

Module 204

[The following is a transcript of the recorded lecture for Module 204 of the PatentX course. The principal purpose of making the transcript available is to enable students in the course to refresh their recollections when preparing for the final examination. The lecture itself and the slides used to illustrate it are accessible through ipxcourses.org.]

Part A: Carrots

Hello, I'm Terry Fisher. This is the fourth and last of a series of lectures exploring the relationship between the legal system and the global health crisis.

In the first of the four lectures, I examined the contours of the current global health crisis and the potential roles of vaccines and medicines in alleviating it.

In the second, I explored a variety of ways of improving the markets for pharmaceutical products. Each involved an adjustment that would redound to the benefit of all players in the system.

In the third lecture in the series, I considered how intellectual property systems – both in developing countries and in developed countries -- might be adjusted so as to mitigate the crisis. In brief, the combination of recommendations I offered in that lecture sought to balance, on the one hand, limitations of the entitlements associated with intellectual property in poor countries, with, on the other hand, selective, strategic augmentation of the availability of intellectual property protections in developed countries designed to improve the pattern of incentives for the creation of new drugs.

In this, the final lecture in the series, I'm going to turn to alternative incentive systems. The premise of this lecture is that none of the changes we've considered thus far will do much to overcome one of the crucial biases in the current regime, namely, the insufficient investment of resources in the development of vaccines and drugs that address neglected diseases – in other words, diseases that are only common in the Global South. To stimulate more research and development on those diseases, we need to supplement the existing set of intellectual property laws with additional incentives.

As usual, the lecture will be divided into two parts. In the first, I'll discuss what could be characterized, using the conventional metaphor, as carrots, meaning, rewards or benefits of some kind designed to pull researchers into fields that are currently neglected. In the second part, I'll consider what could be characterized as sticks, meaning, regulations and penalties that would push potential innovators into fields that are socially beneficial. As we will see, these categories are not watertight, but they are helpful in organizing the options.

When analyzing the potential roles of carrots, it's helpful, I think, to begin with a very broad view of the current flows of revenue in the pharmaceutical industry and then gradually zoom in on the issues that most directly affect research and development.

Currently, over 8 trillion dollars is spent each year, in the world as a whole, on health care. That spending occurs in 4 main forms:

First, expenditures by governments;

Second, out-of-pocket spending by individuals – meaning, the people receiving health care or their parents;

Third, prepaid private spending – meaning premiums paid for private health insurance, which then reimburses the providers of health services;

and finally so-called development assistance for health – which consist of expenditures by both governments and private philanthropies to help in making health care available in other countries – typically low and middle-income countries.

As you can see from this chart, globally, government expenditures have long been the biggest of these channels. Development assistance is the smallest. Indeed, the red band, which represents development assistance, is so thin that it's hard to see in this chart. But that's because the overall amount of spending is so large.

The relative size of the four channels varies sharply by country. Typically, in poor countries, out-of-pocket spending and development assistance are the biggest channels. Generally speaking, the larger the relative size of the channels represented by government spending and private insurance.

But there are exceptions. As you can see, in many wealthy countries – such as most of the countries in Europe, Canada, Japan, and New Zealand, generous public-health services cause the biggest of the 4 channels to be government spending. But in the US, Portugal, and most of the Balkan countries, the share is much more modest.

OK, now let's zoom in on the development assistance sector. How much money is involved and where does that money come from?

Here's a chart showing, over the past 30 years, the total amounts and the biggest donors. As you can see, by 2020, it had grown to \$55b a year. The largest sources have been the governments of the US and the UK. But in recent years, the governments of other countries – such as Germany and Japan – have assumed larger roles.

The most dramatic change has been the increased role of philanthropies. The biggest and best known is the Gates Foundation, represented by the dark green zone on this chart. But, in the aggregate, the shares contributed by other philanthropies, represented by the light green zones, have been as big or bigger. Notice, of course, the big jump in overall DA spending in the COVID pandemic.

Which diseases are the principal targets of these expenditures? Here's the breakdown. As you can see, the big 3 infectious diseases – HIV, TB, and malaria – have traditionally gotten large quantities, as have maternal and infant health. Noncommunicable conditions surprising little. In 2020, the biggest chunk went to the pink zone – other infectious diseases – which means COVID.

Here's where the COVID-related funding was allocated. The sources of the funding are shown on the left; the targets on the right. As you can see, about 500 million of the 13 billion went to research and development on vaccines and therapies.

The following year, the total amount devoted to COVID increased further. We don't yet have data on how it was allocated, but there is little reason to think that it has materially changed.

OK. Now let's approach the target from another angle. How much is being spent each year by governments and philanthropies, not on health care in general, but on research and development pertaining to neglected diseases?

The most comprehensive data comes from the World Health Organization. Here are the relevant numbers. As you can see, for a while it's hovered around 3 to 4 billion current US dollars, adjusted for inflation.

When assessing these data, it's important to keep in mind how the WHO defines "neglected disease." Here's the definition it uses. As you can see, this is an unusually capacious definition. Most importantly, it includes HIV, which many analysts would not define as neglected.

With that scope in mind, here are some details concerning the sources and targets of the funding.

Over the entire period covered by this graph, by far the largest amount of funding originated in the US. That remains true if we focus only on 2020, the most recent year for which we have data.

Here's the list of funders over the entire period. As you can see the National Institutes of Health in the US is by far the largest.

If we limit our attention to philanthropies, the Gates Foundation provided the most money over the entire period, followed by the Wellcome Trust. If we focus just on 2020, that remains true.

R&D aimed at the big 3 infectious diseases got the most money. Most of the other neglected diseases very little. The same distribution can be seen in 2020.

The largest amount went to research on vaccines, next biggest on basic research, next on medicines. In 2020, the relative size of the investment in research on vaccines decreased. It's still the largest category, but by a smaller margin.

A third and final angle asks: what form does the governmental and philanthropic support for research and development on pharmaceutical products take?

There are three main options.

Option 1 is the funder conducts the research in house, using its own financial resources. The simplest example is when a government conducts research in government laboratories, using public monies.

The second option is a grant. The funder identifies a person or institution that it deems capable of engaging in high-quality, productive research and gives that person or institution resources to do so. The clearest illustration is when a national government issues a grant to a university to support a faculty member's research on a particular disease. Here's an example.

The third option is a prize. Instead of selecting a person or institution it deems capable of good research, the government offers a reward to the first person or institution that solves a particular research problem or comes up with a drug or vaccine effective against a specific disease.

As one might expect, all three of the forms of support are typically implemented with distributions of money. But that doesn't always entail disbursements.

For example, governments sometimes make the functional equivalent of grants by granting tax breaks to the recipient. Such tax relief can be generic – for example, by tying it to research of any sort. Or it can be highly specific – for example, by tying it to research on a specific disease. From the standpoint of an institutional recipient, whether the financial benefit comes in the form of a check or in the form of tax forgiveness may not matter much.

In practice, prizes sometimes take even more diverse forms. For example, in the United States, the development and registration of a drug aimed at so-called tropical disease entitles the developer to a so-called priority review voucher – which consists of a right to expedited regulatory review of another drug. Here's the current list of tropical diseases, which I discussed briefly in the last lecture.

The ability to get that another, more valuable drug on the market faster – thus extending its commercial life – can be extremely valuable to a pharmaceutical firm – and thus provide a powerful incentive to conduct research on tropical diseases.

Because these vouchers are transferrable, we know how valuable. The price has varied, but overall has been high. The least lucrative transfer was the sale of a voucher in 2014 from Biomarin to Sanofi and Regeneron for \$67 million. The most lucrative was the sale in 2015 from United Therapeutics to Abbvie for \$350 million. The going price today seems to be around \$110 million.

Finally, prizes sometimes take nonmonetary forms – honors and public recognition. Here’s an example.

In terms of relative usage, grants are by far the most common of these forms. Next in terms of relative importance is in-house research. Least often used are prizes.

OK. That completes my survey of the systems currently used by governments and private philanthropies to support research and development involving medicines and vaccines. How might we improve these systems? Two variants of that question are especially relevant. How might we make these systems more efficient? And how might we harness or adjust them to increase the production of the kinds of vaccines and medicines that are currently underproduced?

Some help in answering those questions can be gleaned from the academic literature. The relative advantages of the three forms of support for research have received a fair amount of attention from economists and, to a lesser extent, legal scholars. As one might imagine, they don’t all agree. But the following guidelines are relatively uncontroversial.

Conducting Research in house has three main advantages. If, as is typical, the fruits of the research are not patented but instead are made available to the public for free, then in-house research avoids the so-called deadweight loss associated with monopoly pricing of patented products. To review, deadweight loss is the term economists use to describe the social welfare losses that occur when some potential beneficiaries of an innovation are unable to gain access to it because it’s unaffordable.

Now, this advantage is not unalloyed, at least when this approach is used by governments. To pay for the in-house research, the government has to raise taxes, which in turn may cause taxpayers to substitute leisure for work, causing **economic losses**. The severity of that drawback is much debated, but most economists contend that it is smaller than the welfare losses associated with monopoly pricing of patented drugs.

Second, in-house research minimizes rent dissipation – a fancy term for wasteful duplicative research, because the government coordinates the research projects by the scientists it employs and can thus avoid redundancy.

Finally, in-house research can respond flexibly to changes in social needs – for example, the emergence of a pandemic.

In-house research, especially when conducted by governments, does, however, have two disadvantages. First, history tells us that Government officials are prone to errors in determining which projects are (most) socially valuable.

Second, Low salaries and bureaucracy make it difficult for governments to enlist the best researchers.

Grants – currently the most popular form, have a different pattern of advantages and disadvantages, which make them more suitable in some contexts. First, grants avoid wasteful redundancy in a different way -- namely, by targeting financial resources to one or a few recipients and by eliminating the inefficiency of multiple potential recipients making redundant assessments of the social value of particular research projects.

Next, grants, like in-house research, minimize deadweight loss through reliance on income-tax funding instead of monopoly pricing

Last but not least, grants enable correction of the misalignment between the market value of innovations and their social value. This, as should be apparent, is a major issue with respect to neglected diseases and vaccines. As we have seen, the market value of both is well below their social value. Private firms motivated by patents focus primarily on market value; government officials and the leaders of philanthropies can instead select grantees on the basis of the social value of their projects.

Like in-house research, grants do have drawbacks. They tend to incur high administrative costs.

Government officials are prone to errors in determining which projects are (most) socially valuable and in determining which grant applicants are most qualified.

Finally, once they have received their grants, researchers can relax a bit. Slowing down has obvious social costs.

We come finally to prizes, currently the least often used of the systems. Economists point out that, in general, prizes have several advantages.

First, they tend to motivate fast-paced research better than grants. Competition in the quest for the pot of gold fosters hard work.

Second, if the prizes are tied to the demonstrated social value of each goal, they optimize incentives for creativity.

Third, like both in-house research and grants – and unlike patents – prizes minimize deadweight loss through reliance on income-tax funding instead of monopoly pricing.

Next, like grants, prizes enable correction of the misalignment between the market value of innovations and their social value.

Finally, unlike grants, prizes result in disbursement of money only if research is successful – in other words, social value is generated.

On the other side of the ledger, prizes have two of the same disadvantages as grants: high administrative costs; and Government officials are prone to errors in determining which projects are (most) socially valuable.

In addition, prizes can lead to rent dissipation by fostering wasteful duplicative innovation.

With these general guidelines in mind, let's turn to how the current pattern of governmental and philanthropic support could be improved.

The broadest implication of the analysis up to this point is that we should use prizes more often than we currently do. The best known variety of prize – namely, Priority review vouchers -- are fairly crude. They have large social costs and fail to draw research into areas where each dollar and hour would generate the greatest benefits.

Here's possible model that would be much better. An innovator who develops a vaccine or drugs aimed at a neglected disease would have a choice. The innovator could either patent it – or could renounce patenting everywhere in the world and receive instead a prize tied to the social benefit of the invention. How would such tying be achieved? One technique would be for the government to commit to pay the innovator every year for 10 years a certain amount of money for every Disability Adjusted Life Year saved as a result of the distribution and consumption of the vaccine or drug in question. To estimate those DALYs, an independent body would use data generated or verified by the World Health Organization.

The result is that generic firms could begin manufacturing and selling the product immediately. The innovator, instead of impeding the generics, would aid them – by transferring the relevant know how – because the magnitude of the innovator's prize is tied to the number of pills or vials sold and consumed, regardless of who sells them.

If a particular innovation had a large market in developed countries – such as a COVID vaccine – the innovator would likely opt for a patent, rather than a prize. But if it addressed a disease largely confined to poor countries, it would likely opt for the prize.

Many details would have to be worked out to make such a system operational. They are discussed at some length in the book that will accompany this lecture series. But the general idea should be clear enough.

OK, that's the biggest implication of the analysis thus far: greater use of prizes. Here are some others.

As was discussed in the preceding lecture, the pattern of incentives generated by the current patent regime is biased against vaccines, neglected diseases, and breakthrough drugs of all sorts. Governmental and philanthropic support for research could be used to help offset those biases. Recall that this is the current pattern of funding for neglected diseases. It should be

larger. More subtly, the proportion devoted to the development of vaccines should be larger. To be sure, it's already the biggest of the zones, but it should be bigger.

If we zero in on the specific diseases to which the support is directed, we again find a misalignment of money and social welfare. As you know by now, HIV remains a very damaging disease – and thus merits substantial research attention. But TB causes more suffering and death. It's thus peculiar that such a large proportion of the funding goes to HIV.

One radical realignment would adjust the shares of funding to match the global burdens, measured in DALYs, of each disease. You'll recall from Lecture 201 that, at least as of 2018, these were the burdens associated with each of the infectious diseases. If we used the relative size of these numbers to determine where the money went, the shares would be very different from the current pattern.

If a single entity controlled all of the funding, that would be administratively easy. But the money comes from many governments and foundations. This suggests another reform: the donors should get together more often and try to coordinate their programs. For example, had that been done years before the West African outbreak of ebola, one or more of the donors would have stepped forward to fund clinical trials of the Canadian vaccine – and many lives would have been saved.

Here's a more controversial potential adjustment. It concerns where the money comes from, rather than where it goes. The country with the largest gross domestic product is the United States. It's thus appropriate that the largest share of the funding for research on neglected diseases come from the government of the US. But it's hard to defend a disproportion on this scale. The US currently contributes 1/100 of the country's GDP to research on neglected diseases. Suppose that every country in the world did the same. The total amount of funding would increase from \$4 billion per year to \$10 billion.

Alright, that seems sufficient for the time being. As you can see, I hope, adjustments in the pattern of governmental and philanthropic support, especially but not exclusively on neglected diseases, offers many opportunities for offsetting the biases in the current regime and more efficiently mitigating the global health crisis. Additional potential adjustments will be discussed in the seminars that accompany this lecture.

Part B: Sticks

Hello, I'm Terry Fisher. This is the second half of a recorded lecture examining incentive systems other than intellectual property law that could be used to mitigate the global health crisis.

In the first half I discussed carrots – in other words, rewards or benefits that could be used to stimulate research and development in fields where it is currently suboptimal. This half examines sticks – a colloquial term used here to describe possible interventions in the

pharmaceutical field that would force participants to change their practices in ways that would help mitigate the crisis.

Over the years, several regulatory regimes of this general sort have been tried or advocated. Most, in my opinion, have not worked well – or would not work well. But there are two regulatory regimes that merit more attention and adoption. The first can be described as “benefit sharing”; the second as the “social-responsibility index.”

Here’s some background for the first. An important subset of the drugs used to treat infectious diseases in developing countries are derived from plants or other natural materials. Frequently, the developers of such drugs learn of the medicinal potential of the material by studying the traditional practices of indigenous groups.

Here’s a recent example: You will recall, from Lecture 201, that the burden of malaria – measured either by DALY losses or by mortality – is heavily concentrated in tropical countries. In 2003, a group of researchers associated with the Institut de Recherche pour le Développement (IRD), traveled to French Guiana, a country where malaria is endemic but the death rate from the disease is unusually low, to determine which materials the residents had found most effective in treating the disease. Of the 117 people they interviewed, 49 identified themselves as members of indigenous groups (either Paliku or Galibi); 7 were European by background; 14 were Brazilian; one was Hmong; and 46 were Creole. The researchers found that most interviewees employed a combination of traditional and modern medicines to treat malaria, that twenty-seven different plants were used in the traditional medicines, and that, of those plants, *Quassia amara*, sometimes known as “bitterroot,” was used most often and was thought to be the most effective. After returning to France, they and their colleagues were eventually able to identify the crucial active ingredient in the plant. Recognizing the potential economic value of this discovery, they then sought patent protection for the compound they had isolated. A U.S. patent was granted in 2013, and an EPO patent followed in 2015. To date, no commercially viable drug has issued from this line of research. However, if resistance to artemisinin-based malaria treatments continues to grow, such a drug may prove both crucial in fighting the disease and valuable.

In recent years, a growing number of scholars and indigenous leaders have contended that, in situations of this sort, the indigenous group whose traditional knowledge contributed to the development of the drug deserves a share of the benefits of it.

Four arguments are most often advanced in support of this claim. First, the labor that members of the group invested (often over centuries) to develop the knowledge at issue gives them a natural right to a portion of its fruits. Second, allocating groups a share of the benefits will prompt them to take socially beneficial efforts to preserve and commercialize their knowledge. Third, the groups are entitled to a share of the benefits as partial compensation for the brutal manner in which they were treated during the period of colonial conquest and exploitation. Fourth, indigenous groups are concentrated in developing countries – and, within those countries, the members of indigenous groups are more impoverished and suffer from more

educational and social disadvantages than the members of all other races and groups; compensating them for uses of their traditional knowledge is one of the few ways in which we could mitigate their suffering.

For what it's worth, my own view is that the fourth of these arguments is compelling – and on its own is sufficient to justify enhanced protections for traditional knowledge, but I have doubts concerning 1, 2, and 3. For present purposes, less important than my own views concerning the strength of these arguments is their growing influence, not just among activists and indigenous leaders, but among the general populations of both developing and developed countries.

This constellation of arguments has now prompted the governments of several countries to adopt legislation governing permissible exploitation of traditional knowledge. Among the most forceful is a South African statute, which in turn has catalyzed several agreements in which companies have promised to make payments to indigenous groups upon whose knowledge the firms relied.

The same beliefs have also spurred adoption of a growing list of multilateral agreements that attempt to compel member countries to grant and enforce enhanced rights to indigenous groups in situations of this sort. Most of those agreements have not fulfilled the hopes of their sponsors, but one of them is proving powerful. That agreement is the Nagoya Protocol on Access and Benefit Sharing. Its current membership is shown on your screen. Countries marked in blue are parties to the protocol; countries marked in green have signed but not yet ratified it. Conspicuously missing is the United States.

In brief, the Nagoya Protocol works as follows: each member country must adopt a statute to ensure that biological resources and traditional knowledge located within its own territory are accessed only “with the prior and informed consent and approval and involvement of these indigenous and local communities, and [after] mutually agreed terms have been established.” All other countries adhering to the Protocol are obliged to adopt statutes ensuring that such resources and knowledge are “utilized” within their own jurisdictions only if the “domestic access and benefit-sharing legislation or regulatory requirements” adopted by the source countries have been properly observed.

The intensified concern with “benefit-sharing” manifested by national rules (such as the one in South Africa) and the Nagoya Protocol provides a lever that might be used to help reduce the scourge of infectious diseases in developing countries. Before putting it to work, however, I'm going to suggest that the manner in which that concern is most often expressed could and should be adjusted in three ways.

The first adjustment concerns the kinds of “benefits” that ought to be shared. The type that figures most prominently in the academic debates – and in the modest number of agreements between pharmaceutical firms and indigenous groups that have thus far grown out of those debates – is money. Typically, the groups demand and the firms agree to pay a percentage of the revenues or profits that the firms earn from selling the drug at issue. Oddly, as yet it has been rare for the firms to commit to providing members of the group access to the drug

developed in part through their efforts and knowledge. For obvious reasons, my view is that access to the medicine itself should be included in the set of benefits to which an indigenous group is entitled.

The second adjustment concerns delineation of the group that is to receive these benefits. In controversies involving nonpermissive uses of traditional knowledge, a great deal of effort is often devoted to determining which indigenous group was the principal source of the knowledge in question – and is thus entitled to a return on it. It would be both historically more accurate and morally more attractive to abandon the quest for a single ethnic source and instead to extend benefits to all of the residents of the country in question.

The third adjustment is analogous. In controversies of this sort, the plant in question frequently can be found in several countries – and, as a result, indigenous groups in several countries contributed to identification of its medicinal potential. Limiting benefits to the particular country in which the pharmaceutical firm happened to conduct its ethnobotanical research produces morally arbitrary outcomes. Again, it would be more sensible, both from the standpoint of historical accuracy and from the standpoint of fairness, to include among the beneficiaries the residents of all of the countries in question.

To summarize, building upon growing public attitudes concerning the unfairness of unauthorized use of traditional knowledge, we could and should recognize a duty on the part of pharmaceutical firms to ensure that the residents of countries from which the firms extract biological materials or traditional knowledge are provided access to the drugs generated through exploitation of those resources.

The firms might satisfy that obligation in any of three ways: by producing the drugs and then providing them to the countries at issue; by licensing generic manufacturers to produce the drugs and provide them to the countries at issue; or, when technology transfer is required, by participating in joint ventures or apprenticeship programs designed to facilitate local production.

Turning finally to the law, how might such a duty be enforced? The most obvious path would be for the United States to join and implement the Nagoya Protocol, after which it would be more likely for firms and groups negotiating access-and-benefit-sharing agreements to include in them provisions embodying the duty.

An alternative path would leverage public opinion. Such a regime would work as follows: the seller of a drug whose development was based in significant part on biological materials or traditional knowledge found in a developing country would be required to disclose, in a label on all packages containing the drug (a) the fact of such reliance and (b) the arrangements made by the seller to ensure that the residents of developing countries had affordable access to the drug.

The purpose of this duty is probably apparent. As I mentioned in the previous lecture, in the United States and in most other developed countries, popular skepticism concerning the pricing

practices of pharmaceutical firms is growing. A substantial subset of the population believes that the firms should do more to ensure that poor people have access to their products, particularly if doing so would not reduce the availability of the drugs in developed countries. This sentiment is especially strong in circumstances in which the drugs were derived in some way from the countries in which such people live. Awareness of this sentiment and a desire to assuage it would put pressure on the firms to agree to benefit-sharing deals of the sort I have outlined.

To be sure, adoption of such laws would alleviate only a portion of the global health crisis. At most, it would increase the availability and affordability in developing countries of drugs for which incentives are already adequate and that are derived in part from materials and traditional knowledge from such countries. But this modest intervention would save many lives.

The second of the two regulatory regimes that, in my view, merits more attention would have a more comprehensive reach. Here's how it would work: Each pharmaceutical firm would be required to achieve, every year, a ratio, which I will call the social-responsibility index (SRI). The numerator of this index would be the total number of Disability Adjusted Life Years saved as a result of the distribution and consumption of the firm's products during the year. The denominator would be a measure of the firm's size, presumptively its global gross revenues during the year.

Who would manage and enforce such a regime? The simplest approach would be for the US Congress to adopt a statute instituting such a requirement as a condition for the right to distribute pharmaceutical products in the United States. Because, as we have seen, the U.S. market for drugs constitutes roughly 40% of the global market, few firms, regardless of where they are based, could or would refuse to comply. Most likely, Congress would delegate responsibility for implementing the system to an administrative agency.

Like carbon emission permits in Europe, the DALYs in this regime would be both tradeable and bankable. Thus, a firm that, in a given year, failed to earn enough DALYs to meet its target could purchase DALYs from a firm that had a surplus. For example, a firm specializing in so-called "lifestyle" products could buy DALYs from a firm specializing in vaccines or neglected diseases. Alternatively, a firm that, in a given year, earned more than enough DALYs to satisfy its obligations, instead of selling the surplus could apply it to the firm's account for the following year.

Each firm would decide for itself how it could most efficiently comply with its obligation. A firm at risk of missing its target would have (at least) the following options:

It could reduce the prices charged in developing countries for drugs already in its portfolio, thereby increasing the number of persons able to afford the drugs and earning more DALYs.

It could alter the formulations of drugs already in its portfolio so that they could be distributed more easily in developing countries – for example, by making them more heat resistant and thus easier to distribute in areas without reliable “cold chains.”

It could increase its investment in research projects that promise to generate drugs with large health benefits (for example, vaccines for infectious diseases).

It could alter its business-acquisition policies to acquire more “startup” biotechnology companies that have developed products that offer large health benefits.

It could collaborate with governments or NGOs in developing countries to improve the distribution systems for its drugs, thereby getting them into more mouths.

It could, as I mentioned, buy DALYs from other firms better positioned to improve public health.

Finally, it could reduce the prices of some or all of its products, thereby lowering the denominator of its ratio. (For obvious reasons, this is the option the firm is least likely to adopt.)

The system would be introduced gradually. During the first year of its operation, the responsible administrative agency would estimate the total number of DALYs saved throughout the globe during the preceding year as a result of the consumption of all pharmaceutical products, divide that number by an estimate of the global gross revenues of the pharmaceutical industry, and set the mandatory ratio slightly higher. The announcement of the ratio would prompt firms to begin trading DALYs. If the agency’s estimates were roughly accurate, the equilibrium price for DALYs during this first year would be very low. In each subsequent year, the agency would increase the ratio. The equilibrium price for DALYs would rise as a result, and the financial pressure on the pharmaceutical industry as a whole to redirect its aggregate energies toward improvements in global health would increase.

A system of this sort would have many advantages. Most fundamentally, it would address simultaneously what I’ve been describing as the “access problem” (the inability of poor countries and residents to afford the drugs they need) and the “incentive problem” (the inadequacy of the financial motivations to develop new drugs). Most reform proposals address only one of the dimensions of the global health crisis and either leave the other dimension untouched or exacerbate it. By contrast, the proposed index would lead both to lower prices in poor countries for existing drugs and to increased investment in new vaccines and drugs for neglected diseases.

The second major advantage of such a regime is that, like a prize system and unlike a grant system, it would capitalize on the informational advantages of the pharmaceutical firms. Their scientists and executives know better than government officials which of the seven paths I just outlined would generate, in a given year, the biggest health benefits for the least cost. By setting a target but not telling the firms how to hit it, the SRI would enable them to use that

knowledge. The result, of course, will be increased efficiency in alleviation of the global health crisis.

Similar efficiency gains would result from the market in DALYs. The firms best positioned to improve global health would do so – relying partly on funds provided by firms less well situated.

The system would also prompt firms to respond rapidly both to scientific advances and to changes in the landscape of diseases. When scientific breakthroughs exposed new paths to the creation of efficacious drugs or when new diseases (like COVID) appeared, the firms would alter course immediately. They would not need to wait for government officials to detect the changes and to adjust accordingly the pattern of government subsidies for research.

The principal disadvantage of such a system is that, to operate well, it would require an enormous amount of information. To be sure, some of the data necessary to implement it has already been developed for other purposes. For example, as you've seen, the World Health Organization already collects and publicizes annual mortality and morbidity data broken down by country and disease. And agencies in many countries have already developed considerable data concerning the relative clinical effectiveness of the various drugs that target each of those diseases. But, to run the system accurately and fairly, the administrative agency in charge would need to supplement these data with additional information. That would be both difficult and expensive.

This drawback could, however, be reduced by asking universities and other nongovernmental organizations, to augment their ongoing pharmacoeconomic evaluations of drugs. That such data would not only have global social benefits but would also enhance the ability of individual doctors to prescribe the right treatments for their patients might also prompt philanthropies, like the Gates Foundation, to fund increased research of this sort.

So, to review, of the various possible ways in which we might employ regulations, rather than financial incentives, to address the global health crisis, I suggest that two are worth pursuing.

First, we might expand and then leverage the Nagoya Protocol to compel firms that rely on the knowledge of indigenous groups to develop lucrative drugs – to make those drugs available at affordable prices to the residents of developing countries.

Second, we might adopt an entirely new regulatory regime that would require all pharmaceutical firms, as a condition of doing business in the US or in other developed countries, to achieve each year a ratio, the numerator of which would be a measure of the global health benefits secured through distribution and consumption of the firm's products; the denominator of which would be a measure of the firm's size.

Is the second of these options likely to be adopted in the foreseeable future? No. But it would work.