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A Consumer's Perspective on Medical Devices - United States. Congress. House. Committee on Commerce. Subcommittee on Oversight and Investigations 1995

Medical Device Regulation - Elijah Wreh 2023-01-01
Medical Device Regulation provides the current FDA-CDRH thinking on the regulation of medical devices. This book offers information on how devices meet criteria for being a medical device, which agencies regulate medical devices, how policies regarding regulation affect the market, rules regarding marketing, and laws and standards that govern testing. This practical, well-structured reference tool helps medical device manufacturers both in and out of the United States with premarket application and meeting complex FDA regulatory requirements. The book delivers a comprehensive overview of the field from an author with expertise in regulatory affairs and commercialization of medical devices. Offers a unique focus on the regulatory affairs industry, specifically targeted at regulatory affairs professionals and those seeking certification Puts regulations in the context of contemporary design Includes case studies and applications of regulations
Improving and Accelerating Therapeutic Development for Nervous System Disorders - Institute of Medicine 2014-02-06
Improving and Accelerating Therapeutic Development for Nervous System Disorders is the summary of a workshop convened by the IOM Forum on Neuroscience and Nervous System Disorders to examine opportunities to accelerate early phases of drug development for nervous system drug discovery. Workshop participants discussed challenges in neuroscience research for enabling faster entry of potential treatments into first-in-human trials, explored how new and emerging tools and technologies may improve the efficiency of research, and considered mechanisms to facilitate a more effective and efficient development pipeline. There are several challenges to the current drug development pipeline for nervous system disorders. The fundamental etiology and pathophysiology of many nervous system disorders are unknown and the brain is inaccessible to study, making it difficult to develop accurate models. Patient heterogeneity is high, disease pathology can occur years to decades before becoming clinically apparent, and diagnostic and treatment biomarkers are lacking. In addition, the lack of validated targets, limitations related to the predictive validity of animal models - the extent to which the model predicts clinical efficacy - and regulatory barriers can also impede translation and drug development for nervous system disorders. Improving and Accelerating Therapeutic Development for Nervous System Disorders identifies avenues for moving directly from cellular models to human trials, minimizing the need for animal models to test efficacy, and discusses the potential benefits and risks of such an approach. This report is a

timely discussion of opportunities to improve early drug development with a focus toward preclinical trials.

Environmental Health Perspectives - 2004

Risk Regulation in the United States and European Union - A. Luedtke 2010-06-07

Globalization and technology have altered public fears and changed expectations of how government should make people safer. This book analyzes how Europeans and Americans perceive and regulate risk. The authors show how public fears about risk are filtered through political systems to pressure governments to insure against risk.

Preparing for Future Products of Biotechnology - National Academies of Sciences, Engineering, and Medicine 2017-07-28

Between 1973 and 2016, the ways to manipulate DNA to endow new characteristics in an organism (that is, biotechnology) have advanced, enabling the development of products that were not previously possible. What will the likely future products of biotechnology be over the next 5â€"10 years? What scientific capabilities, tools, and/or expertise may be needed by the regulatory agencies to ensure they make efficient and sound evaluations of the likely future products of biotechnology? Preparing for Future Products of Biotechnology analyzes the future landscape of biotechnology products and seeks to inform forthcoming policy making. This report identifies potential new risks and frameworks for risk assessment and areas in which the risks or lack of risks relating to the products of biotechnology are well understood.

Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease - Institute of Medicine 2010-06-25

Many people naturally assume that the claims made for foods and nutritional supplements have the same degree of scientific grounding as those for medication, but that is not always the case. The IOM recommends that the FDA adopt a consistent scientific framework for biomarker evaluation in order to achieve a rigorous and transparent process.

Pharmacovigilance- An Industry Perspective - Deepa Arora

FDA in the Twenty-First Century - Holly Fernandez Lynch 2015-09-08

In its decades-long effort to assure the safety, efficacy, and security of medicines and other products, the Food and Drug Administration has struggled with issues of funding, proper associations with industry, and the balance between consumer choice and consumer protection. Today, these challenges are compounded by the pressures of globalization, the introduction of novel technologies, and fast-evolving threats to public health. With essays by leading scholars and government and private-industry experts, FDA in the Twenty-First Century addresses perennial and new problems and the improvements the agency can make to better serve the public good. The collection features essays on effective regulation in an era of globalization, consumer empowerment, and comparative effectiveness, as well as questions of data transparency, conflicts of interest, industry responsibility, and innovation policy, all with an emphasis on pharmaceuticals. The book also intervenes in the debate over off-label drug marketing and the proper role of the FDA before and after a drug goes on the market. Dealing honestly and thoroughly with the FDA's successes and failures, these essays rethink the structure, function, and future of the agency and the effect policy innovations may have on regulatory institutions abroad.

Contraceptive Risk - William Green 2017-05-02

The story of Depo-Provera joins the national struggle over the drug's FDA approval to the state legal issues raised by its contraceptive and criminal justice uses. Depo-Provera is known as an injectable hormonal birth control method, but few are familiar with its dark and complicated history. Depo-Provera was tested on women since the mid-1960s without their informed consent until it was FDA-approved in 1992, but never FDA-approved as chemical castration for male sex offenders. Contraceptive Risk is William Green's landmark study of Depo-Provera. Based on a fascinating combination of archival materials and interviews, the book is framed as three interconnected stories told by Judith Weisz, who chaired the FDA's Public Board of Inquiry on Depo-Provera, a scientific court; by Anne MacMurdo who brought a products liability suit against Upjohn, the drug's manufacturer, for the deleterious side effects

she suffered from the drug's use; and by Roger Gauntlett, an Upjohn heir who, when he was convicted of sexual assault, refused to take a dose of his family's own medicine as a probation condition. Together these three stories of Depo-Provera's convoluted fifty year odyssey call for a paradigm shift in pharmaceutical drug development. Contraceptive Risk is a thoroughly researched and engrossing approach to the scientific, political and institutional forces involved in health law and policy, as well as the multifaceted politics of measuring risk.

Inhaled Pharmaceutical Product Development Perspectives - Anthony J. Hickey 2017-11-23

Inhaled Pharmaceutical Product Development Perspectives: Challenges and Opportunities describes methods and procedures for consideration when developing inhaled pharmaceuticals, while commenting on product development strategies and their suitability to support regulatory submission. It bridges the gap between the aspirations of scientists invested in new technology development and the requirements that must be met for any new product. The book brings together emerging analytical and inhalation technologies, providing perspectives that illuminate formulation and device design, development, regulatory compliance, and practice. Focusing on underlying scientific and technical principles known to be acceptable from the current regulatory perspective, this monograph will remain useful as a high-level guide to inhaled product development for the foreseeable future. Discusses development strategies and best practices in the context of regulatory requirements Written by a broadly qualified expert drawing on the knowledge and critical opinions of key individuals in the field Includes a foreword by Charles G. Thiel

Mitochondrial Replacement Techniques - National Academies of Sciences, Engineering, and Medicine 2016-03-17

Mitochondrial replacement techniques (MRTs) are designed to prevent the transmission of mitochondrial DNA (mtDNA) diseases from mother to child. While MRTs, if effective, could satisfy a desire of women seeking to have a genetically related child without the risk of passing on mtDNA disease, the technique raises significant ethical and social issues. It would create offspring who have genetic material from two women, something never sanctioned in humans, and would create mitochondrial changes that could be heritable (in female offspring), and therefore passed on in perpetuity. The manipulation would be performed on eggs or embryos, would affect every cell of the resulting individual, and once carried out this genetic manipulation is not reversible. Mitochondrial Replacement Techniques considers the implications of manipulating mitochondrial content both in children born to women as a result of participating in these studies and in descendants of any female offspring. This study examines the ethical and social issues related to MRTs, outlines principles that would provide a framework and foundation for oversight of MRTs, and develops recommendations to inform the Food and Drug Administration's consideration of investigational new drug applications.

Food Law and Regulation for Non-Lawyers - Marc C. Sanchez 2018-02-22

Designed and modeled after a six-week introductory food law course taught at Northeastern University, Food Law and Regulation for Non-Lawyers offers a succinct overview of key topics and core concepts for food scientists, quality managers, and others who need to understand the regulation of food in the U.S. This second edition includes critical updates on the Food Safety Modernization Act--the first change to the food safety laws in over 70 years. The seven foundational rules, finalized in 2015, are discussed in detail. The new edition also includes other regulatory updates such as the new Nutrition Fact Panel, changes to the definition of fiber, and the FDA’s attempt to regulate the widely used “healthy” claim. These timely updates, along with the core concepts of the first edition, make the volume an essential and practical tool for regulatory professionals.

Milestones in U.S. Food and Drug Law History - 1985

Research Involving Children - United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1977

Regulating and Managing Food Safety in the EU - Harry Bremmers 2018-08-01
This book analyses EU food law from a regulatory, economic and managerial perspective. It presents an economic assessment of strategies of food safety regulation, and discusses the different regulatory regimes in EU food law. It examines the challenges of food safety in the internal market as well as the regulatory tools that are available. The book's generic theorising and measurement of regulatory effects is supplemented by detailed analysis of key topics in food markets, such as health claims, enforcement strategies, and induced risk management at the level of the organizations producing food. The regulatory effects discussed in the book range from classical regulatory analysis covering e.g. effects of ex-ante versus ex-post regulation and content-related versus information-related regulation to new regulatory options such as behavioral regulation. The book takes as its premise the idea that economic considerations are basic to the design and functioning of the European food supply arena, and that economic effects consolidate or induce modification of the present legal structures and principles. The assessments, analyses and examination of the various issues presented in the book serve to answer the question of how economic theory and practice can explain and enhance the shaping and modification of the regulatory framework that fosters safe and sustainable food supply chains.
Regulation Versus Litigation - Daniel P. Kessler 2011-02
The efficacy of various political institutions is the subject of intense debate between proponents of broad legislative standards enforced through litigation and those who prefer regulation by administrative agencies. This book explores the trade-offs between litigation and regulation, the circumstances in which one approach may outperform the other, and the principles that affect the choice between addressing particular economic activities with one system or the other. Combining theoretical analysis with empirical investigation in a range of industries, including public health, financial markets, medical care, and workplace safety, Regulation versus Litigation sheds light on the costs and benefits of two important instruments of economic policy.
National Strategy for the COVID-19 Response and Pandemic Preparedness - Joseph R. Biden, Jr. 2021-05-18
The ultimate guide for anyone wondering how President Joe Biden will respond to the COVID-19 pandemic—all his plans, goals, and executive orders in response to the coronavirus crisis. Shortly after being inaugurated as the 46th President of the United States, Joe Biden and his administration released this 200 page guide detailing his plans to respond to the coronavirus pandemic. The National Strategy for the COVID-19 Response and Pandemic Preparedness breaks down seven crucial goals of President Joe Biden's administration with regards to the coronavirus pandemic: 1. Restore trust with the American people. 2. Mount a safe, effective, and comprehensive vaccination campaign. 3. Mitigate spread through expanding masking, testing, data, treatments, health care workforce, and clear public health standards. 4. Immediately expand emergency relief and exercise the Defense Production Act. 5. Safely reopen schools, businesses, and travel while protecting workers. 6. Protect those most at risk and advance equity, including across racial, ethnic and rural/urban lines. 7. Restore U.S. leadership globally and build better preparedness for future threats. Each of these goals are explained and detailed in the book, with evidence about the current circumstances and how we got here, as well as plans and concrete steps to achieve each goal. Also included is the full text of the many Executive Orders that will be issued by President Biden to achieve each of these goals. The National Strategy for the COVID-19 Response and Pandemic Preparedness is required reading for anyone interested in or concerned about the COVID-19 pandemic and its effects on American society.
Enhancing Food Safety - National Research Council 2010-11-04
Recent outbreaks of illnesses traced to contaminated sprouts and lettuce illustrate the holes that exist in the system for monitoring problems and preventing foodborne diseases. Although it is not solely responsible for ensuring the safety of the nation's food supply, the U.S. Food and Drug Administration (FDA) oversees monitoring and intervention for 80 percent of

the food supply. The U.S. Food and Drug Administration's abilities to discover potential threats to food safety and prevent outbreaks of foodborne illness are hampered by impediments to efficient use of its limited resources and a piecemeal approach to gathering and using information on risks. Enhancing Food Safety: The Role of the Food and Drug Administration, a new book from the Institute of Medicine and the National Research Council, responds to a congressional request for recommendations on how to close gaps in FDA's food safety systems. Enhancing Food Safety begins with a brief review of the Food Protection Plan (FPP), FDA's food safety philosophy developed in 2007. The lack of sufficient detail and specific strategies in the FPP renders it ineffectual. The book stresses the need for FPP to evolve and be supported by the type of strategic planning described in these pages. It also explores the development and implementation of a stronger, more effective food safety system built on a risk-based approach to food safety management. Conclusions and recommendations include adopting a risk-based decision-making approach to food safety; creating a data surveillance and research infrastructure; integrating federal, state, and local government food safety programs; enhancing efficiency of inspections; and more. Although food safety is the responsibility of everyone, from producers to consumers, the FDA and other regulatory agencies have an essential role. In many instances, the FDA must carry out this responsibility against a backdrop of multiple stakeholder interests, inadequate resources, and competing priorities. Of interest to the food production industry, consumer advocacy groups, health care professionals, and others, Enhancing Food Safety provides the FDA and Congress with a course of action that will enable the agency to become more efficient and effective in carrying out its food safety mission in a rapidly changing world.

Ensuring Safe Food - Institute of Medicine and National Research Council 1998-08-19

How safe is our food supply? Each year the media report what appears to be growing concern related to illness caused by the food consumed by Americans. These food borne illnesses are caused by pathogenic microorganisms, pesticide residues, and food additives. Recent actions taken at the federal, state, and local levels in response to the increase in reported incidences of food borne illnesses point to the need to evaluate the food safety system in the United States. This book assesses the effectiveness of the current food safety system and provides recommendations on changes needed to ensure an effective science-based food safety system. Ensuring Safe Food discusses such important issues as: What are the primary hazards associated with the food supply? What gaps exist in the current system for ensuring a safe food supply? What effects do trends in food consumption have on food safety? What is the impact of food preparation and handling practices in the home, in food services, or in production operations on the risk of food borne illnesses? What organizational changes in responsibility or oversight could be made to increase the effectiveness of the food safety system in the United States? Current concerns associated with microbiological, chemical, and physical hazards in the food supply are discussed. The book also considers how changes in technology and food processing might introduce new risks. Recommendations are made on steps for developing a coordinated, unified system for food safety. The book also highlights areas that need additional study. Ensuring Safe Food will be important for policymakers, food trade professionals, food producers, food processors, food researchers, public health professionals, and consumers.

An Overview of FDA Regulated Products - Eunjoo Pacifici 2018-06-13

Today’s challenge, especially for many newcomers to the regulated industry, is not necessarily to gather regulatory information, but to know how to interpret and apply it. The ability to discern what is important from what is not, and to interpret regulatory documents correctly, provides a valuable competitive advantage to any newcomer or established professional in this field. An Overview of FDA Regulated Products: From Drugs and Medical Devices to Food and Tobacco provides a valuable summary of the key information to unveil the meaning of critical, and often complex, regulatory concepts. Concise and easy to read with practical explanations, key points, summaries and case studies, this book

highlights the regulatory processes involved in bringing an FDA regulated product from research and development to approval and market. Although the primary focus will be on the US system, this book also features global perspectives where appropriate. A valuable resource for students, professors and professionals, An Overview of FDA Regulated Products illustrates the most important elements and concepts so that the reader can focus on the critical issues and make the necessary connections to be successful. Provides an overview of key regulatory requirements using a practical approach that features detailed discussions of hypothetical and real-world case studies in order to highlight the concepts and applications of regulations Covers all FDA regulated products, including drugs, biologics, medical devices, cosmetics, foods, dietary supplements, cosmetics, veterinary products, tobacco and more in one single reference Illustrates complex topics in a clear, succinct and engaging manner by breaking down technical terms and offering straightforward and easy to understand explanations

Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development - Institute of Medicine 2012-04-04

The development and application of regulatory science - which FDA has defined as the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products - calls for a well-trained, scientifically engaged, and motivated workforce. FDA faces challenges in retaining regulatory scientists and providing them with opportunities for professional development. In the private sector, advancement of innovative regulatory science in drug development has not always been clearly defined, well coordinated, or connected to the needs of the agency. As a follow-up to a 2010 workshop, the IOM held a workshop on September 20-21, 2011, to provide a format for establishing a specific agenda to implement the vision and principles relating to a regulatory science workforce and disciplinary infrastructure as discussed in the 2010 workshop.

FDA Regulatory Affairs - David Mantus 2014-02-28

FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that’s broadly useful to both business and academia.

Public Health Effectiveness of the FDA 510(k) Clearance Process - Institute of Medicine 2010-10-04

The Food and Drug Administration (FDA) is responsible for assuring that medical devices are safe and effective before they go on the market. As part of its assessment of FDA's premarket clearance process for medical devices, the IOM held a workshop June 14-15 to discuss how to best balance patient safety and technological innovation. This document summarizes the workshop.

Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests - Institute of

Medicine 2014-03-06
Many drug developers have examined new strategies for creating efficiencies in their development processes, including the adoption of genomics-based approaches. Genomic data can identify new drug targets for both common and rare diseases, can predict which patients are likely to respond to a specific treatment, and has the potential to significantly reduce the cost of clinical trials by reducing the number of patients that must be enrolled in order to demonstrate safety and efficacy. A key component of the approval of targeted therapeutics is the ability to identify the population of patients who will benefit from treatment, and this has largely hinged on the co-development and co-submission to the FDA of a companion diagnostic test.The co-development process, or the development of the test and drug for the simultaneous submission to FDA, has led to a major alteration in the way that drugs are being developed, with traditionally separate entities-pharmaceutical and diagnostic companies-now working in close collaboration. Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests is the summary of a workshop held by the Roundtable on Translating Genomic-Based Research for Health on February 27, 2013 to examine and discuss challenges and potential solutions for the codevelopment of targeted therapeutics and companion molecular tests for the prediction of drug response. Prior to the workshop, key stakeholders, including laboratory and medical professional societies, were individually asked to provide possible solutions to resolve the concerns raised about co-development of companion diagnostic tests and therapies. Workshop speakers were charged with addressing these solutions in their presentations by providing insight on (1) whether the proposed solutions address the problems described, (2) whether there are other solutions to propose, and (3) what steps could be taken to effectively implement the proposed solutions.

Food Safety Culture - Frank Yiannas 2008-12-10
Food safety awareness is at an all time high, new and emerging threats to the food supply are being recognized, and consumers are eating more and more meals prepared outside of the home. Accordingly, retail and foodservice establishments, as well as food producers at all levels of the food production chain, have a growing responsibility to ensure that proper food safety and sanitation practices are followed, thereby, safeguarding the health of their guests and customers. Achieving food safety success in this changing environment requires going beyond traditional training, testing, and inspectional approaches to managing risks. It requires a better understanding of organizational culture and the human dimensions of food safety. To improve the food safety performance of a retail or foodservice establishment, an organization with thousands of employees, or a local community, you must change the way people do things. You must change their behavior. In fact, simply put, food safety equals behavior. When viewed from these lenses, one of the most common contributing causes of food borne disease is unsafe behavior (such as improper hand washing, cross-contamination, or undercooking food). Thus, to improve food safety, we need to better integrate food science with behavioral science and use a systems-based approach to managing food safety risk. The importance of organizational culture, human behavior, and systems thinking is well documented in the occupational safety and health fields. However, significant contributions to the scientific literature on these topics are noticeably absent in the field of food safety.

Building a National Framework for the Establishment of Regulatory Science for Drug Development - Institute of Medicine 2011-03-15
The Food and Drug Administration (FDA) is tasked with ensuring the safety and effectiveness of medicine. FDA's science base must be strong enough to make certain that regulatory decisions are based on the best scientific evidence. The IOM held a public workshop on February 26, 2010, to examine the state of regulatory science and to consider approaches for enhancing it.

Health Information Technologies - United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Oversight and Investigations 2013

Consumer Protection in the 21st Century: A

Global Perspective - William Vukowich 2021-10-25

This comprehensive work covers the consumer protection laws and policies of governing bodies around the world. By presenting materials from edited laws, directives, courts cases, administrative regulations, and commission studies, the author explores the different approaches to the regulation of advertising, sales practices, credit, and product safety and quality. The methods by which consumer protection laws are enforced at the public and private level are also examined. Published under the Transnational Publishers imprint.

Regulation of Functional Foods and Nutraceuticals - Clare M. Hasler 2008-02-28

Regulation of Functional Foods and Nutraceuticals: A Global Perspective offers a comprehensive resource for information on regulatory aspects of the growing and economically important functional food industry. Regulatory systems and definitions of key terms-food, supplement, drug, etc-vary from country to country. A thorough understanding of laws and regulation within and among key countries with regard to functional foods, herbal extracts or drugs, and nutritional supplements is critical to the direction of food companies that are developing products for these markets. International experts with legal and/or scientific expertise address relevant topics from quality issues, to organic foods to labeling. Innovative product development within the framework of existing regulations will be addressed in individual chapters. Overview chapters will discuss global principles, inter-country trading issues, and present a comparison of the laws and regulations within different countries graphically. A "must-have" handbook for research professionals, management, and marketing strategists in the worldwide functional foods/nutritional supplements business. Food technicians and engineers responsible for manufacturing quality in this industry should add it to their library to ensure that they have a thorough knowledge of the applicable legal requirements. The book will also serve as an indispensable shelf reference for lawyers in the food industry and government health professionals with regulatory responsibilities.

Toward Safer Food - Sandra Ann Hoffmann 2005

Publisher Description

Registries for Evaluating Patient Outcomes - Agency for Healthcare Research and Quality/AHRQ 2014-04-01

This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Chemical Heritage - 2007

Complementary and Alternative Medicine in the United States - Institute of Medicine 2005-04-13

Integration of complementary and alternative medicine therapies (CAM) with conventional medicine is occurring in hospitals and physicians

offices, health maintenance organizations (HMOs) are covering CAM therapies, insurance coverage for CAM is increasing, and integrative medicine centers and clinics are being established, many with close ties to medical schools and teaching hospitals. In determining what care to provide, the goal should be comprehensive care that uses the best scientific evidence available regarding benefits and harm, encourages a focus on healing, recognizes the importance of compassion and caring, emphasizes the centrality of relationship-based care, encourages patients to share in decision making about therapeutic options, and promotes choices in care that can include complementary therapies where appropriate. Numerous approaches to delivering integrative medicine have evolved. Complementary and Alternative Medicine in the United States identifies an urgent need for health systems research that focuses on identifying the elements of these models, the outcomes of care delivered in these models, and whether these models are cost-effective when compared to conventional practice settings. It outlines areas of research in convention and CAM therapies, ways of integrating these therapies, development of curriculum that provides further education to health professionals, and an amendment of the Dietary Supplement Health and Education Act to improve quality, accurate labeling, research into use of supplements, incentives for privately funded research into their efficacy, and consumer protection against all potential hazards.

Perspectives on Risk and Regulation - Arthur A. Daemmrich 2007

The Whole of Nature and the Mirror of Art exhibit was at CHF from July through December 2006, opening in conjunction with the International Conference on the History of Alchemy and Chemistry. Alchemy is extremely well represented in the Neville Collection. There are many of the famous emblem-books, numerous works on chrysopoeia (metallic transmutation), and scores of titles from little-known authors. The images in the exhibition and the catalog are photo reproductions of engravings from alchemical books published in the 17th century.

Pain Management and the Opioid Epidemic - National Academies of Sciences, Engineering, and Medicine 2017-10-28

Drug overdose, driven largely by overdose related to the use of opioids, is now the leading cause of unintentional injury death in the United States. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the rising toll of the harms that can arise from the use of opioid medications. Chronic pain and opioid use disorder both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function. In the context of the growing opioid problem, the U.S. Food and Drug Administration (FDA) launched an Opioids Action Plan in early 2016. As part of this plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic, with a particular focus on informing FDA's development of a formal method for incorporating individual and societal considerations into its risk-benefit framework for opioid approval and monitoring.

Fish and Fishery Products - Barry Leonard 2011-08

This guidance will assist processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans. Processors of fish and fishery products will find info. that will help them identify hazards that are associated with their products, and help them formulate control strategies. It will help consumers understand commercial seafood safety in terms of hazards and their controls. It does not specifically address safe handling practices by consumers or by retail estab., although the concepts contained in this guidance are applicable to both. This guidance will serve as a tool to be used by fed. and state regulatory officials in the evaluation of HACCP plans for fish and fishery products. Illustrations. This is a print on demand report.

Ethical and Scientific Issues in Studying the Safety of Approved Drugs - Institute of Medicine 2012-07-30

An estimated 48 percent of the population takes at least one prescription drug in a given month.

Drugs provide great benefits to society by saving or improving lives. Many drugs are also associated with side effects or adverse events, some serious and some discovered only after the drug is on the market. The discovery of new adverse events in the postmarketing setting is part of the normal natural history of approved drugs, and timely identification and warning about drug risks are central to the mission of the Food and Drug Administration (FDA). Not all risks associated with a drug are known at the time of approval, because safety data are collected from studies that involve a relatively small number of human subjects during a relatively short period. Written in response to a request by the FDA, Ethical and Scientific Issues in Studying the Safety of Approved Drugs discusses ethical and informed consent issues in conducting studies in the postmarketing setting. It evaluates the strengths and weaknesses of various approaches to generate evidence about safety questions, and makes recommendations for appropriate followup studies and randomized clinical trials. The book provides guidance to the FDA on how it should factor in different kinds of evidence in its regulatory decisions. Ethical and Scientific Issues in Studying the Safety of Approved Drugs will be of interest to the pharmaceutical industry, patient advocates, researchers, and consumer groups.

Bad Bug Book - Mark Walderhaug 2014-01-14

The Bad Bug Book 2nd Edition, released in 2012, provides current information about the major known agents that cause foodborne illness.Each chapter in this book is about a pathogen—a bacterium, virus, or parasite—or a natural toxin that can contaminate food and cause illness. The book contains scientific and technical information about the major pathogens that cause these kinds of illnesses.A separate “consumer box” in each chapter provides non-technical information, in everyday language. The boxes describe plainly what can make you sick and, more important, how to prevent it.The information provided in this handbook is abbreviated and general in nature, and is intended for practical use. It is not intended to be a comprehensive scientific or clinical reference.The Bad Bug Book is published by the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA), U.S. Department of Health and Human Services.

Pharmaceutical Compliance and Enforcement Answer Book - Howard L. Dorfman 2021