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The Pharmaceutical Paradox: Helping and Harming the Developing World

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The Pharmaceutical Paradox Helping and Harming the Developing World

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College, Political Science, Class of 2008

First Prize

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Pharmaceutical companies are in quite a predicament. With the majority of the global disease burden resting on the developing world and the vast majority of wealth residing in industrialized countries, these corporations are caught in a constant struggle between the altruistic inclinations they are expected to espouse and their responsibility to turn a profit. With the international community placing unprecedented emphasis on the universal right to health, the pharmaceutical industry has become a central facet of humanitarian work. In recent years, wealthy governments have funneled vast sums of money toward treating the world's poor and the United Nations has allocated four of its eight Millennium Development Goals to specifically address health concerns. A passing glance at the issues most plaguing the world today will easily explain this new focus: one billion people worldwide lack access to clean water, ² eleven million die every year from infectious diseases, and the World Health Organization (WHO) now estimates the number of AIDS-related deaths to exceed three million annually. ⁴ These tragedies produce ripple effects that can be felt throughout the inflicted nations and, because of our globalized society, throughout the world. We live amidst a global health crisis of the highest degree—one that simply cannot be addressed without the active participation of the pharmaceutical industry.

But what should we realistically expect from these seeming hybrids of humanitarian actors and corporate entrepreneurs? Certainly we can acknowledge that the products they market are unlike most other commodities. Lifesaving medicines clearly deserve different consideration than an MP3 player or state-of-the-art vacuum. Yet, trying to fulfill both a benevolent agenda

¹ "About the MDGs: Basics." <u>Millennium Development Goals</u>. The United Nations Development Program. 12 Oct. 2005. http://www.undp.org/mdg/basics.shtml

²Evans, Tony. "A human right to health?" Third World Quarterly. 23 (2002) 211.

³ Bailey, Michael, Ruth Mayne and Mohga Smith. "Fatal Side Effects: Medicine Patents under the Microscope." Oxfam Great Britain: London, 2001, 2

⁴ Dawar, Sandrine. "Trade and Human Rights." Diss. The Fletcher School, Tufts University, 2004, 24.

while maintaining sustainable profits is problematic. It has caused these corporations to adopt policies that, paradoxically, harm the developing world. This merely underlines the fact that pharmaceutical companies will act first on their commercial interests and not simply on humanitarian impulses. Albeit far from the ideal that many of us hope for, understanding this reality and garnering more appropriate expectations of these businesses is an essential part of making progress in the field global health and humanitarianism more broadly.

Patent Protection in the Developing World

One of the most controversial issues facing the pharmaceutical industry today is that of patent protection on essential medicines.⁵ Patents are defined as "monopolies granted by the State for a specified length of time for the commercial exploitation of a scientific or technological invention," the goal of which is ultimately to spur innovation.⁶ The Pharmaceutical Research and Manufacturers of America (PhRMA), an organization that represents the nation's leading pharmaceutical companies, argues that such patents "protect their huge investments in researching and developing new drugs," without which they would be unable to "recoup their costs and reinvest in other research projects." These R&D costs can add up to hundreds of millions of dollars to produce a single new drug, thus giving pharmaceutical companies a strong stake in seeing their patents protected across the globe. ⁸ Conveniently for them, the pharmaceutical lobby is an powerful force in Washington. These pharmaceutical corporations have great resources at

⁵ Tarullo, Daniel. "WTO, Developing Countries, and Regionalism." American Enterprise Institute, Washington. 3 Oct. 2006.

⁶ Bailey, Michael, Ruth Mayne and Mohga Smith. "Fatal Side Effects: Medicine Patents under the Microscope." Oxfam Great Britain: London, 2001, 9.

⁷ "Intellectual Property." PhRMA. 20 Dec. 2006.

http://www.phrma.org/index.php?option=com_content&task=view&id=123&Itemid=109&cat=Intellectual+Property

⁸ Grabowski, Henry. "Patents, and New Product Development in the Pharmaceutical and Biotechnology Industries." July 2002. Duke University. 25 Sept. 2006, 4.

their disposal and they know how to use them effectively. GlaxoSmithKline alone brings in \$27.2 billion dollars a year, giving it significant pull amongst policymakers. In 2001, the pharmaceutical industry had 625 registered lobbyists in DC and a combined lobbying and campaign budget of \$197 million from 1999-2000. Pfizer's marketing department alone is larger than the entirety of the World Health Organization. With an industry holding such wealth and power, one would correctly expect policies to be shaped to its benefit.

The inclusion of intellectual property in the World Trade Organization's agenda is directly traceable to the efforts of two powerful U.S. companies, one of which was Pfizer. With great pressure from the pharmaceutical lobby, the United States backed the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreement established a minimum standard for patent protection that was to be reflected in the domestic laws of all WTO members. In terms of medicinal patents, the TRIPS Agreement allows inventors to hold the sole rights to the product or process for a minimum of twenty years—a coup for the U.S. pharmaceutical industry.

Economists estimated that the implementation of the "TRIPS agreement was... expected to bring between \$2.1 and \$14.4 billion in additional profits to pharmaceutical companies in developed countries." While the benefits of the agreement for these corporations are clear, the repercussions on the developing world are starkly different.

Basic economic principles dictate that creating a monopoly for a product allows the corporation to charge a higher price seeing as there are no cheaper alternatives

⁹ Bailey, 12.

¹⁰ Dawar, 17.

¹¹ Thomas, Caroline. "Trade policy and the politics of access to drugs." Third World Quarterly. 23 (2002): 257.

¹² Heywood, Mark. "Drug access, patents and global health: 'chaffed and waxed sufficient." <u>Third World</u> Ouarterly. 23 (2002): 224.

¹³ Dawar, 18.

available. The "rule-of-fives" theory for drug prices "indicates that the lowest prices generally are achieved only when there are five therapeutic alternatives or five competing producers." The difference in price between the original, patented drug and the generic versions is enormous. For a hundred units of Ciprofloxacin, a drug that treats multi-resistant tuberculosis, Bayer will charge somewhere between \$169 and \$549. The generic version from India is sold for \$10.15 Even when drug companies reduce their prices in impoverished countries, the generic versions are still significantly cheaper. A combination of AZT and 3TC, both used to treat HIV/AIDS, is sold for \$18 a day in the United States. GlaxoSmithKline reduces that price to \$7 a day in Uganda. Still, the same drug, produced in Brazil, is marketed for a mere \$1.50.16 This price disparity translates to the difference between life and death for millions of people.

While an undoubtedly complicated issue, the reality is that many of these essential drugs are simply too expensive for the majority of the developing world. Per capita health expenditures amount to barely \$3 in Burundi and only \$5 in Nepal. A total of 61 countries have public drug expenditures of less than \$10 per capita. Compare that to the several thousand dollars that one-year's worth of tri-therapy HIV medicine can cost. Households, burdened by a poverty that is only intensified by disease, are even less likely to be able to pay for more expensive drugs. Because of the low government expenditures on health care in developing countries, poor citizens are already forced to take on a much larger proportion of these costs personally. For example, 85% of healthcare costs in India

¹⁴ "More Equitable Pricing for Essential Drugs: What Do We Mean and What Are the Issues?" The World Health Organization. Geneva: WHO, 2001. 16 Oct. 2006, 17.

¹⁵ Bailey, 17.

¹⁶ Ibid.

¹⁷ Dawar, 25.

¹⁸ Bailey, 5.

come out of the patients' own pockets.¹⁹ Oxfam International conducted a survey that showed three-quarters of poor urban households in Kampala, Uganda cut spending on food to pay for medicine.²⁰ This problem is enormous, and though not solving it entirely, generic manufacturers do provide essential medicines to demographics that are widely excluded by the high prices of Western drug makers.

At the 2001 Doha ministerial meeting, after great controversy over the original TRIPS Agreement and its effect on developing nations, WTO members signed the Declaration on the TRIPS Agreement and Public Health. It stated that the TRIPS Agreement "should not prevent Members from taking measures to protect public health...[and] to promote access to medicines for all."²¹ The TRIPS Agreement allows governments to refuse "to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality."²² These added flexibilities are a significant step toward allowing countries to address urgent national emergencies. However, the pharmaceutical industry continues to heavily lobby the U.S. government, which, in turn, simply seeks the more stringent patent protection in its bilateral trade agreements while threatening sanctions on developing countries who refuse to enforce these intellectual property laws. The issue of access to essential medicines in poor nations is incredibly complex and the product of many factors—extreme poverty, corruption, and poor infrastructure to name a few. However, high prices spawned from monopolistic patent policies are one important facet of the issue. As long as pharmaceutical

¹⁹ More, 9.

²⁰ Bailey, 14.

²¹ "Intellectual Property: Protection and Enforcement." <u>WTO.org</u>. The World Trade Organization. 14 Oct. 2006. http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

corporations continue to endorse and fight for these policies, they will effectively negate much of the good work they currently do in the developing world.

Slanted Research and Development

When trying to assess the priorities of Western pharmaceutical companies, it is wise to first survey the medicines they have developed over the years. A cursory look will show a notable dearth in research for the diseases that primarily target poor populations. Only "ten percent of health research targets the illnesses that make up 90 percent of the global disease burden. A miserly 0.2 percent of research efforts are directed to diarrhea, pneumonia and TB, which cause 18 percent of all illness." Less than 0.5 of global drug development is directed to malaria research. Only eight of the 1,233 drugs licensed by the U.S. Food and Drug Administration from 1975 to 1997 were developed specifically for tropical diseases in humans. PhRMA argues that global patent protection is necessary to promote future R&D, but it is overtly clear that this future R&D is unlikely to reflect the diseases that plague the populations that most need cheaper, generic drugs in the first place.

It is entirely logical for pharmaceutical companies to devote a relatively small percent of their resources to developing treatments for "poor people diseases." Were they to discover an effective new drug, there would still be no market for the medicine despite the millions it could save. The populations that most need these drugs simply cannot afford to pay the prices that would produce a viable incentive to incur steep R&D costs. Even for diseases that affect the wealthy and impoverished alike, it is not

²³ Bailey, 5.

²⁴ Lanjouw, Jean. "Drug Patents: Taking the Poorest Out of the Fight." 28 Dec. 2003. ARE Department, U.C. Berkeley. 17 Oct. 2006 http://are.berkeley.edu/~lanjouw/milken.pdf
²⁵ Ibid.

the poor that are enticing pharmaceutical corporations to develop new treatments. For instance, countries with a cumulative fifty-percent of the world's population "contribute less than two percent to spending on cardiovascular drugs." As our world becomes increasingly smaller and integrated through globalization, large multinational corporations such as Merck and Roche are forced to reevaluate the way they do business and direct their resources. Their products are introduced into previously untapped markets, but is that really enough to alter the allocation of funds for research and development? As of now, it appears as though pure market forces are overriding humanitarian impulses.

Refocusing Responsibility

When allocating blame for issues as complex as a global health crisis, billion dollar corporations make for easy targets. Recent Hollywood productions, like *The Constant Gardner*, depict the pharmaceutical industry as willing to sacrifice anything in order to reap a profit. But is focusing so much critical attention on the practices of pharmaceutical companies really productive? Certainly their role in developing lifesaving drugs places them in a separate category that deserves careful scrutiny, but are our expectations of these companies unrealistic or even unfair? Pharmaceutical corporations survive off commercial success and, like any business, they will logically promote policies that can help foster this success. In this case, that may equate to supporting strict patent protection in developing countries or aligning R&D to target more profitable drugs like Prozac or Viagra. When looked at through this paradigm, the question is not why pharmaceutical companies do not support more humanitarian work. Instead, we must ask ourselves, what motivates them to do any at all? The cynic might argue that it provides

²⁶ Lanjouw

an agreeable public image for marketing purposes. While this is certainly true, I would argue that it also signals the industry's acknowledgment of its critical role in battling the global health crisis and its inherent humanitarian obligations.

I, by no means, hope to excuse pharmaceutical corporations, or any corporations for that matter, from social and ethical accountability. As an undeniable force that permeates health, politics and development, they should be openly chastised when they endorse harmful policies or partake in ethically hazy practices. I only fear that placing so much attention and responsibility on this industry will result in little progress besides assigning an effective scapegoat. If we accept that pharmaceutical companies will act first and foremost in the interest of their businesses, then we can move on to develop new strategies to curb the possible ramifications this will have on treating the world's poor. For example, if the pharmaceutical lobby will fight for patents on essential medicines in developing countries, how can we keep this influence from denying affordable medicine to the millions dying of treatable disease? The WTO's changes to the TRIPS Agreement to better account for public health concerns prove that nations can, in fact, come together to seek a fairer solution. Yes, the pharmaceutical industry is powerful, but it is ultimately the United States government that is responsible for enacting policies that demand this strict patent protection. When addressing the issue of affordable drugs, we must look to the state and our nation's leaders to act justly and promote health throughout the globe, even if it means denying the pharmaceutical lobby.

While pharmaceutical companies will most likely continue to focus their R&D on profitable treatments, we must be creative in addressing the severe lack of research into diseases plaguing the poor. Wealthy governments should provide greater funds to specifically research infectious diseases and deadly epidemics such as HIV/AIDS and

tuberculosis. Perhaps a separate fund should be established to focus on these particular illnesses or such an entity could also be linked to an agency such as the World Health Organization. New actors following different models also show great promise in tackling these issues. One World Health, the first non-profit pharmaceutical company in the United States, seeks out drugs that have been "developed by industry that could be targeted at devastating illnesses in impoverished countries."²⁷ The pharmaceutical industry, in its early stages of research, finds a number of positive leads that could develop into potential drugs. However, these drugs are often shelved due to lack of commercial prospects. One World Health identifies these drug leads, secures the intellectual property, and then fully develops the drug, seeing it through the clinical trials and regulatory approval phases. Afterwards, it partners with a manufacturing company to cheaply produce the drug and later with national health ministries and NGOs to secure its distribution. ²⁸ Certainly, One World Health's non-profit model has its own limitations and is unlikely to become the norm for pharmaceutical companies. However, it is a perfect example of why we must understand how the pharmaceutical industry operates so that other actors with different incentives can better harness its work for humanitarian purposes.

The dire reality of the global health situation has dragged pharmaceutical corporations into the humanitarian realm and forced us to reevaluate our view of the industry. In a globalized society where the troubles of one region can so easily affect the populations of another, the health crises of the developing world are truly disastrous for

²⁷ Corcoran, Elizabeth. "The Irony of Large Numbers." Forbes. 9 Oct. 2006.

http://www.forbes.com/technology/2006/10/08/benetech-philanthropy-fruchterman-tech-cz ec 1009valleyletter.html>

²⁸ "Extraordinary Opportunities, Inspired Solutions." Institute for One World Health. 31 Oct. 2006. www.oneworldhealth.org>

all. As the pioneers in medical innovation, pharmaceutical companies are not only faced with corporate responsibility but should also see themselves in terms of social responsibility. Unfortunately, however, we are confronted with the certainty that they will often fall short of the ethical standard with which we measure them. We must acknowledge the truth that these companies will and must operate first as businesses. While we should certainly encourage practices such as lowering prices in poor regions and sponsoring drug donation programs, but we must look to governments, multilateral institutions and other innovative non-governmental actors to pick up where the industry fails.

The actions of many pharmaceutical companies are seemingly paradoxical—working to save lives in the developing world while perpetuating policies that harm these very countries. The contradiction becomes much more understandable after readjusting one's expectations of these corporations as humanitarian actors. To assume that they should act purely benevolently is both naïve as well as counterproductive. To make any progress in battling the countless health crises that plague the world today, we must first acknowledge the actors involved, understand the roles they can reasonably play, and then focus on how they must interact with each other to best address some of the gravest threats facing society. This alone is not the grand solution that so many seek, but it is an essential beginning to one. A better, more realistic understanding of the pharmaceutical industry may, in fact, prove to be the most essential medicine of all.

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