Product List 2017 Sandoz

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Protein Therapeutics

Biologic and Systemic Agents in Dermatology

With over 400 drug monographs, this book covers the technical, practical and legal aspects that you should consider before prescribing or administering drugs via enteral feeding tubes.

The Very Hungry Pregnant Lady

NEW YORK TIMES BESTSELLER • “A powerfully imagined novel . . . [a] profoundly moving book that engages the heights and depths of human experience.”—Los Angeles Times It is September 8, 1943, and fourteen-year-old Claudette Blum and her father are among the thousands of Jewish refugees scrambling over the Alps toward Italy, where they hope to find safety now that the Italians have broken from Germany and made a separate peace with the Allies. The Blums will soon discover that Italy is anything but peaceful, as it quickly becomes an open battleground for the Nazis, the Allies, Resistance fighters, Jews in hiding, and ordinary Italian civilians trying to survive. Tracing the lives of a handful of fascinating characters—a charismatic Italian Resistance leader, a priest, an Italian rabbi’s family, a disillusioned German doctor—Mary Doria Russell tells the little-known story of the vast underground effort by Italian citizens who saved the lives of 43,000 Jews during the final phase of World War II. A Thread of Grace puts a human face on history. Praise for A Thread of Grace “An addictive page-turner . . . [Mary Doria] Russell has an astonishing story to tell—full of action, paced like a rapid-fire thriller, in tense, vivid scenes that move with cinematic verve.”—The Washington Post Book World “Hauntingly beautiful, utterly unforgettable.”—San Francisco Chronicle “Rich . . . Based on the heroism of ordinary people, [A Thread of Grace] packs an emotional punch.”—People “[A] deeply felt and compellingly written book . . . The progress of each character’s life is marked or measured by

acts of grace. . . . Russell is a smart, passionate and imaginative writer."—Cleveland Plain Dealer "A feat of storytelling . . . an important book [that] needs to be widely read."—Portland Oregonian "Mary Doria Russell's fans (and aren't we all?) will rejoice to see her new novel on the shelves. A Thread of Grace is as ambitious, beautiful, tense, and transforming as any of us could have hoped."—Karen Joy Fowler, author of The Jane Austen Book Club "A story of love and war, A Thread of Grace speaks to the resilience and beauty of the human spirit in the midst of unimaginable horror. It is, unquestionably, a literary triumph."—David Morrell, author of The Brotherhood of the Rose and First Blood

Pocket Guide for Brand and Generic Drugs

Market access is the process by which a pharmaceutical company gets its product available on the market after having obtained a marketing authorization from a regulatory agency and by which the product becomes available for all patients for whom it is indicated as per its marketing authorization. It covers a group of activities intended to provide access to the appropriate medicine for the appropriate group of patients at the appropriate price (in most countries). Market Access may also be seen as activities that support the management of potential barriers, such as non-optimal price and reimbursement levels, the restriction of the scope of prescribing for the drug or complicated prescription writing or funding procedures. Since there are cultural differences among countries, any Market Access strategy needs to be culturally sensitive. Pharmaceutical Market Access in emerging markets has been extensively discussed in our previous book, published in 2016. The present book focuses on developed markets with the goal of helping students, academics, industry personnel, government workers, and decision makers understand the environment in developed markets.

Development and Principles of International Humanitarian Law

What's the Deal with Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Strategic Elements explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters. This includes principal patents and intellectual property, regulatory pathways, and concerns about affordability on a global scale. It addresses the complexity of biosimilar products, and it discusses the utilization of biosimilars and related biological drugs in expanding world markets. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume examines the science, technology, finance, legality, ethics, and politics of biosimilar drugs. It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars, and it provides detailed descriptions of the legal, regulatory, and commercial characteristics. The book also presents a global strategy on how to build, take to market, and manage the next generation of biosimilars throughout their life cycle.

Generic

A lighthearted parody of Eric Carle's much-loved classic The Very Hungry Caterpillar, The Very Hungry Pregnant Lady tackles the mysteries faced by pregnant women everywhere—namely, how can I have so little space for my stomach and yet be hungry all the time? And is it better to try unsuccessfully to sleep, or just give in and have another snack? Pairing playful text with bright, colorful images, The Very Hungry Pregnant Lady is both a send-up and a celebration of this strange, ridiculous, and exciting time in the lives of all mothers-to-be.

An Introduction to Categorical Data Analysis

Drug Pricing and Pharmaceutical Patenting Practices

Who would have thought a simple bean could do so much? Heirloom bean expert Steve Sando provides descriptions of the many varieties now available, from Scarlet Runners to the spotted Eye of the Tiger beans. Nearly 90 recipes in the book will entice readers to cook up bowls of heartwarming Risotto and Cranberry Beans with Pancetta, or Caribbean Black Bean Soup. Close-up photos of the beans make them easy to identify. Packed with protein, fiber, and vitamins, these little treasures are the perfect addition to any meal.

Heirloom Beans

Since the beginning of times, pain treatment has been the motive of research giving birth to multiple groups of pharmacological families and therapies. Pain perception is a construction built over the biological phenomenon of signal transduction surrounded by different factors such as gender, age, and sociocultural status, among others. The concept of pain as the solely biological manifestation of defense is nowadays considered as a narrow-minded view of this topic. In this regard concepts such as newborns feel no pain or older people complain about everything therefore should not be paid attention when referring pain, are being left behind in the understanding that pain alleviation is a human right and everybody feeling pain should be helped for its relief. This book comprises many aspects of pain treatment and the drugs involved in it. From old analgesics with new mechanisms of action for pain alleviation to analgesics potential for diminishing oxidative stress; from pharmacological therapies to electrical ones, going through alternative medicine; and from pain treatment in dentistry to chronic pain therapies, also boarding the treatment of migraine, different experts share their knowledge on the topic.

Pain Relief

A biological product, or biologic, is a preparation, such as a drug or a vaccine, that is made from living organisms. Compared with conventional chemical drugs, biologics are relatively large and complex molecules. They may be composed of proteins (and/or their constituent amino acids), carbohydrates (such as sugars),

nucleic acids (such as DNA), or combinations of these substances. Biologics may also be cells or tissues used in transplantation. A biosimilar, sometimes referred to as a follow-on biologic, is a therapeutic drug that is similar but not structurally identical to the brand-name biologic made by a pharmaceutical or biotechnology company. In contrast, a generic chemical drug is an exact copy of a brand-name chemical drug. Because biologics are more complex than chemical drugs, both in composition and method of manufacture, biosimilars will not be exact replicas of the brand-name product, but may instead be shown to be highly similar. The Food and Drug Administration (FDA) regulates both biologics and chemical drugs. Biologics and biosimilars frequently require special handling (such as refrigeration) and processing to avoid contamination by microbes or other unwanted substances. Also, they are usually administered to patients via injection or infused directly into the bloodstream. For these reasons, biologics often are referred to as specialty drugs, which can be very costly. In April 2006, the European Medicines Agency (EMA) authorized for marketing in Europe the first biosimilar product, Omnitrope, a human growth hormone. Today a total of 35 biosimilars are EMA-authorized for the European market. The introduction of biosimilars in Europe has reduced prices for biologics by up to 33%. For one drug in Portugal, the price reduction was 61%. In contrast, the pathway to marketing biosimilars in the United States has had several barriers. FDA approved Omnitrope in June 2006, following an April 2006 court ruling requiring the FDA to move forward with consideration of the application. At the time the FDA indicated that this action "does not establish a pathway" for approval of other follow-on biologic drugs and stated that Congress must change the law before the agency can approve copies of nearly all other such products. In March 2010 Congress established a new regulatory authority for FDA by creating an abbreviated licensure pathway for biological products demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-licensed biological product. The new authority was accomplished via the Biologics Price Competition and Innovation Act (BPCIA) of 2009, enacted as Title VII of the Affordable Care Act. Congress authorized FDA to collect associated fees via the Biosimilar User Fee Act of 2012 (BsUFA). The five-year biosimilars user fee authority was set to expire on September 30, 2017. Congress reauthorized the biosimilar user fee program via the Food and Drug Administration Reauthorization Act of 2017. As more biosimilars enter the U.S. market, analysts expect to see U.S. price reductions similar to those that have occurred in Europe. However, of the seven biosimilars approved by FDA, sales of five biosimilars have been delayed, or (allegedly) adversely impacted, by actions of the brand-name manufacturers, including patent infringement lawsuits and suits over alleged anticompetitive contracts with insurers in order to prevent coverage of biosimilars that are less expensive substituted for best-selling biologics. The high costs of pharmaceuticals in general-and biologics in particular-has led to an increased interest in understanding the federal government's role in the development of costly new therapeutics. In the case of six of the seven biosimilars approved by FDA, the associated brand-name drug was originally discovered by scientists at public-sector research institutions.

Clariant Clareant

Tell Them We Are Going Home details the courageous journey of the Northern Cheyennes, under the leadership of Little Wolf and Dull Knife, from Indian Territory northward to their homelands in the Powder River country. Incorporating the

perspectives of the Cheyennes, the U.S. military, the Indian Bureau, and the Kansas settlers who encountered the traveling Indians, this book provides a complete account of the odyssey. The dramatic fifteen-hundred-mile trek of the Northern Cheyennes through Kansas, Nebraska, South Dakota, and Montana, lasting from 1878 to 1879, would become one of the most important episodes in American history and in Cheyenne memory.

Biosimilars

A valuable new edition of a standard reference The use of statistical methods for categorical data has increased dramatically, particularly for applications in the biomedical and social sciences. An Introduction to Categorical Data Analysis, Third Edition summarizes these methods and shows readers how to use them using software. Readers will find a unified generalized linear models approach that connects logistic regression and loglinear models for discrete data with normal regression for continuous data. Adding to the value in the new edition is: • Illustrations of the use of R software to perform all the analyses in the book • A new chapter on alternative methods for categorical data, including smoothing and regularization methods (such as the lasso), classification methods such as linear discriminant analysis and classification trees, and cluster analysis • New sections in many chapters introducing the Bayesian approach for the methods of that chapter • More than 70 analyses of data sets to illustrate application of the methods, and about 200 exercises, many containing other data sets • An appendix showing how to use SAS, Stata, and SPSS, and an appendix with short solutions to most odd-numbered exercises Written in an applied, nontechnical style, this book illustrates the methods using a wide variety of real data, including medical clinical trials, environmental questions, drug use by teenagers, horseshoe crab mating, basketball shooting, correlates of happiness, and much more. An Introduction to Categorical Data Analysis, Third Edition is an invaluable tool for statisticians and biostatisticians as well as methodologists in the social and behavioral sciences, medicine and public health, marketing, education, and the biological and agricultural sciences.

State and Local Government Purchasing

Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs, Second Edition addresses the pivotal issues relating to translational science, including preclinical and clinical drug development, regulatory science, pharmaco-economics and cost-effectiveness considerations. The new edition also provides an update on new proteins and genetic medicines, the translational and integrated sciences that continue to fuel the innovations in medicine, as well as the new areas of therapeutic development including cancer vaccines, stem cell therapeutics, and cell-based therapies.

Biosimilars and Interchangeable Biologics

Written by leading experts in the field and designed for dermatologists and residents, this book includes evidence-based medicine that underscores the clinical data, as well as practical tips on how to use both biologic and systemic agents in

the field of dermatology. In the past decade, there have been several groundbreaking advances in medical dermatology. Novel biologic and systemic agents have been developed to treat inflammatory disorders, including psoriasis and atopic dermatitis, as well as skin malignancies such as melanoma. Biologic and Systemic Agents in Dermatology encompasses these developments by describing the mechanism of action of these various agents and the clinical efficacy and safety to treating these respective disorders. The utilization of biologic and systemic agents in other dermatologic conditions, pharmacoeconomics, pharmacovigilance, and clinical trials outcomes are discussed as well as topics including tumor necrosis, conventional systemic agents for psoriatic disease, and oral agents for atopic dermatitis.

Capital City

This is the story of LSD told by a concerned yet hopeful father, organic chemist Albert Hofmann. He traces LSDs path from a promising psychiatric research medicine to a recreational drug sparking hysteria and prohibition.We follow Dr. Hofmanns trek across Mexico to discover sacred plants related to LSD, and listen in as he corresponds with other notable figures about his remarkable discovery.Underlying it all is Dr. Hofmanns powerful conclusion that mystical experience may be our planets best hope for survival. Whether induced by LSD, meditation, or arising spontaneously, such experiences help us to comprehend the wonder, the mystery of the divine in the microcosm of the atom, in the macrocosm of the spiral nebula, in the seeds of plants, in the body and soul of people.Now, more than sixty years after the birth of Albert Hofmanns problem child, his vision of its true potential is more relevant, and more needed, than ever.

Biologics and Biosimilars

Implementing biocatalytic strategies in an industrial setting is a challenging task, especially when commercial scale necessitates a balance between industrial need and economic viability. With invited contributions from a wide range of chemical and pharmaceutical companies, this book bridges the gap between academia and industry. Contributors discuss current processes, types of biocatalysts and improvements, industrial motivation and the key aspects needed for economic success. Focussing on industry related issues, this book will be a useful tool for future research by both practitioners and academics.

A Thread of Grace

"Millions of Americans are taking prescription drugs made in China and don't know it-- and pharmaceutical companies are not eager to tell them. This probing book examines the implications for the quality and availability of vital medicines for consumers"--Provided by publisher.

Biosimilar Drug Product Development

Identifies drug products approved on the basis of safety & effectiveness by the FDA under the Federal Food, Drug, & Cosmetic Act. Composed of 4 parts: approved

prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Sect. 505 of the Act; & products that have never been marketed, have been discontinued from marketing, or that have had their approvals withdrawn for other than safety or efficacy reasons.

Pharmaceutical Market Access in Developed Markets

Describes the contributions of such pioneers in bacteriology as ANtony Leeuwenhoek, Louis Pasteur and Paul Ehrlich.

The Beaver Men

Greene’s history sheds light on the controversies shadowing the success of generics: problems with the generalizability of medical knowledge, the fragile role of science in public policy, and the increasing role of industry, marketing, and consumer logics in late-twentieth-century and early twenty-first century health care.

China Rx

A history of the beaver trade in the Great Plains region ranges from its beginnings along the Saint Lawrence River to the last great rendezvous of traders and trappers in 1834

Hong Kong Fax Directory

This volume of essays addresses some of the most significant issues of contemporary international law. It particularly focuses on questions relating to international humanitarian law, the law of the sea, human rights, the use of force, international environmental law, and the settlement of international disputes. Recent developments in some other issues of international law such as State immunity and State responsibility are also dealt with. The Work contains a number of articles in French and is offered as a tribute to the prominent Iranian Professor of International Law, Djamchid Momtaz, on the occasion of his 75th birthday.

LSD, My Problem Child

The main aim of this book is to inquire into the system of norms regulating the 'internationalization' of internal conflicts. The traditional distinction between international & internal conflict, which entails different legal consequences, is in practice very difficult to detect due to the presence, in many instances, of elements typical of both situations. Through a careful & extraordinarily useful examination of all relevant cases of 'internationalized' internal conflict since 1956, the validity of the traditional framework of rules concerning foreign intervention in internal conflict is reassessed. At the same time, the applicability to these situations of the rules typical of international conflicts are analyzed with a view to providing the existence of a continuum between the two situations, not only as a matter of fact but also with respect to their legal regulation.

Biotechnology and Biopharmaceuticals

A valuable tool for establishing and maintaining system reliability, overall equipment effectiveness (OEE) has proven to be very effective in reducing unscheduled downtime for companies around the world. So much so that OEE is quickly becoming a requirement for improving quality and substantiating capacity in leading organizations, as well as a req

Tell Them We Are Going Home

When a biological drug patent expires, alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps. The assessment of biosimilarity and interchangeability is also complicated and difficult. Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre- and post-approval issues.

Standard Directory of Advertisers

Pocket Guide For Brand And Generic Drugs Contains An Alphabetical List Of Brand Name Drugs And Their Generic Name. This Handy Pocket-Size Guide Is An Excellent Resource For Use In The Classroom To Accompany Additional Educational Products, And As An On-The-Job Reference. Pocket Guide For Brand And Generic Drugs Is An Affordable, Helpful Reference Tool For Both Students And Clinicians Alike. Bundle This Pocket Guide With Additional Jones & Bartlett Texts, And Save Up To 30%! Ask Your Account Specialist About Bundle Options And Bulk Purchase Specials For Your Program!

Microbe Hunters

Biocatalysis

Managing Drug Supply (MDS) is the leading reference on how to manage essential medicines in developing countries. MDS was originally published in 1982; it was revised in 1997 with over 10,000 copies distributed in over 60 countries worldwide. The third edition, MDS-3: Managing Access to Medicines and Health Technologies reflects the dramatic changes in politics and public health priorities, advances in science and medicine, greater focus on health care systems, increased donor funding, and the advent of information technology that have profoundly affected access to essential medicines over the past 14 years. Nearly 100 experts from a wide range of disciplines and virtually every corner of the world have contributed to this third edition. In addition to many new country studies, references, and extensive revisions, MDS-3 offers new chapters on areas such as pharmaceutical benefits in insurance programs, pricing, intellectual property, drug seller initiatives, and traditional and complementary medicine. The revisions and new chapters echo the wide variety of issues that are important to health practitioners and policy makers today. MDS-3 will be a valuable tool in the effort to ensure universal access

to quality medicines and health technologies and their appropriate use.

New Trade Names

"The Sioux Indians came into my life before I had any preconceived notions about them," writes Mari Sandoz about the visitors to her family homestead in the Sandhills of Nebraska when she was a child. These Were the Sioux, written in her last decade, takes the reader far inside a world of rituals surrounding puberty, courtship, and marriage, as well as the hunt and the battle.

These Were the Sioux

Compounded Topical Pain Creams

Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals

Approved Drug Products with Therapeutic Evaluations

Only those who are sure of their origin can know their destination. True to this

principle, Anna Bálint for the first time presents the history of Clariant, the globally operating chemical company which was formed by a merger of Sandoz and Hoechst. Eyewitness accounts complete the portrait and give an informative as well as entertaining insight into the demanding task of successfully melding two distinct corporate cultures into a single strong and innovative enterprise.

Handbook of Drug Administration via Enteral Feeding Tubes, 3rd edition

Medicinal chemistry is both science and art. The science of medicinal chemistry offers mankind one of its best hopes for improving the quality of life. The art of medicinal chemistry continues to challenge its practitioners with the need for both intuition and experience to discover new drugs. Hence sharing the experience of drug research is uniquely beneficial to the field of medicinal chemistry. Drug research requires interdisciplinary team-work at the interface between chemistry, biology and medicine. Therefore, the topic-related series Topics in Medicinal Chemistry covers all relevant aspects of drug research, e.g. pathobiochemistry of diseases, identification and validation of (emerging) drug targets, structural biology, drugability of targets, drug design approaches, chemogenomics, synthetic chemistry including combinatorial methods, bioorganic chemistry, natural compounds, high-throughput screening, pharmacological in vitro and in vivo investigations, drug-receptor interactions on the molecular level, structure-activity relationships, drug absorption, distribution, metabolism, elimination, toxicology and pharmacogenomics. In general, special volumes are edited by well known guest editors

China's Quest for Liberty

"This thundering book by the author of Old Jules is the story of the vast cattle industry of the American West; stupendous in length, concept, and achievement, it is the result of a lifetime of knowledge and research. . . . The whole story is here, long but never dull, written with humor and understatement."—Kirkus Service "Here, tough as whang leather, nourishing as pemmican, turbulent as Dodge City on a Saturday night in the late 1870s, is what time may well decide is the definitive history of the founding and flourishing of the cattle industry on this continent. . . . This splendid book says more (and says it better) about the most romantic figures of the old West than dozens of other books that have ranged over this familiar ground. Mari Sandoz has given herself room to move with tremendous drive and scholarship."—Victor P. Hass, Chicago Sunday Tribune "Drawing the fullest flavor from her expert descriptive technique, Mari Sandoz has written a regional history to stand among the best of its kind."—Library Journal

Crazy Horse

An evocative fictional portrait of the impact of the Depression on the Great Plains captures working-class people of the period as they struggle to overcome the hardships, challenges, and pain of everyday life in the face of poverty, political and economic upheaval, and corruption. Reprint.

Biopharmaceuticals

This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

The Cattlemen

Intellectual property (IP) rights in pharmaceuticals are typically justified as necessary to allow manufacturers to recoup their substantial investments in research, development, and regulatory approval. IP law provides exclusive rights in a particular invention or product for a certain time period, potentially enabling the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices. If rights holders are able to charge such prices, they have an incentive to lengthen the period of exclusive rights as much as possible. Indeed, some commentators allege that pharmaceutical manufacturers have engaged in patenting practices that unduly extend the period of exclusivity. These critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Criticisms center on four such practices: * "Evergreening": So-called patent "evergreening" is the practice of filing for new patents on secondary features of a particular product as earlier patents expire, thereby extending patent exclusivity past the original twenty-year term. Later-filed patents may delay or prevent entry by competitors, thereby allowing the brand-name drug manufacturer (the brand) to continue charging high prices. * "Product Hopping": Generic drug manufacturers allege that as patents on a particular product expire, brand manufacturers may attempt to introduce and switch the market to a new, similar product covered by a later-expiring patent-a process known as "product hopping" or "product switching." This practice takes two forms: a "hard switch," where the older product is removed from the market, and a "soft switch," where the older product is kept on the market with the new product. In either case, the brand will focus its marketing on the new product in order to limit the market for any generic versions of the old product. * "Patent Thickets": Generic

and biosimilar companies also allege that the brands create "patent thickets" by filing numerous patents on the same product. These thickets allegedly prevent generics from entering the market due to the risk of infringement and the high cost of patent litigation. * "Pay-for-Delay" Settlements: Litigation often results when a generic or biosimilar manufacturer attempts to enter the market with a less expensive version of a branded pharmaceutical. Core issues usually include whether the brand's patents are valid, and whether the generic or biosimilar product infringes those patents. Rather than litigate these issues to judgment, however, the parties will often settle. Such settlements may involve the brand paying the generic or biosimilar to stay out of the market-referred to as "reverse payment" or "pay-for-delay" settlements. These settlements are allegedly anticompetitive because they allow the brand to continue to charge high prices without risking invalidation of its patent, thus unjustifiably benefiting the settling companies at the expense of the consumer. Drug manufacturers respond that their patenting practices protect new, innovative inventions, as Congress intended when it created the patent system. In their view, the terms for these practices are unfairly pejorative, or, at most, describe outlier behavior by a few companies. Defenders of these patenting practices reject their characterization as anticompetitive and emphasize that strong patent rights are needed to encourage innovation and life-saving research and development efforts. In recent years, some commentators and Members of Congress have proposed patent reforms that seek to limit or curtail these patenting practices, which some perceive as contributing to high prices for pharmaceutical products.

The International Legal Order: Current Needs and Possible Responses

MDS-3

"China's Quest for Liberty is a personal story of a young man fully engaged in understanding the world he was born into and working toward making that world into a better and freer place to life. It is about an unexpected journey a Chinese journalist hastaken to pursue freedom, involving such diverse fields or disciplines as politics, business, humanities, science and technology, government agencies and non-governmental organizations. Some took place as daily life, and some occurred in detentions or disasters. It is about a world whose dimensions have been basically obscured not only in China but also in the global public square, and walk with this young journalist, step by step, to find, paradoxically, the hope in the depth of hopelessness, the strength in acknowledging weakness, the change in substance by, among other things, keeping the form unchanged for at least a while, the youth in growing up despite growing old, the invisible in the visible, the imperishable in the perishable, the reality in theshadow of numerous fake realities, and the freedom gained not mainly through human efforts but as mercy and grace from the one who created humans and other beings. As well as digging out the overlooked Christian background in the rise of the sanctity of human life, creative culture, constitutionalism, work as a vocation, modern management, servant leadership, and catchphrases like "the global village" and "The medium is the message", the author tells of insider observations about the rise of Christianityin

China generally and about Shouwang Church in particular. Through sharing these findings, this book aims to show how the one who made the universe rules the world and how this creator sets his creatures free by himself"--

The OEE Primer

Pain is both a symptom and a disease. It manifests in multiple forms and its treatment is complex. Physical, social, economic, and emotional consequences of pain can impair an individual's overall health, well-being, productivity, and relationships in myriad ways. The impact of pain at a population level is vast and, while estimates differ, the Centers for Disease Control and Prevention reported that 50 million U.S. adults are living in pain. In terms of pain's global impact, estimates suggest the problem affects approximately 1 in 5 adults across the world, with nearly 1 in 10 adults newly diagnosed with chronic pain each year. In recent years, the issues surrounding the complexity of pain management have contributed to increased demand for alternative strategies for treating pain. One such strategy is to expand use of topical pain medicationsâ€"medications applied to intact skin. This nonoral route of administration for pain medication has the potential benefit, in theory, of local activity and fewer systemic side effects. Compounding is an age-old pharmaceutical practice of combining, mixing, or adjusting ingredients to create a tailored medication to meet the needs of a patient. The aim of compounding, historically, has been to provide patients with access to therapeutic alternatives that are safe and effective, especially for people with clinical needs that cannot otherwise be met by commercially available FDA-approved drugs. Compounded Topical Pain Creams explores issues regarding the safety and effectiveness of the ingredients in these pain creams. This report analyzes the available scientific data relating to the ingredients used in compounded topical pain creams and offers recommendations regarding the treatment of patients.

ROMANCE ACTION & ADVENTURE MYSTERY & THRILLER BIOGRAPHIES & HISTORY CHILDREN'S YOUNG ADULT FANTASY HISTORICAL FICTION HORROR LITERARY FICTION NON-FICTION SCIENCE FICTION