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The Health Impact Fund: A new paradigm in pharmaceutical innovation*

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Summary. We have learned that the speed and quality of innovation can be substantially raised by granting innovators temporary monopolies, such as patents or copyrights, which enable them to profit by charging high mark-ups. But such temporary monopolies promote innovation at the expense of diffusion. In other words, the better we innovate, or incentivize innovation, the more we pay a price in terms of the diffusion of those same innovations. Rewarding innovation in the wrong way in the areas of pharmaceuticals, food production, and environmental innovation has especially serious effects on the poor. The current system does poorly with regard to access targeting and cost-effectiveness. The Health Impact Fund proposes a new way of paying for pharmaceutical innovation by incentivizing the development and delivery of new drugs through pay-for-performance mechanisms. Furthermore, the same idea could be applied to agricultural and environmental innovation. [**Contrib Sci** 10:23-28 (2014)]

Rules governing the development and distribution of new medicines

Human progress has two interlinked components. One is innovation—the creation, invention and discovery of new knowledge—and the other is diffusion—the dissemination or uptake of knowledge. Insofar as either of these two components is stifled, humanity's progress is impeded.

We have learned that the speed and quality of innovation can be substantially raised by granting innovators temporary monopolies, such as patents or copyrights, which enable them to profit by charging high mark-ups. But such temporary monopolies facilitate innovation at the expense of diffusion. In other words, the better we innovate, or promote innovation, the more we pay a price in terms of the diffusion of those same innovations.

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Nowhere is this situation more serious than in the area of medicines or pharmaceuticals. At present, pharmaceutical innovation is rewarded through product patents (vs. process) of minimally 20-year duration. The World Trade Organization (WTO), since its founding in the mid-1990s—and under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement—has required all of the WTO member states to introduce these 20-years patent. Just to give an idea of what a difference the institutionalization of these patents makes, before TRIPS came into effect, India, for example, had 7-year process patents. This allowed pharmaceutical innovators to protect a particular process of producing a drug but they could not protect the molecule as such. And so generic companies were able to invent around the patent, and make inexpensive copies of these patented drugs for the benefit of patients in India and across the world.

Disadvantages of the current system: It does poorly in regard to access. Universal access is seriously undermined, even in affluent countries, during the time the product is under patent by large mark-ups. The profit maximizing monopoly price tends to be 50 times or even 100 times higher than the cost of production. The cost of producing pharmaceuticals is low once their production has been established, because additional units are inexpensive. However, they are sold at very high prices because innovators want to take full advantage of their temporary monopoly. And once the patent period has expired, there are inadequate incentives for the competent provision of generics to patients who are poor or hard-to-reach.

Given the high inequalities in income around the world, the profit maximizing price for pharmaceutical innovators will be high. For them, it makes more sense to sell at prices so that only the top 15 % of the human population can buy the product. It is not worth lowering the price down to the level where more people can buy it, because innovators lose more money on the smaller mark-up than they gain by selling more product to those willing and able to buy at lower prices.

It does poorly in regard to targeting. Focused innovation is distorted by huge economic inequalities, which steer innovators away from diseases predominantly affecting the poor and also excessively reward the development of new "me-too" and maintenance drugs (me-too drugs are drugs with a structure very similar to already known drugs, but with minor differences). Pharmaceutical innovators can make the most money by producing drugs against diseases that affect the rich, affluent or well-insured people; they cannot make

Table 1. Advisory Board of the Health Impact Fund

Kenneth J. Arrow	Nobel Prize in Economics; Professor Emeritus, Stanford University
Noam Chomsky	Institute Professor Emeritus, MIT
John J. DeGioia	President, Georgetown University
Ruth Faden	Director, Berman Institute of Bioethics, Johns Hopkins University
Paul Farmer	Harvard Medical School; co-founder, Partners in Health
Robert Gallo	Institute of Human Virology
David Haslam	Chair, UK National Institute of Health and Clinical Excellence
Paul Martin	Former Prime Minister of Canada
Christopher Murray	Director, University of Washington Institute for Health Metrics and Evaluation
Baroness Onora O'Neill	House of Lords; former British Academy President & Newnham College Principal
Sir Gustav Nossal	Former Director, Hall Institute of Medical Research, University of Melbourne
James Orbinski	Former International President, Médecins Sans Frontières
Sir Michael Rawlins	Former Chair, UK National Institute of Health and Clinical Excellence
Karin Roth	Member of the German Parliament
Amartya Sen	Nobel Prize in Economics; Professor, Harvard University
Peter Singer	Professor, Princeton University
Judith Whitworth	Chair, WHO Advisory Committee on Health Research
Heidemarie Wieczorek-Zeul	Former German Minister of Economic Cooperation and Development
Richard Wilder	Associate General Counsel, Bill and Melinda Gates Foundation

much money from diseases that are concentrated among the world's poorest populations. And for that reason, research and development of new medicines focuses away from large and important diseases that affect the poor, such as malaria, tuberculosis, schistosomiasis, and leishmaniasis.

It does poorly in regard to cost-effectiveness. The current system is very wasteful—a majority of the money that the world spends on pharmaceuticals, about one trillion USD every year, does not go back into the manufacture or the research and development of new drugs. Most of the money actually goes to lobbying and gaming, patenting and litigating, wasteful marketing and counterfeiting, as well as to huge deadweight losses, all of which greatly diminishing overall efficiency.

The Health Impact Fund (HIF)

The solution on which we work involves the creation of the Health Impact Fund (HIF) [www.healthimpactfund.org]. The HIF is a complement to the existing TRIPS which would offer to innovators the opportunity to voluntarily register any new medicine for participation in the 'health impact awards.' These awards would be paid annually out of fixed reward pools that the HIF would establish, in the order of 6 billion USD per year. These annual pools would be divided up among the registered products in proportion to the health impact—in quality-adjusted life-years, which is a measure of disease burden—that each of them have. In other words, for all of these registered drugs, the HIF would measure the health gains that they produce in the world, and would then divide the reward pool accordingly.

The idea is to establish a second track on which innovators can be rewarded. Pharmaceutical innovators will be able to choose which market to enter: they will be free to stay in the existing system and get rewarded through the high markups they can charge, protected by a patent; or they can give up that reward opportunity, agree to sell their product at cost and then be rewarded on the basis of the health gains. Obviously, different products will choose different tracks. A product that is mainly directed at rich people, such as a hair-loss product with little health gain, would stay on the patent-track, whereas a product that addresses a need of poor people, such as a malaria drug, would surely choose the HIF-track, be rewarded according to health impact and sold everywhere at a low price determined by cost.

Savings from lower drug prices would help governments fund the HIF at initially 6 USD billion annually (0.01% of GDP of the world). Registrants would be free to keep intellectual property rights, but would be required to sell the new medicine at the lowest feasible average cost of manufacture and distribution and to grant cost-free licenses after the reward period. This price ceiling would generally be determined by a tender, where alternative manufacturers could offer to produce the drug and the lowest costly manufacturer would be chosen to deliver the drug to the innovator and the innovator would then sell it to wholesalers and retailers.

A distinguished advisory board of Nobel Prize winners and politicians (Table 1) has helped the HIF gain political traction of the idea and also to develop its details further.

Advantages of the HIF

The HIF can solve the three big problems of the status quo. First, it prevents high prices. All HIF-registered drugs are available at their real cost or even below cost from day one. Poor people can gain access to important new medicines either through their own funds or through governments, NGOs, or international agencies. In some cases, innovators would have incentives to sell the product even below cost. For example when, by serving additional patients, the health gains for which they would be rewarded would be larger than the expenses of selling below cost.

The HIF also ends the neglect of the diseases of poverty. The HIF adds powerful targeting incentives to develop new drugs with the greatest health impact—regardless of the socioeconomic composition of patient population. In regard to the diseases of the poor, research companies in the developing world would not be at a disadvantage as they are with regard to diseases like cancer and diabetes. In fact, they would be at peak competitiveness: there is no head-start by "Big Pharma", there is an availability of patients to run clinical trials, as well as a highly committed work force, and a supportive political and social environment.

In addition, the HIF boosts cost-effectiveness. It would reduce costs and losses due to patenting because innovators would not need to patent their drugs in many jurisdictions because nobody would dare to compete with them if they offered their products at very low prices. There would be much less litigation and much less need for competitive marketing. In addition, there would be no incentives for counterfeiting because the real drugs would be available at very low prices. Gaming and lobbying would also be much reduced as would be the enormous deadweight losses that are now costing an additional 220 billion USD per year in lost sales that would be profitable to the innovator.

As a bonus, also for rich populations, the HIF would focus the attention of innovators on the health of patients, because only if you actually promote the health of patients, do you make money. Under the present system, innovators have every incentive to sell medicines at very high prices regardless of whether those medicines promote people's health or not. By combining substantial rewards with low product prices, the HIF encourages efforts toward: (a) efficacy, making sure that the medicine is in good condition with regard to freshness, transportation, and storage; b) targeting of patients who can benefit the most; (c) affordability, price below the ceiling to boost reach; (d) careful prescription with proper instructions; and (e) promotion of high compliance and adherence, for optimal effect. All these incentives are welcome to patients regardless of economic position.

Financing the HIF

The HIF would be funded through governments that are willing to participate in the scheme. Each of them would contribute a sum around 0.03 % of their gross national income (GNI). The investment could be done through long-maturity or perpetual bonds with interest pegged to inflation or GNI per capita. Alternatively, the HIF could be funded through a dedicated international tax, for instance a tax on financial transactions or a tax on pollution, whose future revenue stream could be securitized. Such taxes would also moderate speculative excesses in financial markets or slow climate change.

Ultimately, the idea is to create a diversified endowment, managed to generate a stable income stream that would cover a substantial and growing portion of the annual reward pools. The endowment could accept contributions also from international and non-governmental organizations, foundations, corporations, individuals and states—following the example of private universities. And would thereby give us an opportunity personally to contribute to the long-term improvement of human health.

During 2013, the team developing the HIF proposal received €2 million from the European Union, which will help establish the baseline against which health gains will be measured. The HIF team also received substantial support from Janssen Pharmaceuticals, part of Johnson & Johnson (J&J) Pharmaceutical Research and Development, involving their new drug against multi-drug-resistant tuberculosis—and the first anti-tuberculosis drug developed in over forty years—Sirturo® (Bedaquiline). Because J&J will contribute the drug at zero cost, this pilot will only refine the measurement of health gains and of the preservation of the drug's efficacy. The drug was approved by the US Food and Drug Administration in December 2012, and by the Drugs Controller General of India in January 2015, and the pilot in Mumbai is under way.

The HIF would benefit all parties and stakeholders. Innovators would reap moral and reputational gains, large new markets, and new R&D opportunities. Patients would achieve a broader arsenal of medical interventions, available at more affordable prices, and with a strong focus promoting healthcare, rather than merely selling to patients. It would also benefit governments and tax payers by directly improving the efficiency of healthcare and reducing the human and economic burdens of disease. By relying more on pharmaceuticals we then need to rely less on hospitals or on intensive care units, and we would have less disease in the population. That would mean less economic costs involved with disease. Finally, it would also strengthen North-South partnerships for an important global public good.

Agricultural innovation

The same idea that can potentially work really well in pharmaceuticals could be applied in other fields, such as food production, which faces the same dilemma between innovation and access. Over human history, we have learned that stimulating innovation in food production has allowed, with given inputs, to produce ever-better nutrition, ever more efficiency at greater nutrient-yield per acre, less use of pesticides and fertilizers, etc. To keep hunger at bay, such a progress must continue.

But progress in food production has been incentivized in the wrong way. In agriculture, too, we encourage the innovation we need through patents, temporary monopolies that allow innovators to charge licensing fees or sell products at very high prices. And again, this of course hampers the diffusion of higher-yielding crops among the poor, aggravating the ravishes of malnutrition. It also prevents the diffusion of innovations that would reduce the use of pesticides, fertilizers, methane and antibiotics.

An analogous solution

The solution for food production is analogous to the solution in the case of pharmaceuticals. Agricultural innovators should have at least the option to agree to the cost-free use of their

Table 2. Comparison of total fertility rates in countries that have eradicated poverty (a) and those who have not (b)

Year	Botswana[a]	Colombia[a]	Singapore[a]	Niger[b]	Equatorial Guinea[b]
1950–1955	6.50	6.76	6.40	6.86	5.50
1955–1960	6.58	6.76	5.99	7.05	5.50
1960–1965	6.65	6.76	4.93	7.29	5.53
1965–1970	6.70	6.18	3.46	7.53	5.66
1970–1975	6.55	5.00	2.62	7.74	5.68
1975–1980	6.37	4.34	1.87	8.00	5.68
1980–1985	5.97	3.68	1.69	8.05	5.79
1985–1990	5.11	3.24	1.71	7.94	5.89
1990–1995	4.32	3.00	1.76	7.79	5.89
1995–2000	3.70	2.75	1.57	7.61	5.87
2000–2005	3.18	2.55	1.36	7.38	5.64
2005–2010	2.90	2.45	1.27	7.15	5.36

innovation in exchange for payments from public funds that would be based on the measured total impact of their innovation in terms of nutrients produced with given inputs, on methane emissions averted, and on reduction in the use of pesticides, fertilizers, and antibiotics.

So, as a society, we should define a way of measuring the social value of innovations and should then reward each innovation according to the social value it produces, which is proportional to the number of users and to the benefit to the average user. In other words, we would turn these incentives on their head. Rather than give innovators an incentive to charge high prices, they would be given an incentive to make sure that their innovation was very widely used, even by poor populations.

Environmental innovation

The same could work in terms of environmental innovation. Here too, innovation is of great importance to protect the environment because it allows the production of electricity and other goods at much lower cost to the environment. However, many green technologies—such as efficient solar panels or hybrid cars—are patented, and because of high licensing fees, they do not diffuse among poorer populations. Once again, we are wrongly rewarding innovation in a social issue by giving innovators the right to charge high prices, by granting them a temporary monopoly. This is senseless, because the income from non-diffusion green technologies is small, and the harm from the diffusion of preventable excess pollution created by the use of old, obsolete technologies is large and shared by all. We all have to breathe the foul air and we all have to contend with polluted water and a degrading natural environment, including affluent populations and their progeny.

Again, green innovators should be given at least the option to agree to the cost-free use of their innovations, in exchange for payments from public funds based on the measured total environmental impact of their innovations, assessed according to a pre-announced metric.

A final thought

Rewarding innovation in the wrong way in the areas of pharmaceuticals, food production, and environmental innovation has especially serious effects on the poor. Poor fall ill more often and more severely, they die earlier, they suffer hunger and malnutrition, and they also suffer more from the effects of climate change, as could be seen in the Philippines with Typhoon Haiyan in 2013. And so, incentivizing innovation in these social areas in the wrong way perpetuates poverty.

Poverty, in turn is a key driver of human population growth. Currently the total fertility rate (TFR)—the average number of children per women—is 4.53 for the 50 least developed countries versus 1.66 for the more developed regions, and 2.41 for the remaining middle-income countries. Already, 95 of the richer countries around the world have reached TFRs below 2.00, and thus will stop growing (except through immigration). So, despite the vastly higher mortality, poor countries have a rapid population growth, while the better-off have little or none. In countries that have eradica-

ted poverty, such as Botswana, Colombia, or Singapore, population growth has decreased continuously since the 1950s, but it remains high in countries such as Equatorial Guinea and Niger where poverty continues (Table 2). Also, when we look at the ranking for countries by TFR, we see that most top countries with high TFR are in Africa, the top ten being Niger, Mali, Somalia, Uganda, Burkina Faso, Burundi, Zambia, Afghanistan, South Sudan, and Angola. Approximately 100 countries have TFRs below 2.

The crucial variable for the ecological sustainability of our planet is the number of human beings who will share its limited resources over the coming millennium. Fertility is the main variable determining what the human population will be like in 2100. Depending on what policies our generation will initiate, the United Nations estimates that there will be between 6 billion and 16 billion people by the end of the century (there are 7.2 billion today). Of course, for ecological reasons, it would be much better if, in 2100, the world's population was closer to 6 billion than to 16 billion.

The best way of achieving that is by overcoming poverty, and one way to do that is by changing the way in which we reward medical, agricultural and environmental innovation.

Competing interests. None declared.

For further information

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About the author

Thomas Pogge. PhD Harvard University. President of the Health Impact Fund team, Leitner Professor of Philosophy and International Affairs and Director of the Global Justice Program at Yale. Broadly devoted to moral and political philosophy, and Immanuel Kant, his work has increasingly focused on real-world issues related to justice, poverty and health. Pogge's recent publications include *Politics as Usual* (Polity 2010), *World Poverty and Human Rights* (Polity 2008), *John Rawls: His Life and Theory of Justice* (Oxford 2007), and *Freedom from Poverty as a Human Right* (Oxford & UNESCO 2007). Pogge holds secondary appointments at King's College London and at the Universities of Oslo, Sydney and Central Lancashire. He has held visiting appointments at Harvard, Oslo and Princeton Universities as well as at the Princeton Center for Advanced Studies, All Souls College Oxford and the National Institutes of Health. In 2013 he won the American Philosophical Association Gregory Kavka Prize in political philosophy. He has received honorary doctorates from the Universities of Helsinki, Bucharest and Connecticut and is a member of the Norwegian Academy of Science.

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Resum. Hem après que la velocitat i la qualitat de la innovació es poden augmentar molt mitjançant la concessió als innovadors de monopolis temporals, com ara patents o drets d'autor, que els permeten obtenir guanys mitjançant el cobrament de marges elevats. Però aquest tipus de monopolis temporals promouen la innovació a costa de la difusió. En altres paraules, com més innovem o incentivem la innovació, més paguem en termes de la difusió d'aquestes mateixes innovacions. Premiar la innovació de manera equivocada en les àrees de la producció de medicaments, de la producció d'aliments i en la innovació ambiental té efectes especialment greus per als pobres. El sistema actual no és eficient en termes d'accés, selecció d'objectius i rendibilitat. El Fons per a l'Impacte sobre la Salut (*Health Impact Fund*) proposa una nova manera de pagar la innovació farmacèutica, incentivant el desenvolupament i subministrament de nous medicaments a través de mecanismes de pagament per resultats. A més, la mateixa idea es podria aplicar a la innovació agrícola i ambiental.

Paraules clau: *Health Impact Fund* · sanitat, indústria farmacèutica · innovació · patents · agricultura · ambient · creixement demogràfic