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## Global Pharmaceutical Policy: Ensuring Medicines For Tomorrow's World

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## Book Review

### GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD

*Frederick M. Abbott & Graham Dukes\**

Pharmaceuticals play a central role in health care throughout the world. The pharmaceutical industry is beset with difficulties as increasing research and development expenditure yields fewer new treatments. Public and private budgets strain under the weight of high prices and limited access. The world's poor see little effort to address diseases prevalent in less affluent societies, while the world's wealthy are overusing prescription drugs, risking their health and wasting resources.

As the global economic crisis exacerbates pressure on health care budgets, a new presidential administration in Washington, DC has committed to broad health care reform. These circumstances form the backdrop for this extraordinarily timely examination of the global system for the development, production, distribution and use of medicines. The authors are acknowledged experts in the fields of pharmaceutical law and policy, with many years experience advising governments, multilateral organizations and policy-makers on issues involving innovation, access and use of medicines. Supported by a team of independent scientists, doctors and lawyers, they take an insightful look at the issues surrounding global regulation of the pharmaceutical sector, and offer pragmatic suggestions for reform.

This book will be of interest to government policy-makers, members of industry, healthcare professionals, teachers, students and lawyers in the fields of public health, intellectual property and international trade.

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## GLOBAL PHARMACEUTICAL INDUSTRY: ENSURING PROFITS AT THE EXPENSE OF PUBLIC HEALTH

*Reviewer: David Szostak\*\**

### INTRODUCTION

The pharmaceutical industry has two remarkably different faces. It portrays itself as altruistic and innovative, spending a fortune on research and development to create breakthrough medicines that cure all manner of diseases, alleviating the suffering of humanity. On the flip side, its critics paint the industry as greedy and callous, charging exorbitant prices for life-saving drugs while generally ignoring the poor altogether. *Global Pharmaceutical Policy* lays out a large number of problems in the pharmaceutical industry and various governmental policies that attempt to deal with the industry in an optimal way. The problems run the gamut from excessive use of medication by the rich to the lack of access to drugs by the poor, and from the patent system allowing for market exclusivity by originator drug companies to government subsidies of research and generic drugs. The authors, Abbott and Dukes, do an excellent job of bringing innumerable problems to light. Their solutions and recommendations, however, are modest and overly optimistic, and they fall drastically short of what is necessary to remedy the situation.

The problems with global pharmaceutical policy are too numerous to list in full here, but a number of them are worth mentioning. There is no single, unified worldwide policy when it comes to either promoting innovation or regulation in pharmaceuticals. The authors refer to it as “remarkably disjointed” because each country has its own policies and does whatever it wants.<sup>1</sup> Research and development (R&D) is not coordinated globally very well. Furthermore, the large-scale economic decisions of what exactly to produce and where to supply it are made by a handful of executives seeking, primarily,<sup>2</sup> greater profits and not the greater social good or health of populations.

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<sup>1</sup> Frederick M. Abbott & Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World*, 1 (Edward Elgar Publishing 2009).

<sup>2</sup> *Id.*

A wide gap also exists between the rich and the poor among different countries and also within the same countries. There are many pharmaceuticals that the rich can afford but the poor cannot. R&D is unimpressive: rates of innovation are “surprisingly low.”<sup>3</sup> Since corporate profits dictate everything, companies invest far less in diseases of the poor because, of course, the poor have no money which with to buy the drugs.<sup>4</sup>

The authors argue that the global pharmaceutical industry is extremely complex, and no single solution exists for the many challenges that societies face. It is true that the situation is complex, but the danger of overcomplicated and nuanced solutions is that truly helpful remedies get diluted and watered down. As the current patchwork of a health care reform bill that Congress has been debating for many months demonstrates, shooting for modest reform often results in a trivial change, if any. Why not, at least at the outset, aim for a more ideal solution?

### PROBLEMS

The book opens by confronting the many challenges that plague the pharmaceutical industry and the policies that govern it. A powerful indictment of the industry sets the tone of the rest of the book: “In 2007 total worldwide revenues from sales of pharmaceutical products amounted to approximately \$650 billion, of which \$550 billion went to the originator companies and \$100 billion to the generic companies.”<sup>5</sup> Large corporations have spent a lot of money on advertising and information campaigns to convince the public that their R&D efforts have been highly successful, but in reality they have a very low success rate. It is “decidedly low” and not “well attuned to actual needs.”<sup>6</sup>

Why the low rate of innovation currently? A number of reasons are possibilities: (1) Perverse incentives are abundant. Companies that create “new” drugs are rewarded highly for just making minor changes to previously patented drugs. This extends the life of their monopolies and is low-risk but very profitable. (2) “The low-hanging fruit of pharmaceutical innovation already has been plucked.”<sup>7</sup> Companies have already done the easiest stuff. (3) The whole industry has been consolidating of the past few decades, with a result of fewer opportunities pursued; fewer minds are

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3 *Id.*

4 *Id.*

5 *Id.* at 2.

6 *Id.* at 3.

7 *Id.*

working on fewer projects in fewer labs. (4) There is a disconnect between university research labs and actually transforming new medicines into marketable products. Solutions to these problems include proposals to reform patent laws to remove the perverse incentives, use prizes to focus innovation on specific diseases, and expand government subsidies to R&D (and invest it more wisely).<sup>8</sup>

Other problems pervading the field are a severe lack of access to medicines in developing countries, extremely misleading marketing and promotion, and a lack of R&D in diseases that plague poor people because they are simply not profitable.<sup>9</sup> Additionally, health care costs in the United States and Western Europe are spiraling out of control.<sup>10</sup>

Perhaps the most disturbing question is simply one of profit. Globally, annually, \$100 billion is spent on R&D, and another \$137 billion on total costs of production for pharmaceuticals.<sup>11</sup> This, however, is only a combined \$237 billion out of \$550 billion price tag for original products, so where is the other \$313 billion going?<sup>12</sup> Whether it creates high executive salaries, dividends for stockholders, or enriches the wealthy in some other way, it is one of the largest problems in the health care sector. It is no wonder health care premiums have been increasing so rapidly for so many years; the insurance companies are paying the pharmaceutical industry astronomical sums, from which it profits considerably. The depth of this problem is explored more later in this review.

## INNOVATION

The authors spend several chapters of *Global Pharmaceutical Policy* discussing innovation: how to promote it and what policies are best. This is a worthy topic because new breakthrough drugs are rare; the patent system is supposed to encourage investment and development, but most patents for new drugs are similar to existing drugs.<sup>13</sup> The reason is simply profit. Corporations must remain profitable, so their officers make decisions based on profit, and it is a much safer bet to slightly modify current, well-researched drugs than to try anything truly innovative and brand new.<sup>14</sup>

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<sup>8</sup> *Id.* at 4.

<sup>9</sup> *Id.* at 8.

<sup>10</sup> *Id.* at 12.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 13.

<sup>13</sup> *Id.* at 17.

<sup>14</sup> *Id.* at 18.

The current patent-based system is deeply flawed. Exclusive marketing and patent rights allow originator drug companies to charge 10-20 times more for same drug that a generic producer could manufacture and sell for much less.<sup>15</sup> This might be justified, in theory, if the originator companies were producing revolutionary breakthroughs in treatment, but this is rarely the case. Instead, originators abuse the system by “ever-greening” their patents and their marketing exclusivity by slightly modifying the old drug (e.g., increasing the potency and changing the instructions to take it fewer times per day) and getting a new patent on it.<sup>16</sup> As the authors note, “the desire for financial gain can motivate otherwise reasonable people to take shortcuts that can wreak havoc with public health.”<sup>17</sup> This is a candid and common sense statement, but our entire healthcare system is based on the free market and the desire for financial gain. The essential problem with *Global Pharmaceutical Policy* is that the authors do not carry their arguments to their logical conclusion or elaborate on their implications.

The patent-based system has both positive and negative aspects. On the one hand, it supposedly provides lots of R&D investment;<sup>18</sup> it provides opportunities for large financial reward, which in turn create innovation;<sup>19</sup> and patents are temporary and limited, and many regions are patent-free.<sup>20</sup> On the other hand, however, the level of innovation is low because of the phenomenon of evergreening; investment only occurs in diseases that will be extremely profitable; the whole system “is profit oriented, not public health oriented;” and R&D funding goes to whatever is most profitable, e.g., cosmetics and erectile dysfunction, but for diseases like sleeping sickness, a huge public health issue, no research takes place.<sup>21</sup>

The authors then propose three goals for reforming the system of R&D and distribution of pharmaceuticals: (1) improve the yield of breakthrough products; (2) bring prices of new drugs under control, both for the benefit of the poor and for public health budgets spiraling out of control; and (3) increase R&D for neglected diseases.<sup>22</sup> The three potential approaches to furthering innovation are the patent-based system, subsidies,

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15 *Id.* at 19.

16 *Id.* at 20.

17 *Id.* at 22.

18 *Id.* at 28.

19 *Id.* at 30.

20 *Id.* at 31.

21 *Id.*

22 *Id.* at 33-34.

or targeted prizes. The authors explain the patent process in detail, presenting a clear description of the criteria an invention must meet, and they suggest ways to alter the existing system, such as creating a tiered patent system or quasi-patents, essentially patents with weaker protections.<sup>23</sup> One interesting proposal is that courts could also allow (as they do in some other countries) an infringing party to continue to infringe (rather than issue an injunction to stop), while simply requiring that the party pay the originator company a royalty. Furthermore, the government could choose to fix a specific royalty rate or not.<sup>24</sup> This is a creative solution that would allow the patent-holding companies to be reimbursed for the infringement so their profits are not drastically slashed, but at the same time it would allow generic drug companies to produce much-needed drugs, permitting wider access to medicines for entire populations.

A complete alternative to patents would be a subsidy system, in which the government gives a grant to do research or even develop a drug. As the authors astutely note, “why not spend the money on specifically targeted public health priorities? Why leave questions about the direction of R&D to the market?”<sup>25</sup> The whole current system is premised on the idea that the market is efficient and innovative, and the direction of R&D on pharmaceuticals should proceed according to whatever the market dictates. In practical terms, of course, this means that diseases of the poor – no matter how ravaging, debilitating, fatal, or widespread – are largely neglected; the poor have no money to pay for medicines even if a cure is found. Instead, the industry caters to the wealthy, addressing problems such as baldness and erectile dysfunction because people with money care about these afflictions. The alternative approach would be for society to decide, via governmental and regulatory decisions, that certain widespread diseases should be targeted to develop a treatment or cure, and money should be allocated to do R&D in that specific area, regardless of profitability.

Critics of this approach argue that subsidy recipients may be inefficient or lazy; that government officials do not know enough to evaluate proposals and choose the best research leads; and that favoritism and corruption plague governmental decisions.<sup>26</sup> These are poor arguments. The appropriate governmental agency could simply retain disinterested experts

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<sup>23</sup> *Id.* at 37.

<sup>24</sup> *Id.* at 38.

<sup>25</sup> *Id.* at 45.

<sup>26</sup> *Id.* at 45.

who know as much about research leads as anyone in the private sector, and it could attract such experts by paying adequate, competitive salaries. As for inefficiency or laziness, this is largely a myth. As the authors note, “some of the great scientific successes of the Western world have resulted from government subsidized research projects” like NASA projects, DARPA and the Internet, military projects (e.g., GPS), Airbus in Europe, and many others.<sup>27</sup>

Essentially, an alternative system could involve substantial government funding for universities and institutions that develop new pharmaceuticals, with research targeted on diseases that the government (instead of the market) deems important. Once produced, these medicines could be sold at low cost as generics instead of as high-priced, name-brand patented drugs.

The authors also discuss a prize system as a third alternative to spur innovation, which is certainly worth further study. The bottom line, though, is that the current system is creating a very low rate of innovation and is just plain not working. They conclude “certainly more needs to be done – and at a fairly large scale. Market-based solutions cannot be used to address the needs of people who have no meaningful basis for market participation.”<sup>28</sup> The problem with *Global Pharmaceutical Policy* is its basic refusal to follow through on its observations with viable solutions. While its observations about the current broken system are entirely accurate, the book hesitates to thoroughly condemn the market despite the market’s clear responsibility for so many problems.

Patent law is used as a blunt instrument to protect drug companies’ profits. An illustrative example involves the cancer drug, Taxol. The U.S. government, through the National Institutes of Health (NIH), spent an enormous amount of money on R&D for this drug: from 1977 to 2002, NIH invested a total of \$484 million.<sup>29</sup> Yet the government chose to license Taxol to Bristol-Myers Squibb (BMS). BMS’s sales of Taxol totaled over \$9 billion from 1993 to 2002 alone; BMS agreed to pay NIH royalties of a mere 0.5 percent, totaling \$35 million.<sup>30</sup> The National Cancer Institute actually waived its right to set prices for Taxol, and BMS is

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27 *Id.* at 46.

28 *Id.* at 58-59.

29 Technology Transfer: NIH-Private Sector Partnership in the Development of Taxol, United States General Accounting Office, Report to the Honorable Ron Wyden, U.S. Senate (June 2003), available at <http://www.gao.gov/new.items/d03829.pdf>.

30 *Id.*



not required to disclose its costs of development.<sup>31</sup> BMS sold Taxol for \$4.87 per milligram, more than eight times the government's manufacturing cost of sixty cents.<sup>32</sup>

Pharmaceutical companies are using patents to their advantage, and to the disadvantage of public health generally. On the one hand, they have legal protection for their astronomical profits, and they often do not even have to conduct the initial R&D to begin with. Often the government subsidizes the research, but the pharmaceutical corporations get a license for the results and market an incredibly profitable drug. On the other hand, the typical argument in favor of patents is that they at least encourage innovation, but as we can see from the present low rate of innovation and the insidious technique of 'evergreening' that this rationale is not so strong after all. What is necessary is a much larger system of government subsidies for R&D, with the end result of selling generics at low cost, and simultaneously an abolition of the patent system for pharmaceuticals. Medicines, vital for health and life, should not be subject to patent.

The U.S. Pharmaceutical Research and Manufacturers Association of America (PhRMA) seems to convey the impression that it devotes an immense sum of money to R&D. In practice, however, its expenses consist of about 36 percent on manufacturing, 24 percent on marketing, and a mere 16 percent on R&D.<sup>33</sup> The authors point out a number of serious problems with the current pharmaceutical industry, all seemingly unrelated. In the U.S., the wealthiest nation in the world, up to 90 million people lack access to prescription drugs, an appallingly high number.<sup>34</sup> Globally, the richest 15 percent of the world's population consumes 91 percent of all medicines.<sup>35</sup> And a massive wasteful duplication of effort exists because many companies create new knowledge, but they refuse share it with each other or with the public; data are secret.<sup>36</sup> What do these ostensibly unconnected problems have in common? The profit system: that is, capitalism.

Both in the U.S. and globally, there is a huge gap between the rich and the poor, and even in the wealthiest regions, the poor either cannot afford or lack access to medicines. Furthermore, the idea that knowledge

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31 Ralph Nader, *The Ralph Nader reader* 164 (Seven Stories Press 2000).

32 *Id.*

33 Abbott & Dukes, *supra* note 1, at 67.

34 *Id.* at 66.

35 *Id.*

36 *Id.*

can be protected, patented, and made secret is antithetical to the very notion of science, which requires open sharing of knowledge and collaboration among scientists. While the authors are right to point out a number of inequalities and problems that plague the current system, they will not go so far as to blame the free market.

Instead, what the book recommends for general principles for policy development in biotechnology is a prospective, anticipatory approach: supplement existing law, assist developing countries that lack resources, reconsider the role of animal studies (since biotechnology is fundamentally different from older chemical drugs), reconsider drugs' priorities in the review process in regulatory agencies, ensure the public has access to information and some degree of input, etc.<sup>37</sup>

None of these recommendations will solve the fundamental problems that the profit system is causing when it comes to vast inequalities in wealth and access to drugs, low rates of innovation in PhRMA, and secretive information. Nor do the authors explain how any of these things, which directly contradict and cut into corporate profits, can actually be done. Certainly the public should have access to information and should have a degree of input – but how? Leaving the patent system intact – in fact, leaving PhRMA intact as a whole – rules out any possibility of substantial openness and sharing of scientific data and knowledge, among scientists or among the public. Legislators and regulatory agencies can legally require companies disclose data, but, as we will see later, when it is more profitable to violate the law and pay a small fine, companies have no real incentive to disclose.

## GLOBAL REGULATION

*Global Pharmaceutical Policy* devotes much time to discussing the global regulatory environment, primarily focusing on quality, safety, and efficacy of drugs. As the authors point out, 'caveat emptor' (let the buyer beware) is of little value when it comes to consumer protection in medicines because the patient is totally unable to judge the quality or safety of the drug, and she often cannot figure out whether the drug is effective, even after taking it.<sup>38</sup> This is an important issue. Adverse drug reactions are one of the leading causes of death in the U.S.<sup>39</sup>

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<sup>37</sup> *Id.* at 80-82.

<sup>38</sup> *Id.* at 86.

<sup>39</sup> *Id.* at 93.

Drug policy and regulation is extremely complex, but overall, the book asserts, the system works well: "Malpractice, misjudgment, excessive enrichment and dishonest behavior all occur, but the system accommodates and corrects the individual fault, and policies are progressively adjusted to counter undesirable trends."<sup>40</sup> This is, at best, wishful thinking. Such an assertion makes it sound as if excessive enrichment is the exception rather than the rule. Dishonest behavior and enrichment are not only tolerated, they are in fact encouraged in the current system. The undesirable trends seem to be accumulating in number, and policies are not being adjusted to counter them in any way.

One of the biggest concerns is the lack of transparency and confidentiality of data, as noted briefly above. Regulators who review clinical trial and research data are bound to secrecy; confidentiality is assured and protected by law. Courts and government agencies broadly interpret and apply confidentiality provisions.<sup>41</sup> However, from the public's point of view, or that of the medical profession, openness is crucial: if a drug is causing adverse effects, all relevant data, studies, and reports must be available for scientific and public scrutiny.<sup>42</sup> This creates a fundamental contradiction because the law is jealously guarding pharmaceutical profits by ensuring data remain secret, yet public health and science demand open sharing of knowledge. Once again, the market is at the root of the problem, and any reform will pale in comparison to the staggering power of corporate profits.

### THE DEVELOPING WORLD

Perhaps the most important part of the book, a chapter is devoted to medicines in the developing world. The authors list a few important general points: (1) medicines and vaccines are the most widely used tool for prevention and relief of disease; (2) a very large proportion of world's population still has little or no access to medicines; the situation remains catastrophic as more than 10 million children die every year, mainly in developing countries, from preventable or curable diseases; and (3) the international community has generally assumed the task of providing relief and support to developing countries.<sup>43</sup>

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<sup>40</sup> *Id.* at 87.

<sup>41</sup> *Id.* at 103-04.

<sup>42</sup> *Id.* at 104.

<sup>43</sup> *Id.* at 116.

Particularly compelling is the U.N. Task Force assertion that "the lack of life-saving and health-supporting medicines for an estimated 2 billion poor people stands as a direct contradiction to the fundamental principle of health as a human right."<sup>44</sup> The Task Force has it right, albeit as an understatement: this is an inconsistency – and truly a crime – of global proportions. The direct contradiction here is between the rich and the poor, and neither will it resolve itself over time, nor will gradual reforms solve it. Lives are hanging in the balance today; people around the world are entitled to demand their fundamental human rights immediately, not decades in the future. Drastic and urgent action is necessary.

Of course, three members of U.N. Task Force who represented multinational drug companies had irreconcilable disagreements with the majority of the Task Force members, who all had backgrounds in public health.<sup>45</sup> This is a poignant microcosm, representative of what is wrong with the global pharmaceutical system today: profit-seeking corporations cannot co-exist with humane public health policy. The differences among the members of this Task Force are illustrative of the wider differences between the pharmaceutical industry as a whole and the regulatory agencies and governments attempting to maintain a public health system.

Some interesting statistics that the authors bring to light relate to Africa, where widespread poverty exists. Sub-Saharan Africa has more than 10 percent of the world's population but accounts for barely over 1 percent of the world's drug market;<sup>46</sup> moreover, to really drive the point home, a cow in Europe is subsidized at \$2 a day (in Japan, \$4 a day), while 50 percent of Africans live on less than \$1 daily income.<sup>47</sup> This demonstrates where the priorities of the developed nations lie.

As an example of how easily the wealthy nations (or even the pharmaceutical industry) could greatly alleviate suffering in Africa: \$2 per person per year is sufficient to provide everyone with a basic package of essential medicines (a mere \$1.4 billion per year for all of sub-Saharan Africa), while the world's commercial drug market, in contrast, has revenues of \$700 billion a year, a substantial fraction of which is profit.<sup>48</sup> It is entirely reasonable to argue, as many people have, that large drug companies

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44 *Id.* at 117 (citing *Prescriptions for Healthy Development: Increasing Access to Medicines* (2005), Task Force for the United Nations Millennium Project).

45 *Id.* at 119.

46 *Id.* at 118.

47 *Id.*

48 *Id.* at 119.

are responsible for millions of deaths worldwide as they price their drugs out of reach of the poor while simultaneously fighting generic drug manufacturers tooth and nail to stay out of their markets.

Finally, the authors discuss a number of problems common to many developing countries when it comes to public drug procurement and drug management, as well as a general lack of public drug information and education. One seemingly insurmountable problem is simply the lack of physicians and pharmacists in developing countries: "For every 100,000 population, Australia has some 250 physicians and 70 pharmacists. For an equivalent population sample, Senegal has only five physicians and one half-time pharmacist."<sup>49</sup> This is an appallingly large gap and not easily solved. The authors recommend some guidelines for the people prescribing and dispensing medicines in these countries (since the majority of them are not fully trained or educated in prescribing practices), as well as public information campaigns via radio and posters.

Another problem, though it may seem odd at first glance, is inappropriate donations: charities or large corporations may donate medicines that are poorly prepared, expired, useless, or that have no disposal plan, either in good faith or in bad faith.<sup>50</sup> An article in the *New England Journal of Medicine* in 1998 pointed to abusive, bad-faith drug donations in Bosnia and Herzegovina from 1992 to 1996.<sup>51</sup> Its authors estimated that over 50 percent of the drugs that entered these two nations during this time period were inappropriate.<sup>52</sup> In 1999, the WHO and *Pharmaciens sans Frontières* (Pharmacists without Borders) concluded that Western pharmaceutical companies had dumped tons of unusable and expired drugs in Albania for the Kosovo relief effort.<sup>53</sup> A number of years later, in the wake of the 2004 tsunami that killed hundreds of thousands in Southeast Asia, the same organization concluded that the quality of the drug donation system had not improved; in fact, it had deteriorated.<sup>54</sup> The drugs caused additional health problems for the population, and they are extremely costly to dispose of.

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49 *Id.* at 126.

50 *Id.* at 131.

51 R. Aplenc et al., *Inappropriate Drug-Donation Practices in Bosnia and Herzegovina*, 338 (20) *New Eng. J. Med.* 1472 (1998).

52 *Id.*

53 Study on Drug Donations in the Province of Aceh in Indonesia, *Pharmaciens sans Frontières* 1 (Nov. 2005) available at [http://www.acfid.asn.au/what-we-do/docs\\_what-we-do/docs\\_humanitarian-and-emergencies/docs\\_tsunami/drugdonationsaceh.pdf](http://www.acfid.asn.au/what-we-do/docs_what-we-do/docs_humanitarian-and-emergencies/docs_tsunami/drugdonationsaceh.pdf).

54 *Id.* at 5.

Sometimes a charity or company donates useless or expired drugs in good faith, not realizing that the medicines are useless at best and might actually harm people. However, it is a much more sinister, and yet legal, practice for large pharmaceutical corporations to dump such drugs into developing nations simply to avoid the disposal costs while simultaneously reaping tax benefits of donations, as well as the enhanced public image.

While there are numerous other major problems with the healthcare systems, and more specifically, pharmaceutical policies, in developing countries, the most effective solution and pressing need right now is that these countries simply need money: their research facilities are poorly funded, and their people have little or no access to medicines. They also need information, such as libraries of compounds and biological materials, in order to conduct research.<sup>55</sup> As Abbott and Dukes put it, the “key point is relatively straightforward. Most of the impediments to improving local production of pharmaceuticals in developing countries can be addressed by increasing the financial resources made available.”<sup>56</sup> It is a question of money: the gap between the rich and the poor countries across the globe is exacerbating the healthcare situation, as well as the pharmaceutical industry’s progress. The drive to accumulate as much wealth as possible is causing massive suffering and death; this situation is intolerable.

### INFORMATION AND ADVERTISING

Another main theme of this expansive book is its in-depth discussion of education, information, and – in stark contrast to these two things – what the authors refer to as persuasion (promotion or advertising). Education, for its part, is largely lacking; the public suffers from a number of common misunderstandings when it comes to medicines, such as believing that two doses are more effective than one, while some other people are afraid to take any medicines at all.<sup>57</sup> At least we can rely on physicians to know what they are doing, though, right? Apparently not: for one thing, the pharmaceutical industry largely finances postgraduate medical education, which implies a dangerous level of bias, while at the same time, “most medical schools still lack a formal course in clinical pharmacology, and physicians, pharmacists and other scientists in training may not have access to formal teaching of this subject.”<sup>58</sup> Physicians often never have a

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55 Abbott & Dukes, *supra* note 1, at 147.

56 *Id.* at 142.

57 *Id.* at 168.

58 *Id.* at 169.

chance to learn rational prescribing practices, and any gaps in knowledge are subsequently filled by the pharmaceutical industry, which is not exactly a neutral party.

Information is also limited, even for physicians. While thousands of medical journals exist that could conceivably provide doctors with information about prescribing drugs, there are multiple practical limitations: (1) very few truly authoritative and impartial journals are produced, with fully peer-reviewed studies (e.g., *The Lancet*), and the developing world has nothing like these at all; (2) studies of drugs are scattered across hundreds of medical journals, some of which are not reputable; and (3) lastly, some journals have become highly dependent on the pharmaceutical industry for income, putting their credibility at risk.<sup>59</sup> As a result of all this, physicians end up with very little knowledge about correct prescribing procedures for different people, even for old and relatively well-known drugs. For example, doctors must prescribe different doses for people who have liver problems, and these doses differ for hundreds of drugs, something which no physician could possibly memorize, and many do not even realize. Furthermore, knowledge about new and relatively untested drugs is even scarcer.

The largest segment of this section, however, is devoted to persuasion, or commercial advertising, which often counts for more than the actual merits of the drug.<sup>60</sup> Heavy promotion, however, is highly problematic. Decades ago, industry representatives used to merely convey documented information; today they are high pressure salespeople, often termed 'drug consultants.'<sup>61</sup> These people are an incredibly powerful promotional weapon for pharmaceutical companies; moreover, it is very difficult to regulate messages that drug consultants convey to prescribing physicians: they may promote unauthorized uses for drugs, gloss over problems, or employ any number of deceptive tactics.

To make matters worse, as is well known, drug companies offer doctors gifts, lunches, trips, and other inducements for listening to their drug consultants or other paid speakers.<sup>62</sup> The Pew Prescription Project has found that the pharmaceutical industry spends more than \$7 billion per year on free gifts, meals, travel, speaking fees, and other benefits to per-

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<sup>59</sup> *Id.* at 171-72.

<sup>60</sup> *Id.* at 175.

<sup>61</sup> *Id.* at 179.

<sup>62</sup> *Id.* at 180.

suade physicians to prescribe their drugs.<sup>63</sup> Moreover, in 2005, the same organization found that the pharmaceutical industry spends at least \$18 billion on free samples for doctors' offices per year.<sup>64</sup> While the authors advocate reform, this system is clearly going to continue, with its multitude of serious problems, as long as the drug industry remains privatized. Only a nationalization of the pharmaceutical industry, rendering it completely non-profit, could finally and permanently solve these evils, to the immeasurable benefit of public health.

The practice of advertising prescription drugs directly to the public exists only in the United States and New Zealand.<sup>65</sup> In contrast, in most developed countries, only over the counter (OTC) drugs can be advertised to the public; prescription drugs can only be advertised to physicians because it is thoroughly unnecessary to expose the public to them.<sup>66</sup> The pharmaceutical industry, which aggressively lobbied to expand its advertising rights in the U.S. in the past few decades, argues in favor of direct to consumer advertising for several reasons: (1) it creates consumer pressure on prescribers, who react by ensuring they have relevant info on the drug and are thus well-informed; (2) the doctor-patient relationship will be improved because of increased contact and discussion; (3) earlier knowledge of treatment options will ease anxiety about disease risk; (4) it leads to better patient outcomes because medicines will be used to treat diseases earlier; (5) a prohibition on ads would keep patients in the dark; that is, ads increase the likelihood that patients will consult the doctor; and (6) it fosters innovation for new medicines.<sup>67</sup> While these arguments could each be individually analyzed, the obvious true reason that the industry supports direct to consumer advertising is because it dramatically increases drug sales when patients have heard of specific drugs and ask for them by name. Profits drive this, as they drive every decision and corporate stance in this industry.

Of course, critics have their counter-arguments against direct to consumer advertising: (1) it leads to inappropriate use of medicines because doctors cave in to patient pressure; (2) it undermines the doctor-patient re-

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63 Press Release (2007), *National Physicians Alliance join forces to stem negative influence of marketing on health care*, Pew Prescription Project, Oct. 19, available at <http://www.prescriptionproject.org/news/pressreleases?id=0010>.

64 Press Release (2008), *New survey highlights drug samples' role as marketing tool*, Pew Prescription Project, Jan. 3, available at <http://www.prescriptionproject.org/news/pressreleases?id=0011>.

65 *Id.* at 183.

66 *Id.* at 183-84.

67 *Id.* at 185.



lationship because patients may demand a specific drug and leave their doctor if she refuses to prescribe it; (3) it results in confused or misinformed consumers; (4) it generates consumer anxiety through exaggerated promotion of risk of disease; (5) medicines are widely used before their risks are fully known; (6) it promotes a view of medicines as complete solutions, rather than diet and exercise; and (7) patients will ‘doctor shop’ to find doctors who will prescribe medicines.<sup>68</sup> Unlike the pharmaceutical industry’s arguments, these claims have at least a rebuttable presumption of validity because there is no suspicious profit motive behind them.

### COURTS AND LITIGATION

Since this is a book not just about pharmaceuticals, but rather about policies for dealing with them including national regulation and litigation, it is fitting that a segment of *Global Pharmaceutical Policy* is devoted to the role of the courts. Lawsuits serve an important public purpose in bringing otherwise hidden information to light, and they keep drug companies in check. However, because of the sheer profits involved, even the prospect of a massive settlement or judgment is not too large a deterrent.

In one notable case, in 2005, Eli Lilly paid out \$700 million in a settlement for 8,000 cases filed against it because its anti-psychotic drug, Zyprexa, caused diabetes; however, the drug’s annual sales remained at \$4.4 billion in 2006.<sup>69</sup> Such massive lawsuit judgments and settlements are only a small fraction of the drug’s sales in a single year. From the perspective of the pharmaceutical corporations, the benefits to putting a profitable drug on the market, even if it is risky and may injure or even kill people, vastly outweigh the costs. In fact, a company will sometimes hide negative information from the regulatory agency, like the FDA, in order to get approval;<sup>70</sup> the billions in revenue will outweigh even the sanctions for violating the law, and that illegal activity may never be exposed, anyway. Companies are more than willing to gamble.

The authors spend a good deal of time discussing (and criticizing) the idea that when a regulatory agency approves a drug, the company that created it should have a safe harbor or immunity from private lawsuits when the drug later turns out to injure people; this principle is more concisely referred to as pre-emption of tort lawsuits. In the United States, such pre-

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68 *Id.* at 185-86.

69 *Id.* at 194.

70 *Id.* at 198.

emption and immunity for drug companies is largely the case in the state courts, although the Supreme Court rejected this approach in 2009; in other countries, the authorities' registration and approval of a drug does not abolish liability.<sup>71</sup> In Michigan, for example, since 2006, if the FDA approves a drug, consumers cannot sue for defective warning or defective design unless the manufacturer obtained approval by omitting or fraudulently misrepresenting information.<sup>72</sup>

The authors, for their part, argue that "broad acceptance of pre-emption in the pharmaceutical area would run seriously counter to the public interest" because the civil litigation process serves the public interest, bringing significant facts to light.<sup>73</sup> The litigation process itself often uncovers a lot of private, secret information, such as adverse results from a clinical trial or internal company memos. One entirely typical illustration of the useful role litigation can play is when it uncovered that Pfizer, the manufacturer of the anti-inflammatory drug Celebrex, had conducted an unpublished clinical study in 1999 to determine whether the drug could treat Alzheimer's disease, and the study found an increased incidence in heart attacks – but Pfizer delayed submission of the study to the FDA until 2001.<sup>74</sup> Thus, the label carried no warning for this, and innumerable people were severely injured or killed as a result. Had litigation been preempted because of FDA approval, this unpublished study may have easily never surfaced.

Similarly, Merck knew that Vioxx caused an increased risk of heart attack, and GlaxoSmithKline (GSK) knew that Paxil, an antidepressant, increased the risk of suicide in children; both companies had internal memos, emails, and other documents showing clear knowledge, which they covered up.<sup>75</sup> In fact, GSK's memos urged company officials to 'manage the dissemination of data in order to minimize any potential negative commercial impact' while telling sales reps to tell doctors that 'Paxil demonstrates remarkable efficacy and safety in the treatment of adolescent depression.'<sup>76</sup>

As for Merck, Vioxx is not the only scandal that has plagued the

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71 *Id.* at 202.

72 *Id.* at 205.

73 *Id.* at 206.

74 *Id.*

75 *Id.* at 207.

76 *Id.* (citing Press Release (2004), 'Settlement sets new standard for release of drug information', Office of the NY State Attorney General, 26 August).

company in recent years. In 2008, Merck and its partner Schering-Plough belatedly released the results of a company-sponsored study of Zetia, a cholesterol-lowering drug.<sup>77</sup> The study had been completed in April 2006 and its findings were long withheld; they were only released under pressure from consumer groups, the media, and a federal investigation. The findings of the study, however, showed that the Zetia does not reduce fatty arterial plaque that causes heart attacks and strokes.<sup>78</sup> The companies knew this for years, hiding the information from the public. They also used false and deceptive marketing techniques to claim that Vytorin was more effective – and safer – than the much cheaper generic Zocor, another cholesterol-lowering drug that had been around for a while and had just recently gone off-patent.<sup>79</sup> In fact, the data suggest that plaque built up in the arteries of patients on the newer Vytorin at an even faster rate than in those taking the older Zocor.

The most appalling, and yet entirely predictable, part about this illegal activity was the profit motive that drove it. Zocor lost its patent protection in June 2006; Merck and Schering-Plough developed Vytorin to help extend the profitable life of Zocor (Vytorin is simply a combination of Zetia and Zocor).<sup>80</sup> Once Zocor went generic, it costs a mere three cents per pill, in contrast with the \$3 per pill the drug companies charged for Vytorin. While not discussed in *Global Pharmaceutical Policy*, this is a perfect and very recent demonstration of a number of themes in the book. Drug companies slightly alter existing drugs just to keep ‘evergreening’ their patents rather than develop any true breakthroughs; they grossly overcharge for patented drugs; often the patented drugs are no better (and in some cases actually less safe and less effective) than earlier generics; and the pharmaceutical companies will ruthlessly hide negative results, cover things up, and lie to the public through advertising. While the authors call for a number of reforms to the patent system, advertising regulations, and other laws, it is really the profit system fueling all these systemic problems.

To be fair, the FDA is not performing its job as guardian of public health, either. If it were, all the greed of the pharmaceutical industries could not simply slip past its impenetrable walls, creating dangers for consumers. The pharmaceutical industry pours vast sums of money into the

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77 Sophia Pearson, *Merck, Schering-Plough Sued Over Zetia, Vytorin Costs*, Bloomberg, June 8, 2009.

78 *Id.*

79 *Id.*

80 *Id.*

FDA to fund its drug approval process, an obvious conflict of interest: according to the public health and safety organization Public Citizen, in 2008, the industry gave \$400 million to the FDA's drug division, which funds the salaries of the scientists who review drugs.<sup>81</sup>

In that case, perhaps not surprisingly, the FDA's own pharmacology reviewer recommended against approving Vytorin because of test results that showed serious toxicity in laboratory animals, even with very small amounts of the drug.<sup>82</sup> The FDA approved it anyway. Because of a lack of federal funding, the pharmaceutical industry is now paying for more and more of the FDA's drug evaluations. A New England Journal of Medicine article from April 2007 documents this sharply increasing trend, pointing out that, as of 2004, drug companies were paying over 40 percent of the budget for the FDA division that reviews new drug applications.<sup>83</sup> This brings into question whether the FDA's client is the public or the pharmaceutical industry. Undoubtedly, this is not a rhetorical question: the answer is the drug industry.

To sum up, if a drug company does a cost-benefit analysis, it will see powerful incentives to hide or cover up negative data. If the company is honest to the regulatory agency and to the public, the drug may never get approved and cannot be sold at all, or even if approved, the public may be so frightened by its severe side effects that the company loses billions of dollars in sales. However, if the PhRMA corporation hides or alters negative data, at most it will lose a few hundred million dollars to settlements, judgments, or criminal fines and sanctions, and that is only if it is sued or prosecuted in the first place, which may well never happen. Even if it happens, though, the pharmaceutical company will still earn billions of dollars per year in sales, more than enough to make up for any losses. The system is set up in a way that always benefits the drug industry and only sporadically benefits public health.

Abbott and Dukes conclude that private civil litigation plays an important and useful role, not only compensating victims but uncovering crucial hidden information, especially when pharmaceutical companies cover up negative data or clinical trial results.<sup>84</sup> This is doubtlessly accu-

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81 Press Release (2008), *Drug Companies, FDA Lagged in Warning Public About Zetia, Vytorin*, Public Citizen, Jan. 14, available at <http://www.citizen.org/pressroom/release.cfm?ID=2586>.

82 *Id.*

83 Jerry Avorn, *Paying for Drug Approvals – Who's Using Whom?* 356 (17) *New Eng. J. Med.* 1697 (2007).

84 Abbott & Dukes, *supra* note 1, at 213.

rate, but the real question is whether private litigation is sufficient to address these ills. A typical governmental response is that of the House of Commons when it examined such systemic problems in Britain in 2005. Noting that “[m]anufacturers are known to have suppressed certain trials for these drugs in the US and may have done the same in the UK,”<sup>85</sup> the legislative body recommended greater transparency, better communication, more government funding of research, and similar reforms.<sup>86</sup> Given the outcome of a cost-benefit analysis that any rational company is certain to perform, can there be any doubt that as long as the pharmaceutical companies remain in a profit-maximizing private industry, they will simply ignore regulation and reform? The problems are ingrained, entrenched, and intertwined with the core of the industry.

### SPECIALIZED POLICY AREAS

A few particular medical policy areas are given attention in one chapter of the book, beginning with vaccines. Interestingly, one big difference between vaccines and other pharmaceutical products is that in many countries, vaccine manufacturers are state-owned or non-profit institutes, not private corporations.<sup>87</sup> Blood, too, is treated preferentially, in contrast with typical medicines. The authors note that “[p]ublic policy requires that blood and its derivatives be readily available without quality defects or barriers of price, and there is in many places a preference for non-commercial supply channels.”<sup>88</sup> Blood is generally not considered a commercial product because of its human origin, unlike pharmaceutical products; thus, a government agency or a nonprofit, like the Red Cross, usually obtains and processes blood.<sup>89</sup> So why are vaccines and blood products treated with such care? They are vital to public health, and society has determined that they are above commercialization, not to be reduced to the level of other base commodities. The perplexing question, however, is why the same logic does not apply to other life-saving medicines. Why should HIV or malaria drugs be manufactured privately, bought and sold on private markets?

Alternative and traditional medicines merit a brief discussion, as well.

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85 The House of Commons, *The Influence of the Pharmaceutical Industry*, Health Committee, Fourth Report of Session 2004-05, 4 (London: The Stationery Office Limited, Apr. 5, 2005).

86 *Id.* at 5.

87 Abbott & Dukes, *supra* note 1, at 218.

88 *Id.* at 225.

89 *Id.* at 226.

Alternative medical systems, like homeopathy, are complete junk science. They have no scientific credibility and clinical trials show no evidence that they work. Yet homeopathy has a large following, so regulatory agencies have made special provision for licensing homeopathic remedies: basically, they must be safe even though they have no efficacy, and the labeling must make it clear that the drug has not been evaluated for efficacy.<sup>90</sup> As long as they are properly informed and warned, consumers are free to use any of these medicines as they see fit.

Traditional medicines, largely consisting of herbal medicines, in contrast, can be extremely valuable; many Western drugs, such as opium, were discovered because of traditional medical practices.<sup>91</sup> The public policy problem with traditional medicines is that very few systematic studies or data exist, so they remain unregulated, yet they continue to be widely used, sometimes with disastrous effects.<sup>92</sup>

This section of the book addresses one last specialized policy area worth noting: counterfeit medicines. The problem of counterfeit drugs is enormous, and since "they are disseminated internationally, the problem can only be solved by coordinated international effort."<sup>93</sup> The authors' logic here is irrefutable, yet their proposed solution is impossible.

Coordinated international effort in a capitalist global economy, divided into nation-states competing for markets, is simply out of the question. There is no coordinated international effort on anything: in arms control, for example, despite agreements like the Non-Proliferation Treaty and the Comprehensive Test Ban Treaty, India and Pakistan have exploded nuclear weapons in the post-Cold War era, and other countries like North Korea and Iran are challenging the current global regime.<sup>94</sup> Arms control law lacks coherent global unity. Similarly, in global warming and climate change, the recent debacle in Copenhagen is summed up by one recent news headline: "Copenhagen Climate Conference Ends With Whimper, No Legally Binding Pact, No Commitment to Pursue One in 2010."<sup>95</sup> Such failed attempts at international cooperation are persuasive

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90 *Id.* at 234.

91 *Id.* at 234-35.

92 *Id.* at 235-36.

93 *Id.* at 245.

94 John Freeman, *Is Arms Control Law in Crisis?* 9 *J. Conflict & Security L.* 303, 308 (2004).

95 Major Garrett, *Copenhagen Climate Conference Ends With Whimper, No Legally Binding Pact, No Commitment to Pursue One in 2010*, Fox News, White House Blog, Dec. 18, 2009, available at <http://whitehouse.blogs.foxnews.com/2009/12/18/copenhagen-climate-conference-ends-with-whimper-no-legally-binding-pact-no-commitment-to-pursue-one-in-2010/>.

evidence that such a goal in the context of pharmaceutical policy is overly optimistic.

In any case, there are two types of counterfeit drugs: (1) copies of genuine drugs that are identical to the real ones but merely in breach of trademark and patent laws, and (2) fake drugs that only superficially resemble the real ones and have no medicinal value at all; the latter are dangerous to public health and can severely injure or kill people.<sup>96</sup> The originator industry has for decades attacked counterfeiting on both fronts, but it has also tried to prevent generic drug manufacturers from entering their markets even when it would be perfectly legal, so their efforts in this arena are properly viewed with skepticism.<sup>97</sup>

The problem is extremely widespread: while no global surveys of this problem exist, a survey of Cambodia found that 60 percent of the 133 sampled drug vendors, who were selling an anti-malarial drug, sold either a highly diluted version or a fake version with no active ingredient at all.<sup>98</sup> In fact, the estimated rate of counterfeiting in Southeast Asia is somewhere between 38 and 53 percent of all medicines.<sup>99</sup> This is, of course, an extremely insidious problem, as people who genuinely need medicines are receiving substances with little to no therapeutic value at all. The public health danger here is enormous.

The WHO drew up an extensive report on counterfeit drugs in 1999, explaining in great detail what many different parties must do at various levels; moreover, a major international conference on the subject was held in Rome in 2006. However, despite these things, “there is still little sign of a truly coordinated global effort” to fix the problem of counterfeit drugs.<sup>100</sup> Similarly, the authors conclude that an international criminal court with the power to prosecute drug counterfeiters “does not presently appear a realistic prospect.”<sup>101</sup> The question must be asked: why? The above discussion about the impossibility of truly coordinated international effort is unavoidably applicable here, as well. In a competitive global environment, in which each country attempts to gain markets at the expense of its neighbors, there can be no truly meaningful cooperation on a global scale. The authors are absolutely correct to assert that such prospects do

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96 Abbott & Dukes, *supra* note 1, at 246.

97 *Id.*

98 *Id.* at 247.

99 *Id.*

100 *Id.* at 249.

101 *Id.*

not appear to be realistic, but they do not explore the underlying causes.

One final quote from Abbott and Dukes sheds some light on this: they point out that the “counterfeit movement is fuelled primarily by a dishonest urge for enrichment, but it is catalyzed at every level by ignorance, indifference or both.”<sup>102</sup> While education and the spread of information would certainly be beneficial in attempting to attack the evils of counterfeiting drugs, the core problem is, not surprisingly, the drive for profit. Here, though, it fuels the problem in two different ways: on the one hand, the individuals and organizations producing the counterfeit drugs are doing so in order to profit. At the same time, however, the lack of any coordinated global response to hunt these people down and stop them from distributing fake medicines, so injurious to public health, is the inevitable result of a chaotic, cutthroat system of nation-states each trying to maximize its own stake in the world’s markets and shift any burdens onto others. In such a system, any effort at coordinated, strong international action is inevitably doomed.

### THE RICH AND THE POOR

A number of healthcare problems plague wealthy nations. The gap between the rich and the poor, even in the developed world, can be enormous, particularly in the United States. As a result of this extreme inequality in wealth distribution, many people lack access to medicines. At the same time, wealthy countries have the reverse problem, as well: the rich are over-medicating, due to advertising and poor prescribing practices.<sup>103</sup> This excessive consumption of drugs causes two entirely independent problems: it is financially wasteful, but it also endangers public health.<sup>104</sup> The consequences of over-consumption of drugs for society as a whole are dramatic, both financially and in terms of public health: as one example, of the 300 million pounds spent annually in Britain in 1990 on antibiotics alone, about half this sum was the result of unnecessary prescribing.<sup>105</sup> At the same time, there is a growing antibiotic resistance worldwide; supply of new, superior antibiotics is diminishing; and multi-antibiotic resistance is increasingly common. All of this “constitutes an increasing threat to the world community as a whole.”<sup>106</sup>

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102 *Id.* at 250.

103 *Id.* at 256.

104 *Id.* at 258.

105 *Id.* at 259.

106 *Id.* at 259-60.



It would be wise to momentarily pause here and reflect on what this means. The overmedication of the wealthy in industrialized nations is heavily contributing to the skyrocketing costs of healthcare, if the British study is any indication. The health implications, though, are even more disturbing. While overmedication is causing more and more resistance to antibiotics, the drug companies are at the same time taking the easy route, tweaking existing drugs and obtaining a patent on something that is only incrementally better. No fundamental breakthroughs are taking place to replace the current (soon useless) supply of antibiotics. This spells disaster for humanity, as a disease could easily turn into a full-blown pandemic at any time, decimating societies across the globe.

The authors recommend increasing drug regulation and education, such as teaching health professionals about the rational use of medicines, to curb the growing problem of excessive use of medicines.<sup>107</sup> Without even getting into how such measures would be implemented – for educating both the public and professionals is an expensive undertaking – a more basic concern is that this would probably not be sufficient. Neither increased regulation nor more widespread education will do anything to increase the rate of innovation of pharmaceutical companies; there will not be any sudden uptick in their new breakthrough drugs. The lack of innovation is driven by the poorly conceived patent system for drugs combined with the drive for profit.

Regulation of advertising so that the drug companies would be prohibited from directly promoting their products to consumers, as is the case in almost all other developed countries, would certainly help curb the problem of overmedication, but the authors do not explain how such regulatory measures are to be enacted. The pharmaceutical industry has a plethora of lobbyists and is willing to spend astronomical sums of money in the United States Congress. When the entire legislature is subservient to the drug industry, who exactly is going to stand up to PhRMA and pass regulatory reform measures prohibiting direct advertising?

This situation is all the more preposterous given the recent Supreme Court decision in *Citizens United v. Federal Election Commission*.<sup>108</sup> In this landmark decision, the Court abolished long-standing restrictions on corporate financing of elections under the guise of First Amendment freedom of speech, equating corporate money with speech. This, of course, is

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107 *Id.* at 260.

108 *Citizens United v. Federal Election Commission*, No. 08-205 (2010).

patently absurd, and it flies in the face of the Enlightenment principles that drove the Framers of the Constitution. Jefferson, for example, in a letter to John Taylor, expressed his view that “banking establishments are more dangerous than standing armies.”<sup>109</sup> This clearly was not a man who would have favored allowing banks, or any other large corporations, the ability to spend unlimited amounts to influence democratic elections.

Nevertheless, the Supreme Court in 2010 has done just this. What this means for the pharmaceutical industry (as well as health insurance companies more broadly) is that the massive power they already wield will be increased even further. The drug companies were already getting their way as they pressured Congress in the 1990s into undoing the restrictions on direct advertising of prescription drugs to consumers. How will any restrictive regulation pass in the future, in light of this Supreme Court decision? While the Court rendered this decision shortly after the authors finished writing *Global Pharmaceutical Policy*, it was already an overly optimistic assumption to rely on Congress to heavily restrict the lucrative practices of the drug industry. Now it is simply unthinkable.

### CONCLUSION

In the conclusion of the book, Abbott and Dukes make it clear that they wholeheartedly support the free market, even in the context of the pharmaceutical industry. In fact, they go so far as to claim that “one is obliged to conclude that the genius of the free market as a whole lies in its ability to harness the ambition and energy of women and men striving for wealth, fame, personal satisfaction and other (perhaps more modest) indicia of accomplishment.”<sup>110</sup> In support of this, the authors point to corporations’ successful management of complex R&D, production and distribution chains, and assurances of quality, as well as the beneficial relationship between originators and generic producers.<sup>111</sup>

However, the authors point out a number of distinct flaws, too: the market provides the biggest rewards for products that people want (or can be persuaded to want), not for products that address real public health concerns; the increasing consolidation of industry; the risk-averse behavior in R&D that limits breakthroughs; unreasonable market exclusiv-

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109 Letter from Thomas Jefferson to John Taylor (May 28, 1816), in *The Works of Thomas Jefferson in Twelve Volumes* (Fed. Ed.), available at The Library of Congress: American Memory, <http://memory.loc.gov/ammem/index.html>.

110 Abbot & Dukes, *supra* note 1, at 269.

111 *Id.*

ity; misleading advertising, on which drug companies spend staggeringly large amounts of money; generics companies may be bought out or scared off by litigation; and suppression of data or political pressure obstructs government regulation and other corrective measures.<sup>112</sup> Their conclusion upon reviewing all these grave problems? "None of these negative aspects justifies such measures as would tie down the free market excessively, let alone eliminate it, but they all call for firm correction."<sup>113</sup>

This conclusion does not make sense. The problems they list are real, and they are critical. *Global Pharmaceutical Policy* is an excellent resource and a fascinating read for an in-depth discussion of many of the evils in the current state of the pharmaceutical industry. This book is worth reading for that reason alone; it really delivers when it comes to describing the industry and the policies we have in place governing that industry today. Where it falters, however, is in its implications and proposed solutions. While the authors sincerely want to address the problems that they depict, and some of their solutions would truly be beneficial, they do not address the root cause: the profit system. Operating in the private sector, accumulating vast wealth with few restrictions on its behavior, the pharmaceutical industry puts profit before human life or public health. This is the cold (and obvious) truth, and this is how things will remain indefinitely unless the entire system is fundamentally changed, i.e., nationalized. Nothing short of this will be sufficient.

The authors briefly consider and summarily reject this point of view: "In the eyes of the critic, the industry has become the epitome of capitalist greed, grossly overcharging for its products, manipulating the profession and the public in its own interests, investing much more heavily and successfully in seduction than in innovation, economical with the truth and indifferent to the needs of the developing world."<sup>114</sup> Indeed. Yet the authors disdainfully refer to this view as "too simplistic to be helpful".<sup>115</sup> This view, though, is exactly correct, and it is from this that we must extrapolate. These evils will not be remedied with meager Congressional reform, if that is even possible anymore in the wake of the *Citizens United* decision. The drug industry, as always, would simply find ways to get around the restrictions, or ignore the law and pay relatively small fines for violating it, or push via lobbyists to get the laws changed in their favor.

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<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.* at 289-90.

<sup>115</sup> *Id.* at 290.

Even the authors point out that corporations, not individuals, may dominate government because of lobbying efforts. According to the U.S. Center for Public Integrity, from January 2005 to June 2006, the pharmaceutical industry spent \$182 million on federal lobbying (in contrast to very few lobbyists or money spent for consumer and patient interests).<sup>116</sup> Not surprisingly, due to the Congressional efforts to pass a health care reform bill under President Obama, lobbying has substantially increased in the past year or two. The Center for Responsive Politics (CRP), Northwestern University, and the *Chicago Tribune* conducted a study in December 2009, finding that health care lobbyists spent \$635 million over the two-year period of 2008-09.<sup>117</sup> As the study was finished before 2009 even ended, and given the zealous lobbying in the last quarter of 2009, the two-year total will come close to, or may even exceed, \$1 billion.

Finally, as noted previously, in light of the recent decision in *Citizens United*, this quantity of money spent to buy politicians can only be expected to swell even further, distended like the bloated corpse that the drug industry has become.

Abbott & Dukes mildly assert that “it seems evident that public policy in this field must increasingly strike a balance” between the pharmaceutical industry and public health.<sup>118</sup> This timid suggestion will get us nowhere. The drug industry is unbelievably powerful and is gaining more power every year. It is an inexorable and relentless juggernaut, and attempting meek reforms or striking a balance would be, at best, temporary, and in any case this would be too little, too late. The only realistic, long-term, and truly effective solution is to nationalize the entire pharmaceutical industry. Leaving it in private hands, corporate executives will base their decisions primarily on what is most profitable, whether beneficial to or in reckless disregard of public health. Such a system is economically foolish and morally outrageous. Global pharmaceutical policy should be, first and foremost, to bring the drug industry under public and democratic control, with the ruthless motivation of profit replaced by the humane goal of serving the public health.

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116 *Id.*

117 Andrew Zajac, *How health lobbyists influenced reform bill*, *Chicago Tribune*, Dec. 20, 1999.

118 Abbott & Dukes, *supra* note 1, at 292.

