Prescription for the People
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There Is a Better Way to Develop Medicines

I have discussed in chapter 20 how small but significant changes can be easily accomplished under current law or with small tweaks to it. Here I review how to make more substantial fixes to our broken system.

When pharmaceutical corporations defend the current patent medicine system, they say that the massive profits generated from monopoly pricing are necessary to provide the incentive for the research and development of new medicines. This argument should not be dismissed lightly: on behalf of anyone facing a diagnosis of terminal or incurable illness, and on behalf of their loved ones, the search for new medicines is a life-or-death priority. But, as we have seen in chapter 14, government funding, not private dollars, provides the foundation for that kind of research. And those government funds can provide incentives for drug development without the deadly side effects of patent monopolies.

Most comprehensive medicine-development reform proposals provide those incentives using some combination of “push” and “pull” mechanisms.¹ Push incentives include grants or other subsidies offered to innovators at
the early stage of medicine research. Governments are already playing the most critical role in this early-stage medicine research. The most prominent example of push funding is the substantial investment by the NIH, which provides $32 billion annually in government funding for medical research. The long list of NIH success stories includes supporting the work of 148 Nobel Prize winners, along with the funding of the research that led to the antiretroviral medicines that revolutionized the treatment of HIV/AIDS and saved millions of lives worldwide.²

Beyond the NIH, an example of smaller but more targeted push funding is the Drugs for Neglected Diseases Initiative, a not-for-profit collaboration among the public sector, academia, nongovernmental organizations, and for-profit companies.³ Under the Drugs for Neglected Diseases Initiative umbrella, this coalition spurs research and development for neglected diseases. It now has more than thirty projects in its research and development pipeline, including fifteen entirely new chemical entities.⁴ The success of the Drugs for Neglected Diseases Initiative, as well as that of the Italian Mario Negri Institute, which refuses to take patents on its discoveries, has helped spur calls in Europe for an expansion in nonprofit medicine research and development.⁵ Also in the push category are government-provided tax credits for pharmaceutical research, credits that are sometimes increased to reward research that addresses diseases with limited profit potential.⁶

When governments provide push funding, they can and should be requiring that the resulting knowledge be made public and available to all in an open access database.⁷ That approach will reverse the anti-innovation character of patents and tear down the many isolated secretive silos of current patent medicine research. It is exciting to contemplate the prospects for global health when the proven power of open sourcing is unleashed to tackle the most vexing health challenges of our time.

In contrast, pull funding usually focuses on the later stages of the research and development process. The most widely discussed pull proposals center on offering significant prizes to innovators who discover and develop a valuable drug.⁸ Such prizes are certainly not a new idea; there is a long history of prizes being used to spur innovation. Architectural design prizes, for example, date back to the fifteenth century. And Charles Lindbergh’s famous 1927 trans-Atlantic flight earned him the $25,000 Orteig prize.⁹
In fact, the current medicine patent system is itself a prize model. The problem is that the prize of a monopoly market leads to bloated prices and siloed research, and it fails to provide incentives for the development of medicines that address diseases that plague the global poor. Therefore, most modern medicine-development prize proposals include, as a condition of acceptance, an open-source commitment: the release of any monopoly rights to the medicine formula.10

Just as with conditional push funding, the expectation is that the resulting open development of prize-induced medicines will lead to low-cost manufacturing and innovations in delivery methods. This is much more than wishful thinking because that kind of innovation already characterizes the current generic drug industry, in which formulas are not locked away from those who wish to improve on them.11

The Health Impact Fund is one prize proposal that has attracted high-profile supporters, including Amartya Sen, Nobel laureate economist; Dr. Paul Farmer, global health activist; and Peter Singer, philosopher. The plan of the fund is to offer drug developers prizes in amounts that correspond to the impact of their innovation on global health. In return for the prizes, recipients surrender any rights to monopoly pricing, which means that drug prices will be more closely linked to the costs of manufacture.12

The Health Impact Fund and most other medicine prize proposals are still on the drawing board, but some prize programs are already in place. Those include a European Union prize for vaccines innovation, the National Health Service England Innovation Challenge Prizes, and the Longitude Prize for developing antibiotics.13 As health economists have noted, the structure of these prize programs does not present a radical change to the current medicines research model. As we have seen in chapter 6, much of the current private-sector innovation comes from small research firms, whose “prize” is having their most successful projects bought up by large pharmaceutical corporations.14 There are examples of medicine development prizes that are funded by private philanthropy in whole or in part, but substantial government investment will be necessary for prizes to replace the lucrative rewards of a patent monopoly.

The same is true for related pull proposals, such as advanced purchase commitments that provide incentives for drug development by guaranteeing a market for a medicine that may not otherwise appear profitable to an innovator.15 As with push funding, the need for substantial government
investment in pull programs does not pose as much of a challenge as it may initially appear: the government dollars needed for prize systems or advanced purchase commitments already undergird the current patent system. Governments pay at both the push and pull stages already in the form of the public funding of research followed by high-volume government purchases of patent-priced medicines. In the United States, for example, Medicare and Medicaid programs now purchase many drugs at patent prices, including the drugs the government paid to develop.

We simply need to change the direction of those government funds to benefit patients rather than enrich corporations. If we just commit to that switch in priorities, there is more than enough money in the current system to finance medicine research and development. As an added bonus, that government investment would not be handcuffed by for-profit priorities that neglect major diseases in favor of maladies that impact the comparatively wealthy. Further savings would be realized by the elimination of the need for medicine prices to be set high enough to recoup the cost of for-profit drug marketing. The five largest US pharmaceutical companies spend a combined $50 billion annually on marketing, an expense that currently gets passed on to medicine purchasers. We can do without that!

When considering how to provide incentives for medicine research, it is important to realize that different stages of medicine research and development pose different challenges. Effective incentives to spur basic research may not work to motivate the launch of clinical trials, which are currently conducted largely by private corporations but are often beset with profit-connected ethical problems. As a result, many reformers advocate the use of a combination of push and pull approaches. For example, Médicins Sans Frontières/Doctors Without Borders is pursuing a 3P project—push, pull, and pooling (sharing of research results)—to develop an effective TB treatment.

Another well-known example of combining push and pull incentives is the U.S. Orphan Drug Act. This law was introduced to spur research to find medicines to address diseases whose remedies are not likely to produce a huge profit for the manufacturer, usually because the diseases affect a small number of people. The Orphan Drug Act provides an early-stage push, in the form of research grants and increased tax credits, along with a late-stage pull from government-guaranteed market exclusivity for the resulting drugs. Australia and the European Union have created similar
push-pull mechanisms to stimulate the research and development of medicines that target rare (orphan) diseases.\textsuperscript{22}

James Love, the director of the medicine-access group Knowledge Ecology International, is a former longshoreman turned community activist who then decided to study economics, eventually becoming a staffer for Ralph Nader, the famed consumer advocate.\textsuperscript{23} Love played a key role in convincing Indian generic drug manufacturer Cipla to make a dramatic 2001 pledge to manufacture and sell antiretroviral medicines at a cost of $1 per day.\textsuperscript{24} That offer of a 96 percent reduction from the patented price gained immediate international attention, put pressure on both drug companies and governments to respond to the HIV/AIDS pandemic, and helped lead to a huge expansion in HIV/AIDS treatment.

Love and his organization are known for in-depth analyses of proposed drug regulations and the profits and research investments of the pharmaceutical industry. He was instrumental in devising the UN-backed Medicines Patent Pool (chapter 20), in which companies have voluntarily surrendered their monopolies on antiretrovirals in poor countries in return for royalties on cheaply produced generic versions.

The Medicines Patent Pool has been a success. But Love and other medicine advocates point out that there is a ceiling on such a plan. After all, pharmaceutical companies will voluntarily surrender their patents only in countries where they know they cannot sell their drugs at higher costs. “The pool is a transition thing,” Love said. “The transformative change comes with delinkage.”\textsuperscript{25}

\textit{Delinkage} is the term used to describe a set of proposals that breaks the connection between medicine prices and the costs of research and development. Many of the reform proposals we have mentioned include meaningful alterations to the current medicines patent model. But most do not completely delink medicine prices from research costs, nor do they discard the existing patent system. The Medicines Patent Pool, for example, does not disturb the rights of the patent-holders to charge monopoly prices in middle- and high-income countries. Similarly, the aim of the Health Impact Fund is the patent-free development and distribution of drugs for neglected diseases only. It does not affect the ability of the patent-holders to charge monopoly prices for medicines with high market values, which includes many cancer medicines.
In contrast, Love and others call for the complete delinkage of medicine prices from the costs of research and development. The aim of delinkage proposals is to support research for needed medicines while bypassing the need for patients to pay for the enormous marketing costs now poured into noncritical drugs and “me-too” variations of existing medicines. “The amount of marketing goes up with the unimportance of the drug,” Love says. “You don’t have to convince people of the value of antiretrovirals or a cancer drug that saves lives.”

An example of a full delinkage proposal is the Medical Innovation Prize Fund proposed by Love and others, which would reward innovations that impact public health while requiring the surrender of all monopoly patent rights. Under proposals such as these, medicine prices would closely correspond to manufacturing costs, which are often quite inexpensive. The idea of delinkage is grounded in both the pre-TRIPS history of treating medicines as a public good (chapter 16) and the modern acknowledgement of the human right to health (chapter 22).

Under delinkage, one aspect of the current drug research model would remain intact. Love insists that any medicine development program has to include sufficient monetary incentives to entice research from the private sector. Love’s wife, Manon Ress, also an intellectual property expert and activist, has Stage IV breast cancer. Love points out that patients like her—and loved ones like him—understandably want the search for new medicines to be aggressive and relentless. And if that research is done by the pharmaceutical companies that currently embrace the patent model, so much the better. “If you do the delinkage right, with real rewards for innovation, the companies that are good at innovation will do just fine,” Love says. Others agree. Writing in the prestigious British medical journal *The Lancet*, World Health Organization leaders discussed how the private sector could play the role of government contractors in a publicly-funded medicines system. Economist Dean Baker has promoted this model, comparing it to the existing system of government defense contracting to private companies to conduct research and develop products, an arrangement that Baker points out has led to ground-breaking technological advances.

The escalating global outrage over the flaws in the current medicine monopoly system is allowing these delinkage arguments to gain traction. An August 2015 article in the *Economist* conducted a thorough and skeptical review of the value of patents for medicines, concluding that
reform proposals deserve an opportunity to demonstrate whether they can provide better results than the current system.\textsuperscript{32} The concept of delinking received an extensive and favorable review in a 2013 joint report of the WTO, the World Intellectual Property Organization, and the World Health Organization, and in a 2016 report from an expert international panel convened by the British medical journal \textit{The Lancet}.\textsuperscript{33} “I’m absolutely optimistic that there can be big changes, and soon,” Love says. “We just need to get the messaging right, and we need the political leadership to step up. I mean, the benefits are so obvious.”\textsuperscript{34}

An important opportunity for the global political leadership to heed Love’s call to step up was presented by the convening of the UN Secretary-General’s High-Level Panel on Access to Medicines, announced in late 2015. Human rights advocates, however, have learned to approach with restraint the news of a high-profile group convening to review a crisis: too often, such groups issue a promising report that is ignored or, worse, completely contradicted by binding trade agreements that elevate corporate profits over human rights.\textsuperscript{35}

But human rights history also gives us reason for some optimism. That history shows that discussions about a right usually goes on for decades, if not generations, before it becomes an enforceable reality. Plenty of blue-ribbon panels were convened and reports written along the path to overcoming slavery, apartheid, and colonialism—even though it took more pro-active in-the-street and in-your-face protests, boycotts, and political action to put those movements over the top.

As for this particular panel, its membership was undeniably impressive. Notably, it included Yusuf Hamied, the chair of the generic drug manufacturer Cipla who worked with James Love and others to make sure that low-cost generic medicines helped fuel the historically successful HIV/AIDS treatment movement.\textsuperscript{36} There were politicians and a Big Pharma CEO on the panel, too, but other members include Winnie Byanyima of Oxfam and Stephen Lewis, a veteran Canadian diplomat and HIV/AIDS treatment activist. Lewis has seen such panels come and go without having much impact, but he believed that this time might be different. “Access to medicines has become one of humankind’s greatest crises, perhaps right behind climate change,” he said in December 2015. “This has become a problem for the developed world alongside the developing world, and I think that means great changes are coming.”\textsuperscript{37}
Lewis’s fellow panel members seemed to recognize the problem as well. The panel ultimately issued a report that began with a clear recognition that millions die each year from AIDS, TB, hepatitis C, and noncommunicable diseases, all due to lack of access to medicines that would have saved their lives. The report also affirmed the fundamental right to access medicines and vaccines, and that there is abundant evidence to show that the market alone cannot be trusted to provide lifesaving medicines.

Ultimately, the panel issued a strong call for governments to exercise their existing legal rights to pursue generic manufacturing of unaffordable patented medicines and tightly restrict medicine patents and extensions. Two-thirds of the panel supported a process to allow immediate generic manufacture of all essential medicines, although consensus was not reached on that point. But the whole panel did not shy away from making the big-picture recommendation that the secretary-general and UN member states should work toward a binding research and development convention (agreement). That convention would delink the price of medicines from the cost of research and development, a necessary step toward treating essential medicines as a core component of the human right to health instead of a for-profit commodity ripe for exploitation.

The suggestion for an international agreement on medicines research and price is not a new one. In 2012, a working group created by the World Health Assembly, the decision-making body of the World Health Organization, issued a report proposing a binding treaty to enforce government funding of health-related research and development. The proposal called for all countries to spend at least 0.01 percent of their gross domestic product on neglected diseases.

Under the proposed treaty terms, 20 percent of this investment would be pooled at the international level, but some could be directed by individual nations toward early-stage research, prize funds, patent buy-outs, or other push-pull mechanisms. The treaty was designed to lay the platform for open-source development of the next generation of medicines. But the United States led opposition to the treaty during the 2012 World Health Organization discussions, and the consideration of the proposal was postponed.

After that postponement, a renewed effort to push a global research and development pact was organized by Universities Allied for Essential
Medicines (UAEM), a student-led global organization that has traditionally focused on promoting wide access to university-developed medicines.\textsuperscript{44} Beginning in 2015, the students decided to set their sights more broadly. “On the whole, patent monopolies have proven to be the wrong incentive for research and development of medical products to meet global health needs,” the students said in a UAEM report. “Delinking the price of drugs from their R&D costs (is necessary) in order to delink the main incentive for their production from a market base and bring it back to public interest.”\textsuperscript{45}

The foundation for the current global push for a research and development agreement has been a November 2015 letter to the World Health Organization signed by dozens of academics and scientists, including two Nobel laureates. “Patent monopolies increasingly enable rising drug prices, without any corresponding increase in innovation,” they wrote the World Health Organization. “We have witnessed stagnation in the face of public health emergencies.”\textsuperscript{46} The letter favorably cited current prize funds, patent pools, and open-source efforts, but it also noted that these efforts are fragmented. “A global agreement for an equitable biomedical R&D system can provide a much needed structure,” the signers wrote. “It can provide guiding principles which can move us to a system that incentivizes research and technology transfer based on global health needs and recognizes the human right to health.”\textsuperscript{47} Many others have endorsed the idea of a global research and development agreement, including the essential medicines panel convened in 2016 by \textit{The Lancet}, which noted precedent for such an agreement provided by the impactful 2005 Framework Convention on Tobacco Control.\textsuperscript{48} The members of the World Health Organization did not adopt the global agreement during their 2016 meeting, but they did agree on a resolution calling for more examination of a pooled research and development funding model, leading advocates to be hopeful that a global research funding agreement would still be possible.\textsuperscript{49}

Admittedly, delinkage proposals, including the global research and development agreement, are not without complexities and challenges. Push funding requires rigorous compliance monitoring and cannot guarantee success for every effort to discover innovative medicines. For prize systems, it is not easy to determine a monetary value and terms that will provide sufficient motivation for innovators, along with robust returns for the prize funders.
But none of the possible limitations of reform proposals approaches
the fatal dysfunction of the present skewed reward system, which causes
needless suffering and death. The medicine patent system produces toxic
results, and medicine advocates have come together to support effective
and equitable alternatives. These alternatives deserve global support.