainty in
the Assessment of Benefits and Risks of
Pharmaceutical Products**

Institute of
Medicine, Board on Health Sciences Policy, Forum on
Drug Discovery, Development, and
Translation, 2014-12-19

Despite the extensive body of evidence that informs regulatory decisions on pharmaceutical products, significant uncertainties persist, including the underlying variability in human biology, factors associated with the chemistry of a drug, and limitations in the research and clinical trial process itself that might limit the generalizability of results. As a result, regulatory reviewers are consistently required to draw conclusions about a drug's safety and efficacy from imperfect data. Efforts are underway within the drug development community to enhance the evaluation and communication of the benefits and risks associated with pharmaceutical products, aimed at increasing the predictability, transparency, and efficiency of pharmaceutical regulatory decision making. Effectively communicating regulatory decisions necessarily includes explanation of the impact of uncertainty on decision making. On February 12 and May 12, 2014, the Institute of Medicine's Forum on Drug Discovery, Development, and Translation held public workshops to advance the development of more systematic and structured approaches to characterize and communicate the sources of uncertainty in the assessment of benefits and risks, and to consider their implications for pharmaceutical regulatory decisions. Workshop presentations and discussions on February 12 were convened to explore the science of identifying and characterizing uncertainty in scientific evidence and approaches to translate uncertainties into decisions that reflect the values of stakeholders. The May 12 workshop presentations and discussions

explored tools and approaches to communicating about scientific uncertainties to a range of stakeholders in the drug development process. Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products summarizes the presentation and discussion of both events. This report explores potential analytical and communication approaches and identifies key considerations on their development, evaluation, and incorporation into pharmaceutical benefit-risk assessment throughout the entire drug development lifecycle.

The Protection of Human Rights and Fundamental Freedoms in the Fight against Terrorism Irina Wiegand, 2012-05-24 With the terrorist attacks of 9/11, the threat of international terrorism - a threat to peace and stability - became evident to the world. Even though this event was not directed against European Union member states, it triggered the expansion of common anti-terrorist laws and policies. This cooperation aimed at fighting terrorism has led to the introduction of legal instruments that do not comply with international and European human rights law. Despite this drastic shift, the question in how far the European Union abides by human rights law in its fight against terrorism has rarely been discussed so far. Irina Wiegand looks exactly at this question. Her book gives extensive background information and yet has high scholarly value. It offers a general introduction on terrorism and an overview of today's legal framework with regard to terrorism and looks at the European Union's responses to terrorism. The main focus of the book is then on the analysis of these responses in the light of human rights law. This scrutiny provides the background of international and regional human rights legislation and continues with the analysis of the current legal practice of the European

Union and the European Courts. If you want to know why we cannot agree on the definition of the term 'terrorism', whether states can claim the right of self-defense after a terrorist attack, how the European anti-terrorist legislation developed over time, and whether the European Union violates certain human rights conventions, this book is a must-read for you.

Emerging Markets and the World Patent Order

Frederick M. Abbott, Carlos M. Correa, Peter Drahos, 2013-12-27 The patent has emerged as a dominant force in 21st century economic policy. This book examines the impact of the BRICS and other emerging economies on the global patent framework and charts the phenomenal rise in the number of patents in some of these countries.

Monstrosity, Disability, and the Posthuman in the Medieval and Early Modern World Richard H. Godden, Asa Simon Mittman, 2019-11-21 This collection examines the intersection of the discourses of "disability" and "monstrosity" in a timely and necessary intervention in the scholarly fields of Disability Studies and Monster Studies. Analyzing Medieval and Early Modern art and literature replete with images of non-normative bodies, these essays consider the pernicious history of defining people with distinctly non-normative bodies or non-normative cognition as monsters. In many cases throughout Western history, a figure marked by what Rosemarie Garland-Thomson has termed "the extraordinary body" is labeled a "monster." This volume explores the origins of this conflation, examines the problems and possibilities inherent in it, and casts both disability and monstrosity in light of emergent, empowering discourses of posthumanism.

International Cooperation in Counter-terrorism Giuseppe Nesi, 2016-04-22 This volume provides a timely analysis of global and regional responses to international terrorism. The work assesses the

role of the United Nations and its various organs, particularly the General Assembly and the Security Council, and discusses the key legal issues. The second part of the book examines the activity of regional organizations both in their own right as well as their interaction with the UN. The volume concludes with a discussion of whether, to what extent and how the fight against terrorism has encroached upon fundamental rules of international law such as the international protection of human rights or the use of force among states. The volume is the latest in a series drawing on the presentations of high ranking scholars, diplomats and representatives of international organizations. The result is a stimulating and thought-provoking book which will be of interest to researchers and policy-makers alike.

99 Jumpstarts for Kids' Science Research Peggy Whitley, Susan Williams Goodwin, 2005-12-30 This third entry in the Jumpstarts series focuses on Science topics for upper elementary and middle school students. Maintaining the 99 Jumpstarts format of the two previous books, 99 Jumpstarts for Kids Science Research is divided into ten broad topical sections. Each topic is arranged in alphabetical order under its section. Topics include Body Parts, Energy, Animals, Heavens, Weather, Matter, Medicine, Technology, Environment, and Geology. This pathfinder approach aides students in the research process, helping them define important terms, offer beginning questions to help narrow their topic, furnish source ideas and some fun activities to explore each topic. Grades 4-8.

Privacy Enhancing Technologies George Danezis, David Martin, 2006-06-22 This book constitutes the thoroughly refereed postproceedings of the 5th International Workshop on Privacy Enhancing Technologies, PET 2006, held in Cavtat, Croatia, in May and June 2005. The 17

revised full papers presented were carefully selected from 74 submissions during two rounds of reviewing and improvement. The papers address most current privacy enhancing technologies in various application contexts.

Jethro Tull's Thick as a Brick and A Passion Play Tim Smolko, 2013-10-07 Since the 1960s, British progressive rock band Jethro Tull has pushed the technical and compositional boundaries of rock music by infusing its musical output with traditions drawn from classical, folk, jazz, and world music. The release of *Thick as a Brick* (1972) and *A Passion Play* (1973) won the group legions of new followers and topped the Billboard charts in the United States, among the most unusual albums ever to do so. Tim Smolko explores the large-scale form, expansive instrumentation, and complex arrangements that characterize these two albums, each composed of one continuous song. Featuring insights from Ian Anderson and in-depth musical analysis, Smolko discusses the band's influence on popular culture and why many consider *Thick as a Brick* and *A Passion Play* to be two of the greatest concept albums in rock history.

Democratizing Central and Eastern Europe Luca Tomini, 2015-05-22 At first, it was believed that accession to the EU would have a positive effect on the process of democratization in former communist countries. However, over time it became clear that difficulties with the democratic system endured in a number of these countries. This book reconsiders the results of the process of democratization in Central and Eastern Europe and evaluates the nature and effectiveness of the Europeanization process. It comparatively explores the process of democratic consolidation and accession to the European Union in Poland, Slovakia and Bulgaria. Using these case studies, the book assesses the impact of the EU on the accountability and integrity of governments in

this part of Europe. This text will be of key interest to scholars and students of democratization studies, European studies, EU studies, transition studies, area studies, and international relations.

Fundamental Principles of EU Law Against Money Laundering Emmanuel Ioannides, 2016-04-22 This book critically analyses fundamental principles of EU law for the control of international economic crime. Discussing how the reporting system and the exchange of information are at the heart of the global anti-money laundering regime, the study also looks at the inferential force of financial intelligence in criminal proceedings and the responsibilities this places on prosecutors and criminals alike. The author closely examines the application of Article 8(2) of the European Court of Human Rights for the retention and movement of the fingerprints, cellular samples and DNA profiles of unconvicted persons, and argues the incompatibility with the ECHR, along with the effect of socially stigmatising unconvicted persons. The work concludes with exploring how financial regulation has, inter alia, shifted responsibility to businesses and financial institutions to become more transparent and accountable to financial regulators and tax authorities. This critical analysis is essential reading for law students and the Judicial Body, as well as financial crime investigators and regulators.

Combating Money Laundering and the Financing of Terrorism, 2009 Combating Money Laundering and the Financing of Terrorism: A Comprehensive Training Guide has been developed by the Financial Market Integrity Unit of the World Bank to support the World Bank's Capacity Enhancement Program on AML/CFT. The modules are comprised of the following eight Modules: Module 1 – Effects on Economic Development and International Standards

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International Standards Module 3a - Regulatory and
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Requirements for Financial Institutions Module 4 -
Building an Effective Financial Intelligence Unit
Module 5 - Domestic (inter-agency) and
International Cooperation Module 6 - Combating the
Financing of Terrorism Module 7 - Investigating
Money Laundering and Terrorist Financing

The Internationalisation of Corruption Clare
Fletcher, Daniela Herrmann, 2012 With an inclusive
and broad-based understanding of corruption from
the perspective of international studies as an
interdisciplinary space in the social sciences,
the authors of *The Internationalisation of
Corruption* have produced a book that is accessible
to anyone approaching the study of corruption from
any one of the different disciplinary traditions.

*Standard-setting through monitoring? The role of
Council of Europe expert bodies in the development
of human rights* Renate Kicker, Markus
Möstl, 2013-04-01 A variety of mechanisms has been
established in the Council of Europe to monitor
compliance with human rights standards. This
publication discusses four specific monitoring
bodies, namely the Advisory Committee on the
Framework Convention for the Protection of
National Minorities, the European Committee for
the Prevention of Torture and Inhuman or Degrading
Treatment or Punishment, the European Commission
against Racism and Intolerance, and the European
Committee of Social Rights. By assessing and
comparing the monitoring procedures and standard-
setting activities of these expert bodies, the
authors make an essential contribution to the
discourse on the Council of Europe's role - both
current and future - with regard to human
rights. This book constitutes a rich source of
information on the dialogue between the four
committees and European states. It is addressed to

practitioners, diplomats and decision makers at national level to deepen their understanding of the aims and functioning of Council of Europe monitoring mechanisms. Students and academics will gain a comprehensive insight into the legal bases, mandates and procedures of such mechanisms. Finally, it is hoped that the expert bodies themselves will gain much from the authors' analysis of present-day challenges for monitoring and the impact their implementation standards may have on the development of the European human rights order.

At the Helm of USS America James E. Wise, Jr., Scott Baron, 2014-08-22 Only the best officers are given command of U.S. Navy ships, and only the elite of these are selected for aircraft carriers. The USS America was the third of four Kitty Hawk-class super-carriers. Commissioned in 1965, decommissioned in 1996, she served three times in Vietnam, and once each in Libya, the Persian Gulf and Bosnia. This book profiles the 23 men who commanded the America and her crew of 5,000 during 31 years. Most of them were combat veterans—World War II, Korea, Vietnam, Mayaguez Rescue Operations, Lebanon, Haiti, Libya, Bosnia, and Desert Storm. Four were Naval Academy graduates; seven were test pilots; one became Inspector General of the Navy; one wore both Navy wings and submariner dolphins; and one was a prisoner of war in Vietnam for nearly six years. Two retired as admirals—one was Chief of Naval Operations—five as vice admirals, and 11 as rear admirals. Each profile gives a career account based on official biographies, published memoirs, and interviews with the commanders or their families.

Design, User Experience, and Usability: Interactive Experience Design Aaron Marcus, 2015-07-20 The three-volume set LNCS 9186, 9187, and 9188 constitutes the proceedings of the 4th International Conference on Design, User

Experience, and Usability, DUXU 2015, held as part of the 17th International Conference on Human-Computer Interaction, HCII 2015, in Los Angeles, CA, USA, in August 2015, jointly with 13 other thematically similar conferences. The total of 1462 papers and 246 posters presented at the HCII 2015 conferences were carefully reviewed and selected from 4843 submissions. These papers address the latest research and development efforts and highlight the human aspects of design and use of computing systems. The papers accepted for presentation thoroughly cover the entire field of Human-Computer Interaction, addressing major advances in knowledge and effective use of computers in a variety of application areas. The total of 132 contributions included in the DUXU proceedings were carefully reviewed and selected for inclusion in this three-volume set. The 64 papers included in this volume are organized in topical sections on designing the social media experience, designing the learning experience, designing the playing experience, designing the urban experience, designing the driving experience, designing the healthcare patient's experience, and designing for the healthcare professional's experience.

Corruption, Asset Recovery, and the Protection of Property in Public International Law Radha Ivory, 2014-08-21 A human rights analysis of international efforts to confiscate wealth in grand corruption cases that focuses on protections for property.

Terrorism Ben Saul, 2012-02-07 International anti-terrorism measures existed long before 11 September 2001 but have increased markedly since. A myriad of norms in different branches of law are now deployed to confront transnational and domestic terrorism. There is also a proliferating body of 'soft law' addressing terrorism, stemming from United Nations organs, specialised

international bodies and regional organisations. It is timely to draw together these diverse legal developments over time into a single reference work. Bringing the original documents together provides for ease of reference and enables scholars, practitioners and students to more easily compare and contrast various sources. The book's coverage is comprehensive (thematically, organisationally, geographically and temporally) and open to a balance of sources (hard and soft), but is judicious in its selection and prioritisation of the most significant and representative documents – in a field where there are many repetitive or insubstantial documents. Importantly, the book looks beyond the traditional trans-Atlantic bias towards European, British and American sources in this area to include materials from Asia, Africa, Latin America and the Middle East. Taken as a whole, the book aids in evidencing the emerging field of international anti-terrorism law.

Migration, New Nationalisms and Populism Rada Ivekovic, 2022-02-28 This book examines the antagonistic relationship between new European nationalisms as these often go hand-in-hand with populism, and the phenomenon of migration. Migration has become a significant issue both in Europe and the whole world. Although it has always existed, much of public opinion sees it now as a problem. The latter has been exaggerated through a crisis in hospitality exacerbated by the relatively recently constructed and misplaced feeling of a civilisational threat from islam. Migration is then countered by the escalation of new nationalisms, at least some of which are supported by populism. This book offers an understanding of this conjunction of migration and nationalism in the post-cold war European context. More specifically, the book takes up how the end of the simplified cold war cognitive binary means

an unprecedented epistemological confusion and depoliticisation which takes migration as its target, but could resort to other targets too. Discussing the postcolonial background to the new migrations, the book also considers womens' rights, postsocialism and the relevance of the current pandemic, as the issue of migration is addressed in the context of the European crisis-ridden present. This wide-ranging interrogation of how contemporary European migration is conceived and understood will appeal to students, academics, activists, policy makers, and others with interests in contemporary migration, new nationalisms, populism, feminism, colonial, postcolonial, and decolonial issues, as well as socialism and postsocialism.

Water Quality for Ecosystem and Human Health

Geneviève M. Carr, James P. Neary, 2008 This document is intended to provide an overview of the major components of surface and ground water quality and how these relate to ecosystem and human health. Local, regional and global assessments of water quality monitoring data are used to illustrate key features of aquatic environments, and to demonstrate how human activities on the landscape can influence water quality in both positive and negative ways. Clear and concise background knowledge on water quality can serve to support other water assessments.

Europe in Crisis Ivan Berend, 2012-11-12 This book analyzes the European Great Recession of 2008-12, its economic and social causes, its historical roots, and the policies adopted by the European Union to find a way out of it. It contains explicit debates with several economists and analysts on some of the most controversial questions about the causes of the crisis and the policies applied by the European Union. It presents the cases of Iceland, Greece and Ireland, the countries that first declined into crisis in

Europe, each of them in a different way. Iceland is a case study for reckless banking practices, Greece of reckless public spending, and Ireland of reckless household indebtedness. At least seven other countries, mostly from the peripheries of Europe, had similarly reckless banking and spending practices. In the center of the book are the economic and social causes of the crisis. Contemporary advanced capitalism became financialized, de-industrialized and globalized and got rid of the straitjacket of regulations. Solid banking was replaced by high-risk, casino-type activity. The European common currency also had a structural problem – monetary unification without a federal state and fiscal unification. The other side of the same coin is European hyper-consumerism. A new lifestyle emerged during two super-prosperous periods in the 1950s to 1960s, and during the 1990s to 2006. Trying to find an exit policy, the European Union turned to strict austerity measures to curb the budget deficit and indebtedness. This book critically analyzes the debate around austerity policy. The creation of important supra-national institutions, and of a financial supervisory authority and stability mechanisms, strengthens integration. The correction of the euro's structural mistake by creating a quasi-fiscal unification is even more important. The introduction of mandatory fiscal rules and their supervision promises a long-term solution for a well-functioning common currency. These measures, meanwhile, create a two-tier European Union with a fast-track core. This book suggests that the European Union will emerge stronger from the crisis. This book will be of particular interest to students and researchers of economics, history, political science and international finance, but will also prove profitable reading for practitioners and the interested public.

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