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~~Understanding Compulsory Licensing How Drug Prices Work | WSJ Regulatory Compliance in the Pharmaceutical Industry, by Ali Pirzada | Ernst & Young Pharmaceutical Positioning - the book Business Development & Licensing Solutions | Clinical Trials | Drug Discovery~~  
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Since the publication of the Institute of Medicine (IOM) report Clinical Practice Guidelines We Can Trust in 2011, there has been an increasing emphasis on assuring that clinical practice guidelines are trustworthy, developed in a transparent fashion, and based on a systematic review of the available research evidence. To align with the IOM recommendations and to meet the new requirements for inclusion of a guideline in the National Guidelines Clearinghouse of the Agency for Healthcare Research and Quality (AHRQ), American Psychiatric Association (APA) has adopted a new process for practice guideline development. Under this new process APA's practice guidelines also seek to provide better clinical utility and usability. Rather than a broad overview of treatment for a disorder, new practice guidelines focus on a set of discrete clinical questions of relevance to an overarching subject area. A systematic review of

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evidence is conducted to address these clinical questions and involves a detailed assessment of individual studies. The quality of the overall body of evidence is also rated and is summarized in the practice guideline. With the new process, recommendations are determined by weighing potential benefits and harms of an intervention in a specific clinical context. Clear, concise, and actionable recommendation statements help clinicians to incorporate recommendations into clinical practice, with the goal of improving quality of care. The new practice guideline format is also designed to be more user friendly by dividing information into modules on specific clinical questions. Each module has a consistent organization, which will assist users in finding clinically useful and relevant information quickly and easily. This new edition of the practice guidelines on psychiatric evaluation for adults is the first set of the APA's guidelines developed under the new guideline development process. These guidelines address the following nine topics, in the context of an initial psychiatric evaluation: review of psychiatric symptoms, trauma history, and treatment history; substance use assessment; assessment of suicide risk; assessment for risk of aggressive behaviors; assessment of cultural factors; assessment of medical health; quantitative assessment; involvement of the patient in treatment decision making; and documentation of the

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psychiatric evaluation. Each guideline recommends or suggests topics to include during an initial psychiatric evaluation. Findings from an expert opinion survey have also been taken into consideration in making recommendations or suggestions. In addition to reviewing the available evidence on psychiatry evaluation, each guideline also provides guidance to clinicians on implementing these recommendations to enhance patient care.

Analyzes the costs, risks, and economic rewards of pharmaceutical R&D and the impact of public policy on both costs and returns. Examines the rapid increase in pharmaceutical R&D that began in the 1980s in the light of trends in science, technology, drug discovery, and health insurance coverage; Government regulation; product liability; market competition; Federal tax policy; and Federal support of prescription drug research. 12 appendices, including a glossary of terms.

Royalty Rates for Licensing Intellectual Property includes critical information on financial theory, rules of thumb, industry guidelines, litigation based royalty rates, and tables of actual rates from real deals for different industries.

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This open access book presents a unique collection of practical examples from the field of pharma business management and research. It covers a wide range of topics such as: 'Brexit and its Impact on pharmaceutical Law - Implications for Global Pharma Companies', 'Implementation of Measures and Sustainable Actions to Improve Employee's Engagement', 'Global Medical Clinical and Regulatory Affairs (GMCRA)', and 'A Quality Management System for R & D Project and Portfolio Management in a Pharmaceutical Company'. The chapters are summaries of masters theses by "high potential" Pharma MBA students from the Goethe Business School, Frankfurt/Main, Germany, with 8-10 years of work experience and are based on scientific know-how and real-world experience. The authors applied their interdisciplinary knowledge gained in 22 months of studies in the MBA program to selected practical themes drawn from their daily business.

Scores of talented and dedicated people serve the forensic science community, performing vitally important work. However, they are often constrained by lack of adequate resources, sound policies, and national support. It is clear that change and advancements, both systematic and scientific, are needed in a number of forensic science disciplines to ensure the reliability of work, establish enforceable standards, and promote best practices with consistent application.

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Strengthening Forensic Science in the United States: A Path Forward provides a detailed plan for addressing these needs and suggests the creation of a new government entity, the National Institute of Forensic Science, to establish and enforce standards within the forensic science community. The benefits of improving and regulating the forensic science disciplines are clear: assisting law enforcement officials, enhancing homeland security, and reducing the risk of wrongful conviction and exoneration. Strengthening Forensic Science in the United States gives a full account of what is needed to advance the forensic science disciplines, including upgrading of systems and organizational structures, better training, widespread adoption of uniform and enforceable best practices, and mandatory certification and accreditation programs. While this book provides an essential call-to-action for congress and policy makers, it also serves as a vital tool for law enforcement agencies, criminal prosecutors and attorneys, and forensic science educators.

This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza, and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international fora, such as the World Trade Organization, the

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World Health Organization and the World Intellectual Property Organization. Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions which encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, open-source drug development and forms of 'creative capitalism'.

More than we ever anticipated, alliances among firms are changing the way business is conducted, particularly in the global, high-technology sector. The reasons are clear: companies must increasingly pool their capabilities to succeed in ever more complex and rapidly changing businesses. But the consequences for managers and for the economy have so far been underestimated. In this new book, Benjamin Gomes-Casseres presents the first in-depth account of the new world of business alliances and shows how collaboration has become part of the very fabric of modern competition. Alliances, he argues, create new units of competition that do battle with one another and with traditional single firms. The flexible capabilities of these multi-

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firm constellations give them advantages over single firms in certain contexts, offsetting the advantage of a single firm's unified control. When managed effectively, alliances can strengthen a firm's competitive advantage and narrow the gap between leading firms and second-tier players. This often results in intensified rivalry, and the competition within an industry is transformed. Alliances often spread swiftly through an industry as firms jockey for advantage. Yet the very spread of alliances increases their costs and poses new limits on their use. Gomes-Casseres concludes that firms need to manage their constellations to enhance collaboration within their groups, while raising what he calls "barriers to collaboration" for rivals. These ideas are developed and illustrated through original case studies of alliances among U.S., Japanese, and European firms in electronics and computers, including Xerox, IBM, and Fujitsu as well as other small and large companies. The book should be of interest to business academics, managers, and general readers concerned with contemporary capitalism.

This book offers a primer on the valuation of digital intangibles, a trending class of immaterial assets. Startups like successful unicorns, as well as consolidated firms desperately working to re-engineer their business models, are now trying to go digital and to

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reap higher returns by exploiting new intangibles. This book is innovative in its design and concept since it tackles a frontier topic with an original methodology, combining academic rigor with practical insights. Digital intangibles range from digitized versions of traditional immaterial assets (brands, patents, know-how, etc.) to more trendy applications like big data, Internet of Things, interoperable databases, artificial intelligence, digital newspapers, social networks, blockchains, FinTech applications, etc. This book comprehensively addresses related valuation issues, and demonstrates how best practices can be applied to specific asset appraisals, making it of interest to researchers, students, and practitioners alike.

This book provides a multi-disciplinary framework for developing and analyzing health sector reforms, based on the authors' extensive international experience. It offers practical guidance - useful to policymakers, consultants, academics, and students alike - and stresses the need to take account of each country's economic, administrative, and political circumstances. The authors explain how to design effective government interventions in five areas - financing, payment, organization, regulation, and behavior - to improve the performance and equity of health systems around the

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