Innovation Breakdown How The Fda And Wall Street Cripple Medical Advances

How do you convert a potentially life-saving new idea into an actual medical product and then make it available to doctors and patients? Joseph Gulfo thought he knew what to do but he thought wrong.

Economists examine the genesis of technological change and the ways we commercialize and diffuse it. The economics of property rights and patents, in addition to industry applications, are also surveyed through literature reviews and predictions about fruitful research directions. Two volumes, available as a set or sold separately Expert articles consider the best ways to establish optimal incentives in technological progress Science and innovation, both their theories and applications, are examined at the intersections of the marketplace, policy, and social welfare Economists are only part of an audience that includes attorneys, educators, and anyone involved in new technologies

Did you know... Medical interventions have become the third leading cause of death in America. An estimated 10 percent of Americans are implanted with medical devices -- like pacemakers, artificial hips, cardiac stents, etc. The overwhelming majority of high-risk implanted devices have never undergone a single clinical trial. In The Danger Within Us, award-winning journalist Jeanne Lenzer brings these horrifying statistics to life through the story of one working class man who, after his "cure" nearly kills him, ends up in a battle for justice against the medical establishment. His crusade leads Lenzer on a journey through the dark underbelly of the medical device industry, a fascinating and disturbing world that hasn't been written about before. What Lenzer exposes will shock readers: rampant corruption, elaborate cover-ups, shameless profiteering, and astonishing lack of oversight, all of which leads to dangerous devices (from artificial hips to pacemakers) going to market and into our bodies. In the vein of America's Bitter Pill and A Civil Action, The Danger Within Us is a stirring call for reform and a must-read for anyone who cares about the future of American healthcare. "Before you get anything implanted in your body, read this book."-Shannon Brownlee, author of Overtreated

Provides a clear and accessible summary of all stages and aspects of the discovery, design, development, validation and clinical use of anticancer drugs This new edition provides an update on the current state of the art of cancer chemotherapy and clinical practice and presents new pipeline anticancer agents and promising therapeutic strategies that are emerging alongside new breakthroughs in cancer biology. Its unique approach enables students to gain an understanding of the pathological, physiological, and molecular processes governing malignancy, while also introducing the role of health professionals and scientists in the research and treatment of cancer. Invaluable for its clarity and accessibility, Cancer Chemotherapy: Basic Science to the Clinic, 2nd Edition offers complete coverage of the scientific and clinical aspects of the creation, development, and administration of drugs or drug regimens used in the treatment of the disease. Chapters look at: cancer epidemiology and histopathology; carcinogenesis; current research; tumor hypoxia; antiangiogenic and antivascular agents; protein kinase and Ras blockers; new targets associated with development such as Hedgehog and Wnt signaling; stem cells; immunotherapy and oncolytic viruses; and more. Presents a

clear, accessible, and comprehensive approach to cancer chemotherapy from basic science to clinical practice Offers a major update that reflects the latest developments in personalized chemotherapy Provides in-depth coverage of advances in biomarker diagnostics Includes new chapters/sections on bioinformatics and the ‘omic sciences’; pharmaceutical strategies used to achieve tumor-selective drug delivery; and cancer cell autophagy Combines descriptions of both clinical protocol and explanations of the drug design process in one self-contained book Features numerous diagrams and illustrations to enhance reader understanding Aimed at upper undergraduate, graduate, and medical students, Cancer Chemotherapy: Basic Science to the Clinic, 2nd Edition is also an excellent reference for health professional, especially clinicians specializing in Clinical Oncology, and their patients who want to gain an understanding of cancer and available treatment options.

Recognize market opportunities, master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. Outlining a systematic, proven approach for innovation - identify, invent, implement - and integrating medical, engineering, and business challenges with real-world case studies, this book provides a practical guide for students and professionals.

An FDA economist discovers that solutions for food safety and nutrition lie in the hands of entrepreneurs--not government regulation and education. With about half of the U.S. population expected to be obese by 2030 and one out of six Americans getting sick every year, why is the Food and Drug Administration spending years trying to figure out if almond milk should be called "milk"? As a twenty-seven-year veteran of the FDA's Center for Food Safety and Nutrition, Dr. Richard A. Williams poses this question. Dr. Williams also questions the accuracy of more than thirty years of food labeling, coupled with consumer education on diet/disease relationships and failed attempts to get consumers to track intakes. It is time for the American people to look elsewhere for solutions, rather than relying on the FDA. Fixing Food takes you inside the FDA and explores the inner workings that drove failed strategies. Following his tenure at the FDA, Dr. Williams spent more than a decade investigating new sciences--including genetic and microbial sciences--that are leading to innovative foods and products. With one of the greatest public health crises in American history ongoing, this research aims to solve our issues with food--once and for all. In this book, you will learn: * How FDA controls Congress, the Courts, and the Executive Branch and others who might be a threat to their resources and growth of power * How the FDA misuses risk assessment and cost-benefit analysis * How the FDA's most recent innovation to keep food safe is fifty years old * Why food labeling has been a disaster * How entrepreneurs are remaking foods to be safer and healthier * How new medical devices will ultimately make nutrition as easy as using a cell phone * How trying to educate consumers through food labeling has been a public health disaster Ultimately, the role of the FDA in the new world of food safety and nutrition must change if the agency is to stay relevant.

Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-

protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.

How can great companies do everything right - identify real customer needs, deliver excellent innovations, beat their competitors to market - and still fail? The sad truth is that many companies fail because they focus too intensely on their own innovations, and then neglect the innovation ecosystems on which their success depends. In our increasingly interdependent world, winning requires more than just delivering on your own promises. It means ensuring that a host of partners -some visible, some hidden- deliver on their promises, too. In The Wide Lens, innovation expert Ron Adner draws on over a decade of research and field testing to take you on far ranging journeys from Kenya to California, from transport to telecommunications, to reveal the hidden structure of success in a world of interdependence. A riveting study that offers a new perspective on triumphs like Amazon's e-book strategy and Apple's path to market dominance; monumental failures like Michelin with run-flat tires and Pfizer with inhalable insulin; and still unresolved issues like electric cars and electronic health records, The Wide Lens offers a powerful new set of frameworks and tools that will multiply your odds of innovation success. The Wide Lens will change the way you see, the way you think - and the way you win.

Companies, entrepreneurs, and complexity -- Capitalism and economic dynamism -- What is wrong - the map or the reality? -- Technology and income - are they decoupling? -- Jobs and technology -- Innovation famine rather than innovation feast -- 9 THE FUTURE AND HOW TO PREVENT IT -- From corporate globalism to global corporatism -- The continued rise of regulatory uncertainty -- The "silver tsunami" for cash -- Future imperfect -- Preventing the future -- NOTES -- REFERENCES -- INDEX

Regulatory Breakdown: The Crisis of Confidence in U.S. Regulation brings fresh insight and analytic rigor to what has become one of the most contested domains of American domestic politics. Critics from the left blame lax regulation for the housing meltdown and financial crisis—not to mention major public health disasters ranging from the Gulf Coast oil spill to the Upper Big Branch Mine explosion. At the same time, critics on the right disparage an excessively strict and costly regulatory system for hampering economic recovery. With such polarized accounts of regulation and its performance, the nation needs now more than ever the kind of dispassionate, rigorous scholarship found in this book. With chapters written by some of the nation's foremost economists, political scientists, and legal scholars, Regulatory Breakdown brings clarity to the heated debate over regulation by dissecting the disparate causes of the current crisis as well as analyzing promising solutions to what ails the U.S. regulatory system. This volume shows policymakers, researchers, and the public why they need to question conventional wisdom about regulation—whether from the left or the right—and demonstrates the value of undertaking systematic analysis before adopting policy reforms in the wake of disaster.

The Care Quotient is a leadership book that presents caring as the single most important character trait needed to drive business success and employee followship. The Care Quotient is a prescription for business and personal success based on caring about the right things. Selfless caring is based on a moral belief system that demands that principles and truth are your highest goals and that taking personal responsibility is your defining quality. Selfless caring drives you to leave people and circumstances better than you found them. It is a virtually limitless source of energy that fuels tireless preparation and incessant trial and error and personal reinvention. If you selflessly care, you will: Realize that management is a gift and a profound responsibility Reinvent yourself and your approach as often as it takes to be successful Take the time to teach and mentor and to be taught and mentored Make difficult decisions Set a great example, all the time Take chances on people and cultivate talent. From these critical behaviors come the winning strategies and desired outcomes, time after time. True followship flows from the engagement, alignment, inspiration, and motivation that a selflessly caring leader engenders.

While plenty can be said about the dysfunction of our health care system, rarely do business and private players in health care innovation get a good rap. This book takes on skeptics of the partnership between the medical community, political groups, and private businesses, by illustrating how such cooperation can result in world-class innovation and health care delivery.

Life improves under the economic system often called "entrepreneurial capitalism" or "creative destruction," but more accurately called "innovative dynamism." Openness to Creative Destruction: Sustaining Innovative Dynamism shows how innovation occurs through the efforts of inventors and innovative entrepreneurs, how workers on balance benefit, and how good policies can encourage innovation. The inventors and innovative entrepreneurs are often cognitively diverse outsiders with the courage and perseverance to see and pursue serendipitous discoveries or slow hunches. Arthur M. Diamond, Jr. shows how economies grow where innovative dynamism through leapfrog competition flourishes, as in the United States from roughly 1830-1930. Consumers vote with their feet for innovative new goods and for process innovations that reduce prices, benefiting ordinary citizens more than the privileged elites. Diamond highlights that because breakthrough inventions are costly and difficult, patents can be fair rewards for invention and can provide funding to enable future inventions. He argues that some fears about adverse effects on labor market are unjustified, since more and better new jobs are created than are destroyed, and that other fears can be mitigated by better policies. The steady growth in regulations, often defended on the basis of the precautionary principle, increases the costs to potential entrepreneurs and thus reduces innovation. The "Great Fact" of economic history is that after at least 40,000 years of mostly "poor, nasty, brutish, and short" humans in the last 250 years have started to live substantially longer and better lives. Diamond increases understanding of why.

Will innovators be forced to seek the blessing of public officials before they develop and deploy new devices and services, or will they be generally left free to experiment with new technologies and business models? In this book, Adam Thierer argues that if the former disposition, “the precautionary principle,” trumps the latter, “permissionless innovation,” the result will be fewer services, lower-quality goods, higher prices, diminished economic growth, and a decline in the overall standard of living. When public policy is shaped by “precautionary principle” reasoning, it poses a serious threat to technological progress, economic entrepreneurialism, and long-run prosperity. By contrast, permissionless innovation has fueled the success of the Internet and much of the modern tech economy in recent years, and it is set to power the next great industrial revolution—if we let it.

"Four months into the coronavirus pandemic, as the death count surged, the FDA made a risky decision: it approved an anti-malarial drug as a treatment for coronavirus, despite limited data on its efficacy or side effects. A month later, the FDA withdrew its

recommendation, but by then, the damage had been done. The drug was ineffective and sometimes even lethal. The mistake was hardly a one-off. As virologist Paul. A. Offit shows in You Bet Your Life, from antibiotics and vaccines to x-rays and genetic engineering, risk, and our understanding of it, have shaped the course of modern medicine, paving the way for its greatest triumphs and tragedies. By telling the stories of the events--and of the frequent hypocrisy and cravenness of the characters at their center--Offit shows how risk, and failure, have driven innovation, and importantly, how by examining our mistakes we can make better medical predictions and decisions going forward. From the outlandish origins of blood transfusions, which began with humans receiving blood for barnyard animals, to the the disastrous debut of the first polio vaccine, and the backstabbing and infighting that surrounded early gene therapies, he captures the drama that surrounds medical research, the way ego and laziness can collide with science, and ultimately how those factors should inform what we choose to do and have done to us in the clinic. The history is fascinating in its own right, but the worldwide rush to create a coronavirus vaccine only makes learning from the lessons of history essential. Weighing the uncertainties of a treatment against its potential benefits is one of medicine's greatest ethical dilemmas, and Offit examines it from every angle. He explores not just how patients and their families respond to risk but how everyone from physicians and researchers to universities and regulators do, too, and how that ultimately determines what treatments are put forward. Not everyone has the same goal. And too often the patient's health is secondary. But as Offit shows, we can all minimize risk and failure by learning how to recognize conflicts of interest, to draw inferences from animal models, and to evaluate risk, even when we have limited data. Along the way, Offit asks who should decide what risks are acceptable, and who should pay when the results are fatal. In the end, however, Offit argues that we are gambling whatever we do--and that we need to take that seriously, whether we pursue a treatment or decide to do nothing at all. The answers aren't simple, and the outcomes are life or death. Examining these questions with the compassion of a pediatrician and the rigor of a scientist, Offit reminds us that we all have a role to play in ensuring that medicine upholds its very first principle: to do no harm"--

There are numerous reasons to hasten the introduction of new and improved contraceptives--from health concerns about the pill to the continuing medical liability crisis. Yet, U.S. organizations are far from taking a leadership position in funding, researching, and introducing new contraceptives--in fact, the United States lags behind Europe and even some developing countries in this field. Why is research and development of contraceptives stagnating? What must the nation do to energize this critical arena? This book presents an overall examination of contraceptive development in the United States--covering research, funding, regulation, product liability, and the effect of public opinion. The distinguished authoring committee presents a blueprint for substantial change, with specific policy recommendations that promise to gain the attention of specialists, the media, and the American public. The highly readable and well-organized volume will quickly become basic reading for legislators, government agencies, the pharmaceutical industry, private organizations, legal professionals, and researchers--everyone concerned about family planning, reproductive health, and the impact of the liability and regulatory systems on scientific innovations.

This book examines an increasingly important phenomenon for competitiveness and

innovation in industry: namely, the growing use of scientific principles in industrial research. Industrial innovation still arises from systematic trial-and-error experiments with many designs and objects, but these experiments are now being guided by a more rational understanding of phenomena. This has important implications for market structure, firm strategies, and competition. Science and innovation focuses on the pharmaceutical industry. It discusses the changes that the notable advances in the life sciences in the 1980s have brought to the strategies of drug companies, the organization of their internal research, their relationships with scientific institutions, the division of labor between large pharmaceutical firms and small research-intensive suppliers, the productivity of drug discovery, and the productivity of R&D.

The pharmaceutical industry is one of today's most dynamic and complex industries, involving commercialization of cutting-edge scientific research, a huge web of stakeholders (from investors to doctors), multi-stage supply chains, fierce competition in the race to market, and a challenging regulatory environment. The stakes are high, with each new product raising the prospect of spectacular success—or failure. Worldwide revenues are approaching $1 trillion; in the U.S. alone, marketing for pharmaceutical products is, itself, a multi-billion dollar industry. In this volume, the editors showcase contributions from experts around the world to capture the state of the art in research, analysis, and practice, and covering the full spectrum of topics relating to innovation and marketing, including R&D, promotion, pricing, branding, competitive strategy, and portfolio management. Chapters include such features as: · An extensive literature review, including coverage of research from fields other than marketing · an overview of how practitioners have addressed the topic · introduction of relevant analytical tools, such as statistics and ethnographic studies · suggestions for further research by scholars and students The result is a comprehensive, state-of-the-art resource that will be of interest to researchers, policymakers, and practitioners, alike.

The Business of Healthcare Innovation is the first wide-ranging analysis of business trends in the manufacturing segment of the health care industry. In this leading edge volume, Professor Burns focuses on the key role of the 'producers' as the main source of innovation in health systems. Written by professors of the Wharton School and industry executives, this book provides a detailed overview of the pharmaceutical, biotechnology, genomics/proteomics, medical device and information technology sectors. It analyses the market structures of these sectors as well as the business models and corporate strategies of firms operating within them. Most importantly, the book describes the growing convergence between these sectors and the need for executives in one sector to increasingly draw upon trends in the others. It will be essential reading for students and researchers in the field of health management, and of great interest to strategy scholars, industry practitioners and management consultants.

"This is a must read book if you care about your health." Jeff Kanter, Co-Founder HealthExcellencePlus.com The 1962 Amendments to the Food & Drug Act have probably shaved at least 5 years off of your lifespan without making drugs safer and more effective. They shifted our medical paradigm from inexpensive prevention to costly treatment, censored life-saving nutritional approaches to disease, added a decade to the time it takes to get a new drug from the lab bench to market place, destroyed over half of our medical/pharmaceutical/nutritional innovations, and caused

the prices of drugs to soar without improving safety or effectiveness. Find out how to reclaim our Golden Age of Health. The life you save may be your own! "Death by Regulation is one of the most important books of the 21st Century. The tragic impact of FDA regulations makes this a cause of life and death to all of us." Ken Schoolland, Associate Professor of Economics at Hawaii Pacific University Dr. Ruwart's rigorous and hard-hitting analysis is a shocking eye opener and essential reading for anyone who wants to understand why medical progress is so painfully slow in the United States. Kyle Varner, MD, Medical Director, Elite Locum Tenens LLC, Spokane, Washington "Death by Regulation is undoubtedly the most insightful and comprehensive analysis of the unintended consequences-and mind-numbing costs in terms of shortened lives and suffering-of the 1962 legislation." Bartley Madden, author of Free to Choose Medicine

The forces that shape America's most powerful consumer agency Because of the importance of what it regulates, the FDA comes under tremendous political, industry, and consumer pressure. But the pressure goes far beyond the ordinary lobbying of Washington trade groups. Its mandate-one quarter of the national economy-brings the FDA into the middle of some of the most important and contentious issues of modern society. From "designer" babies and abortion to the price of prescription drugs and the role of government itself, Inside the FDA takes readers on an intriguing journey into the world of today's most powerful consumer agency. In a time when companies continue to accuse the FDA of nitpicking and needlessly delaying needed new drugs, and consumers are convinced that the agency bends to industry pressure by rushing unsafe drugs to market, Inside the FDA digs deep to reveal the truth. Through scores of interviews and real-world stories, Hawthorne also shows how and why the agency makes some of its most controversial decisions as well as how its recent reaction to certain issues-including the revolutionary cancer drug Erbitux, stem cell research, and bioengineering of food-may jeopardize its ability to keep up with future scientific developments. Inside the FDA takes a closer look at the practices, people, and politics of this crucial watchdog in light of the competing pressures and trends of modern society, revealing what the FDA is supposed to do, what it actually does-and fails to do-who it influences, and how it could better fulfill its mandate. The decisions that the FDA makes are literally life and death. Inside the FDA provides a sophisticated account of how this vitally important agency struggles to balance bureaucracy and politics with its overriding mission to promote the country's health.

Have an idea for a new tool or instrument? This a great resource to use to bring your invention ideas to the bedside! Written for clinicians, researchers, students, and entrepreneurs, this concise yet comprehensive review presents a clear process to identify, invent, and implement new technology solutions that aid in effective and safe practice in orthopedic surgery.

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.

A Real Plan for Making Drugs Affordable–and Promoting Innovation, Too "This book is a necessity for understanding the pharmaceutical industry. Both the pluses and minuses of the present system are set forth with a judicious combination of historical narrative, economic analysis, and statistical data. The highly original proposals for reform will be a major stimulant to analysis and policy-making." –Kenneth Arrow, Nobel Laureate in Economics, Professor Emeritus, Stanford University "This is a timely book by authors who know what they are talking about. They tackle a big problem: rising drug prices that are threatening to overwhelm us all–and especially those with limited or absent health care insurance. Will we drive people overseas for healthcare? Will there be social unrest? This book describes the problem and then offers a solution. Worth a careful read by everyone, pharmaceutical manufacturers and government policymakers especially." –Roger Williams, M.D., Chief Executive Officer of the United States Pharmacopeia and a former senior official of the Food and Drug Administration "This book confounds two sets of skeptics: Those who say there's no way to resolve the conflict between the need to fund pharmaceutical research and our desire to keep medicine affordable; and those who think that economics never has anything good to say." –Honorable Barney Frank, Congressman from Massachusetts "This book comes at the right time and could become the starting point of discussions, which will eventually lead us into new era in the healthcare care industry. It will without a doubt become a must for insiders of the pharma- and biotech industries." –Dr. Jürgen Drews, retired President of Roche Pharmaceutical Group Global Research Acknowledgments viii About the Authors ix Introduction xi Chapter 1: Drugs and Drug Prices 1 Chapter 2: The American Way to Discover Drugs 21 Chapter 3: The Drug Industry Today 39 Chapter 4: Are Drug Companies Risky? 59 Chapter 5: How Not to Lower Drug Prices 77 Chapter 6: Squandering R & D Resources 103 Chapter 7: How to Lower Drug Prices 129 Appendix: Our Solution in Detail 155 Index 177

A NEW YORK TIMES BESTSELLER New York Times 100 Notable Books of 2019 New York Public Library Best Books of 2019 Kirkus Reviews Best Health and Science Books of 2019 Science Friday Best Books of 2019 New postscript by the author From an award-winning journalist, an explosive narrative investigation of the generic drug boom that reveals fraud and life-threatening dangers on a global scale—The Jungle for pharmaceuticals Many have hailed the widespread use of generic drugs as one of the most important public-health developments of the twenty-first century. Today, almost 90

percent of our pharmaceutical market is comprised of generics, the majority of which are manufactured overseas. We have been reassured by our doctors, our pharmacists and our regulators that generic drugs are identical to their brand-name counterparts, just less expensive. But is this really true? Katherine Eban's Bottle of Lies exposes the deceit behind generic-drug manufacturing—and the attendant risks for global health. Drawing on exclusive accounts from whistleblowers and regulators, as well as thousands of pages of confidential FDA documents, Eban reveals an industry where fraud is rampant, companies routinely falsify data, and executives circumvent almost every principle of safe manufacturing to minimize cost and maximize profit, confident in their ability to fool inspectors. Meanwhile, patients unwittingly consume medicine with unpredictable and dangerous effects. The story of generic drugs is truly global. It connects middle America to China, India, sub-Saharan Africa and Brazil, and represents the ultimate litmus test of globalization: what are the risks of moving drug manufacturing offshore, and are they worth the savings? A decade-long investigation with international sweep, high-stakes brinkmanship and big money at its core, Bottle of Lies reveals how the world's greatest public-health innovation has become one of its most astonishing swindles.

Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicinesâ€"and health care at largeâ€"more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription drugsâ€"coupled with the broader trends in overall health care costsâ€"is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.

The focus of food science and technology has shifted from previous goals of improving food safety and enhancing food taste toward providing healthy and functional foods. Today's consumers desire foods that go beyond basic nutrition—foods capable of

promoting better health, or even playing a disease-prevention role. To meet this need for innovation, academic research must be combined with the development and commercialization strategies of industry. Innovation in Healthy and Functional Foods brings together this knowledge, with contributions from experts in biological science, food science, engineering, marketing, regulation, law, finance, sustainability, and management. Focusing on functional foods that have components added—such as omega-3, probiotics, and protein—to provide health benefits, this book presents various aspects of the innovation process. These include consumer insights, trends in developed and developing markets, and technological advances in functional foods and ingredients. It also addresses the key drivers of food industry innovation—affordability, sustainability, and tightening government regulations. Chapters cover characteristics of various markets around the world; consumer perception; food processing, packaging, and ingredients; innovation in functional ingredients; and functional ingredient delivery. Given the importance and challenges of getting functional food products into the marketplace, this book also covers the business aspects of innovation in food science, including marketing, financial implications, and commercial feasibility. Additionally, contributors provide insights into future trends, such as food tourism, nanotechnology, sustainability, and globalization. Bringing together expertise from academia and industry, this text provides an overview of contemporary food science, with wisdom and know-how in both innovation and commercialization, placing functional foods in a broader context for readers.

This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products’ commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelsstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

On June 20, 2012, the House of Representatives passed, by voice vote and under suspension of the rules, S. 3187 (EAH), the Food and Drug Administration Safety and Innovation Act, as amended. This bill would reauthorize the FDA prescription drug and medical device user fee programs (which would otherwise expire on September 30, 2012), create new user fee programs for generic and biosimilar drug approvals, and make other revisions to other FDA drug and device approval processes. It reflects

bicameral compromise on earlier versions of the bill (S. 3187 [ES], which passed the Senate on May 24, 2012, and H.R. 5651 [EH], which passed the House on May 30, 2012). The following CRS reports provide overview information on FDA's processes for approval and regulation of drugs: CRS Report R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, by Susan Thaul; CRS Report RL33986, FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective, by Susan Thaul; CRS Report R42130, FDA Regulation of Medical Devices, by Judith A. Johnson; CRS Report R42508, The FDA Medical Device User Fee Program, by Judith A. Johnson. (Note: The rest of this report has not been updated since December 28, 2011.) Prior to and since the passage of the Medical Device Amendments of 1976, Congress has debated how best to ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices; examples range from a simple tongue depressor to a life-sustaining heart valve. The regulation of medical devices can affect their cost, quality, and availability in the health care system. In order to be legally marketed in the United States, many medical devices must be reviewed by the Food and Drug Administration (FDA), the agency responsible for protecting the public health by overseeing medical products, including devices. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. CDRH activities are funded through a combination of public money (i.e., direct FDA appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees. FDA's authority to collect user fees, originally authorized in 2002 (P.L. 107-250), has been reauthorized in five-year increments. It will expire on October 1, 2012, under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85). FDA requires all medical product manufacturers to register their facilities, list their devices with FDA, and follow general controls requirements. FDA classifies devices according to the risk they pose to consumers. Premarket review is required for moderate- and high-risk devices. There are two paths that manufacturers can use to bring such devices to market. One path consists of conducting clinical studies, submitting a premarket approval (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective. The other path involves submitting a 510(k) notification demonstrating that the device is substantially equivalent to a device already on the market (a predicate device) that does not require a PMA. The 510(k) process results in FDA clearance and tends to be much less expensive and less time- consuming than seeking FDA approval via PMA.

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.

A wide-ranging look at an industry that is central to the health and welfare of humanity, this pioneering work documents how science has provided an astonishing array of medicines for coping with human ailments over the last 150 years. Pharmaceutical Innovation covers the history of the pharmaceutical industry and its many contributions to human health. Underpinning the volume is an outline of the five generations of medicine, from the 1820s to present day. The volume also addresses industry leaders, economic influences, and the development of individual products. These factors have particular significance for the pharmaceutical industry today. This book's account of research and development in a key industry makes Pharmaceutical Innovation required reading for policy makers, economists, corporate executives, research managers, and historians of science, technology, and medicine.

Investigates the impact of information technology, biogenetic, and pharmacological innovation on individuals quality of life, safety, individual and system health care utilization, occupational and environmental health and formulary decision making, and costs.

A practical guide to understanding and navigating the unique challenges faced by physicians and other professionals who wish to undertake research in the ED or other acute care setting. Focusing on the hyper-acute and acute care environment and fulfilling two closely-related needs: 1) the need for even seasoned researchers to understand the specific logistics and issues of doing research in the ED; and 2) the need to educate clinically active physicians in research methodology. This new text is not designed to be a complex, encyclopedic resource, but instead a concise, easy-to-read resource designed to convey key “need-to-know” information within a comprehensive framework. Aimed at the busy brain, either as a sit-down read or as a selectively-read reference guide to fill in knowledge gaps, chapters are short, compartmentalized, and are used strategically throughout the text in order to introduce and frame concepts. This format makes it easy - and even entertaining - for the research novice to integrate and absorb completely new (and typically dry) material. The textbook addresses aspects of feasibility, efficiency, ethics, statistics, safety, logistics, and collaboration in acute research. Overall, it grants access for the seasoned researcher seeking to learn about acute research to empathically integrate learning points into his or her knowledge base. As the ED is the primary setting for hyper-acute and acute care, and therefore a prime site for related clinical trial recruitment and interventions, the book presents specific logistical research challenges that researchers from any discipline, including physicians, research nurse coordinators, study monitors, or industry partners, need to understand in order to succeed.