

The Health Impact Fund: Enduring Innovation Incentives for Cost-effective Health Gains



Thomas Pogge

Leitner Professor of Philosophy and
International Affairs at Yale University

HUMANITY SPENDS over 500 billion euros on medicines each year, some 1¼ percent of world income. Is this money well spent? Data for answering this question are sparse. While new medicines must pass through elaborate clinical trials before they are allowed on the market, there is very little systematic study of their subsequent use and impact. We don't know to what extent medicine dispensed (i) is actually used, (ii) while it still has its potency, (iii) in accordance with the correct instructions, and (iv) by patients for whom it is indicated and (v) whose condition and circumstances allow them to benefit from it.

Given the magnitude of the expenditure, we ought to learn more. But we know enough to conclude that there are huge inefficiencies in the current system.

These inefficiencies are generally related to how we pay for the introduction of new

medicines. Development and especially testing of new medicines is expensive; and invariably such expenditures often fund failures as when a candidate drug's safety and efficacy cannot be demonstrated. Most basic research is done with public monies at universities and governmental institutions. The later stages of development and testing are typically funded by pharmaceutical companies. These firms obtain patents on promising compounds, which secure them a temporary monopoly on the manufacture and sale of any product allowed on the market. During this period of market exclusivity, companies can drastically mark up the price of a medicine, selling it at 10 or even 100 times the average manufacturing cost. At the end of this period, competing generic producers usually make the medicine available at much lower prices.

Predictably, this incentive system creates a lot of unneeded innovation. When one company pioneers a genuinely new kind of medicine, other firms scramble to introduce similar drugs. Having more than one medicine in a therapeutic class can be beneficial as physiological variations among patients affect how well they respond to specific treatments. But this benefit

‘Companies can drastically mark up the price of a medicine, selling it at 10 or even 100 times the average manufacturing cost’

rapidly declines as additional ‘me-too’ drugs are introduced — the twelfth cholesterol-lowering product, for example, adds very little value for patients. But it can add much value to the bottom line of the company introducing it, especially as competition among patented medicines tends not to result in meaningful price reductions.

This leads to four important inefficiencies. First, the incentives for copycat innovations are too strong: too much is spent on developing and introducing me-too drugs that barely improve our pharmaceutical arsenal. Second, the incentives for genuine break-through innovations are too weak: the profits of the first-in-class innovator are predictably decimated as me-too competitors gain market share at its expense. Third, marketing battles among therapeutically similar high-margin drugs are extremely costly and represent a major component of total industry expenditures. Fourth, such marketing often has adverse effects, inappropriately influencing doctors or patients to choose a suboptimal product or one that does not benefit the patient at all.

The current incentive system also sustains three important biases that cause additional

inefficiencies. One bias is against medicines likely to come into wide use only after their patent has expired. To prevent the build-up of drug resistance, the medical establishment wisely uses certain advanced treatments only on patients who do not respond to the usual ‘first-line’ regimen. It is extremely important to have such last-resort treatments available (for drug-resistant TB, for instance, which is infectious and does not respond to any of the standard treatments). But the resulting anemic outlook for profits — dependent as they are on sales volume prior to patent expiration — provides only weak incentives for introducing such drugs.

The second bias favors maintenance drugs and disfavors vaccines. The former are to be taken continuously in order to relieve patients’ symptoms and perhaps prolong their lives. They tend to earn much more for their patent owners than cures of similar therapeutic benefit. Preventative medicines (such as vaccines) tend to earn even less as they are typically bought by large purchasers who can press for substantial reductions in the mark-up. This bias influences not merely how pharmaceutical companies research some given disease, but affects even

more profoundly their preferred targets: in favor of diseases where research is likely to yield a maintenance drug and against diseases where a vaccine or cure is the likely outcome.

The third bias favors diseases afflicting a sizable proportion of the affluent and well-insured. Having introduced a new medicine for such a disease, a firm can sell substantial quantities even at a very high mark-up. Like profits cannot be reaped from drugs for diseases concentrated among the poor, and such diseases are typically neglected by commercial biotechnology and pharmaceutical firms. The result is that billions are spent on researching hair loss and minor skin ailments even while huge gains in global health could be realized through additional research into neglected tropical diseases and tuberculosis.

Poor people are also the main victims of two further inefficiencies resulting from temporary monopolies. Due to the huge gap between price and average manufacturing cost, a patent owner is losing many profitable sales to patients who are willing and able to pay more than manufacturing cost but not the much higher monopoly price. The patent-holding firm may wish to sell to the poor at lower prices, but if it served the poor more cheaply, then many of the more affluent would also find ways to buy at lower prices. So prices remain high, and mutually beneficial sales forgone amount globally each year to over 100 billion euros in deadweight losses. This economists’ expression is especially fitting here as millions of poor patients actually die because generic manufacturers are no longer permitted to serve

‘Billions are spent on researching hair loss and minor skin ailments even while huge gains in global health could be realized through additional research into neglected tropical diseases and tuberculosis’

and save them under the tight patent rules that Western governments have managed to globalize as the WTO TRIPS Agreement.

When life-saving drugs are known to be available at huge mark-ups, the desperation of poorer patients creates illegal supply. Some such illegal products are bioequivalent to the genuine article, but most are not. Common in the less developed countries are counterfeit products that contain a much-diluted dose of the genuine medicine. The product makes patients feel a little better (so they buy more). But in cases of infectious diseases, it may have the particularly pernicious effect of allowing the disease to survive and to adapt to the medicine. Counterfeit products accelerate the development of drug-resistant strains of the target disease which, in the case of communicable diseases, endanger us all.

Litigation over monopolies constitutes a tenth major inefficiency. Innovators patent their discoveries in many countries, monitor all these jurisdictions for possible infringements, and then fight protracted legal battles with other innovators and especially with generic manufacturers. This activity has very little social value and reduces sharply the profits of pharmaceutical companies — as does the extensive lobbying these firms undertake toward defending and expanding their patenting and other privileges. Billions of euros are wasted annually on these rent-seeking activities.

The enormous inefficiencies of our pharmaceutical patent regime are known, and so are the burdens it places on the poor. But what choice do we have? Without patent-protected

‘The enormous inefficiencies of our pharmaceutical patent regime are known, and so are the burdens it places on the poor’

mark-ups most commercial pharmaceutical R&D would cease; and in any case there is no chance for the unanimous agreement among WTO members that any amendment to TRIPS would presuppose.

Yet, we do have a choice, and a good one. We can create the Health Impact Fund as a complement to the current patent regime. The HIF is a pay-for-performance mechanism that would offer innovators the option — no obligation — to register any new medicine. By registering a product, the innovator would agree to make it available, during its first decade on the market, wherever it is needed at no more than the lowest feasible cost of production and distribution (to be determined through competitive tenders submitted by generic manufacturers). The innovator would further agree to allow, at no charge, generic manufacture and distribution afterwards (if some relevant patents on the product are still unexpired). In exchange, the registrant would receive, during that first decade, annual reward payments based on its product’s therapeutic benefits. Each year, the HIF would divide its annual reward pool among all registered products in proportion to their assessed health impact in that year.

The HIF would do more than foster the introduction of new high-impact medicines,

especially against the long-neglected diseases of the poor, and facilitate access to registered products by tightly limiting their price. In addition, the HIF would also motivate registrants to ensure that their products are widely available (perhaps at even lower prices), competently prescribed and optimally used. This marks another sharp contrast with the current innovation system which provides an incentive only to sell, without regard to whether the product is right for the patient. (This incentive to sell is excessively strong in the case of patent holders and often too weak in the case of generic producers, with the result that the end of market exclusivity usually brings a drop not only in price but also in sales volume because the product is no longer heavily promoted.)

The HIF can provide optimal innovation incentives only if potential registrants are assured that the HIF will continue to have annual rewards pools to distribute throughout the decade following market approval. The HIF’s core funding is therefore best guaranteed by a broad partnership of countries. If all countries agreed to contribute just 0.01 percent (1 euro of every 10,000) of their gross national incomes forward-going, then the HIF could get started with nearly 5 billion euros annually. This is a reasonable

‘Affluent patients, insurance companies, governments, and international organizations would benefit from the existence of a permanent source of new, high-impact medicines that from day 1 are sold cheaply and nonetheless with much dedication’

minimum because the high cost of introducing new medicines requires large rewards, because the reward rate should not be affected a lot by any single registration and also because the health impact assessment costs (which are subject to substantial economies of scale) should absorb no more than about ten percent of the HIF budget.

The HIF can be seen as sustaining an enduring competition among innovators that ranges over all countries and all diseases, with earnings tied to impact on health. Health impact can be measured in quality-adjusted life years (QALYs) saved. The QALY metric has been refined over the last 20 years and is already extensively used by insurers in deciding which new drugs to cover. Taking as baseline the pharmaceutical arsenal before a registered medicine was introduced, the HIF would estimate to what extent this medicine has added to the length and quality of human lives. Starting from clinical trial data, this assessment process would also draw on pragmatic trials in real-life settings, on randomized follow-up of specific doses and patients,

and on geographically disaggregated statistical analysis of sales data as correlated with data about the evolution of target diseases. These estimates would be imperfect — but they would achieve a vastly better correlation between profits and actual health impact than the current system. And so long as any errors are random, they would only have a relatively slight effect on the incentives of potential innovators. (I would be only slightly less willing to work in my present job if my salary varied randomly in a plus/minus 30 percent range around its current level.)

With the HIF so designed, innovators would seek to develop for HIF-registration products that can reduce the burden of disease most cost-effectively. And because registration is optional, the reward rate is bound to be reasonable. Taxpayers can anticipate that pharmaceutical innovators won't profit excessively because windfalls would cause the entrance of new registrants which would decrease the uniform reward rate (euros per QALY). Registrants can anticipate that their rewards won't

be unreasonably small because a low reward rate would be self-correcting by slowing new registrations. Competition would ensure that registered products are rewarded at a rate that is profitable for innovators and maximizes the effect of the HIF.

To ensure that the HIF is cost-effective also relative to other public health expenditures, a maximum reward rate can be set, with any remaining funds to be rolled over into future years. To reassure potential innovators, one can also add some protection against an unreasonably low reward rate. A further attractive optional feature is to allow registration (perhaps with a 5-year reward period) of traditional medicines and new uses of existing medicines in order to incentivize clinical trials on their efficacy and optimal use. (It is yet another inefficiency of the current system that it provides no such incentives because traditional medicines are not patentable and market exclusivity on new uses is effectively unenforceable.)

Is the HIF proposal politically realistic? The legal suppression of the generic manufacture and sale of advanced medicines, such as second-line AIDS drugs, has seriously harmed many poor people. This alone should lead affluent people to support the HIF; we should not want pharmaceutical innovations developed for us to be incentivized and rewarded in a way that harms the poor. But our interest in cost-effective provision of medicines can also be invoked, as the HIF addresses ten of the eleven inefficiencies discussed above. (We are working on the last: designing stronger incentives for the development

of last-resort medicines.)

Affluent patients, insurance companies, governments, and international organizations would benefit from the existence of a permanent source of new, high-impact medicines that from day 1 are sold cheaply and nonetheless with much dedication. By refocusing pharmaceutical firms on achieving health impact, the HIF would engender substantial reductions in the global burden of disease and thereby also reduce the dangers affluent populations face from invasive diseases (such as SARS, drug-resistant tuberculosis and strains of influenza).

Do pharmaceutical companies oppose the HIF? Not so far. And why should they? Most people working in the pharmaceutical industry choose this career because they hope to play a role in the introduction of important medicines for the benefit of humankind. They are far more eager to defeat malaria than hair loss. But any such research effort must be sustainable and accord with management's responsibilities to shareholders. The HIF would make such important research sustainable by adding substantial financial rewards to the less tangible benefits of image enhancement and brand recognition (which help a firm market all its other products). For innovators in developing countries, the HIF provides new opportunities to sharpen their teeth by researching local diseases in regard to which their more established foreign competitors do not enjoy a huge head start. And the HIF brings generic manufacturers the opportunity to submit tenders for producing HIF-registered medicines for their registrants.

The creation of the HIF would be an important structural reform, creating the first genuine global public good. It would be a step toward the much-needed moralization of the supranational sphere by manifestly embodying the idea that all human lives are of equal value. It would lift huge burdens of disease and insecurity from the poor and thereby empower them to take a more active role in their further political and social emancipation. It would be possible to modify the HIF if/as experience warrants, and its annual reward pools could be scaled up to attract an increasing share of new medicines. The model could be replicated in other domains, such as agriculture and green clean technologies, where the current patent system also leads to the inefficient underutilization of beneficial innovations to the detriment especially of the poor.

The HIF is a work in rapid progress. You can keep track through www.healthimpactfund.org