Global Pharmaceuticals Ethics Markets Practices

The phenomenal growth of global pharmaceutical sales and the quest for innovation are driving an unprecedented search for human test subjects, particularly in middle- and low-income countries. Our hope for medical progress increasingly depends on the willingness of the world's poor to participate in clinical drug trials. While these experiments often provide those in need with vital and previously unattainable medical resources, the

outsourcing and offshoring of trials also create new problems. In this groundbreaking book, anthropologist Adriana Petryna takes us deep into the clinical trials industry as it brings together players separated by vast economic and cultural differences. Moving between corporate and scientific offices in the United States and research and public health sites in Poland and Brazil, When Experiments Travel documents the complex ways that commercial medical science, with all its benefits and risks, is being integrated into local health systems and emerging drug markets. Providing a unique perspective on globalized clinical trials, When

Experiments Travel raises central questions: Are such trials exploitative or are they social goods? How are experiments controlled and how is drug safety ensured? And do these experiments help or harm public health in the countries where they are conducted? Empirically rich and theoretically innovative, the book shows that neither the language of coercion nor that of rational choice fully captures the range of situations and value systems at work in medical experiments today. When Experiments Travel challenges conventional understandings of the ethics and politics of transnational science and changes the way we think about global medicine

and the new infrastructures of our lives. When a French biotechnology company seeks patients in Buenos Aires with bipolar disorder for its gene discovery program, they have unexpected trouble finding enough subjects for the study. In Argentina, the predominant form of mental health expertise - psychoanalysis - does not recognize the legitimacy of bipolar disorder as a diagnostic entity. This problem points to a broader set of political and epistemological debates in global psychiatry. Drawing from an ethnography of psychiatric practice in Buenos Aires, Andrew Lakoff follows the contested extension of novel techniques for

understanding and intervening in mental illness. He charts the globalization of the new biomedical psychiatry, and illustrates the clashes, conflicts, alliances, and reformulations that take place when psychoanalytic and biological models of illness and cure meet. Highlighting the social and political implications that new forms of expertise about human behavior and thought bring, Lakoff presents an arresting case study that will appeal to scholars and students alike.

Despite the pharmaceutical industry's notable contributions to human progress, including the development of miracle drugs for treating

cancer, AIDS, and heart disease, there is a growing tension between the industry and the public. Government officials and social critics have questioned whether the multibillion-dollar industry is fulfilling its social responsibilities. This doubt has been fueled by the national debate over drug pricing and affordable healthcare, and internationally by the battles against epidemic diseases, such as AIDS, in the developing world. Debates are raging over how the industry can and should be expected to act. The contributions in this book by leading figures in industry, government, NGOs, the medical community, and academia discuss and

propose solutions to the ethical dilemmas of drug industry behavior. They examine such aspects as the role of intellectual property rights and patent protection, the moral and economic requisites of research and clinical trials, drug pricing, and marketing.

The Strategic Pricing of Pharmaceuticals explains how pharmaceutical prices are, and should be set, in the US and international markets. The book discusses how pharmaceuticals are different from other products in terms of value and why typical assumptions and approaches to pricing fail to consider the true nature of pharmaceuticals or

to capture their value. This book provides pharmaceutical marketers with needed guidance through the use of in-depth discussions and analyses of the factors that should be considered when setting and managing pharmaceutical prices.

The Strategic Pricing of Pharmaceuticals

Critical Studies in Global Health

Glocal Pharma (Open Access)

Life Exposed

Ethics and the Pharmaceutical Industry

Ethics, Markets, Practices

The Making of Our Bodies, Ourselves

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. As one of the most massive and successful business sectors, the pharmaceutical industry is a potent force for good in the community, yet its behaviour is frequently questioned: could it serve society at large better than it has done in the recent past? Its own internal ethics, both in business and science, may need a careful reappraisal, as may the extent to which the law - administrative, civil and criminal - succeeds in guiding (and where neccessary contraining) it. The rules of behavior that may be considered to

apply to today's pharmaceutical industry have emerged over a very long period and the process goes on. Even the immensely detailed standards for quality, safety and efficacy laid down in drug law and regulation during the second half of the twentieth century have their limitations as tools for ensuring that the public interest is well served. In particular, national and regional regulatory agencies are heavily dependent on industrial data for their decision-making, their standards and competence vary, and even the existing network of agencies does not cover the entire world. What is more there are many areas

of law and regulation affecting the industry, concerning for example the pricing of medicines, the conduct of clinical studies, the health protection of workers and concern for the environment. In some fields it is indeed hardly possible to maintain standards through regulation. Professor N.M. Graham Dukes, a physician and lawyer with long term experience in industrial research management, academic study and international drug policy, provides here a powerfully documented analysis into the way this industry thinks, acts, and is viewed, and examines the current trends pointing to change.

**Provides a balanced picture of the current role of the pharmaceutical industry in society *Includes indices of conventions, laws, and regulations; as well as judicial and disciplinary cases *This is the only book addressing the legal implications of big pharma activities and ethical standards*
When People Come First critically assesses the expanding field of global health. It brings together an international and interdisciplinary group of scholars to address the medical, social, political, and economic dimensions of the global health enterprise through vivid case studies and bold conceptual work. The book demonstrates the

crucial role of ethnography as an empirical lantern in global health, arguing for a more comprehensive, people-centered approach. Topics include the limits of technological quick fixes in disease control, the moral economy of global health science, the unexpected effects of massive treatment rollouts in resource-poor contexts, and how right-to-health activism coalesces with the increased influence of the pharmaceutical industry on health care. The contributors explore the altered landscapes left behind after programs scale up, break down, or move on. We learn that disease is really never

just one thing, technology delivery does not equate with care, and biology and technology interact in ways we cannot always predict. The most effective solutions may well be found in people themselves, who consistently exceed the projections of experts and the medical-scientific, political, and humanitarian frameworks in which they are cast. When People Come First sets a new research agenda in global health and social theory and challenges us to rethink the relationships between care, rights, health, and economic futures.

In some parts of the world spending on

pharmaceuticals is astronomical. In others people do not have access to basic or life-saving drugs. Individuals struggle to afford medications; whole populations are neglected, considered too poor to constitute profitable markets for the development and distribution of necessary drugs. The ethnographies brought together in this timely collection analyze both the dynamics of the burgeoning international pharmaceutical trade and the global inequalities that emerge from and are reinforced by market-driven medicine. They demonstrate that questions about who will be treated and who will not filter through every

phase of pharmaceutical production, from preclinical research to human testing, marketing, distribution, prescription, and consumption. Whether considering how American drug companies seek to create a market for antidepressants in Japan, how Brazil has created a model HIV/AIDS prevention and treatment program, or how the urban poor in Delhi understand and access healthcare, these essays illuminate the roles of corporations, governments, NGOs, and individuals in relation to global pharmaceuticals. Some essays show how individual and communal identities are affected

by the marketing and availability of medications. Among these are an exploration of how the pharmaceutical industry shapes popular and expert understandings of mental illness in North America and Great Britain. There is also an examination of the agonizing choices facing Ugandan families trying to finance AIDS treatment. Several essays explore the inner workings of the emerging international pharmaceutical regime. One looks at the expanding quest for clinical research subjects; another at the entwining of science and business interests in the Argentine market for psychotropic

medications. By bringing the moral calculations involved in the production and distribution of pharmaceuticals into stark relief, this collection charts urgent new territory for social scientific research. Contributors. Kalman Applbaum, João Biehl, Ranendra K. Das, Veena Das, David Healy, Arthur Kleinman, Betty Kyaddondo, Andrew Lakoff, Anne Lovell, Lotte Meinert, Adriana Petryna, Michael A. Whyte, Susan Reynolds Whyte

The Government of Emergency

Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry

The Demise and the Path to Recovery
How Pharmaceutical Companies Define Our Health
Illicit Medicines in the Global South
Innovation and Technology Management in Japan
International Brands and the Imagination of Local Masculinity

Claiming 1.5 million lives in 2015, tuberculosis is the world's most deadly infectious disease. Because of the population it overwhelmingly affects, however, pharmaceutical companies are uninterested in developing better drugs for

the disease. Compound Solutions examines Product Development Partnerships (PDPs), which arose early in the twenty-first century to develop new drugs and vaccines for infectious diseases in low-income countries. Here, for the first time, is a sustained examination of PDPs: the work they do, the partnerships they form, their mission, and their underlying philosophy of addressing global health needs--with implications that extend well beyond tuberculosis. Focusing on two PDPs for tuberculosis--the Global Alliance for TB Drug Development (TB

Alliance) and Aeras (a nonprofit focused on vaccine development)--Susan Craddock argues that PDPs do much more than product development. As innovative sites of humanitarian pharmaceutical production, they are contravening mainstream pharmaceutical production by tying drug and vaccine research to global health needs rather than shareholder demand. In largely untethering the profit incentive from pharmaceutical production, Craddock shows, PDPs exhibit more creative and efficient scientific practices, reshaping

regulatory norms and implementing more ethical forms of clinical trials that enhance community engagement and capacity building. An unparalleled, interdisciplinary analysis of PDPs as politically, socially, scientifically, and economically innovative sites of pharmaceutical production, Compound Solutions is a must for readers in the fields of public health, science and technology studies, and medical social science.

This open access book explores how young people engage with chemical substances in

their everyday lives. It builds upon and supplements a large body of literature on young people's use of drugs and alcohol to highlight the subjectivities and socialities that chemical use enables across diverse socio-cultural settings, illustrating how young people seek to avoid harm, while harnessing the beneficial effects of chemical use. The book is based on multi-sited anthropological research in Southeast Asia, Europe and the US, and presents insights from collaborative and contrasting analysis. Hardon brings new perspectives to debates

across drug policy studies, pharmaceutical cultures and regulation, science and technology studies, and youth and precarity in post-industrial societies.

THE CRITICAL WORK IN GLOBAL HEALTH, NOW COMPLETELY REVISED AND UPDATED "This book compels us to better understand the contexts in which health problems emerge and the forces that underlie and propel them." -Archbishop Emeritus Desmond Mpilo Tutu H1N1. Diabetes. Ebola. Zika. Each of these health problems is rooted in a confluence of social,

political, economic, and biomedical factors that together inform our understanding of global health. The imperative for those who study global health is to understand these factors individually and, especially, synergistically. Fully revised and updated, this fourth edition of Oxford's Textbook of Global Health offers a critical examination of the array of societal factors that shape health within and across countries, including how health inequities create consequences that must be addressed by public health, international aid, and social

and economic policymaking. The text equips students, activists, and health professionals with the building blocks for a contextualized understanding of global health, including essential threads that are combined in no other work: · historical dynamics of the field · the political economy of health and development · analysis of the current global health structure, including its actors, agencies, and activities · societal determinants of health, from global trade and investment treaties to social policies to living and working conditions · the role of

health data and measuring health inequities · major causes of global illness and death, including under crises, from a political economy of health vantage point that goes beyond communicable vs. non-communicable diseases to incorporate contexts of social and economic deprivation, work, and globalization · the role of trade/investment and financial liberalization, precarious work, and environmental degradation and contamination · principles of health systems and the politics of health financing ·

community, national, and transnational social justice approaches to building healthy societies and practicing global health ethically and equitably Through this approach the Textbook of Global Health encourages the reader -- be it student, professional, or advocate -- to embrace a wider view of the global health paradigm, one that draws from political economy considerations at community, national, and transnational levels. It is essential and current reading for anyone working in or around global health.

Moral Laboratories is an engaging ethnography and a groundbreaking foray into the anthropology of morality. It takes us on a journey into the lives of African American families caring for children with serious chronic medical conditions, and it foregrounds the uncertainty that affects their struggles for a good life. Challenging depictions of moral transformation as possible only in moments of breakdown or in radical breaches from the ordinary, it offers a compelling portrait of the transformative powers embedded in day-to-day existence.

From soccer fields to dinner tables, the everyday emerges as a moral laboratory for reshaping moral life. Cheryl Mattingly offers vivid and heart-wrenching stories to elaborate a first-person ethical framework, forcefully showing the limits of third-person renderings of morality.

The Financial Crisis Inquiry Report

A 2020 Reader

Addiction Trajectories

Clinical Trials and the Global Search for Human Subjects

Moral Laboratories

Pharmaceutical Industry Antitrust Handbook
Pharmaceutical Alternatives for Global Health

Global PharmaceuticalsDuke University Press
Provides an exciting approach to some of the most contentious issues in discussions around globalization—bioscientific research, neoliberalism, governance—from the perspective of the "anthropological" problems they pose; in other words, in terms of their implications for how individual and collective life is subject to technological, political, and ethical reflection

and intervention. Offers a ground-breaking approach to central debates about globalization with chapters written by leading scholars from across the social sciences. Examines a range of phenomena that articulate broad structural transformations: technoscience, circuits of exchange, systems of governance, and regimes of ethics or values. Investigates these phenomena from the perspective of the “anthropological” problems they pose. Covers a broad range of geographical areas: Africa, the Middle East, East and South Asia, North America, South America, and Europe. Grapples with a number of empirical problems of popular and academic interest —

from the organ trade, to accountancy, to pharmaceutical research, to neoliberal reform.

"This book tells the story of how the fragile and still-uncertain machinery of global health security was cobbled together over a two-decade period, beginning in the early 1990s. It is neither a heroic account of visionary planning by enlightened health authorities, nor a sinister story of the securitization of disease by an ever-expansive governmental apparatus. Rather, it is a story of the assemblage of disparate elements - adapted from fields such as civil defense, emergency management and international public health - by well-meaning experts and

officials, and of response failures that have typically led, in turn, to reforms that seek to strengthen or refocus the apparatus. The analysis centers on the ways that authorities - whether public health officials, national security experts, life scientists, or other privileged observers - conceptualize and act on an encroaching future of disease emergence. This uncertain future can be taken up and made into an object of present intervention according to multiple rationalities: as an object of probabilistic calculation, as a specter that must be avoided through precautionary intervention, or as a potential catastrophe that cannot be evaded but can only be

prepared for. In the chapters that follow, we see how these various logics come into tension or combine in response to actual and anticipated disease emergencies."--Provided by publisher.

Physician-historian Jeremy A. Greene examines the mechanisms by which drugs and chronic disease categories define one another within medical research, clinical practice, and pharmaceutical marketing, and he explores how this interaction has profoundly altered the experience, politics, ethics, and economy of health in late-twentieth-century America.

Public Health Access and Pharmaceutical Regulation

The Global Guide to Pharma Marketing Codes
Drugs and the Definition of Disease
The Law and Ethics of the Pharmaceutical Industry
Hooked
Chemical Youth
Drugs for Life

In this unprecedented account of the dynamics of Nigeria's pharmaceutical markets, Kristin Peterson connects multinational drug company policies, oil concerns, Nigerian political and economic transitions, the circulation of pharmaceuticals in the Global South, Wall Street machinations, and the needs and

aspirations of individual Nigerians. Studying the pharmaceutical market in Lagos, Nigeria, she places local market social norms and credit and pricing practices in the broader context of regional, transnational, and global financial capital. Peterson explains how a significant and formerly profitable African pharmaceutical market collapsed in the face of U.S. monetary policies and neoliberal economic reforms, and she illuminates the relation between that collapse and the American turn to speculative capital during the 1980s. In the process, she reveals the mutual constitution of financial

speculation in the drug industry and the structural adjustment plans that the IMF imposed on African nations. Her book is a sobering ethnographic analysis of the effects of speculation and "development" as they reverberate across markets and continents, and play out in everyday interpersonal transactions of the Lagos pharmaceutical market.

 An exploration of how global

pharmaceutical products are localized – of what happens when they become 'glocal' – this book examines the tensions that exist between a global pharmaceutical market and the locally bounded discourses and regulations encountered as markets are created for new drugs in particular contexts. Employing the case study of the emergence, representation and regulation of Viagra in the Swedish market, Glocal Pharma offers analyses of commercial material, medical discourses and legal documents to show how a Swedish, Viagra-consuming subject has been constructed in relation to the drug and how Viagra is

imagined in relation to the Swedish man. Engaging with debates about pharmaceuticalization, the authors consider the ways in which new identities are created around drugs, the redefinition of health problems as sites of pharmaceutical treatment and changes in practices of governance to reflect the entrance of pharmaceuticals to the market. With attention to 'local' contexts, it reveals elements in the nexus of pharmaceutcalization that are receptive to cultural elements as new products become embedded in local markets. An empirically informed study of the the ways in which the

presence of a drug can alter the concept of a disease and its treatment, understandings of who suffers from it and how to cure it - both locally and internationally - this book will appeal to scholars of sociology and science and technology studies with interests in globalization, pharmaceuticals, gender and the sociology of medicine.

DIVAnthropological study of the globalization of pharmaceuticals and its effects on local cultures, health, and economics./div

The book Our Bodies, Ourselves is a feminist success story. Selling more than four million copies since its debut in 1970, it has

challenged medical dogmas about women's bodies and sexuality, shaped health care policies, energized the reproductive rights movement, and stimulated medical research on women's health. The book has influenced how generations of U.S. women feel about their bodies and health. Our Bodies, Ourselves has also had a whole life outside the United States. It has been taken up, translated, and adapted by women across the globe, inspiring more than thirty foreign language editions. Kathy Davis tells the story of this remarkable book's global circulation. Based on interviews with members of the Boston

Women's Health Book Collective, the group of women who created Our Bodies, Ourselves, as well as responses to the book from readers, and discussions with translators from Latin America, Egypt, Thailand, China, Eastern Europe, Francophone Africa, and many other countries and regions, Davis shows why Our Bodies, Ourselves could never have been so influential if it had been just a popular manual on women's health. It was precisely the book's distinctive epistemology, inviting women to use their own experiences as resources for producing situated, critical knowledge about their bodies and health, that

allowed the book to speak to so many women within and outside the United States. Davis provides a grounded analysis of how feminist knowledge and political practice actually travel, and she shows how the process of transforming Our Bodies, Ourselves offers a glimpse of a truly transnational feminism, one that joins the acknowledgment of difference and diversity among women in different locations with critical reflexivity and political empowerment.

Recovering from Success

Textbook of Global Health

Bottle of Lies
Technology, Politics, and Ethics as Anthropological Problems
When People Come First
Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook

Documents what the author believes to be an unethical and patient-compromising practice of self-serving cooperation between the pharmaceutical and health-care industries, arguing that the medical profession must take responsibility for its own integrity.

Drawing on medical anthropology and science and technology studies,the contributors to Addiction Trajectories examine the epistemic, therapeutic, and experiential dimensions of contemporary addiction.

This book investigates pharmaceutical regulation and the public health issue of fake or illicit medicines in developing countries. The book analyses the evolution of pharmaceutical capitalism, showing how the entanglement of market and health interests has come to shape global

regulation. Drawing on extensive fieldwork in India, Kenya and Europe, it demonstrates how large pharmaceutical companies have used the fight against fake medicines to serve their strategic interests and protect their monopolies, sometimes to the detriment of access to medicines in developing countries. The book investigates how the contemporary dynamics of pharmaceutical power in global markets have gone on to shape societies locally, resulting in more security-oriented policies. These processes

highlight the key consequences of contemporary "logistical regimes" for access to health. Providing important insights on how the flows of commodities, persons, and knowledge shape contemporary access to medicines in the developing countries, this book will be of considerable interest to policy makers and regulators, and to scholars and students across sociology, science and technology studies, global health, and development studies.

Joseph Dumit argues that underlying

Americans' burgeoning consumption of prescription drugs and the skyrocketing cost of healthcare is a relatively new perception of ourselves as inherently ill and in need of chronic treatment.

Global Assemblages

An Anthropology of Biomedicine

Pharmaceutical Reason

When Experiments Travel

Knowledge and Value in Global Psychiatry

Compound Solutions

The Long Year

Pharmacists face ethical choices constantly -- sometimes

dramatic life-and-death decisions, but more often subtle, less conspicuous choices that are nonetheless important. Among the topics confronted are assisted suicide, conscientious refusal, pain management, equitable distribution of drug resources within institutions and managed care plans, confidentiality, and alternative and non-traditional therapies. Veatch and Haddad's book, first published in 1999, was the first collection of case studies based on the real experiences of practicing pharmacists, for use as a teaching tool for pharmacy students. The second edition accounts for the many changes in pharmacy since 1999, including assisted suicide in Oregon, the purchasing of less expensive drugs from Canada, and the influence of managed care on prescriptions. The

presentation of some cases is shortened, most are revised and updated, and two new chapters have been added. The first new chapter presents a new model for analyzing cases, while the second focuses on the ethics of new drug distribution systems, for example hospitals where pharmacists are forced to choose drugs based on cost-effectiveness, and internet based pharmacies.

In a rapidly growing global economy, where there is a constant emergence of new business models and dynamic changes to the business ecosystem, there is a need for the integration of traditional, new, and hybrid concepts in the complex structure of supply chain management. Within the fast-paced pharmaceutical industry, product strategy, life cycles, and distribution must maintain the highest level of

agility. Therefore, organizations need strong supply chain capabilities to profitably compete in the marketplace. Global Supply Chains in the Pharmaceutical Industry provides innovative insights into the efforts needed to build and maintain a strong supply chain network in order to achieve efficient fulfillment of demand, drive outstanding customer value, enhance organizational responsiveness, and build network resiliency. This publication is designed for supply chain managers, policymakers, researchers, academicians, and students, and covers topics centered on economic cycles, sustainable development, and new forces in the global economy.

The Global Guide to Pharma Marketing Codes will help marketers maximise public relations opportunities around

the world. This publication provides an overview of basic healthcare promotional regulations, and answers the most frequently asked questions about what is and isn't permitted with respect to the media and third party involvement. This truly unique guide was produced with the insight and expertise of the largest independent public relations group dedicated exclusively to health and medical communications worldwide. GLOBALHealthPR (GHPR) is an international partnership uniting some of the world's most successful independent healthcare public relations firms and their affiliates from major markets in Europe, the Americas and Asia.

Andrew Lakoff argues that a new 'pharmaceutical' way of thinking about and acting upon mental disorder is coming

to reshape not only the field of psychiatry, but also our very notions of self. Drawing from a comprehensive ethnography of psychiatric practice in Argentina (a country which boasts the most psychoanalysts per capita in the world) Lakoff looks at new ways of understanding and intervening in human behaviour. He charts the globalization of pharmacology, particularily the global impact of US psychiatry and US models of illness, and further illustrates the clashes, conflicts, alliances and reformulations that take place when psychoanalytic and psychopharmacological models of illness and cure meet. Highlighting the social and political implications that these new forms of expertise about human behaviour and human thought bring, Lakoff presents an arresting case-study that

will appeal to scholars and students alike.

The Final Report of the National Commission on the Causes of the Financial and Economic Crisis in the United States Including Dissenting Views

Ethics, the Medical Profession, and the Pharmaceutical Industry

Case Studies in Pharmacy Ethics

Global Health in a Time of Emergency

Vital Systems, Expertise, and the Politics of Security

Biological Citizens after Chernobyl

The Global Pharmaceutical Industry

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the

production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is 'current good manufacturing practice (CGMP)'', which is applied within the frame of a pharmaceutical quality system (PQS). This

implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book

gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical

sector.

Some years—1789, 1929, 1989—change the world suddenly. Or do they? In 2020, a pandemic converged with an economic collapse, inequalities exploded, and institutions weakened. Yet these crises sprang not from new risks but from known dangers. The world—like many patients—met 2020 with a host of preexisting conditions, which together tilted the odds toward disaster. Perhaps 2020 wasn't the year the world changed; perhaps it was simply the moment

the world finally understood its deadly diagnosis. In The Long Year, some of the world's most incisive thinkers excavate 2020's buried crises, revealing how they must be confronted in order to achieve a more equal future. Keeanga-Yamahtta Taylor calls for the defunding of police and the refunding of communities; Keisha Blain demonstrates why the battle against racism must be global; and Adam Tooze reveals that COVID-19 hit hardest where inequality was already greatest and welfare states weakest. Yarimar Bonilla,

Xiaowei Wang, Simon Balto, Marcia Chatelain, Gautam Bhan, Ananya Roy, and others offer insights from the factory farms of China to the elite resorts of France, the meatpacking plants of the Midwest to the overcrowded hospitals of India. The definitive guide to these ongoing catastrophes, The Long Year shows that only by exposing the roots and ramifications of 2020 can another such breakdown be prevented. It is made possible through institutional partnerships with Public Books and the Social Science

Research Council.

How did Japan fall from challenger to US hegemonic leadership in the high tech industries in the 1980s, to stumbling giant by the turn of the century? What is it doing about it? This book examines the challenges faced by Japan's high tech companies through successful emulation of some of their key practices by foreign competitors and the emergence of new competitive models linked to open innovation and modular production. High tech companies were slow to respond,

relying at first on formulae which had worked in the past, but in a new environment, some of these traditional strengths had now become sources of weakness. Stability and success, moreover, had decreased their appetite for risk. Early in the new century, however, there were signs of a more concerted response, which opened up past practices to scrutiny, and modification through selective learning and adaptation of the new models. The 'MOT' (management of technology) movement provided a vehicle for

this change. It was linked, in turn, to efforts to change the national innovation system, giving universities a more central role, and encouraging spin-offs and startups. The book features contributions from Japanese and Western scholars and practitioners who have distinctive insights into the nature of these challenges and responses, with substantial introductory and concluding chapters. The result is a highly accessible account of innovation, technology, and change management in the world's second largest

economy.

In this fully revised and updated second edition of An Anthropology of Biomedicine, authors Lock and Nguyen introduce biomedicine from an anthropological perspective, exploring the entanglement of material bodies with history, environment, culture, and politics. Drawing on historical and ethnographic work, the book critiques the assumption made by the biological sciences of a universal human body that can be uniformly standardized. It focuses on the

ways in which the application of biomedical technologies brings about radical changes to societies at large based on socioeconomic inequalities and ethical disputes, and develops and integrates the theory that the human body in health and illness is not an ontological given but a moveable, malleable entity. This second edition includes new chapters on: microbiology and the microbiome; global health; and, the self as a socio-technical system. In addition, all chapters have been comprehensively revised

to take account of developments from within this fast-paced field, in the intervening years between publications. References and figures have also been updated throughout. This highly-regarded and award-winning textbook (Winner of the 2010 Prose Award for Archaeology and Anthropology) retains the character and features of the previous edition. Its coverage remains broad, including discussion of: biomedical technologies in practice; anthropologies of medicine; biology and human experiments; infertility and

assisted reproduction; genomics, epigenomics, and uncertain futures; and molecularizing racial difference, ensuring it remains the essential text for students of anthropology, medical anthropology as well as public and global health.

Family Peril and the Struggle for a Good Life

Countering the Problem of Falsified and Substandard Drugs

Speculative Markets

Unprepared

Medical Monopoly

Drug Circuits and Derivative Life in Nigeria Navigating Uncertainty in Search of the Good Life

During much of the nineteenth century, physicians and pharmacists alike considered medical patenting and the use of trademarks by drug manufacturers unethical forms of monopoly; physicians who prescribed patented drugs could be, and were, ostracized from the medical community. In the decades following the Civil War, however, complex changes in

patent and trademark law intersected with the changing sensibilities of both physicians and pharmacists to make intellectual property rights in drug manufacturing scientifically and ethically legitimate. By World War I, patented and trademarked drugs had become essential to the practice of good medicine, aiding in the rise of the American pharmaceutical industry and forever altering the course of medicine. Drawing on a wealth of previously unused archival material, Medical Monopoly combines legal, medical,

and business history to offer a sweeping new interpretation of the origins of the complex and often troubling relationship between the pharmaceutical industry and medical practice today. Joseph M. Gabriel provides the first detailed history of patent and trademark law as it relates to the nineteenth-century pharmaceutical industry as well as a unique interpretation of medical ethics, therapeutic reform, and the efforts to regulate the market in pharmaceuticals before World War I. His book will be of

interest not only to historians of medicine and science and intellectual property scholars but also to anyone following contemporary debates about the pharmaceutical industry, the patenting of scientific discoveries, and the role of advertising in the marketplace.

"In the middle decades of the twentieth century, in the wake of economic depression, war, and in the midst of the Cold War, an array of technical experts and government officials developed a substantial body of expertise to contain

and manage the disruptions to American society caused by unprecedented threats. Today the tools invented by these mid-twentieth century administrative reformers are largely taken for granted, assimilated into the everyday workings of government. As Stephen Collier and Andrew Lakoff argue in this book, the American government's current practices of disaster management can be traced back to this era. Collier and Lakoff argue that an understanding of the history of this initial formation of the "emergency state" is essential to an

appreciation of the distinctive ways that the U.S. government deals with crises and emergencies-or fails to deal with them-today. This book focuses on historical episodes in emergency or disaster planning and management. Some of these episodes are well-known and have often been studied, while others are little-remembered today. The significance of these planners and managers is not that they were responsible for momentous technical innovations or that all their schemes were realized successfully. Their true significance lies

in the fact that they formulated a way of understanding and governing emergencies that has come to be taken for granted"-- The Financial Crisis Inquiry Report, published by the U.S. Government and the Financial Crisis Inquiry Commission in early 2011, is the official government report on the United States financial collapse and the review of major financial institutions that bankrupted and failed, or would have without help from the government. The commission and the report were implemented after Congress passed an

act in 2009 to review and prevent fraudulent activity. The report details, among other things, the periods before, during, and after the crisis, what led up to it, and analyses of subprime mortgage lending, credit expansion and banking policies, the collapse of companies like Fannie Mae and Freddie Mac, and the federal bailouts of Lehman and AIG. It also discusses the aftermath of the fallout and our current state. This report should be of interest to anyone concerned about the financial situation in the U.S.

and around the world.THE FINANCIAL CRISIS INQUIRY COMMISSION is an independent, bi-partisan, government-appointed panel of 10 people that was created to "examine the causes, domestic and global, of the current financial and economic crisis in the United States." It was established as part of the Fraud Enforcement and Recovery Act of 2009. The commission consisted of private citizens with expertise in economics and finance, banking, housing, market regulation, and consumer protection. They examined and reported on

"the collapse of major financial institutions that failed or would have failed if not for exceptional assistance from the government."News Dissector DANNY SCHECHTER is a journalist, blogger and filmmaker. He has been reporting on economic crises since the 1980's when he was with ABC News. His film In Debt We Trust warned of the economic meltdown in 2006. He has since written three books on the subject including Plunder: Investigating Our Economic Calamity (Cosimo Books, 2008), and The Crime Of Our

Time: Why Wall Street Is Not Too Big to Jail (Disinfo Books, 2011), a companion to his latest film Plunder The Crime Of Our Time. He can be reached online at www.newsdissector.com.

The pharmaceutical industry, long thought of as a recession-proof investment, now faces a day of reckoning. The reasons for this impending downfall are not hard to discern. The prices the industry charges for its prescription drugs have escalated at four to five times the cost-of-living increases during the past two decades and

have reached a point where 30% of Americans must choose between filling a prescription, paying for housing, and buying food. This has brought about public pressure on governments around the world to control drug prices, yet the world's twenty largest pharma companies realized 80% of their growth as a result of exorbitant price hikes. Pharma currently enjoys its extraordinary profitability by exploiting the world's most vulnerable populations. Yet even their ability to increase prices in the face of falling

demand does not satisfy their profit demands. The breadth and depth of pharma's marketing transgressions exceed those of any other industry and have now reached a point where authorities around the world have found it necessary to take legal action against its violations. Drastic change is needed if the pharmaceutical industry can equitably advance the health of the world's population and regain public esteem. This book illustrates the range and extent of pharma's violations and addresses the actions that should be

implemented in order to make the drug industry a more constructive, less venal part of contemporary society. It will be of interest to researchers, academics, practitioners, and students with an interest in the pharmaceutical industry, healthcare management, regulation, and bioethics.

Social Lives of Medicines

Standards of Practice Handbook, Eleventh Edition

The Inside Story of the Generic Drug Boom

Prescribing by Numbers

Global Supply Chains in the Pharmaceutical Industry

Global Pharmaceuticals

How Feminism Travels across Borders

On April 26, 1986, Unit Four of the Chernobyl nuclear reactor exploded in then Soviet Ukraine. More than 3.5 million people in Ukraine alone, not to mention many citizens of surrounding countries, are still suffering the effects. Life Exposed is the first book to comprehensively examine the vexed political, scientific, and social circumstances that followed the disaster. Tracing the story from an initial lack of disclosure to post-Soviet democratizing attempts to

compensate sufferers, Adriana Petryna uses anthropological tools to take us into a world whose social realities are far more immediate and stark than those described by policymakers and scientists. She asks: What happens to politics when state officials fail to inform their fellow citizens of real threats to life? What are the moral and political consequences of remedies available in the wake of technological disasters? Through extensive research in state institutions, clinics, laboratories, and with affected families and workers of the so-called Zone, Petryna illustrates how the event and its aftermath have not only shaped the course of an independent nation but have made health a negotiated realm of entitlement.

She tracks the emergence of a "biological citizenship" in which assaults on health become the coinage through which sufferers stake claims for biomedical resources, social equity, and human rights. Life Exposed provides an anthropological framework for understanding the politics of emergent democracies, the nature of citizenship claims, and everyday forms of survival as they are interwoven with the profound changes that accompanied the collapse of the Soviet Union.

An anthropological study of the social functions and meanings of medicines in different cultures.

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by

modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning

is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.