Health Impact Fund

The Health Impact Fund: learning from COVID19

Could the rules and practices organizing health care around the world have been better suited to the COVID19 outbreak? The non-profit Incentives for Global Health advocates the Health Impact Fund as a plausible institutional reform of the current regime for developing and marketing new pharmaceuticals.

The Pharmaceuticals Sector

Medicines have helped realize dramatic gains in health and longevity as well as huge cost savings through reduced sick days and hospitalizations. The global market for pharmaceuticals is currently worth USD 1,430 billion annually, 1.7% of the gross world product (IPFPA 2017, 5). Roughly USD 800 billion thereof goes for brand-name products, which are typically under patent (ibid., 51).

Commercial pharmaceutical research and development (R&D) efforts are encouraged and rewarded through the earnings that innovators derive from sales of their branded products. These earnings largely depend on the 20-year product patents they are entitled to obtain in WTO member states. Such patents give them a temporary monopoly, enabling them to sell their new products without competition. Under the protection of their patents, they can raise a product's price far above manufacture and distribution costs while still maintaining a substantial sales volume. Such markups yield large profits for commercial innovators and enable them to invest in new R&D, currently at a rate of USD 189 billion a year (Mikulic 2020).

While we should evidently want pharmaceutical R&D to be sustainable, we should ask whether our current way of funding it is optimal. There are three main concerns.

First, innovators motivated by the prospect of large markups tend to neglect the – mostly communicable – diseases specific to poor people, who cannot afford expensive medicines. The twenty WHO-listed neglected tropical diseases together afflict over a billion people (WHO n.d.) but attract only 0.35% of pharmaceutical-industry R&D (IFPMA 2017, 15 and 21). Another 0.12% of this R&D spending goes to tuberculosis and malaria, which kill 1.7 million people each year.[1]

Second, thanks to a large number of affluent or well-insured patients, the profit-maximizing price of a new medicine tends to be quite high. A typical example is the hepatitis-C drug Sovaldi. It was introduced in the U.S. at a price of USD 84,000 per 12-week course of

[1] Annual R&D spending is USD 900 million for tuberculosis (https://www.treatmentactiongroup.org/resources/tbrd-report/tbrd-report-2019) and USD 252 million for malaria (https://www.who.int/news-room/feature-stories/detail/world-malaria-report-2019), but only 1/5 thereof is spent by the pharmaceutical industry (IFPMA 2017, 21). Each year, tuberculosis kills 1.2 million people (https://ourworldindata.org/grapher/the-number-of-deaths-due-to-tuberculosis-by-who-and-ihme-data), malaria 500,000 (https://ourworldindata.org/malaria).

treatment while production cost was estimated at USD 68–136 (Sachs 2015) – a near-thousandfold (100,000%) markup. In the poorer countries, Sovaldi is much cheaper, but still unaffordable with the also much lower ordinary incomes there. Sad but true: most people around the world cannot afford advanced medicines – at least until their patents expire, which, with Sovaldi, will start happening in 2032. Every year, millions suffer and die from lack of access to medicines that could be mass-produced quite cheaply.

This exclusion of the poor entails another disaster, specific to communicable diseases: those who avoidably remain sick continue to spread the disease. In doing so, they often facilitate the emergence of more dangerous drug-resistant strains, whose rise is facilitated by patients who – desperate and short of money – take less than the full course of treatment or self-medicate with drugs in diluted dosage, often peddled by street vendors.[2] Drug-resistant disease variants constitute a rising share of the disease burden and pose a grave danger to public health, as drug-resistant (MDR, XDR) tuberculosis does in India.

Third, rewards for developing and marketing pharmaceutical products are poorly correlated with health gains. Firms earn billions by developing duplicative drugs that add little to our pharmaceutical arsenal – and billions more by cleverly marketing their products for patients who won't benefit. By contrast, there is no profit in developing new antimicrobials, or vaccines against diseases of poverty, nor in providing even life-saving treatments to the world's poor.

The COVID19 pandemic brings out these grave flaws in how our pharmaceuticals sector is structured. We need better incentives for innovation and marketing to motivate 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 must ensure that all people everywhere have access to important medicines and can use them to optimal effect.

Adding New Incentives through the Health Impact Fund

To address all these problems, we propose a complement to the present regime: the Health Impact Fund. Each year, this Fund would disburse a fixed pool of reward money. Innovators would be invited to register any of their new pharmaceuticals for participation in ten consecutive annual payouts, each of which would be divided among registered products according to health gains achieved. In return, the innovator would agree to sell its registered product at or below manufacturing cost and to license it cost-free for generic production after the reward period expires. Some variant of quality-adjusted life years (QALYs), as widely employed and refined in recent decades, could be used as a common metric for comparing and aggregating health gains across diverse diseases, pharmaceuticals, demographic groups, lifestyles and cultures. To reassure funders or innovators, a maximum or minimum reward per QALY could be stipulated.

[2] Important examples are drug-resistant tuberculosis (https://tbfacts.org/drug-resistant-tb) and malaria (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058555).

With emerging epidemics like Ebola, swine flu and COVID19, measurement of health impact is complicated by the fact that we lack here a well-established baseline representing the harm the disease would have done in the absence of the new pharmaceutical to be assessed. For malaria, such a baseline can be established on the basis of a stable disease trajectory observable over many years. In the case of a new epidemic, one must rely on a modeling exercise that estimates the baseline trajectory on the basis of obtainable data about the spread of the disease and its impact on infected patients. This surely is a challenging exercise, which cannot yield precise or uncontroversial results about what damage the epidemic would truly have done if the vaccine or medication in question had not appeared. Still, despite the roughness of such a modeled baseline, the Health Impact Fund would give innovators the right incentives.

The Health Impact Fund might start with annual pools of USD 6 billion. This is less than 1% of the USD 800 billion *per annum* the world currently spends on branded pharmaceuticals. Because a healthy population and workforce is a common good, the Fund could plausibly be financed from public revenues – for instance, by countries representing one-third of gross world product contributing 0.02% of their gross national incomes. Non-contributing affluent countries would lose the benefits: the price ceiling on registered products would not apply in them. This exclusion would give innovators more reason to register (they could still sell their product with markup in some affluent countries) and affluent countries reason to join the funding coalition.

A commercial innovator would develop and register a product only if it expected to make a profit over and above recouping its R&D expenses. There is some controversy over the size of such R&D outlays per marketing approval. The Health Impact Fund would throw light on this question by revealing at what level registrations settle. If the Fund hosted about 20 products, with two entering and two exiting in a typical year, this would show that the prospect of USD 3 billion over ten years is seen as satisfactory – neither windfall nor hardship. Actual results would vary, of course, depending on the product and on how well it is marketed: some products would earn more by having greater therapeutic value or by benefitting more people.

The Health Impact Fund would attract investment to specific R&D projects that are unprofitable under the current regime: ones expected to produce large health gains among mostly poor people. Most such projects would address communicable diseases, which continue to impose devastating disease burdens mainly upon the poor. In consequence, there would be much deeper and broader knowledge about such diseases, a richer arsenal of effective interventions and greater capacities for developing additional, more targeted responses quickly. Pharmaceutical innovators would thus be much better prepared to supply or develop medicines suitable for confronting emerging threats such as Ebola or the current COVID19 pandemic.

The Health Impact Fund would also transform how pharmaceutical companies tackle diseases. A firm rewarded for merely selling malaria drugs need not be distraught by the fact that malaria still, each year, infects over 200 million people (WHO 2019, xii) and kills half a million. A firm rewarded for reducing the malaria burden, by contrast, would aim to

stop the proliferation of malaria as rapidly and cost-effectively as possible. This aim will shape both its development and its marketing efforts.

For innovators seeking to profit from temporary monopolies, the ideal product typically is a maintenance drug, which extends patients' life or makes them feel and function better, without disturbing the proliferation of the disease. The innovator then sets the profit-maximizing price and tries to sell the drug to those who can afford it for as long as they shall live.

By contrast, innovators seeking health impact rewards would ideally want to develop a preventative product (vaccine) or cure, suitable for fighting the disease at the population level. Collaborating with national health systems, international agencies and NGOs, such an innovator would seek to build a strong public-health strategy around its product, involving diagnostics and other factors relevant to treatment outcomes, bolstered by real-time monitoring to recognize and address possible impediments to uptake or therapeutic success. Such an innovator's highest ambition would be to supply not many patients but – after eradicating the target disease – none at all. If it achieved eradication in year 7, it could enjoy the world's gratitude while still collecting three large payouts toward its next R&D project.

The existing regime motivates pharmaceutical innovators to develop marketable products and then to achieve high sales at high markups. We could also motivate innovators to develop effective products and then deploy them to help reduce the disease burden as efficiently as possible. The COVID19 pandemic makes evident that the decision to give pharmaceutical innovators only the former incentive is profoundly unwise. This bad decision helps explain why, with all our scientific sophistication, all the trillions spent on pharmaceuticals, we have managed to eradicate only a single disease: smallpox, over 40 years ago.

The Health Impact Fund is based on a compelling thought: if the purpose of the pharmaceuticals sector is to help reduce the burden of disease, then let's reward innovators for exactly that and not for something quite different.

Piloting the Health Impact Fund Approach

The COVID19 pandemic offers a natural pilot opportunity. Governments could set aside a multi-billion amount to reward the creation of relevant new vaccines and therapies. This sum would be distributed among participating products according to their assessed impact on the pandemic over the subsequent two years, say, on condition that said products be sold without markup and licensed cost-free for generic manufacture and sale.

We have also advocated a much smaller USD-100-million pilot that, like the Health Impact Fund itself, would not be disease-specific. Though too small to incentivize the entire development of even one new pharmaceutical, this pilot would substantiate our approach by pioneering measurement and reward of health gains. Innovators – including non-commercial ones like Drugs for Neglected Diseases Initiative or TB Alliance – would be asked

to propose initiatives through which they could achieve additional health gains in poor countries or regions with an existing or new pharmaceutical, priced without markup. They might propose an affordable heat-stable or pediatric version of one of their medicines, perhaps, or a fixed-dose combination. The most promising four proposals would be chosen and given three years for implementation. Health gains achieved would then be assessed, and the reward pool divided accordingly.

Any such pilot would bring real health gains to poor populations, who are especially under-served by existing health-care systems, and would anticipate and prepare a permanent Health Impact Fund also by showing that health gains can be reliably assessed and that pharmaceutical innovators are able and willing to deliver them quite cost-effectively.

With a pilot available for detailed study, potential funders could then make a well-grounded decision about the Health Impact Fund itself. Even a few major states and foundations would suffice to launch it; and, if successful, it could of course be expanded over time to include more funders and an increasing share of new medications.

The Health Impact Fund would bring the world together for the creation of global public goods and would give real meaning to our noble commitment to leave no one behind.

The Transformative Power of the Health Impact Fund

Monopoly rewards turn innovators into jealous spies, scouring the Earth to find possible patent infringers, who may be using their innovation without license. The Health Impact Fund does the opposite: it encourages innovators actively to promote widespread and effective deployment of their innovation so as to enlarge its impact. Wider deployment can be promoted by adding one's innovation to a patent pool, for instance, or by subsidizing its use among the poorest even below variable cost. More effective deployment can be promoted by various means that help users get the most out of their product.

In this regard, the Health Impact Fund is superior to compulsory licensing, which relies on generic manufacturers to drive down prices. Compulsory licensing remains caught in the tension between price and promotion: the cheaper the product, the less incentive there is to bring it, in top condition, to remote and impoverished places, with clear local-language instructions and adherence support for patients and medical staff. The Health Impact Fund avoids this tension by giving innovators an interest in both: affordability and widespread optimal use of their product. It does so by enabling innovators to earn more than the sales price from selling a product, by assigning more value to the health and survival of poor people than what they can afford to pay. Doing so is a moral imperative – and also collectively advantageous, especially with communicable diseases, which would be central to the Health Impact Fund. By containing and ideally eradicating such a disease among the poor, we protect everyone from the threat it poses, especially through the danger of new drug-resistant strains.

The Health Impact Fund is superior to compulsory licensing also in another respect: by not jeopardizing innovators' recovery of their massive R&D outlays. It is not smart to put

commercial innovators on notice that, if any of their innovations is really important, states may appropriate it with token compensation. Promoting access in a way that undermines innovation is no better than what we do now: promote innovation in a way that undermines access. Neither regime delivers what we want: abundant innovation ***and*** universal access. If we delink the price of pharmaceuticals from the fixed cost of R&D – as we should! – then we should also delink innovator earnings from the sales price. Innovation will flourish only if innovators can recover their R&D outlays and make a decent profit.

Reducing disease with pharmaceuticals is complicated and involves many stages – from research on specific diseases and computer exploration of molecules, *via* clinical trials, to motivating diverse medical staff and patients in many countries and cultures to use a medicine to optimal effect. All these stages and components of disease reduction are interdependent, posing a highly complex global logistics problem. Optimal progress requires not merely the solution of many disparate tasks but also harmony among these solutions. Early decisions about conceiving and pursuing R&D projects should already anticipate the challenges of successful deployment: how to identify the patients who can benefit the most and, for infectious diseases, those whose timely treatment would do most to slow contagion? How to make the product reach and help patients in remote and impoverished locations? How to build a strong collaborative public-health strategy around the product? How to fashion the best plan toward eradicating the disease worldwide?

These great potential synergies suggest that the Health Impact Fund would give rise to actors who can optimally run an entire worldwide operation, R&D plus marketing, though perhaps outsourcing specific subtasks, such as manufacturing. Some pharmaceutical firms are well-positioned to reconfigure themselves for this new role. Other existing actors may also be: certain NGOs, for instance, or product-development partnerships. Open to all, the Health Impact Fund would, over time, bring forth innovators that really excel at achieving cost-effective health gains through a well-coordinated global strategy of disease containment.

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