The Power of Pills

Social, Ethical and Legal Issues in Drug Development, Marketing, and Pricing

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Contents

Part III: The social, ethical, and political challenge: neglected diseases

Part IV: Patents and access to medicines

Part V: Research ethics

Part VI: Political activism and treatment access

THE POWER OF PILLS

Why does one-third of the global population not have access to essential medicines? What drives new drug research priorities? How do we manage the ethical, legal and social challenges associated with improving drug access? Answering these questions and more, this book is one of the first comprehensive and critical guides to global pharmaceutical policy issues.

This multidisciplinary book is a one-stop resource for students, policy makers, academics and anyone working in the fields of medicine, bioethics, public health, law and corporate responsibility.

It brings together the insights of over thirty specialists from around the world to examine:

- the structure of the pharmaceutical industry
- current regulation of the industry
- ethical issues in developing and distributing drugs
- the importance of essential medicines in the pursuit of global justice
- how the industry prices and markets drugs
- recommendations on how to improve pharmaceutical policy

"An impressive book focusing on one of the most pressing issues of our time. *The Power of Pills* provides the resources for a debate we urgently need to have."
Professor Peter Singer, Princeton University

"This concise, incisive book offers a comprehensive review of pharmaceutical industry dynamics."
Professor Bernard M. Dickens, University of Toronto

Jillian Clare Cohen is an Assistant Professor at the University of Toronto and Director of the Comparative Program on Health and Society. She has advised governments and international organizations on pharmaceutical policy. **Patricia Illingworth** is an Associate Professor at Northeastern University. She has written three books on healthcare including *Trusting Medicine* (2005), and *Ethical Health Care* (2006) with Wendy Parmet. **Udo Schüklenk** is co-editor of the journal *Bioethics* and author of *Access to Experimental Drugs in Terminal Illness* (1998).

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Introduction

Pharmaceutical policy lies at the intersection of a diverse range of disciplines. Although this makes pharmaceutical policy immensely interesting, it also makes it challenging to understand, for the student, the policymaker, and even the educator. We were motivated by the pressing need for an interdisciplinary approach to pharmaceutical policy. No doubt our different disciplinary backgrounds helped us meet this ambitious goal. To that end, we have assembled a collection of thoughtful papers that illuminate many of the wide range of issues that pharmaceutical policy embraces. In the pages that follow, we include contributions of a social, ethical, and legal nature in an effort to develop more comprehensive thinking on the subject.

Health is a necessary precondition for all in our attempts to live satisfying, happy lives. In a global world, each of us has an interest in the health of others, including those who live in the developing world. The common concern of most contributors to this volume is that today's main approaches to drug research and development are suboptimal. Diseases that do not provide sufficient profit incentives to multinational pharmaceutical companies are disregarded. Those most affected by this response are the developed world's poor and hundreds of millions of people living in the developing world. Our authors analyze the international trade frameworks that determine these undesirable outcomes from legal, ethical, and policy perspectives. They provide a critique as well as constructive responses designed to tackle these problems. Contributions reflect on both international and national regulatory frameworks, fundamental issues such as the moral sustainability of intellectual property rights-based incentives for drug research and development, as well as the equitable sharing of benefits derived from research undertaken in developing countries. Long overdue critical analysis is also applied to recent high-profile attempts at wedding non-profit initiatives to market-driven solutions.

Although our focus is the pharmaceutical industry, this should not be interpreted to mean that we believe that changes to that industry will magically solve global health problems. We realize that the global poor face public health problems that go beyond what pharmaceutical companies can address. Nonetheless, it is necessary for each stakeholder to do what it can to alleviate the health problems that face the global poor.

Part I offers a wider perspective on the pharmaceutical industry. Joel Lexchin's chapter introduces many of the criticisms the industry faces. He discusses how pharmaceutical companies are motivated to increase their profits rather than focus on the healthcare needs of populations. He identifies a number of strategies firms use to increase profits

that can lead to unethical practices. These include setting research priorities on "blockbuster" drugs, suppressing unfavorable results from post-marketing studies, and drug promotion practices which include direct-to-consumer advertising (DTCA) as well as drug promotion to physicians, which ignore the possible serious side-effects of a drug while overstating the drug's benefits.

Kristina M. Lybecker focuses on the tensions inherent in the socioeconomic construct that is today's pharmaceutical industry. On the one hand, it has a social contract to develop medicines that enhance the health of the public, but on the other it seeks to maximize profit. Lybecker explains the major challenges facing the industry today, such as longer drug development times, rising R&D costs, generic competition, and parallel importation.

Ann Mills, Patricia Werhane, and Michael Gorman, in a provocative essay, discuss how the pharmaceutical industry needs a new framework so that health needs in developing countries are addressed. The authors note that the patent system may be perceived as a prerequisite for business development for richer countries, but developing countries view it as an enormous obstacle to improving access to drugs. Mills et al. suggest alternatives which could help remedy this situation, including strengthening the ability of governments to require universities to grant non-exclusive licenses.

Warren Kaplan argues that we should expect hybrid structures to appear in the pharmaceutical industries of the important middle-income producers of generic medicines (e.g., India). Notwithstanding the possible effect of these structures on pharmaceutical innovation in middle-income countries, this restructuring is likely to have important consequences for access to affordable medicines. The effect of these hybrid structures on real pharmaceutical innovation in the established pharmaceutical industry and in the newer public–private initiatives is still unclear.

Next, Ian Marshall examines the relationship between physicians and the pharmaceutical industry and the issue of gift-giving to physicians. He enumerates several codes that are in place to regulate the relationship and notes that one major deficiency is that they are not being vigorously enforced.

Finally in Part I, Robert Freeman provides an industry perspective. He answers some of the criticisms directed at the pharmaceutical industry, particularly those concerning drug prices. For instance, in response to the criticism that the industry has excessive expenditures for marketing and sales of drugs, which from the public's perspective makes the industry seem profit-driven, Freeman argues that it is important for a company to develop various marketing tools because new drugs will not be prescribed by physicians in the absence of constant, repetitive communication through marketing. In contrast to the majority of the contributors to this volume, Freeman emphasizes that the pharmaceutical industry is aware of its corporate social responsibility to communities and countries in which they operate.

In Part II, we include a diverse group of chapters that address the normative and legal implications of the view that medicines are global public goods. Wendy Parmet points out that even though pharmaceuticals are not "classical" public goods insofar as they do not fulfill the criteria of being non-excludable or non-rivalrous, they are

partial public goods because of their impact on public health. Parmet gives a number of examples drawn from the history of public health, including herd immunity, which is activated when the rate of vaccination is sufficiently high to interrupt the chain of transmission of a particular disease for everyone, including those who have not received the vaccination. Parmet also points out that medicines have not only a public nature, but also a global one. Given that the conditions of ill health are global, she argues that, from a normative point of view, we ought to share the medications that will reduce those illnesses. From a public policy perspective, and in the name of global public health, it is imperative that each nation adopts laws and policies that will facilitate the use of these medicines by the global community.

The demands of global justice are further explored by David Resnik. Resnik believes that international justice depends not on individuals, but primarily on nations because they stand to have the greatest impact. In view of international justice goals, global health inequalities need to be considered. Resnik looks at the implications of the main theories of justice and what our international obligations of justice are. He begins with Rawlsian egalitarianism and then considers the implications of utilitarianism in relation to questions about international justice.

In "Pharmacogenetics and Global (In)Justice" Søren Holm explains the effects of pharmacogenetics on global justice. The moral problem with pharmacogenetics is that it seems unlikely that there will be a trickle-down effect. He reasons in the following way. According to the trickle-down theory, the benefits of pharmaceutical R&D eventually trickle down to the poor once they become generics. While it is questionable whether this happens to a sufficient extent in practice, the question that concerns Holm is how pharmacogenetics will impact the poor. Holm considers two possible scenarios and concludes that on both the implications for the poor are dismal. Problems of global justice will thus be exacerbated.

In Part III, our contributors focus on the moral, social, and political issues surrounding the apparently intractable problem of neglected diseases, offering analysis and potential solutions. Nathan Ford outlines the reasons why some diseases are neglected, explaining that this phenomenon cannot easily be accounted for on the basis of a lack of knowledge, but is more readily explained by the fact that R&D in pharmaceuticals is driven by the markets of wealthy countries. The patent system fails to stimulate innovation for neglected diseases. Ford argues that adequate drug development should be viewed as a government responsibility and not as solely that of private philanthropy.

The next chapter focuses on more practical matters. James Orbinski and Barry Burciul discuss the efforts of the Drugs for Neglected Diseases Working Group (DND-WG) to find creative solutions to the problems of neglected diseases. For this group any solution or recommendation had to be "sustainable, affordable, need driven and involve input and active engagement of developing countries." In a short time, the working group created the Drugs for Neglected Diseases Initiative (DNDI). DNDI focused not only on funding and conducting R&D itself, but also on strengthening the R&D efforts of others. The authors draw an important distinction between neglected diseases and most-neglected diseases. The former may affect a few people in wealthy countries while the latter are

exclusively the diseases of those in developing countries. Because of the poverty in developing countries, they offer no market to pharmaceutical companies for R&D. Orbinski and Burciul also examine various efforts to generate R&D for neglected diseases. They pose the important question: "Does a country's membership in the community of nations not entitle it to make certain demands of the rest of humanity?"

Aidan Hollis continues the discussion about neglected diseases and illuminates how research can foster R&D for neglected diseases. He makes the important point that poor countries not only face the problem of neglected diseases, but also must usually contend with a number of other problems, including a lack of doctors, nurses, clinics, hospitals, and equipment.

One of the more promising approaches to neglected diseases to surface in recent years, embraced by many government and non-government organizations (NGOs), are advanced purchase commitments (APC) in which large donors create markets for vaccines or medicines, thus generating R&D. After identifying significant moral and practical problems with this approach, Donald Light explores some of the social and political impetus behind the somewhat surprising international support for APCs.

Thomas Pogge, in "Harnessing the Power of Pharmaceutical Innovation," provides a good example of a workable pull mechanism. As with many contributors to this volume, Pogge finds the present patent system morally troubling as it pits the vital needs of impoverished patients against the desire of pharmaceutical companies to recoup their investment. He recommends rewarding pharmaceutical research in proportion to its impact on the global disease burden. Such an approach would have the advantage of both reducing the impact of neglected diseases on the poor and stimulating new profitable research for pharmaceutical organizations.

In Part IV, we turn to the issue of patents and pharmaceuticals. Adam Mannan and Alan Story argue that drug access could be improved if product patents were abolished. They argue that even if a process patent is present, competitors can find alternative processes or uses for the chemical compound and create price competition. To further support their argument, the authors explain how the patent system was created not because it had to create conditions for sustainable innovation, but for market protection. They note that, until recently, few countries even recognized pharmaceutical product patents and some countries, such as India, were able to develop a thriving industry as a result of the absence of product patents.

Michael Selgelid and Elin Sepers argue that there is a need to "incentivize" pharmaceutical firms to undertake research for diseases of the developing countries. They highlight and analyze the costs and benefits of a select number of international proposals, including those advanced by Thomas Pogge and the Consumer Project on Technology and Health. They conclude soberly that each proposal requires political will and substantial funding from wealthy developed nations. On each of these schemes the funds for pharmaceutical innovation would need to be assured upfront, and the vast majority of funds would need to come from NGOs, charities, and national governments.

Finally in this part, Kevin Outterson's thoughtful and comprehensive essay argues that low-income populations should not pay any patent appropriation rent for essential pharmaceuticals because to do so is both cruel and unnecessary – cruel in that people will die if a treatment is available yet unaffordable to them; unnecessary because low-income populations would never have contributed much toward global pharmaceutical rent extraction. Drugs used to treat global diseases, he argues, should be exempt from appropriation by providing generic drugs to the poor without undermining innovation from the pharmaceutical company. He concludes by proposing four new paradigms that could help resolve drug access issues.

In her paper, Lisa Forman demonstrates how bilateral and regional free trade agreements are imposing rigorous intellectual property law obligations on developing countries. This has in turn created TRIPS-plus standards for countries, which has potentially dire consequences on access to medicines in these countries. These trade agreements have effectively undercut countries' capacity to use flexibilities within the TRIPS Agreement to support public health objectives.

In Part V, we examine research and ethics. Increasingly, clinical research is undertaken in multi-center studies involving numerous countries and jurisdictions. Argentinian bioethicist Florencia Luna, a past president of the International Association of Bioethics, introduces one of the major issues debated in recent years in international research ethics in this context, namely the question of what constitutes appropriate standards of care for participating patients. The line taken by the U.S. National Institutes of Health and many American bioethicists has been that it is acceptable for developed world sponsors of such trials to provide less than the best proven therapeutic means of treatment to the trial participants. Developed world-based bioethicists do not always agree and Luna explains why.

Steve Miles takes this discussion further by asking how it can be ensured that the benefits of human genomic research that is undertaken in the developing world are equitably shared with the peoples living there. Miles argues that the socioeconomic gap between rich and poor nations is likely to grow unless developing countries establish research capacity prioritizing the health needs of their peoples. He takes a strong stance against the Human Genome Organization's view that the human genome should be seen as the collective property of humankind and should be freely explored by anyone so interested. Such an interpretation would primarily serve developed nations and compound the injustice committed against developing nations over centuries.

Next, in Part VI, we offer some insights into political activism and treatment access. Given market failures in drug access and R&D, activists in developed and developing countries are working on sustainable answers to the moral challenges posed to the patent system. Richard Elliott describes how Canadian civil society groups came together and began – successfully – lobbying their government about the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and its relationship to access to essential medicines. The primary target of this coalition of civic society organizations was to see legislation introduced that would permit producers of generic drugs to obtain

compulsory licenses for products under patent protection in Canada for the purpose of producing affordable medicines for export to developing countries.

Similarly, Brook K. Baker, in his passionate contribution, argues that treatment access activists should focus on placing access to essential drugs on the human rights agenda. Baker bases his arguments on the health-related provision in the 1948 UNDHR, and the UN's ICESCR. They effectively make provision of access to essential medicines a fundamental duty of all member states of the UN system. Baker acknowledges theoretical and historical concerns about human rights-based strategies, but maintains that important policy objectives in the realms of women's reproductive rights, labor, and environmental rights for instance, and on health-related rights have been realized by means of rights-based campaign tactics. He warns that human rights declarations are stillborn in the absence of civic society organizations and responsive states.

In Part VII we look at the role of governmental or national responsibilities. South African pharmacist João L. Carapinha addresses these issues from his country's perspective. Carapinha proposes a comprehensive public–private sector response to the treatment access challenge. He comes out strongly in favor of an interventionist government, noting the need for the developing country to intervene in the manufacturing sector and to direct it to produce affordable medications.

In line with reasons developed by Baker and Carapinha, Kinsley Wilson and colleagues also accept the premise that the state is primarily responsible for ensuring access to essential medicines. They suggest that countries should develop a National Drug Policy (NDP) and accompanying implementation plans. Countries need to establish adequate processes as far as the registration, selection, procurement, and distribution of drugs are concerned.

Thomas A. Faunce from Australia's National University explores appropriate policy options in response to pharmaceutical industry lobbying designed to undermine regulatory systems. He proposes the establishment of a global, socially responsive, cost-effective pharmaceutical pricing system. Faunce describes how currently employed national regulatory processes variably include encouraging generic competition, issuing compulsory licenses, and limiting pharmaceutical companies' profits, amongst others. He suggests that it is desirable to establish a "gold standard" global cost-effectiveness evaluation for pharmaceuticals.

As the chapter summaries demonstrate, this volume may help us to foster conditions in which our biomedical R&D capacities are truly serving the majority of people living on this planet. More R&D development must be undertaken to achieve this. Strong political will – in other words, resolute commitment by governments – is required. Lastly, we hope this volume inspires you to think differently about some of these topics if you are already familiar with them. If you are not, we hope it helps you to better understand them. For that, no matter how trivial, is a vital first step in helping to improve access to medicines globally.

Invariably, a book such as this relied on the assistance of many people to allow it to come to fruition. We are grateful to Neil McPherson for his outstanding help with research and manuscript preparation. Audrey Capuano helped with administration and

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Finally, a word in defense of our decision to make extensive use of abbreviations in this book. Space constraints motivated us to create a register of acronyms and make extensive use of abbreviations. This is likely to require you to check occasionally for abbreviations with which you might be unfamiliar. We thank you for your understanding in this regard.

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