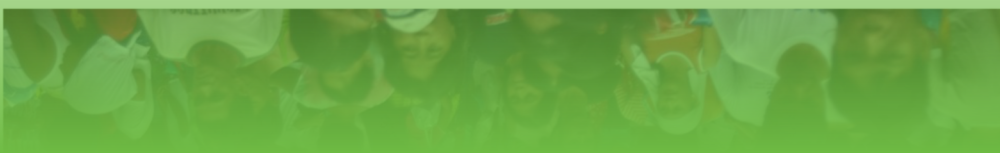


INCENTIVES FOR GLOBAL HEALTH

Health Impact Fund Pilot Proposal



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Executive summary

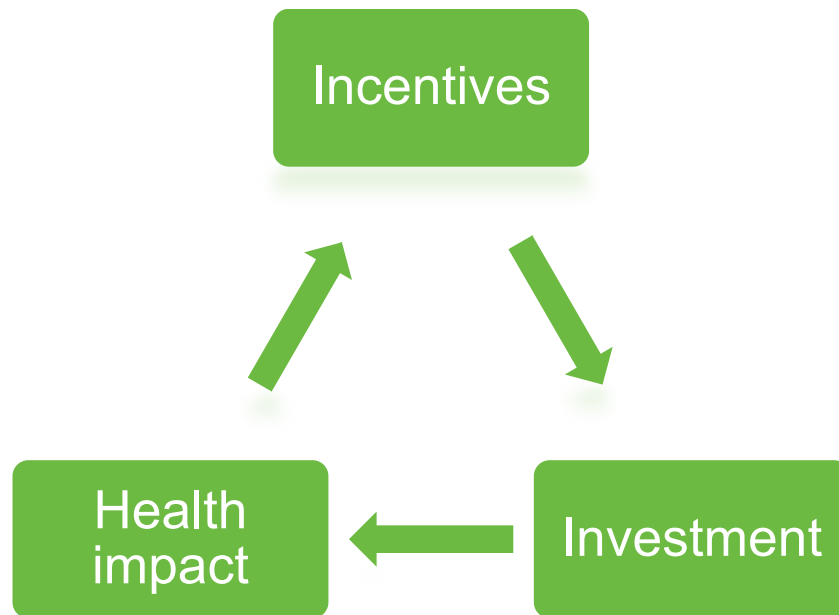
The Health Impact Fund is intended to provide competitive returns to firms that develop drugs and vaccines to treat the diseases mostly prevalent in low- and middle-income countries. A smaller version – the Health Impact Fund Pilot – could effectively demonstrate viability of this approach. The benefits of supporting the Health Impact Fund Pilot are

- Helping to kickstart a transformative, sustainable solution to generate incremental revenues from therapies targeted at developing countries
- Helping to launch an institution that would increase commercial incentives to develop therapies for neglected diseases
- Leading a highly visible, innovative global public health initiative

The most effective Health Impact Fund Pilot would be funded in the range of \$60m - \$200m, ideally with funding from several sources including foundations and governments.

The Health Impact Fund Pilot would be a competition for pharmaceutical manufacturers to achieve health impact through an existing patented drug, vaccine, delivery mechanism or formulation used mainly in low- and middle-income countries (a “project”). Firms would be invited to bid through a Request for Proposals; successful proposals would become eligible for rewards based on health impact achieved through the initiative. The available reward pool would be divided among the accepted projects in proportion to the health impact achieved by each.

The Health Impact Fund Pilot would create incentives for investment into improving the health of poor people.



Health Impact Fund Pilot design and terms

a. Summary

Incentives for Global Health (IGH), funded by donations from governments and foundations, would conduct a competition for pharmaceutical firms to achieve health impact in low- and middle-income countries (“LMICs”) through pre-specified projects. The donations would fund a reward, to be allocated on the basis of health impact achieved during a defined period of time (e.g. 3 years) through each project. This competition would constitute the Health Impact Fund Pilot.

b. Request for Proposals

IGH would issue a Request for Proposals. Firms wishing to compete would submit a proposal, describing a proposed initiative, its anticipated impact on health, and how health impact could be assessed. IGH would evaluate the proposals on the following criteria:

- Anticipated impact on health
- Ability to measure impact reliably and consistently
- Improved access to the therapy

IGH would, in collaboration with its partners, select the leading proposals in order to limit the number of competitors dividing the reward.

c. Project requirements

A project should meet the following criteria:

- Supply of an existing patented medicine to a region or one or more countries where it is currently under-used.
- The price should be reduced to a level at or below anticipated future generic pricing.

- The firm should commit to ensuring widespread availability as needed in the targeted territory, including support of accompanying diagnostics or other efforts as need to ensure appropriate take-up of the product.
- Firms are encouraged to consider broadly how to overcome the barriers they face for their products to achieve maximum health impact.
- Products may address *any* area of health need.

d. Competition to achieve health impact

After the selection process, successful proposals would compete for health impact rewards. At defined intervals, the impact of each firm's initiative will be assessed in terms of QALYs or a similar measure. Each proponent would receive a share of the total reward proportional to the health impact of its project. The Health Impact Fund Pilot will last for a fixed period of time, e.g. 3 years.

e. Terms

1. Proponent eligibility

Eligibility would be restricted to pharmaceutical firms or related organizations such as product-development partnerships wishing to supply a new product, or increase access to or availability of a patented product, in LMICs. IGH would be the final arbiter of proposal eligibility. An eligible organization could partner with another firm or organization to undertake the project.

2. Project eligibility

Proponents would establish the terms of the project, including territorial extent, products or diseases covered, activities involved, and duration up to three years. The project would, however, be required to increase availability of and access to a patented pharmaceutical product, including vaccines and drugs, within a pre-specified set of low- and middle-income countries. Firms would be expected to maximize access to the product being evaluated within the territorial limits and duration of the proposed project. Proposals should include a plan explaining how access will be maximized.

3. Project entry

IGH would create a project assessment expert committee to evaluate proposals. The expert committee would include experts with relevant field expertise, and would be selected to minimize conflicts of interest. The expert committee would select proposals based on criteria specified in the RFP, including expected impact, access terms, and ability to assess impact.

In order to ensure that all proponents were committed to the process, there would be a further stage. Selected proponents would be informed of the number of other selected proposals, as well as their geographic scope and medical indication. The proponents would then have the chance to accept to continue in the competition or to withdraw. If any proposal were withdrawn, IGH might add one or more new proposals, and then again invite proponents to accept or withdraw. Once all selected proponents had accepted,

contracts would be signed, proponent identity and the general project scope of the proposals would be published, and the competition would begin.

Each selected proponent would have up to one year to start its project. This would give firms flexibility to develop their projects, recognizing that some projects would likely be “shovel-ready” and others still in development.

4. Assessment

IGH would commission an “Evaluator” such as the Institute for Health Metrics and Evaluation to measure and assess project outcomes on a basis that allowed, to the greatest extent possible, for a fair comparison across different proposals. The process for evaluating health impact would likely vary across proposals. Because measurement of health impact is complex and health benefits are often specific to each therapy, proponents would be requested to explain how their proposal could be assessed, including specifying (and justifying) a correspondence between measurable outcomes and QALYs or healthy year equivalents. Firms would have the opportunity to comment on a draft evaluation of health impact. The Evaluator would, however, be the final arbiter of assessment methodology and health impact assessed.

Assessment would rely on existing data from clinical trials complemented by newly collected data on real-world compliance, access, volume, patient characteristics and therapeutic outcomes. The Health Impact Fund Pilot would not require new clinical trials to assess effectiveness but mainly monitor how each drug is being used in each setting.

5. Reward payments

IGH would pay out the entire reward payment, divided between the proponents on the basis of total measured health impact of each proposal, within one year of the end of the Health Impact Fund Pilot. Firms would not be compensated for any project costs. Rewards paid would be based only on assessed health impact of the project.

Subject to credible evidence of success in an interim assessment, IGH would pay out up to 30% of the total reward payments following the first 18 months of the competition. Any payments made on the basis of the interim assessment would be subtracted from the final reward payment due at the end of the competition. Interim payments would, however, not be repayable except in cases of fraud and/or intentional misrepresentation on the part of the proponent.

Notwithstanding the above, no proponent would be paid a final reward exceeding a maximum payment per unit of health impact achieved (e.g. \$2,000 per QALY). If, because of this condition, there were any funds remaining following payment for all projects, these funds would be donated to [the Global Fund].

The total reward payment would be equal to the funding given for the Health Impact Fund Pilot, less the expenses of managing the competition and assessing health outcomes.

It is anticipated that [the World Bank] would be the trustee of funds, and responsible for payment of rewards according to the contracts and the determination of health impact as assessed by the Evaluator.

6. Termination

A proponent would be able to terminate its participation in the competition by sending notice of withdrawal. In this case, the proponent would forfeit the right to any payment under the competition; it would also be liable for any costs of assessment of its project incurred by the Evaluator up to the time of termination.

If a proponent failed to make a good faith effort to achieve the access/availability plan outlined in its proposal, IGH would possibly, following a warning, and consultations with the company, retain a third party to mediate. If this were unsuccessful, IGH may disqualify the proponent from the competition. In this case, the proponent would forfeit the right to any payment under the competition.

7. Confidentiality

Proposals would be confidential, including the identities of proponents and their projects. Summaries of accepted proposals and the identities of proponents would be published by IGH. Highlights of projects would be publicized, in collaboration with proponents. IGH would also publish final summaries of projects' health impact, including a discussion of assessment methodologies and outcomes by country.

8. Other terms

Legal jurisdiction

Rights of appeal quite limited.

Why the Health Impact Fund Pilot?

a. The Health Impact Fund offers a way forward

Traditionally, there has been little commercial incentive for pharmaceutical firms to invest in solving health problems that are specific to LICs. Effective demand is extremely weak, even where the health benefits are substantial, since poor people typically lack insurance and cannot pay high prices. Organizations such as the Global Fund, GAVI, and PEPFAR have helped increase access to older (and occasionally newer) drugs and vaccines, but have not created a climate that favors investment in new therapies; their mandate is to achieve the maximum health gains given their budgets, and this has necessarily precluded paying for performance.

The Health Impact Fund offers a new model that encourages firms to invest in developing therapies that achieve significant health gains among the poor. The Health Impact Fund would offer pharmaceutical firms a choice of whether to sell their drugs in the usual way, or to register with the Fund. Registered drugs would be eligible for health impact rewards paid by the Fund, based on the assessed global health benefits of each registered

product. Firms, in exchange, would be required to sell registered products at the cost of production. Funding for rewards would come from governments, proportional to national income. A reasonable scale for the Health Impact Fund to achieve its goals of stimulating innovation to tackle the most important diseases affecting people in low- and middle-income countries is approximately \$2bn to \$6bn per year in rewards. The Health Impact Fund would not constrain intellectual property; it would be a reimbursement mechanism for drugs and vaccines for which the therapeutic value is large but the commercial value is small. The Health Impact Fund would be a permanent institution that would enable firms to achieve a competitive (or at least meaningful) return from investments in neglected diseases and other health conditions principally prevalent in low- and middle-income countries.

For more on the Health Impact Fund proposal, see <https://www.healthimpactfund.org/>.

The Health Impact Fund Pilot would be a demonstration project for the Fund and is not intended to replicate it in terms of its incentives on developing new drugs. Instead, it would be focused on demonstrating the feasibility of rewarding new drugs based on assessed health impact. The Health Impact Fund Pilot would establish the groundwork needed to make a push to fund the Health Impact Fund permanently at a scale that would make a real difference to the health of the world.

b. The Health Impact Fund is good for the world – and for pharmaceutical companies

There are many worthy initiatives for increasing access to drugs in low- and middle-income countries. The Health Impact Fund is the only one that offers a way of rewarding firms for developing new products to treat diseases specific to, or mainly prevalent in, these countries, so it is synergistic with these other approaches.

Other initiatives fall into one of several groups:

Large-scale purchase and provision of (mainly generic) drugs

Global Fund; Unitaid; PEPFAR; GAVI; Clinton Foundation

Even when these organizations purchase patented products, they tend to do so at generic prices.

Licensing advocacy

Medicines Patent Pool; various civil society organizations focused on compulsory licensing

This approach does not create incentives to develop new drugs or vaccines.

Product Development Partnerships

TB Alliance; Medicines for Malaria Venture

These organizations, funded substantially by the Gates Foundation, collaborate with pharmaceutical companies to develop new drugs within their areas of specialization. Pharmaceutical partners typically retain commercial rights in high-income countries in exchange for sharing their product library or other research contribution. Generally, commercial returns are not substantial.

Notably, none of these initiatives offers pay-for-performance or creates a competitive environment. Pay-for-performance is essentially the mechanism that is used very successfully for pharmaceuticals generally: drugs that have a large impact on health tend to generate high profits. Whether the system of determining price is formalized – as in the UK – or informal and set through negotiation – as in the US – the underlying principle is that insurers and patients look for value in the product being offered. Products with high perceived value and large volume can earn substantial profits.

The pharmaceutical market in high-income countries is also inherently competitive. Innovative firms compete to develop new, valuable products and then to achieve high utilization. Competition is important since it pushes firms to achieve a high level of performance and innovation. Competition and pay-for-performance together drive firms to be efficient in their allocation of capital. Unfortunately, these principles are not applied in the development or supply of pharmaceuticals in low-income settings, because the market is not lucrative, and the existing alternative initiatives do not reward firms for value.

The Health Impact Fund is designed to introduce the two principles of pay-for-performance and competition into the development and supply of drugs and vaccines mainly used in low- and middle-income settings. Through the Fund, firms would be motivated to deliver value in a competitive environment.

This would be good for the world, since the existing system of drug development and supply is very productive and delivers enormous value to humanity. The Health Impact Fund could extend these same benefits into disease areas where well-targeted investment could make a significant difference.

The Health Impact Fund would also be good for pharmaceutical companies, since it would open up new commercial opportunities, aligning social goals of improved health in all corners of the world with the corporate mandate to earn a return for investors.

The competition is not designed so that one firm wins and another loses, in that firms are competing with different proposals and investments, different therapeutic classes and geographies. All the participating firms win by achieving a measurable improvement in human health and are paid proportionally.

c. Who is Incentives for Global Health?

Incentives for Global Health is US-registered non-profit focused on promoting the Health Impact Fund proposal. Its leadership and team members are shown at <https://healthimpactfund.org/team>.

International Advisory Board

Noam Chomsky	Institute Professor Emeritus, MIT
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Richard Wilder	General Counsel and Director of Business Development at the Coalition for Epidemic Preparedness Innovations
Formerly:	
Kenneth J. Arrow	Nobel Prize in Economics; Professor Emeritus, Stanford University

d. Supplementary information on the Health Impact Fund

For a **comprehensive set of documents** on the Health Impact Fund, see <https://www.healthimpactfund.org/>

Videos describing the Health Impact Fund idea can be found at <https://www.youtube.com/watch?v=rTMqGbTNkNg> (18 minutes) and <https://www.youtube.com/watch?v=yGUgAHTyYMs> (3 minutes)