More Drugs for More Developing World Diseases
By Roger Bate and Karen Porter

The research-based pharmaceutical industry has a key role in improving access to medicines. By continuing to pursue innovative research and development (R&D), it can improve the availability and effectiveness of drugs. By adopting tiered prices for more drugs—charging people in different countries different prices according to ability to pay and market size—the industry can also increase the number of people who are able to buy medicines, improving consumer welfare while retaining and even improving profit margins. It can work with its competitors and partners in nonprofit and government sectors to explore the practicality of public-private partnerships and the synergies that may come with them. The United Nations (UN), however, appears to want these companies to assume the responsibilities of government—a role with dubious legal and practical implications. If the UN and its supporters get their way, the long-term consequences for public health could be dire.

Last fall, the UN unveiled a draft of its Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, which attempt to tackle one of the most talked-about problems in international public health: the affordability of lifesaving pharmaceutical drugs. Access to health care appears to be improving. More of the global population has access to essential medicines today than in 1977; in twenty-two of thirty-five countries surveyed by the Pew Research Center, significantly fewer people said that they were unable to afford health care for their families in 2007 than in 2002. But access is far from universal. Nearly 2 billion people, most in the developing world, still lack access to essential medicines. Improving access could save 10 million lives each year—4 million in Africa and Southeast Asia alone.

Better access is an important goal with powerful implications for individual health and, in the long run, economic development. The links between good health, domestic stability, and improvements in GDP and standards of living are well established, with the weight of evidence suggesting that open trade and wealth generation drive health improvements—not the other way around. But little agreement exists on exactly who should be responsible for improving access, especially to pharmaceuticals, and how it will best be accomplished.

The Problem of Access

In its draft guidelines, the UN places the primary responsibility for providing access on the pharmaceutical industry. It suggests that the pharmaceutical sector’s pricing practices and R&D priorities have ignored the human “right to health,” as defined by the World Health Organization (WHO) and, it is argued, enshrined in international law. While acknowledging that “states have primary responsibility for enhancing access to medicines,” it also argues that the “private business sector” has a fundamental role to
play in the “realization of the right to the highest attainable standard of health.”

The UN’s report is problematic both legally and practically. According to a traditional interpretation of international law, pharmaceutical companies—or any private, nonstate entity, for that matter—cannot be held accountable under international legal treaties or agreements, unless the states under whose laws they operate ratify these treaties. In its response to the guidelines, the U.S. government, which has not ratified the key treaties codifying a right to health, affirmed this interpretation.

Furthermore, the guidelines cannot be implemented in practice. In defense of the “right to health,” the report suggests a battery of changes for the pharmaceutical industry: transparent pricing, more research allocated to neglected diseases, commitments not to extend old patents or issue new patents for medicines, and support of local production enterprises via technology transfer. These prescriptions are similar to those made by prominent activist groups in recent months, including Médecins Sans Frontières (MSF, known in English as Doctors without Borders) and the British aid organization Oxfam. While some critiques of the current system contain kernels of truth, they fall short on several counts. Critics implicitly blame the pricing policies of private companies but give scant attention to the impact of market segmentation, such as out-of-pocket private purchases, private insurance markets, Medicaid-style help for the poorest, other forms of socialized medicine, or other income-related pricing mechanisms. After all, some people in the wealthiest countries cannot afford high prices; some in the poorest countries can afford them. The critics largely ignore corruption, taxes, tariffs, and markups by middlemen, as well as the lack of attention many governments give to health. They fail to address demand-side variables that influence access to health care, including household income, the expenses of travel and lost work, general education and knowledge of health care, and other social and cultural characteristics. As one World Bank study illustrates, demand-side variables may actually be more important than the supply-side official price. The price charged by producers (generally much lower than the retail price) is just one of many important variables.

Theoretically, the UN’s call for greater transparency in pricing and full disclosure of R&D priorities is good, but it fails to anticipate unintended consequences. To be sustainable, greater transparency in pricing must be matched by a political commitment to allow companies to price at the level each market segment can bear—not necessarily at the level some political elites or activist organizations want. It also must be met by countries’ commitments to prevent reimportation of drugs. Without this guarantee, transparency may only undermine tiered pricing, which has had some success in balancing access for patients who need drugs and incentives for long-term R&D.

For their part, companies can reaffirm their commitment to tier prices for drugs in more countries and for all diseases, not simply high-profile ones like HIV/AIDS. Analyzing drug procurement and purchasing in Guatemala, Honduras, Thailand, and Ukraine, MSF concluded that differential prices were not available in many “Medium Human Development” countries outside sub-Saharan Africa. Furthermore, while some companies have offered tiered pricing for drugs that treat diseases other than HIV/AIDS, the usual approach—which Oxfam criticizes—is for pharmaceutical companies to adopt specific policies on a “case-by-case basis, largely reflecting the degree of publicity surrounding the disease or country.”

If a tiered-pricing system is efficient—as the theoretical model suggests it is—why have pharmaceutical companies failed to embrace it in more countries and for more diseases? Inertia is one explanation. It is easier to sell small amounts of medicine at higher prices than larger amounts at lower prices. Uncertainty or ignorance about what price to offer in what markets is also a factor.
Prices in the free market are determined in a push-and-pull process between buyers and sellers with imperfect knowledge about the most efficient price. When in doubt, companies price high, particularly because government involvement in the global procurement of life-saving pharmaceuticals can complicate the bargaining process and lead to suboptimal prices.

**Pooling Prices Hurts the Poorest**

“Pooled procurement”—in which several countries’ governments agree to bargain collectively for one price for a given product—is illustrative. Such procurement has recently won favor with several prominent international organizations—including WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria—as a way to encourage bulk purchasing and create a larger, more certain market. Pooled procurement promises several benefits, mostly realized by capitalizing on higher sales volumes. According to the Global Fund, benefits include greater speed and reliability in the drug procurement process, reductions in price volatility, higher-quality products, and lower negotiated prices.24 In a January 2007 report, WHO praised pooled procurement as an “innovative” approach responsible for savings that averaged 37 percent on twenty-five drugs purchased by member states of the Organisation of Eastern Caribbean States between 1998 and 2002.25

But pooled procurement can have significant shortcomings. Because procurement pools are most often organized by region and do not discriminate between high-, middle-, and low-income countries, they effectively circumvent tiered pricing. Countries often negotiate for one single price that the company then offers to all countries in the pool. In the 2003 negotiations of the Pan American Health Organization Strategic Fund, a regional pooled procurement initiative under WHO’s umbrella, many of the ten participant countries—Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay, and Venezuela—had previously been charged different prices by the single innovator company involved in the negotiations (seven generic firms also participated).26 Because the negotiators demanded one price for all countries, the company may have had a commercial incentive to bargain for a price higher than what would have been strictly efficient for some countries.

Some countries—even those not involved directly in pooled procurement negotiations—may use negotiated prices as “references” for procurement of their own pharmaceuticals.27 It is likely that smaller, less powerful governments may also demand the same price offered a neighboring country, under the assumption that this country negotiated a better price. Under this system, larger countries—such as Brazil, Thailand, South Africa, and Nigeria—may set the “reference price” for pharmaceutical drugs in the region. But such “reference pricing” ignores significant economic differences within regions: Bolivia is much poorer than Brazil, which is much poorer than Argentina.28 The most efficient pricing would prescribe different prices for these different countries. Corporations are aware of the role that key “reference” countries play and therefore tend to push for higher prices than may be strictly efficient.

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The price-setting process is further muddied by rebates. Companies tend to demand high official prices but then pair such prices with rebates for poorer and politically powerful countries. (Keeping the official price high puts companies in a stronger bargaining position with other countries.) Drugs are often priced higher in Brazil than in Belgium, but in the end Belgians pay more because Brazil gets rebates, according to corporate sources from two companies.29

Because pharmaceutical pricing is a dynamic process, not a static decision, an increase in transparency and a commitment to tiered prices should be encouraged from all participants—companies, countries, and activists.

**Remedies for Tiered Pricing’s Defects**

Under the system of patents and tiered pricing, pharmaceutical innovation has improved health care quality and made it cheaper as well.30 Still, most advances in medicine have involved drugs for diseases affecting the developed—not developing—world. Far more money is spent on research for wealthier markets: during the past thirty years, only 1 percent of new compounds marketed have been for developing-world diseases.31 For tuberculosis, which killed 1.6 million people in 2005,32 only three of 1,156 new chemical entities were marketed between 1975 and 2004.33
This lack of development for neglected diseases is the result of low effective demand—that is, the value of drugs that would be purchased by patients and governments in these markets. With low effective demand, the prospect of recouping investment remains low, too, and companies opt for more lucrative markets such as North America, Europe, and Japan, which together account for 85.6 percent of the world pharmaceutical market.

The UN, Oxfam, and like-minded groups highlight this discrepancy and demand greater investment by pharmaceutical companies in neglected diseases—a worthy and important goal. Yet they fail to address the deeper financing issue: can pharmaceutical companies responsible to profit-minded investors pursue expensive and risky R&D for medicines from which there may be no profit? When activists address this issue, they suggest that the industry should move from low volume (sales), high margin (prices) to low margin (prices), high volume (sales) in developing countries. This will supposedly increase both access to drugs and company profits. But the empirical record shows that large pharmaceutical companies that have invested in neglected disease development have not done so for commercial reasons, but rather long-term, less quantifiable ones, including polishing their reputations; embracing corporate social responsibility; positioning themselves strategically in emerging markets; and cultivating access to low-cost, highly skilled developing-country researchers.

Making decisions based upon these long-term, less-quantifiable considerations may be risky, particularly at a time when the pharmaceutical industry as a whole is underperforming the market (see figure 1). It may generate positive publicity, but there is no evidence indicating whether or by how much this is likely to affect consumer behavior. Studies appear to confirm the intuitive: consumers (patients as well as dispensers such as doctors and pharmacists) make decisions mostly based upon perceptions of drug efficacy, safety, and especially price—not a producer’s record for corporate social responsibility.

Hence, drug development for low-return areas may also cause some shareholders to switch to companies investing in products for wealthier markets, constricting access to lifesaving drugs still further.

Since the vast majority of patients who need drugs for neglected diseases live in very poor countries, tiered pricing is not widely practical: companies would only be able to charge prices at levels that would not permit them to recoup R&D investment. There are cases of these diseases of poverty in rich or middle-income countries, such as dengue fever in Singapore or malaria in Brazil, but on the whole, the number of people affected in these countries is highly variable and generally too small to encourage a profitable market for the medicines.

Some economists have rallied around an ex ante prize system in which governments, often in partnership with humanitarian or philanthropic organizations, would offer cash prizes in exchange for the rights to market and distribute given drugs. But such a system is riddled with problems, including how big the prize should be, which diseases to target, and how to agree when a “cure” is found. Prizes for pharmaceutical breakthroughs, as a form of advanced market commitment, may even inhibit development by rewarding scientific secrecy rather than sharing as companies race to develop the sole product that will be rewarded rather than the plethora of products that could be rewarded under the market system.
The prize system may also inadvertently lead to treatments that are less effective than those that would have been developed under a market system: nothing suggests that the first drug to meet prize requirements would be necessarily the most effective. Even Nobel economics laureate Joseph Stiglitz, one of the most prominent proponents of the prize system, acknowledges that a prize fund might only work well in areas in which “needs are well known . . . allowing clear goals to be set in advance. For innovations that solve problems or meet needs that have not previously been widely recognized, the patent system would still play a role.”41

Some point to the work of foundations as a way forward. Princeton’s Donald Light, for example, argues that through “push efforts”—leveraging contracts, funds, and grants to “push” leading projects and programs—the Gates Foundation, along with other similar organizations, is effectively “transform[ing] vaccine and drug research and development.” According to Light, “over a dozen promising new vaccines are entering clinical trials or soon will be.” But push efforts are likely to be most successful for supporting drugs already in development, when risk is lower. The few companies engaged in tuberculosis drug development have generally embarked on drug development initiatives only when given “evidence of rigorously validated targets.”42

Global public-private partnerships are also being championed as a way to finance neglected drug research. But as a relatively new development in drug innovation, the extent of their effectiveness remains uncertain. In 2005, the Wellcome Trust, in conjunction with the London School of Economics and Political Science, assessed ninety-two ongoing public-private collaborations and concluded that they performed more strongly on a battery of health and cost-effectiveness metrics than either industry or public groups working alone. This was particularly true for small companies, which benefited from the knowledge of developing-world markets the partnerships provided. Still, after three years, the record of delivery of products to market is less promising. Wellcome reported sixty-three projects underway at the end of 2004 and projected that with sufficient funding and a standard attrition rate, such projects would deliver “eight to nine” new neglected-disease drugs within the following five years.43

By late 2007, only one product—an unpatented fixed-dose combination therapy for malaria using amodiaquine—had made it to the market under the auspices of global public-private partnerships.44

Indeed, while the UN guidelines’ call to eliminate patents in poor and middle income countries may lower prices in the short run, they fail to acknowledge the ways they would undermine incentives to invest in new and better treatments, constricting access over the long run. Discussions of consumer welfare in the access debate often fail to make the distinction between static welfare benefits of cheaper drugs today and the dynamic welfare benefits of innovative prescription drugs in the future. A model created by three economists from Bates College, the University of Virginia, and the University of Chicago finds that while short-run benefits from relaxing patent protection of pharmaceuticals were substantial (consumers gained an additional $800 billion), the costs in reduced future innovation were about three times more ($2.5 trillion).45

As a virtual short-run monopoly, with all the potential for economic inefficiencies that implies, the patent system is flawed. But it is not the primary factor constraining drug access—poverty is. As WHO’s Commission on Intellectual Property Rights, Innovation and Public Health acknowledged in its 2006 report, while prices are an “important factor in determining access,” so are “poverty and the lack of infrastructure for delivering health care to poor people.”46 Empirical evidence has
not established a link between tighter patent interpretation and poorer public health.48 To the contrary, preliminary evidence suggests that increased patent protection tends to encourage investment in original R&D in local industries,49 which may help ensure long-term access.50

Someone Has to Pay

Welfare economists often claim that the lack of drugs for the poor is due to “market failure.” Market failure generally means that an exchange between parties does not take into consideration a third party effect from that exchange. But the lack of affordable drugs in the developing world is a consequence of a limited market—a lack of buyers able to pay the prices needed to drive entrepreneurs to pursue research and development for neglected diseases—not a failed one. Someone, somewhere, at some time must pay for drugs for the poor, whether private companies, public-private partnerships, or governments. Each will pass expenses to consumers to one degree or another. Otherwise, lifesaving drugs will not be developed.

In accounting for the significant decrease in the number of people reporting that they had been unable to afford health care for their families, the Kaiser/Pew Global Health Survey observed that the decreases were generally associated with economic growth: the true, long-term hope for the world’s developing countries.51 In the meantime, because economic growth can be a slow process, the most important indirect source of R&D funding for developing world diseases is and should remain the public and nonprofit sectors.52 These sectors can best promote R&D by increasing effective demand—purchasing pharmaceuticals at the transparently tiered prices that the market can bear. (One of the complaints made against Thailand was that the government cut its health budget in 2007 at the same time as it demanded lower prices from pharmaceutical companies.53) While paying a higher price may be more expensive for governments in the short run, it is ultimately the most sustainable option.

Governments can also consider offering incentives, such as accelerated clinical trials and longer periods of patent exclusivity, which have both been leveraged successfully to encourage orphan drug development. With the U.S. Orphan Drug Act of 1983, the federal government promoted the development of drugs for orphan diseases, defined as those for which “there [was] no reasonable expectation that the cost of developing and making [the drug] available . . . [would be] recovered from sales in the United States.”54 Allowing for longer periods of market exclusivity virtually guaranteed that buyers—consumers, insurance pools, and Medicaid—would pay higher prices than if free competition were permitted. Even so, the program has been widely successful in encouraging the development of drugs for several neglected diseases, including some affecting populations primarily outside the United States.55

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Governments can also lower barriers to international trade, which brings down importation costs for medicines and can lead to beneficial knowledge spillovers.56 Governments can encourage economic freedom, given the robust connection between such freedom and better health. They also can consider investing in public-private partnerships when synergies in these initiatives can be demonstrated to be cost-effective.

The state has a crucial role in improving access to lifesaving pharmaceuticals. As MSF acknowledges, high medicine prices are just “one of the many barriers to providing . . . treatment for people living . . . in developing countries.” Other barriers include “political will, social stigma, health infrastructure, and insufficient funding”57—all problems first and fundamentally of the state, best addressed by political leaders held accountable to their people.

For its part, the research-based pharmaceutical industry can support long-term, sustainable access by focusing on what it does best—continued innovation and development of profitable drugs. Profits are the lifeblood of business, and companies must answer to shareholders.58 As profits tighten, investors may become even less willing to pour their money into developing-world markets where they may be liable to non-profit pricing and patent battles. If so, public health would suffer. Even the UN’s draft guidelines acknowledge that any “right to health,” however vaguely defined, is “subject to resource constraints and progressive realization.”
Notes


4. UN, Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.


7. WHO Constitution, art. 1.


11. Ibid.


15. Although Oxfam mentions this issue, it does so only to suggest the opposite point: that market segmentation in middle-income countries demands that companies price at the level at which the lowest income segment is able to pay. (Oxfam International, “Investing for Life: Meeting Poor People’s Needs for Access to Medicines through Responsible Business Practices.”)


19. Roger Bate, “The War against Big Pharma.”


21. See Michael Kremer, “Pharmaceuticals and the Developing World,” Journal of Economic Perspectives 16, no. 4 (Fall


27. Several countries—including those not involved directly in negotiations—saw PAHO as important for setting an implicit “reference” price for procurement of their own pharmaceuticals. See ibid.

28. According to the International Monetary Fund’s (IMF) 2008 figures, GDP at purchasing power parity per-capita in Argentina is $18,662; in Brazil, it is $11,110, and in Bolivia, it is $3,217. (IMF, World Economic and Financial Surveys World Economic Outlook Database, available at www.imf.org/external/pubs/ft/weo/2007/02/weodata/index.aspx [accessed February 2, 2008].)

29. Undisclosed sources, personal communication with the authors, January 22, 2008.


31. Ibid.


34. WHO, Public Health: Innovation and Intellectual Property Rights. 35. Ibid.


38. There is high demand elasticity between generics and branded products, especially at the dispensing (pharmacy) level. See Sara Fisher Ellison, Iain Cockburn, Zvi Griliches, and Jerry Hausman, “Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins,” RAND Journal of Economics 28, no. 3 (Autumn 1997): 426–46. The connection between good corporate behavior and good financial performance is “fuzzy at best.” The latest academic research indicates that “a positive link exists, but that it is a weak one.” (“Ethical Capitalism: How Good Should Your Business Be?” The Economist, January 17, 2008.)

39. Roger Bate, “The War against Big Pharma.”

40. It is uncertain whether corporate initiatives such as the Novartis Institute for Tropical Disease in Singapore are sustainable over the long run.


43. Martina Casenghi et al., “New Approaches to Filling the Gap in Tuberculosis Drug Discovery.”


50. For more detail on this complex argument, see Roger Bate, “Paging Dr. Ricardo: A Dose of Economics for Healthier Pharmaceutical Production.”


