**Just Rules for Incentivizing Pharmaceutical Research**

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Bringing new, safe and effective life-saving medications to market is hugely expensive, as inventor firms must pay for the research and development of new drugs as well as for elaborate testing and the subsequent approval process.¹ In addition, newly developed medical treatments often turn out to be unsafe or not effective enough, to have bad side effects, or fail to win government approval for some other reason, which may lead to the loss of the entire investment.

Given such large investment costs and risks, very little innovative pharmaceutical research would take place in a free market system. The reason is that an innovator would bear the full cost of its failures, but would be unable to profit from its successes because competitors would copy or retro-engineer its invention (effectively free-riding on its effort) and then drive down the price close to the marginal cost of production.

The classic solution, also prescribed by the TRIPs regime (adopted under WTO auspices in the Uruguay Round), corrects this market failure through patent rules that grant inventor firms temporary monopolies on their inventions, typically for 20 years from the time of filing a patent application. With competitors barred from copying and selling any newly invented drug during this period, the inventor firm (or its licensees) can sell it at the profit-maximizing monopoly price typically very far above — as in 400 times greater than — its marginal cost of production. In this way, the inventor firm can recoup its research and overhead expenses plus some of the cost of its other research efforts that failed to bear fruit.

This solution corrects one market failure (undersupply of medical innovation), but its monopoly feature creates another. During the patent’s duration, the profit-maximizing sale price of the new medicine will be far above its marginal cost of production. This large differential is socially harmful by precluding mutually beneficial sales to potential buyers who are willing and able to pay more than the cost of production but not the much higher monopoly price. If modified rules could facilitate these potential transactions, then many patients would benefit — and so would the drug companies as they would book additional profitable sales and typically also, through economies of scale, reduce their marginal cost of production. Such a reform would also avoid countless premature deaths and much severe suffering worldwide which the present patent regime engenders by blocking mutually advantageous sales of essential medicines.

There are two basic reform strategies for avoiding this second market failure associated with monopoly pricing powers: differential-pricing and public-good strategies. The differential-pricing strategy comes in different variants. One would have inventor firms themselves offer their proprietary drugs to different customers at different prices, thereby realizing a large profit margin from sales to the more affluent without renouncing sales to poorer buyers at a lower margin. This solution is generally unworkable unless the different categories of buyers can be prevented from knowing about, or from trading with, one another. Another variant is the right of governments, recognized under TRIPs rules, to issue compulsory licenses for inventions that are urgently needed in a public emergency. Exercising this right, a government can force down the price of a patented invention by compelling the patent holder to license it to other producers for a set percentage (typically below 10 percent) of the latter’s sales revenues. Experience shows that governments, especially those of the poorer countries, succeed only very rarely, against heavy pressure from pharmaceutical companies and often their governments, in exercising their rights to issue compulsory licenses. Were they to succeed more often, they would bring

¹ This point may be controversial to some extent. It has been asserted that pharmaceutical companies wildly overstate their financial and intellectual contributions to drug development and that most basic research is funded by governments and universities and then made available to the pharmaceutical industry for free. See Angell 2004; Consumer Project on Technology (www.cptech.org/ip/health/econ/rndcosts.html); UNDP 2001: ch. 5.
back the first market failure of undersupply: Pharmaceutical companies will tend to spend less on the quest for essential drugs when the uncertainty of success is compounded by the additional unpredictability of whether and to what extent they will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers.

It seems more likely that the public-good strategy can spawn a reform plan that avoids the main defects of the present monopoly-patent regime while preserving most of its important benefits. We may think of such a plan as consisting of three components. First, the results of any successful effort to develop (research, test, and obtain regulatory approval for) a new essential drug are to be provided as a public good that all pharmaceutical companies may use free of charge. This reform would eliminate the second market failure (associated with monopoly pricing powers) by allowing competition to bring the prices of new essential drugs down close to their marginal cost of production. Implemented in only one or a few countries, this reform would engender problems familiar from differential-pricing solutions: Cheaper drugs from countries where drug development is treated as a public good would seep back into, and undermine research incentives in, countries adhering to the monopoly-patent regime. The reform should therefore be global, just like the current TRIPs regime is. The first reform component is then that results of successful efforts to develop new essential drugs are to be provided as public goods that all pharmaceutical companies anywhere may use free of charge.

Implemented in isolation, this first reform component would destroy incentives for pharmaceutical research. This effect is avoided by the second component which is that, similar to the current regime, inventor firms should be entitled to take out a multi-year patent on any essential medicines they invent, but, during the life of the patent, should be rewarded, out of public funds, in proportion to the impact of their invention on the global disease burden. This reform component would reorient the incentives of such firms in highly desirable ways: Any inventor firm would have incentives to sell its innovative treatments cheaply (often even below their marginal cost of production) in order to help get its drugs to even very poor people who need them. Such a firm would have incentives to prioritize prevention over treatment (the conventional patent system has the opposite effect, with new treatments offering much greater profit opportunities than new vaccines.) It would have incentives also ensure that patients are fully instructed in the proper use of its drugs, so that, through wide and effective deployment, they have as great an impact on the global disease burden as possible. Rather than ignore poor countries as un lucrative markets, inventor firms would moreover have incentives to work together toward improving the health systems of these countries in order to enhance the impact of their inventions there. In addition, any inventor firm would have reason to encourage and support efforts by cheap generic producers to copy its drugs, because such copying would further increase the number of users and hence the invention’s favorable impact on the global disease burden. In all these ways, the reform would align and harmonize the interests of inventor firms with those of patients and the generic drug producers — interests that, under the current regime, are diametrically opposed. The reform would also align the moral and prudential interests of inventor firms who are currently forced to choose between recouping their investments in the search for essential drugs and preventing avoidable suffering and deaths.

This second component of a plausible public-good strategy realizes yet another tremendous advantage over the status quo: Under the current regime, inventor firms have incentives to try to develop a new medical treatment only if the expected value of the temporary monopoly pricing power they might gain, discounted by the probability of failure, is greater than the full development and patenting costs. They

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2 The absence of such incentives under the present rules gravely undermines the effectiveness even of donated drugs delivered into poor regions (UNDP 2001: 101).

3 This opposition was displayed most dramatically when a coalition of 31 pharmaceutical companies went to court in South Africa in order to prevent their inventions from being reproduced by local generic producers and sold cheaply to desperate patients whose life depended on such affordable access to these retroviral drugs. In April 2001, the attempted law suit collapsed under a barrage of worldwide public criticism (Barnard 2002).
have no incentives, then, to try to develop any treatment that is needed by people unable to afford it at a price far above the marginal cost of production: diseases affecting mainly the poor. Consequently, very few treatments are developed for medical conditions that cause most of the premature deaths and suffering in the world today. Even if common talk of the 10/90 gap is now an overstatement, the problem is certainly real: Malaria, pneumonia, diarrhea, and tuberculosis, which together account for 21 percent of the global disease burden, receive 0.31 percent of all public and private funds devoted to health research (GFHR 2004: 122). And diseases confined to the tropics tend to be the most neglected: Of the 1393 new drugs approved between 1975 and 1999, only 13 were specifically indicated for tropical diseases and, of these 13, five were byproducts of veterinary research and two commissioned by the military (Trouiller et al 2001; DNDWG 2001: 11).

One may worry that the second component of the reform would reduce incentives to develop treatments for medical conditions that, though they add little to the global disease burden (on any plausible conception thereof), affluent patients are willing to pay a lot to avoid. This worry can be addressed, at least in part, by limiting the application of the reform plan to essential drugs: for diseases that destroy human lives. Drugs for other medical conditions can remain under the existing regime with no loss in incentives or rewards.

Incorporating this distinction between essential and non-essential drugs into the reform plan raises the specter of political battles over how to define this distinction and of legal battles over how to classify particular inventions. These dangers can be averted by allowing inventor firms to classify their inventions as they wish and then designing the rewards in such a way that these firms will themselves choose to register under the reform rules any inventions that stand to make a substantial difference to the global disease burden. Such freedom of choice would also greatly facilitate a smooth and rapid phasing-in of the new rules, as there would be no disappointment of the legitimate expectations of firms that have undertaken research for the sake of gaining a conventional patent. The reform plan should be attractive for pharmaceutical companies by winning them new lucrative opportunities for research into currently neglected diseases without significant losses in the lucrative research opportunities they now enjoy — and by restoring their moral stature as benefactors of humankind.

This second reform component requires a way of funding the planned incentives for developing new essential medicines, which might cost some $45-90 billion annually on a global scale. (A more precise estimate is impossible because the cost each year would depend on how successful innovative treatments would be in reducing the global disease burden. The reform would cost billions of Dollars only if and insofar as it would save millions of lives.) The third component of the reform plan is then to develop a fair, feasible and politically realistic allocation of these costs, as well as compelling arguments in support of this allocation.

While the general approach as outlined may seem plausible enough, the great task is to specify it concretely in a way that shows it to be both feasible and politically realistic. To be feasible it must, once implemented, generate its own support from governments, pharmaceutical companies, and the general public (as these three key constituencies would be under the reformed regime). To be realistic, the plan

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4 “Only 10 percent of global health research is devoted to conditions that account for 90 percent of the global disease burden” (DNDWG 2001: 10; cf. GFHR 2004). This imbalance may have been reduced, notably through spending by the Gates Foundation.

5 My rough estimate assumes that the reformed rules would stimulate the pharmaceutical industry to spend somewhat more on research toward new essential drugs (especially for heretofore neglected diseases) than it is now spending on all pharmaceutical research (cf. GFHR 2004: 112). I also assume that the rewards offered under the reformed rules must substantially exceed these projected expenditures, because pharmaceutical companies will brave the risks of an expensive research effort only if its expected return substantially exceeds its cost.
must possess moral and prudential appeal for governments, pharmaceutical companies, and the general public (as these three constituencies are now).

Here one main task concerns the design of the planned incentives. This requires a suitable measure of the global disease burden and ways of assessing the contributions that various new medical treatments are making to its reduction. When several medicines are alternative treatments for the same disease, then the reward corresponding to their aggregate impact must be allocated among their respective inventors on the basis of each medicine’s market share and effectiveness. More complex is the case of “drug cocktails” that combine several drugs developed by different companies. Here the reform plan must formulate clear and transparent rules for distributing the overall reward, proportional to the impact of the drug cocktail, among the inventors of the drugs it contains. And it must also include specific rules for the phase-in period so as not to discourage ongoing research efforts motivated by the existing patent rules. It is of crucial importance that all these rules be clear and transparent, lest they add to the inevitable risks and uncertainties that complicate the work of inventor firms and sometimes discourage them from important research efforts.

Another main task concerns the design of rules for allocating the cost of the incentives as well as the formulation of good arguments in favor of this allocation. Effective implementation of the reform requires that much of its cost be borne by the high-income countries. This is feasible even if these countries, after re-targeting existing subsidies to the pharmaceutical industry in accordance with the reformed rules, still had to shoulder around $70 billion in new expenditures. This amount, after all, is only 0.22 percent of their aggregate gross national incomes or $70 for each of their residents. To make this planned spending increase realistic, taxpayers and politicians of the high-income countries need to be given compelling reasons for supporting it.

This expense can be supported by prudential considerations. The taxpayers of the wealthier countries gain a substantial benefit in the form of lower drug prices or insurance premiums. To be sure, such a shifting of costs, within affluent countries, from patients to taxpayers would benefit less-healthy citizens at the expense of healthier ones. But such a mild mitigation of the effects of luck is actually morally appealing — not least because even those fortunate persons who never or rarely need to take advantage of recent medical advances still benefit from pharmaceutical research which affords them the peace of mind derived from knowing that, should they ever become seriously ill, they would have access to superb medical knowledge and treatments.

A second prudential reason is that, by making pharmaceutical research sensitive to the interests also of poor populations, we are building good will in the developing world by demonstrating in a tangible way our concern for their horrendous public-health problems. This argument has a moral twin: In light of the extent of avoidable mortality and morbidity in the developing world, the case for including the interests of the poor is morally compelling.

These last twin arguments have wider application. The reform plan would not merely encourage the same sort of pharmaceutical research differently, but would also expand the range of medical conditions for which inventor firms would seek solutions. Under the current regime, these firms understandably show little interest in tropical diseases, for example, because, even if they could develop successful treatments, they would not be able to make much money from selling or licensing them. Under the alternative regime, inventor firms could make lots of money by developing such treatments whose potential impact on the global disease burden is enormous.

There are three further prudential reasons. The reform would create top-flight medical-research jobs in the developed countries. It would enable us to respond more effectively to public health emergencies and problems in the future by earning us more rapidly increasing medical knowledge combined with a

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6 See World Bank (2005: 293) for the aggregate gross national income ($32,064 and $39,834 billion) and the aggregate population (1001 and 6345 million) of the high-income countries and the whole world in 2004.
stronger and more diversified arsenal of medical interventions. In addition, better human health around
the world would reduce the threat we face from invasive diseases. The SARS outbreak and the avian flu
scare illustrate the last two points: Dangerous diseases can rapidly transit from poor-country settings
into cities in the industrialized world; and the current neglect of the medical needs of poor populations
leaves us unprepared to deal with such problems when we are suddenly confronted with them. Bringing
enormous reductions in avoidable suffering and deaths worldwide, the reform would furthermore be
vastly more cost-effective and also be vastly better received in the poor countries than similarly
expensive humanitarian interventions and the huge, unrepayable loans. Last, not least, there is the
important moral and social benefit of working with others, nationally and internationally, toward
overcoming the horrendous, poverty-induced and largely avoidable morbidity and mortality in the
developing world.

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