REPLACING MONOPOLIES WITH IMPACT REWARDS

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Globalized in 1995 through the TRIPs Agreement, humanity’s favored mechanism for encouraging innovations involves 20-year product patents, whose monopoly features enable innovators to reap large markups or licensing fees from early users. This system encourages innovations in a way that impedes their diffusion and withdraws innovator attention away from the needs of the poor. These defects being most harmful in the domain of pharmaceuticals, we urge the creation of a supplementary alternative mechanism that would reward pharmaceutical innovations from fixed annual reward pools, divided according to the health gains achieved with each, while capping the sales price at a variable cost of manufacture and distribution. Such a Health Impact Fund would create powerful new incentives to develop remedies against diseases concentrated among the poor, rapidly to provide such remedies with ample care at very low prices, and to deploy them strategically to contain, suppress, and ideally eradicate the target disease. By promoting innovations and their diffusion together, impact funds include poor people in the orientation and in the benefits of innovation and thereby massively increase its social value and cost-effectiveness.

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Imagine a Health Impact Fund that, jointly supported by many countries, invites innovators to register any of their new pharmaceuticals for participation in ten consecutive annual payouts, each to be divided among registered products according to health gains achieved in the preceding year. With these reward payments enabling innovators to recoup their R&D expenses and to make appropriate profits, the price of registered products is capped to merely covering their lowest feasible costs of manufacture and distribution. Registrants must also agree to their registered product going generic after its 10-year reward period, even if it still has unexpired patents. To reassure funders and/or registrants, a maximum and/or minimum reward rate could be specified.

The Health Impact Fund might get started with annual pools of $6 billion – less than 1% of the $800 billion per annum the world currently spends on branded pharmaceuticals, and obtainable if countries representing one-third of gross world product contributed 0.02% of their gross national incomes. This contribution would be offset by savings on registered medicines and other health care costs as well as by gains in economic productivity and associated tax revenues.

Innovators would remain free to charge patent-protected high prices in non-contributing affluent countries. This would give innovators more reason to register products with the Health Impact Fund and affluent countries more reason to join the funding coalition. Over time, the Fund might grow – through economic growth in contributing countries, accession of new countries, or agreement to raise the contribution percentage – and
would then attract an increasing number of new pharmaceutical products.

There are three main reasons for adding the Health Impact Fund to the current regime. First, it would end the neglect of the neglected tropical diseases, which afflict over a billion people, and of other major diseases concentrated among the poor, like tuberculosis, malaria, hepatitis, and pneumonia, which together kill some 7 million people annually. By inducing innovators to prioritize these diseases, against which the most cost-effective health gains can be achieved, the Health Impact Fund would be a valuable partner for organizations like the Global Fund, GAVI, and MSF by making available to them, at very low prices, the novel pharmaceuticals they need in their work. The Health Impact Fund would also engender much deeper and broader knowledge about such diseases and greater capacities for developing additional, more targeted responses quickly. Innovators would thus be much better prepared to develop and supply pharmaceuticals suitable for confronting emerging threats such as Ebola or COVID-19.

Second, the Health Impact Fund would motivate innovators to build, in collaboration with national health systems, international agencies, and NGOs, a strong public-health strategy around their product. To earn maximum rewards, they would aim at supplying not many patients but – after eradicating the target disease – none at all. If an innovator achieved eradication in year 7, it could enjoy the world’s gratitude while still collecting three large payouts toward its next R&D project. Patent rewards, by contrast, penalize such efforts: a pharmaceutical that slashes the incidence of its target disease thereby ruins its own future market. The Health Impact Fund is needed, then, to motivate innovators to fight communicable diseases, such as COVID-19, at the population level. The absence of such incentives heretofore may well be the reason why, with all our scientific sophistication, all the trillions spent on pharmaceuticals, humanity has ever managed to eradicate only a single human disease: smallpox, over 40 years ago.

Third, while sales prices of patented medicines often exceed 1000 times manufacturing costs, causing millions of people avoidably to suffer and die every year, Health-Impact-Fund-registered pharmaceuticals would be available without markup from day 1. Yet, despite their low sales price, innovators would nonetheless have strong incentives reliably to deliver such products, in top condition, to remote and impoverished places, with clear local-language instructions and adherence support for patients and providers. This is so because the Health Impact Fund lets innovators earn more than the sales price from supplying a product. It leaves no one behind by assigning more value to the health and survival of poor people than what they themselves can afford to pay. Doing so is morally right. It is also collectively advantageous, especially with communicable diseases, which would be central to the Health Impact Fund: By containing and ideally eradicating such disease among the poor, we protect everyone from the threat it poses, including the threat of new drug-resistant strains, which often emerge in patients who cannot afford to take the full dosage or full course of treatment of an expensive drug.
The recent outbreaks of Ebola, swine flu and COVID-19 bring into sharp relief all three reasons for supplementing the current regime: we have too little knowledge and know-how in regard to the infectious diseases of poverty, we allow poor populations to be breeding grounds for new diseases and (often drug-resistant) disease strains and we lack incentives toward coordinated global efforts to contain and eradicate diseases. Such efforts must include poor populations: we need good new treatments for the diseases of poverty, and we must ensure that people everywhere have access to important pharmaceuticals and can use them to optimal effect.

Impact funds are a meta-innovation, an innovation in how we reward innovations. They can work in any domain where a uniform metric of social value can be formulated, such as health gains (pharmaceuticals), pollution reduction (green technologies), knowledge and employment (education), nutrient yield, and reduced use of fertilizers and pesticides (agriculture). Their key features are:

- Impact funds are optional for both innovators and funders – a complementary alternative to monopoly rewards, designed to mitigate their main moral defects and inefficiencies. Such dual optionality makes it easier to establish any impact fund in a gradual way.

- While monopoly patents reward innovation through the sales price, thereby severely impeding their diffusion, impact funds cap the sales price at or near the lowest feasible cost of manufacture and distribution, thereby disconnecting the sales price from the cost of innovation.

- Impact funds then cover the fixed cost of innovation plus appropriate profits through additional reward payments based on the innovation’s performance of which diffusion is an integral part: we need innovations, and we need these innovations to spread and be used to good effect.

- Impact funds tie performance rewards to an objective value standard that is sensitive to externalities (effects of parties other than the innovation’s buyers and intended users) and insensitive to the buyers’ economic position and willingness to pay.

- Impact funds train innovators to work holistically: to optimize the whole venture from conception of R&D to realized social benefits.

- Impact funds engender a wide competition across an entire domain of innovation, thereby sustaining a broad quest for the most cost-effective progress (the lowest-hanging fruits).

An impact fund’s reward rate is self-adjusting: when innovators find it unattractive, a decline in registrations will raise it; when innovators find it highly attractive, a rise in registered innovations will lower it. Such automatic self-adjustment reassures innovators that the reward rate will not become unprofitable and reassures contributors that this rate will be held down by competition among innovators.
• While patent rewards turn innovators into jealous spies in search of possible infringers, impact rewards encourage innovators actively to promote widespread and effective deployment of their innovation with an eye to optimizing its overall impact.

• Impact funds motivate registrants to invest in promoting optimal use and even in subsidizing the innovation to poor buyers if and insofar as the increase in impact rewards gained from such investments is expected to exceed their cost. Innovators would typically collect much more money in impact rewards than from sales proceeds.

• While monopoly rewards tempt innovators in various ways to “put profits over people,” impact rewards can align profits with human needs, thereby making the business of innovation much more equitable in terms of research priorities and access to its fruits. Innovators do well by doing good.

• Impact funds would guide innovators to make their investment decisions in light of each potential innovation’s full expected impact and to facilitate each registered innovation’s fast and wide and impactful diffusion. Such large gains in cost-effectiveness would enable a triple win: for beneficiaries of innovations, for the innovators, and also for governments/taxpayers.

Any impact fund should ideally be global to serve more people at a lower per-capita cost. Richer people and societies should contribute more – as they do under the present system, where early users provide the rewards through large markups or licensing fees. The difference is that when the affluent contribute through ordinary taxes, there is no need to exclude the poor. Promoting innovations and their diffusion together, impact funds include poor people in the orientation and benefits of innovation and thereby massively increase its social value and cost-effectiveness.

The proposed Health Impact Fund is a large agency with a budget between those of the World Food Program and the Global Fund. Because it works with long-term incentives, its funding must be secured for some 15 years into the future. To win governments’ support for such an ambitious undertaking, a significant pilot is essential. With funding from the European Research Council, we have concluded a small pilot in India, focused on data collection for health impact assessment. The next pilot must be substantially larger and involve real rewards to innovators, showing how they respond to incentives and how much can be achieved with a given pool of reward funds.

The planned pilot would involve a reward pool of ca. $100 million, collected from a few governments and foundations (US, Germany, Italy, South Korea, India, UK, Gates Foundation). This is not enough to fund the full development of even a single new pharmaceutical. Instead, we would invite innovators to submit proposals of how they might, with one of their existing molecules, achieve additional health impact in some selected poor country or region. They might propose, for instance, to develop especially
for, and then to provide in, some poor tropical region a heat-stable or pediatric version of one of their drugs or vaccines, a fixed-dose combination, a new distribution or treatment protocol, or a suitable new diagnostic. An expert committee would select the four best proposals based on, *inter alia*, anticipated incremental health gains, prospects for broad, equitable access especially by the poor, susceptibility to reliable, consistent, and inexpensive health impact assessment, and promise of follow-on social value. Selected proponents (which might include non-commercial innovators such as DNDi and the TB Alliance) would then be given three years for implementation. At the end of this period, achieved health gains would be assessed (according to pre-agreed criteria, by an agency like IHME or IQWiG) and the reward pool be divided proportionately. If this pilot were reasonably successful, an international agreement on the establishment of the Health Impact Fund would become a real possibility.

We ask for collaboration and moral support from African states toward advocating and implementing this pilot and – based on what will be learned from it – toward advocating and implementing the Health Impact Fund itself.

More fully including the poor in the benefits of pharmaceutical innovation is an imperative of justice and fully in line with prevailing rhetorical commitments as enshrined, for example, in the *Universal Declaration of Human Rights*: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care…” (Article 25), in the *International Covenant on Economic, Social and Cultural Rights*, recognizing “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” (Article 12), and in the *Sustainable Development Goals*, especially “Goal 3. Ensure healthy lives and promote well-being for all at all ages” with its associated targets to “reduce the global maternal mortality ratio” (3.1), to “end preventable deaths of newborns and children under 5 years of age” (3.2), to “end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases” (3.3), to “achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all” (3.8), to “support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines … for all” (3b), to “strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks” (3d). The Health Impact Fund would be highly effective at promoting all these rights and targets.

Perhaps the most remarkable thing about the Health Impact Fund is that thanks to the astounding inefficiencies of monopoly rewards, it could dramatically improve global health, especially among the world’s poor, without cost to anyone. Raising the social benefits achieved with pharmaceutical innovations, vastly extending their reach, and
greatly reducing wasteful expenditures by patentees, the Health Impact Fund would greatly improve the efficiency of the pharmaceutical sector.