

Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases

By Michael Kremer and Rachel Glennerster

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Imagine you were handed the secret to stopping over 600 million people from getting sick each year, and saving over 6 million people from death. *Strong Medicine* holds that secret. Malaria infects over 300 million people per year, and kills 1.1 million.¹ Tuberculosis in its latent form infects approximately one third of the world's population, or about two billion people, and kills two million people each year.² More than 42 million people are infected with HIV or full-blown AIDS, and about 3.1 million people die of the disease each year.³ Thirteen million children have been orphaned by AIDS, and that number is projected to reach 26 million by 2010.⁴ Those are the star diseases, but many other diseases that the developed world has never heard of take their own toll, such as schistosomiasis, Chagas' disease, leishmaniasis, pertussis, trypanosomiasis, onchocerciasis, and lymphatic filariasis.⁵ The combined death toll of those diseases is nearly half a million people a year.⁶

The above diseases have been killing people in low income countries for decades. However, those diseases, with the exception of HIV, are almost entirely absent in the developed world. An outbreak of tuberculosis in the late 1980s, early 1990s in New York City caused the city to spend almost \$1 billion to stop the outbreak. And yet, there is very little research into

¹ See Michael Kremer and Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* 12 (Princeton University Press 2004) (citing a 2001 World Health Organization estimate).

² *Id.*

³ *Id.* at 15 (citing a 2002 UNAIDS study).

⁴ *Id.*

⁵ *Id.* at 9 (chart).

⁶ *Id.*

vaccination or treatment for those mentioned diseases. Although about \$70 billion is spent worldwide on research and development in the health field, only about 10% of that is spent on researching the health problems of 90% of the world's population.⁷

Michael Kremer and Rachel Glennerster argue that the reason for the lack of research and development is that there is no money to be made providing vaccines or other medical treatments to poor countries. Pharmaceutical companies have no incentive to spend private resources on research and development of medical treatments that neither the patients nor their governments can afford. Even if the richer countries step in and pay for treatments for poorer countries' citizens, governments have a tendency to use their huge purchasing power to force drug prices below the cost of producing the treatment. How are we to get out of this rut, where the poor are dying because the rich refuse to invest for fear of bankrupting their companies and backlash from shareholders?

The authors of *Strong Medicine* suggest an incentive in the form of "pull" economics to stimulate research into these neglected diseases. Incentive systems can generally be categorized into one of two categories – push programs or pull programs. Push programs subsidize research on the road toward completion, while pull programs only reward the finished product. Kremer and Glennerster argue that while push programs are suitable for early stages of research, pull programs are better suited for vaccines and for later stages of research because they encourage researchers to pick the research route that has the best chance of success versus push programs, which allow researchers to stay with ideas that are unworkable long after what's practical.

Strong Medicine is a well organized and clear argument for the use of pull programs as incentives to research treatments and (primarily) vaccines for neglected diseases. The authors lead the reader through each aspect of their argument slowly and thoroughly, leaving no

⁷ *Id.* at 26 (describing the 10/90 gap).

questions unanswered. After a touching narrative of Michael Kremer's experience contracting malaria while teaching in Kenya, the authors discuss the state of people's health and the health systems in low income countries. The weak health care systems in low income countries do little to slow the spread of infectious diseases and present unique challenges for the dissemination of treatment to those who need it. The authors lead the reader through staggering death counts and horror stories of treatment resistant diseases, but point out many success stories of simple treatments that save millions of lives each year.

Moving along in their argument, the authors demonstrate the scarcity of research and development efforts toward diseases in poor income countries, and explain why neither the market, nor governmental intervention will cure the inequity. Several scientific publications assert that vaccines for malaria, HIV and schistosomiasis are feasible. In fact, much research has gone into an HIV vaccine, but only for the genetic form of HIV that effects the developed world, rather than for the very different genetic form of HIV that primarily effects low income countries. The authors also argue that market failures for vaccine are caused by two phenomena: each person that takes a vaccine slows the spread of the disease, so that each vaccine benefits more than just the person treated; and once a vaccine is developed, it will likely be reverse engineered and offered at a reduced price, and with little intellectual property protection in third world countries, the efforts of the vaccine developer will go unrewarded. Government purchases of vaccines cannot fully address market failures unless the government purchases the vaccines at above manufacturing cost to cover research and development costs. However, governments are likely to push down the price they will pay since they will likely be the primary buyer and have unequal bargaining power. Even if the government does not push down prices, the threat of a

primary buyer doing so would cool any pharmaceutical interest in entering the market for vaccine development.

The authors then compare push and pull programs through a series of examples of both successful and failed programs. The classic model in high income countries is a combination of both push and pull programs – the governmental supports basic research and private companies are pulled to produce by the reward of patent protection. Due to the threat of reverse engineering, this system will not work where patent protection is slim. While not discounting the idea of a combination of both push and pull programs, the authors advocate for a pull incentive program organized by private funding sources. Several problems manifest themselves in push programs, such as researchers exaggerating their chance of success, or political forces working on governmental grants for research. Pull programs have their problems as well, such as the need for great specificity in developing requirements for the desired final products, but the problems presented by pull programs are more easily sidestepped than those posed by push programs. The authors go on to fully describe such preventative measures later in their argument.

After examining the different options for pull program design, such as patent extensions on other pharmaceuticals, best entry tournaments, and commitments to buy patents, the authors determine that a commitment to purchase a certain number of doses from any developer of any vaccine that meets the technical requirements is the best option. Under this sort of program, an organization or charitable foundation would make a legally binding commitment to purchase 250 million doses of a malaria vaccine that fits the technical requirements at \$15 per vaccine, for example. Making the commitment legally binding would dispel any fear on the part of pharmaceutical companies that they would not receive reimbursement after developing a suitable

vaccine. A private foundation would make the commitment to reduce fears of the government forcing pharmaceutical prices down. Technical requirements would include approval of any potential treatment by the Food and Drug Administration to be sure it is safe, a goal reduction in the rate of incidence of the targeted disease in vaccinated populations to make sure the treatment is effective, and parameters regarding how many doses the vaccine requires to be sure the vaccine is useful. Many factors can make a vaccine that is effective against a disease useless, such as terrible side effects, difficulty in the method of administration of the vaccine or treatment, or a long schedule of doses needed for protection from a disease, since many people will not return for a full course of vaccination. If the technical requirements are not strict enough, the committing foundation would be liable for purchasing 250 million useless vaccines – a very negative result. Accordingly, the authors give a lot of attention to what the requirements should be for the vaccine. The authors also suggest a market test requirement, especially if copayments for vaccines are required, exit clauses in case too much time passes before a vaccine is developed or the disease landscape changes significantly, and the appointment of an independent committee to rule whether vaccines submitted meet the requirements to avoid concerns about bias on the part of the incentive sponsor.

The authors then discuss the final details of any vaccine commitment. They thoroughly outline how much should be paid for a vaccine, and how such payments should be structured, especially in cases where a more effective vaccine was developed after the acceptance of an inferior vaccine, or the organizers want to pay more for very high quality vaccine submissions. The authors encourage raising the promised price over time if no pharmaceutical companies are starting research, taking such as indication that the promised price was not high enough to induce research. Mention is made of widening the incentive program to reward not just vaccines, but

anything that significantly reduces disease burden, such as insecticides that kill the mosquitoes that spread malaria. The authors suggest what diseases to cover, and even go so far as to suggest potential sponsors that would have the funds to legitimately commit to such a large purchase.

This book is an extremely thorough analysis of a very real way to save millions of lives. The authors view every angle of a pull incentive system set up as they described, meticulously consider every possible problem and solution with no indication of bias toward their own ideas, and finally present the reader with a very viable way of solving a significant problem the world faces. There are no holes in this argument – no stones are left unturned in the search for a way to solve the problem the authors tackle. This is an excellent book for any reader interested in economics, the pharmaceutical industry, or the health of low income countries. The legal implications of pharmaceutical patents and the regulatory aspects of incentive programs make this book a good read for those in the legal community as well. In fact, this book should be required reading for policy makers, pharmaceutical companies, and students of all disciplines alike, if not to spur action toward adoption of an incentive program, than to open the eyes of readers to the problems neglected diseases pose and suggest a potential solution.