

Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won't Work

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Separating the cost of biopharmaceutical research and development from the final market price of medicines would misalign incentives, raise bureaucratic costs, and limit innovation.

KEY TAKEAWAYS

- Opponents of market-based drug development are working with intergovernmental organizations to replace intellectual property rights with government-managed prizes as the main incentive to drive biopharmaceutical innovation.
- Advocates claim “delinking” drug prices from R&D investments will make innovative medicines far cheaper. But the truth is it would almost surely lead to less new drug development and slower progress in improving human health.
- For prizes to work, governments would have to replace \$180 billion per year in private medical R&D with taxpayer funds—unlikely, given the budget challenges many governments face and the fact many of the benefits would flow to other countries.
- The true value of a new medicine is hard to measure before it is created, so prizes could be underfunded. That would lead to fewer companies taking the risk of investing in expensive R&D, and hence to fewer new medicines.
- Handing over significant control of global biomedical R&D flows to government bodies would be a recipe for inefficiency and for politicizing drug development.
- The current market-based system delivers a tremendous amount of biomedical innovation. Intergovernmental organizations should focus on solutions that improve it, including expanding drug access, rather than promoting flawed concepts like delinkage.

INTRODUCTION

Should the market-based system of drug development, which relies on IP as its primary incentive, be replaced by a system of government-funded prizes?

The answer is an emphatic “yes” according to proponents of the idea, who claim the current market- and patent-based system makes drugs too expensive, while failing to provide cures for those in need who may be unable to pay, such as citizens of developing countries.¹

Under a prize system, the developers of new drugs would no longer receive the investment and legal certainty patents provide to incentivize R&D and innovation, but would be rewarded for the successful development of a new medicine via a cash prize from a government or group of governments.

In return, winning companies would have to surrender their IP to that government or group thereof, allowing generic manufacturers to enter the market immediately. Subsequent competition between generic drug manufacturers, so the theory goes, would allow new drugs to be sold at their marginal cost of manufacture (plus extra for a reasonable rate of profit), enabling access to those in need.

Meanwhile, countries’ governments and international organizations would control and determine which disease areas are rewarded by prizes, supposedly ensuring funding is allocated to health priorities in a fair and transparent fashion.

Delinking the cost of R&D from the final price paid for a medicine, and making governments the planners and funders of drug development, sounds like a simple solution to the complex range of factors that are responsible for poor health care provisions in many nations. Although the idea is constantly promoted at international multilateral organizations by a small coalition of developing countries and nongovernmental organizations (NGOs), no country has yet taken the plunge.

The reason for this hesitance could be that replacing patents with prizes would almost certainly do more harm than good, resulting in a politicized drug development system that misaligns incentives, raises bureaucratic costs, and stifles innovation.

PRIZES AS INNOVATION INCENTIVES

Using prizes to encourage inventors to solve problems is not a new idea. The Longitude Prize, sponsored by the British government, was famously awarded in 1737 to John Harrison for his novel, clock-based solution for determining a ship’s longitude. Prizes were also offered in Napoleonic France for a functional water turbine, and for a method of preserving food for the army: the precursor of the now ubiquitous tin can.

Innovation prizes fell out of academic and political fashion for most of the 20th century (with the exception of the technologically backward Soviet Union), as patents and other forms of IP rights prevailed as the main driver of technological innovation. This move away from innovation prizes toward today’s market-based system of innovation reward was hardly surprising given the deep structural problems with prizes, as documented by economic historian Dr. Zorina Khan in her 2015 analysis of dozens of 19th-century innovation prizes administered in Britain, France, and the United States.² As Khan concluded, “History indicates that the evolution of the institution of innovation prizes over the past three centuries serves as a cautionary tale rather than a success story.”³

Nevertheless, since the early 2000s there has been a resurgence of academic and political interest in replacing intellectual property rights with prizes, particularly within the field of drug development. Proponents of prizes see two fundamental problems with the current system of drug development, which they believe could be solved by government-funded prizes.

First, the intellectual property system's mechanism for encouraging innovation—granting patents and an attendant temporary period of market exclusivity to inventors—creates what economists call “deadweight losses.” Put simply, patents theoretically enable their holders to exploit their market monopoly by inflating prices many multiples beyond the marginal cost of production. Under this view, this leads to significant welfare losses to society: Patients who may be unable to pay are prevented from accessing the new medicine, while those who do have access are forced to spend money on expensive drugs rather than on other items within the wider economy, thus creating economic distortions. But while patents may harm short-term allocation efficiency, they are critical to dynamic efficiency—the development of new products and services—and the economic literature is clear that the benefits of dynamic efficiency are vastly larger than the modest allocation efficiency losses.⁴

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Second, delinkage proponents assert that the IP system misdirects innovation activity, leaving it focused mainly on disease areas that affect large patient populations in well-to-do countries at the expense of citizens in developing nations. But this is wrong. It's not that the IP system fundamentally misdirects innovation activity, it's that there are market failures in drug development related to some markets that are too small, from diseases that either only affect a small number of patients or are prevalent in nations where incomes are so low people cannot afford to spend very much on medicines.

Nevertheless, delinkage proposals have emerged worldwide. In the United States, Senator Bernie Sanders (D-VT), as part of his campaign to become the 2020 Democratic presidential nominee, has called for the creation of a Medical Innovation Prize Fund that would launch a prize fund equal to 0.55 percent of U.S. gross domestic product (GDP), an amount greater than \$80 billion per year, with the federal government supplying half the fund and private health insurance companies the other half.⁵ Nobel Prize-winning economist Joseph Stiglitz has backed prizes, as has U.S. economist Dean Baker of the Center for Economic and Policy Research, who has written that “a prize system would have enormous advantages over the current [life-sciences innovation] system.”⁶ At the international level, a small coalition of NGOs and countries (including Brazil, China, Egypt, India, Indonesia, and South Africa) have for many years tried to get delinkage written into international law by pushing it at rule-setting intergovernmental organizations such as the World Health Organization (WHO) and the United Nations (UN) Human Rights Council.⁷ For these countries, it's a clear opportunity for them to convince developed nations to spend money on drug development (through prizes) to address diseases in their nations, and to also lower drug prices for them.

Thanks to the efforts of this coalition, delinkage featured in a 2017 WHO resolution on cancer and the 2018 declarations for UN High-Level Meetings on Tuberculosis and Non-Communicable Diseases.⁸ The 2016 UN High-Level Panel on Access to Medicines mentioned delinkage 32 times, and even included a recommendation for a binding R&D Treaty.⁹

More recently, delinkage was adopted in 2019 by the UN Human Rights Council's agenda on access to medicines, while in July 2019, delegates in New York considered a range of delinkage provisions in the Political Declaration for the UN High-Level Meeting on Universal Health Coverage.¹⁰

There is clearly a great deal of political and diplomatic energy being expended on making delinkage a policy reality. But is this effort appropriate and worth it?

WEAKNESSES OF THE DELINKAGE APPROACH

Prizes have a place, but as the following sections argue, there are many weaknesses with a delinkage approach that would make prizes the primary mechanism for incentivizing global life-sciences innovation.

The first and most significant is that it is extremely unlikely governments would truly adequately fund such prizes as the primary mechanism for underpinning global life-sciences innovation. If anything, a pure prize system would likely stimulate more free-riding by nations, and thus actually exacerbate underinvestment.

The second is a prize approach would be unlikely to engender the risk-intensive innovative activity necessary to develop new medicines, and certainly not in comparison with a global life-sciences innovation system that is generally working effectively today toward new drug discovery.

Third, there are significant administrative, mechanical, and operational challenges associated with administering prize systems that would likely introduce inefficiency and politicization.

While the use of prizes can make important and meaningful contributions to helping address some global health care challenges, prizes cannot represent the “be all end all” approach to underpinning the global biomedical innovation system or tackling difficult public health challenges.

Fourth, while there are certainly myriad challenges in the provision of global health care, other approaches can more effectively help solve many of these problems.

Put simply, while the use of prizes can make important and meaningful contributions to addressing some of these challenges, prizes cannot represent the “be all end all” approach to underpinning the global biomedical innovation system or tackling difficult public health challenges.

Governments Would Be Unlikely to Adequately Fund a Delinkage System

Governments worldwide would need to come up with nearly \$200 billion a year to comprehensively replace the current market- and patent-based system with a prize system. As noted, in America, U.S. Senator Bernie Sanders’s plan calls for an \$80-billion-a-year prize fund. As Dean Baker has written, “The [U.S.] government already spends more than \$30 billion a year to finance biomedical research through the National Institutes of Health. It would probably be necessary to increase this amount by \$50–\$60 billion a year in order to replace the funding currently supported through patent monopolies.”¹¹ In fact, drug companies invest in excess of \$180 billion per year in R&D related to drug development.¹² But even accepting Baker’s lower number, in a political and fiscal environment wherein the U.S. Congress cannot even index the gas tax to inflation to pay for badly needed roads and bridges (even with gas prices close to their lowest levels in nearly a generation), the chances Congress would be willing to appropriate the funds needed for any of these proposals is close to zero.¹³

In fact, the U.S. Congress’s modus operandi is to enact policies to shift public-sector costs to the private sector through mandates, not to take away private-sector costs with public-sector spending. And with government balance sheets tight everywhere (government debt as a share of GDP in Europe reached an all-time high in the mid-2010s, for instance), it is equally unlikely governments in other countries would be willing to allocate the sums needed. Given the general unwillingness of the public or lawmakers to support higher taxes or spending (in the United States or elsewhere), such proposals to replace private revenue with government spending would almost certainly lead to reduced overall investment (combined private and public) in biomedical innovation.

Moreover, if the United States did not step up to the plate, the effort would be stillborn from the start. That is because the United States currently accounts for just under half of global biomedical R&D investment.¹⁴ And even that figure belies how significant U.S. contributions have been to biomedical R&D

in recent years, with one study finding that the United States has been the world's largest global funder of biomedical R&D investment over the past two decades, with a share some analyses suggest reached as high as 70 to 80 percent over that time period.¹⁵ A prize-based system would largely replace U.S. private capital with U.S. taxpayers as the leading funder of global biomedical innovation, and make the resulting IP and innovation a freely available global public good—a key reason why so many developing countries favor the scheme.

Indeed, in a prize system, innovators would hold few cards. Their R&D costs would already be sunk at the time of prize disbursement, and to qualify for the prize, details of the invention would have to be disclosed to the government (or an international agency) at a level of detail far beyond that currently required by the patent system. Thus, the main advantage of a delinkage system for countries such as China—which as part of its “Made in China 2025” plan has targeted building the largest generic drug industry in the world—would be to obtain free IP for its budding industry, the lion's share of which would be funded by prizes paid for by taxpayers from developed nations.¹⁶ In other words, what delinkage proponents really want is for taxpayers in developed countries (principally the United States) to finance the bulk of global biomedical research and innovation, which would then become freely available for generic drug manufacturers to immediately copy at marginal cost and then export back to the countries paying the most for the prizes. As such, a prize model would almost surely mean large trade deficits in biopharmaceutical products for developed nations.

Delinkage would further advance proponents' fundamental goal of undermining a global IP system they abhor, as reflected in reports such as Dean Baker's “Is Intellectual Property the Root of All Evil? Patents, Copyrights, and Inequality.”¹⁷ Or, as Baker wrote with Joseph Stiglitz and Arjun Jayadev in a *Project Syndicate* article, “The IP standards advanced countries favor typically are designed not to maximize innovation and scientific progress, but to maximize the profits of big pharmaceutical companies and others able to sway trade negotiations.”¹⁸ In this way, delinkage isn't much different from the compulsory licensing policies they've advocated for several middle-income countries—including Brazil, Colombia, India, Indonesia, Malaysia, and Thailand—to issue on patents for innovative medicines over the past 20 years. Whether through delinkage or compulsory licenses, advocates want to weaken global IP rights, and force divulgence of IP at prices that would usually be far below market (if not outright free).

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But returning to the underlying underinvestment and free-riding challenge; this challenge isn't just theoretical, it's already a reality. That's because a drug development system in which prizes replaced intellectual property would have very limited impact if only one country chose to adopt it. Companies would be discouraged from applying for prizes in that country because unless the award were large enough to cover what otherwise would have been their global revenues from development of a patent-protected drug, they would not apply. Instead, they would focus their efforts elsewhere on countries that retained robust standards of IP protection.

This explains why proponents of a prize-based delinkage system have also been pushing for a global and legally binding Medical R&D Treaty (MRDT). In its most complete form, such a treaty would place R&D spending obligations on all countries, and centrally direct public funding toward disease areas the treaty secretariat considers a priority. Under such a treaty, intellectual property rights would gradually be replaced by delinkage mechanisms such as prizes.

Various efforts have been made to promote this treaty at WHO over the years, without success. Perhaps this is because the idea, while appearing simple on the surface, would give rise to all manner of complexities and perverse incentives. For instance, in his analysis of the feasibility of a global medical R&D treaty, Oxford University's Andrew Farlow has raised several pertinent questions, including:

How would it be possible to compel countries to meet their R&D funding obligations and prevent free-riding, particularly in the face of historic government underinvestment in R&D? How would the treaty secretariat be able to properly value medical inventions, and accurately measure R&D spending flows? How could politics be removed from the determination of R&D spending priorities, and how could countries be prevented from gaming the system? These are complex issues which an R&D treaty would struggle to overcome.¹⁹

Answers to such questions thus far have been clearly wanting. As part of WHO's push to increase investment in global health R&D, WHO member states in 2013 agreed to establish a Global Observatory on R&D to monitor spending and set priorities, and also to undertake a number of global health R&D demonstration projects. At the World Health Assembly in Geneva in May 2017, Marie-Paule Kieny, WHO assistant director-general for Health Systems and Innovation, remarked on the chronic underfunding of this "critically important" agenda, noting that one of the demonstration projects (on a nano-based malaria drug delivery system) is being cancelled unfinished due to a lack of funding.²⁰



WHO member states have failed to honor very modest commitments to global health R&D.

According to WHO, \$85 million was needed between 2014 and 2017 to complete these projects, yet by the end of 2016, only \$11 million had been committed by only 10 WHO member states, leaving a shortfall of \$73 million.²¹ WHO's website on the R&D demonstration projects has not had any significant updates in several years.²²

A \$73 million shortfall is one thing; a roughly \$180 billion shortfall would be another. Put simply, if WHO members cannot agree among themselves to provide the relatively small amounts of funding for even this modest agenda, it seems highly unlikely they will stump up the hundreds of billions of dollars required to implement delinkage.

We can see the expected result of such a treaty by looking at national government commitments to invest in clean energy R&D. As important as biopharmaceutical innovation is, today most policymakers and pundits would agree that clean energy innovation is even more important. That is why, in 2015, 24 mostly developed nations (plus the European Union) signed up to Mission Innovation, an effort to double their public funding of clean energy R&D. However, as the Information Technology and Innovation Foundation has shown, only two nations (Finland and Norway) are on track to make the requisite investments by this year, with nine countries actually investing less in 2019 than they did in 2015.²³

The Current System Has Produced a Tremendous Amount of Life-Sciences Innovation

The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.²⁴ And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that noncommunicable diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities in developing countries.²⁵ Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.²⁶ Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.²⁷ To develop treatments or cures for these conditions, novel biomedical innovation will be needed from everywhere.

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Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over \$1.36 trillion in R&D in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach \$181 billion by 2022.²⁸ In no small part due to that investment, 943 new active substances have been introduced globally over the prior 25 years.²⁹ The U.S. Food and Drug Administration (FDA) has approved more than 500 new medicines since 2000 alone. And these medicines are getting to more individuals: Global medicine use in 2020 will reach 4.5 trillion doses, up 24 percent from 2015.³⁰ Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.³¹ In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).³²

And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the world’s most intractable diseases, including cancer and Alzheimer’s.³³ Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved 41 new medicines (at that point, the most since 1996) many of which were first-in-class medicines.³⁴ In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.³⁵

Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through enhanced clinical efficacy (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, or better treatment for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures.

For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients' liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.³⁶

“If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the *Financial Times*. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”³⁷ Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.³⁸ As Geoffrey Dusheiko and Charles Gore write in *The Lancet*, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”³⁹

As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because ... without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”⁴⁰ Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary to induce companies to invest in researching new chemical entities.”⁴¹ This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investments.⁴² Indeed, it’s the ability to recoup fixed costs, not just marginal costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, there would be no new drugs developed, just as there would be no new products developed in any industry.

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Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.⁴³ A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to \$2.8 billion.⁴⁴ Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of \$1.7 billion to \$3.2 billion.⁴⁵ IP rights—

including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the confidence to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.⁴⁶

Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.⁴⁷ As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, in the global public’s long-term interests. Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”⁴⁸

Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”⁴⁹ For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.⁵⁰ In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—withstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

Mechanical Challenges With Prize Systems

Beyond the reality that governments simply aren’t going to invest the hundreds of billions of dollars required to fund a prize system—and that this would mean less drug innovation—the organization and management of prize systems is confronted with numerous challenges that call into question such an approach’s capacity to represent a wholesale replacement of the current biomedical innovation system. These include challenges such as the introduction of new costs and inefficiencies, difficulties in evaluating how much an innovative drug would be worth, the vulnerability of prize systems to political influence, and the risk that prize systems could sacrifice serendipity.

New Costs and Inefficiencies

Drug development prize committees would need to decide what kinds of discoveries should be eligible for prizes—and their market value—before any actual R&D begins. This kind of centralized planning would inefficiently require prize agencies to avail themselves of technological expertise and market foresight equal to that of the global pharmaceutical industry.

The assumption made by advocates of government-run prizes that they would have minor deadweight costs compared with the (temporary) “monopolies” created by the IP system has been called into question by many. For instance, as Daniel Spulber, Professor of International Business at the Kellogg School of Management, Northwestern University, and an award-winning expert on innovation policy, notes, “Prize

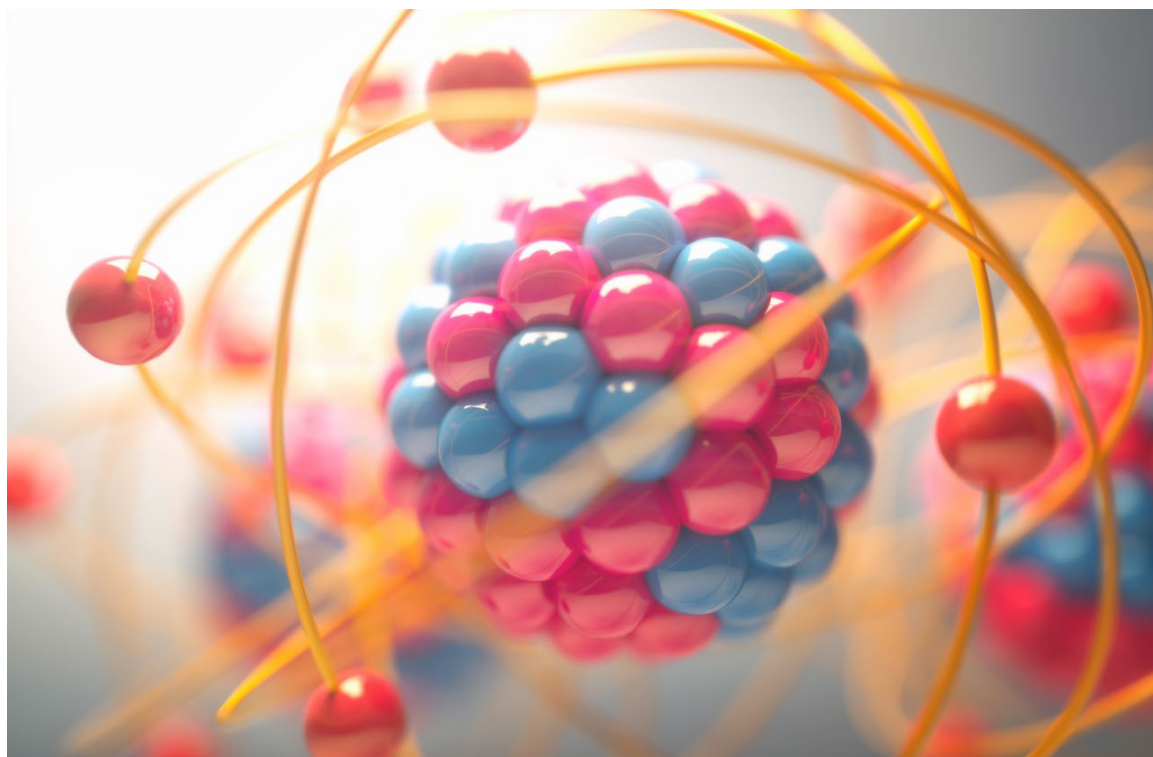
advocates tend to assume that the government would expend no resources in administering the prize system, including managing contests, selecting winners, and allocating inventions.” However, as he continues, “The government could not replace the entire patent system with contests and awards in every area of science and technology covered by the patent system without incurring astronomical administrative costs.”⁵¹

There would be other costs as well. As noted, it’s expected the global pharmaceutical industry will invest \$181 billion annually in R&D by 2022.⁵² This is privately raised capital which governments moving toward a delinkage drug development system would have to replace through taxation. Replacing the money raised through prices with money raised through taxes would likely lead to some distortions and reduced economic growth. As Spulber observes, “Most prize advocates assume free money. In fact, the government raises money for the prizes through taxation, which causes economic distortions that involve significant deadweight losses. The deadweight welfare losses resulting from a government prize system are likely to substantially exceed any such losses from competitive markets—replacing prices with prizes would lower social welfare.”⁵³

Evaluating How Much a Drug Is Worth

A major—and as yet unresolved—problem with delinkage in general, and prizes in particular, is governments find it very hard to determine accurately the true economic and social value of an invention. In the past, this failure has resulted in government prize committees undervaluing inventions.

“There is an inherent conservative bias in the prizes granted by administrative and quasi-judicial bodies. Munificence is a rare committee virtue,” wrote Harvard economist FM Scherer.⁵⁴ For instance, under the U.S. Atomic Energy Act of 1946, military uses of atomic energy were made ineligible for patent protection. Instead, monetary awards were disbursed to inventors by a specialist government committee. Professor Scherer has observed that atomic-energy innovators—including inventors of early methods of producing plutonium and basic liquid rocket engines—were awarded sums far below what they could have earned had their inventions been patented.



Early atomic energy innovators lost out from being ineligible for patents.

Undervaluing a new medicine in a prize system matters for future innovation. In a situation wherein innovators know their inventions are unlikely to be properly rewarded, they are less likely to invest in R&D and compete for the prize. With the cost of drug development approaching \$3 billion, innovators—and the venture capitalists on which many biopharmaceutical start-ups rely—need to be certain the potential rewards are worth the risk of this capital.⁵⁵ If there is a real prospect of under-reward, innovators could direct their capital away from medicines and toward sectors in which the expected rate of return would be higher.

Some prize advocates have suggested the problems of under-valuation and expropriation could be avoided by allocating a fixed amount to prize agencies and legally requiring them to disburse all their monies according to pre-set rules and criteria.⁵⁶ But this would not prevent governments from underfunding the prize committee in the first place. Another challenge is that even for a prize winner, there would still be no guarantee the prize amount would sufficiently cover costs of development. Moreover, the prize would have to be large enough to account for the expected value of winning, which would be low given not only the technical challenges of successfully developing a drug that could be approved by governments, but that is ahead of all other competitors globally that would also hope to win the prize. The problem of under-rewarding invention is likely to be a fatal flaw in a prize system that could seriously disrupt innovation. In turn, that would harm society, as fewer new medicines would be developed.

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In her study of the history of prizes, economic historian Khan reiterates these last two mechanical challenges discussed. As she writes, “A systematic assessment of the role of incentives for innovation in the nineteenth century highlights the advantages of market-oriented policies which economize on information, especially in the decentralized determination of prize, value, and ‘winners.’ Market mechanisms also bypassed many of the high transactions costs attendant on negotiating, monitoring, and contracting with applicants and winners.”⁵⁷

Vulnerability to Political Influence

Opponents of the market-based system of drug development decry funds spent by the pharmaceutical industry on lobbying governments to ensure a favorable policy regime, such as a reasonably strong patent system and a global trading system that respects IP rights. But a prize system would hand significant new discretionary powers to government officials, who would be the ultimate arbiters of whether a new medicine wins a prize. This would create major new incentives for rent seeking and crony capitalism, and potentially result in the wholesale politicization of drug development.



John Harrison's lack of social standing may explain why it took him 47 years to receive compensation for his prize-winning Longitude idea.

Khan observes that some of the earliest (and most famous) prizes were tainted by politics. For instance, John Harrison, a poor, uneducated English clockmaker, is credited as the inventor of the method of determining a ship's longitude at sea, yet the British government's Longitude Prize was never officially won, and it took him 47 years to receive compensation for his invention—which eventually came from a different source. His lack of social standing, difficulties in dealing with the prize board, and political interference from better-connected competitors may have been responsible for his maltreatment, according to Khan. In fact, statistical analysis of dozens of prizes granted to British inventors in the 19th century shows that those with an elite, Oxbridge education were twice as likely to win awards. Technical qualifications or accomplishments had little bearing on the likelihood of prize success.

The problem of under-rewarding invention is likely to be a fatal flaw in a prize system that could seriously disrupt innovation. In turn, that would harm society, as fewer new medicines would be developed.

To be sure, the experience of the United Kingdom in the 19th century does not mean any new system would be subject to the same distortions. But, to be sure, under a prize-based system, there is a risk that political factors, rather than clinical demand, would influence decision-making. Political connections and lobbying could both play a role in securing a prize, while elected officials may attempt to influence R&D spending by government agencies.

Patents, on the other hand, are a nonarbitrary form of innovation incentive. Government merely sets the framework of patent law, under which all inventors and companies compete.

Sacrificing Serendipity

A prize system would reward innovators that arrive at a specific biomedical innovation. But one of the more subtle problems with a prize system is that it would not facilitate serendipitous discoveries, such as new uses for existing drugs. "Serendipity" in drug discovery refers to the discovery of something while looking for something else.⁵⁸ Serendipity has played a prominent part in the discovery of many drugs and medical treatments, including vaccination, insulin to treat diabetes, penicillin, quinine, and Viagra.⁵⁹ Similarly, in

has paper, “The role of serendipity in drug discovery,” Dr. Thomas A. Man analyzes a half-dozen cases of serendipity contributing to important advances in pharmacological treatment in psychiatry alone.⁶⁰ Likewise, as Philip Rea, Mark Pauly, and Lawton Burns write in their book, *Managing Discovery in the Life-sciences: Harnessing Creativity to Drive Biomedical Innovation*, a key facet of biomedical innovation is serendipity.⁶¹ As Burns et al. explain, “The serendipity part is, first you’re doing experiments, you have a hypothesis in mind, you are looking for some expected findings, and then they don’t turn out. [So, the researcher thinks], ‘Those were some unusual findings which I didn’t expect. What do those mean?’ And then they pursue a new line of inquiry or investigation, which leads to some really fundamental discoveries.”⁶² But if a prize system means an innovator will only be rewarded for a particular invention, it would likely undermine the ability of serendipitous research discoveries contributing to the life-sciences innovation process.

TACKLING GLOBAL HEALTH CARE CHALLENGES

To be sure, much more needs to be done to tackle global health care challenges, including expanding the availability of health care services in developing countries, and finding cures or treatments to diseases that affect citizens in developing countries in particular. But while the narrow and targeted use of prizes could certainly augment these efforts, it doesn’t merit a wholesale embrace of a prize-based system.

Increasing Investment in and Access to Health Care Coverage

If prizes can outperform the intellectual property system in delivering innovative medicines across all disease areas with minimal deadweight costs to the wider economy, as its proponents claim, the question is why no country has yet made the switch.

“The obvious answer is that the benefits from eliminating drug patents would be much smaller than predicted by the prize literature, and there might not be any benefits at all,” argues Benjamin Roin of the MIT Sloan School of Management.⁶³ Professor Roin points out that patents are frequently mischaracterized as giving the right to monopoly profits, effectively forcing consumers to pay the full monopoly price of medicines. In reality, patents grant no such right, merely giving the right to exclude others from copying a specific patented product, and even then only for a limited period of time. Moreover, while patents do provide temporary exclusive rights, there are usually many substitutes and alternatives to a patented product that make market monopoly very rare and always, if they exist, temporary. Markets for products covered by IP are often intensely competitive, because there are usually many substitutes and alternatives. This is particularly true of medicine.

If prizes can outperform the IP system in delivering innovative medicines across all disease areas with minimal deadweight costs to the wider economy, as its proponents claim, the question is why no country has yet made the switch.

Further, due to various government interventions into the market for medicines, most notably national health insurance systems, consumers almost never pay the full monopoly price of a patented medicine. Health insurance coverage, whether publicly or privately funded, means patented medicines are made available to end consumers at lower costs, while payers and innovators negotiate to reach mutually acceptable pricing that balances accessibility with rewarding the value of innovation.

What about lower- and middle-income countries, where public health coverage is often minimal and most health spending comes out of individuals’ pockets? Here, the real problem is not so much drug pricing, but a lack of coverage. For instance, a survey of 33 low-income countries found that out-of-pocket payments represent more than half of total health expenditures.⁶⁴ As a result, many people struggle to afford even cheap essential medicines that have been off-patent for decades, let alone far more expensive physician fees and hospital costs.

And while delinkage proponents assert the high cost of medicines as key a rationale for their proposals, the reality is the far bigger challenge in developing nations is with access to health care services in general, and access to needed medicines in particular. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.⁶⁵ A 2014 WHO study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.⁶⁶ More than 80 countries fail to meet the basic threshold of 23 skilled health professionals per 10,000 people.⁶⁷

In other instances, individuals lack access to essential medicines, with their cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.⁶⁸ A 2009 survey of 36 countries found that 15 common generic medicines listed on the WHO Essential Medicines list were frequently unavailable in either the public or private sectors, with regional availability ranging from 29 percent in Africa to 54 percent in the Americas.⁶⁹

Again, cost remains only part of the problem. Indeed, the vast majority of drugs—at least 90 percent—currently on WHO’s Essential Medicines list are off-patent.⁷⁰ Yet essential generic medicines are frequently unavailable or unaffordable.⁷¹ The problem, in much larger part, stems from countries’ underdeveloped health systems and many people living in rural areas, far from care. In fact, approximately 70 percent of the world’s poor live in rural areas, where it becomes very difficult to cost-effectively deliver health care services and supplies. Improving health coverage and health systems is the answer to better health care in these countries. And of course, boosting productivity and per capita incomes in these nations, in large part through helping all industries—traded and non-traded alike—become more productive is the ultimate solution.⁷²

Developing Treatments for Tropical and Rare Diseases

To be sure, because patent holders accrue rewards from innovating in medical areas where there is high consumer ability to pay, the focus logically is on those areas. Diseases for which there is still significant need for treatment but where consumers are less able to pay tend to get under-researched. This report is not implying that, for some diseases not currently receiving adequate investment because the market for the drug is too small to support the R&D needed to develop a drug, a prize system could not be tried as an experiment. Clearly in these cases—diseases wherein the affected population is too small or too poor to generate sales needed to offset the costs of risky R&D—some role for government other than relying on market forces only is needed. Countries have dealt with this in different ways. In some nations, including the United States, drug developers can qualify for a tax credit for “orphan drugs”: drugs that address diseases with only a small number of patients. There is no reason a pilot program for prizes for drug development for other similar diseases should not be tried. But that is very different from applying that model to areas where market forces already lead to effective drug development.

One example of this is Neglected Tropical Diseases (NTDs), a group of parasitic, bacterial, and viral infectious diseases that primarily affect the most impoverished and vulnerable populations in the world and, as such, have received scant attention until the past decade.⁷³ Examples of NTDs are diseases such as schistosomiasis and Buruli ulcer, which, despite afflicting millions of individuals in the poorest countries, have a dearth of viable treatments and cures. More than 1 billion people—one-sixth of the world’s population—are infected with 1 or more NTDs, and an additional 2 billion are at risk, while each year, about 185,000 people die as a result of NTDs.⁷⁴

Governments, foundations, and private-sector actors have responded by mobilizing unprecedented levels of resources and expertise to address neglected tropical-disease R&D, often through PDPs, nonprofit organizations that bring together stakeholders from the private and public sectors to research, develop, and support access to new health technologies that target diseases disproportionately affecting citizens in

developing countries.⁷⁵ PDPs have been created for a range of diseases, from tuberculosis and malaria to meningitis and dengue fever. But importantly, many of these PDPs work within the existing international framework of IP rights protection, for example, granting royalty-free licenses for use in low-income countries or agreeing to share IP among research partners in a way that promotes access to eventual products.⁷⁶ Innovative life-sciences companies are also contributing to the challenge. In fact, in 2017, innovative biopharmaceutical companies were the second-largest funder of R&D for neglected diseases in the world, ahead of all philanthropic organizations and nations except the United States.⁷⁷ This is another way in which the effectiveness of the current system generates resources that can be reinvested in global health challenges.

Prizes can and should play a role in providing an additional incentive to stimulate innovation in such areas as rare or neglected tropical diseases.

To be sure, prizes can and should play a role in providing an additional incentive to stimulate innovation for these types of diseases. For instance, the annual NTD Innovation Prize, a project of American Leprosy Missions, identifies and supports innovators with creative ideas to solve some of the most challenging issues posed by NTDs across the globe, awarding a \$25,000 cash prize annually.⁷⁸ Other prizes of note include the European Commission prizes on better use of antibiotics and vaccines, and the U.K. Longitude Prize for addressing antimicrobial resistance. In fact, a 2017 report by the Pugatch Consilium for the International Federation of Pharmaceutical Manufacturers and Associations, *Charting the Course to Sustainable Innovation in Neglected Diseases Globally: An “Optimization Model” for the Use of R&D Incentives*, provides a comprehensive list of implemented and proposed R&D prizes aimed at incentivizing biomedical research.⁷⁹ But as the report notes, “Biopharmaceutical R&D prizes are mainly intended as voluntary schemes that complement market-based rewards and allow winners to retain the IP rights over their products.”⁸⁰ And as the report concludes, “The utility of R&D prizes for the development of actual medicines and other therapies remains unproven. Few hard results have issued from biomedical prizes.”⁸¹

Delinkage Is Not the Answer

In the end, focusing on a global R&D treaty and replacing intellectual property rights with prizes would be a major distraction from more-practical activities that could deliver results now. “There are plenty of current innovations, medical and otherwise, that are woefully underused, a situation which will not be resolved by a medical R&D Treaty,” says Oxford’s Farlow.

“There are multiple ways to achieve impact with global health innovations, without complicating, distracting and delaying us from this goal... Given all the recent initiatives to invest in global health, the real challenge is to turn all of that investment and activity into things that will improve the lives of the poor immediately. We should favour the simple, direct, and immediate over the grandiose and bureaucratic, as typified by the MRDT,” he writes.⁸²

Activist NGOs are busy at the United Nations trying to write delinkage into international law, at the cost of tremendous political and diplomatic energy. Yet member states of the World Health Organization are currently struggling to properly finance modest R&D demonstration projects and a Global Observatory to track R&D flows. It’s unlikely they will reach consensus on the endlessly complex and continually evolving field of biomedical R&D without handing an enormous amount of discretionary power to a new, centralized global R&D body.

Such a top-down body would be open to politicization and rent seeking, and by replacing patents with prizes and other delinkage mechanisms, it would significantly weaken incentives that have been responsible for the vast panoply of medicines and treatments on which physicians and patients can draw today.

The planners in this body would need all the knowledge of the entrepreneurs and managers currently engaged in biopharmaceutical innovation, as well as have the capacity to accurately estimate market prices for all new required medicines. Getting this wrong would result in private-sector investors walking away from pharmaceutical R&D and committing their capital to economically and politically safer but less socially useful areas.

Most sensible governments realize delinkage won't work. This is why its proponents are targeting international organizations rather than convincing individual countries to commit the funds and effort to their agenda.

No country has yet taken this leap into the unknown, not least because in developed nations health insurance and other forms of medical coverage already insulate patients from most of the cost of medicines—and indeed all health care. Most sensible governments realize this, which is why proponents of delinkage target international organizations (and developing nations) to advance their agenda rather than persuade individual countries to commit the funds and effort to their inefficient schemes.

The current market-based system of drug development allows for experimentation and competition within and between therapeutic classes. Thousands of promising leads enter the drug development pathway, but only a few make it through the rigorous process of clinical trials. The cost of failures and the risks are borne almost entirely by the private sector at no cost to taxpayers. “There is nothing wrong with awarding prizes. But replacing markets for medicines with government prizes would destroy one of the most innovative areas in the economy, and stop the endless source of life-saving medicines,” notes Professor Spulber.

WHO member states should beware throwing the baby out with the bathwater.

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