

# Executive Summary

The Health Impact Fund (HIF) is a new proposal based on two simple insights: (1) privately funded pharmaceutical R&D responds to incentives, and (2) new drugs can have a much larger impact if their prices are low. At present, the most profitable research efforts are not the ones most needed to alleviate the global burden of disease. And high prices often put new drugs out of reach of most of the world's population.

The HIF seeks to correct both of these failings by offering to reward any new medicine, if priced at cost, on the basis of its global health impact. Any firm receiving marketing approval for a new medicine would be offered a choice between (a) exercising its usual patent rights through high prices *or* (b) registering its product with the HIF. Registration would require the firm to sell its product worldwide at an administered price near the average cost of production and distribution. In exchange, the firm would receive from the HIF a stream of payments based on the assessed global health impact of its drug. The HIF is, in other words, an optional pay-for-performance scheme for new pharmaceuticals.

Innovative companies would benefit from this new option because they could profitably introduce important new medicines that are needed mainly by patients who cannot pay high prices. Patients—especially those in the developing world—would benefit through access to new drugs at low prices. By supporting the HIF, citizens and governments in all countries would reap large cost savings on medicines

as well as substantial reductions in the human and economic burdens of disease.

The chief problems with the present system governing the development and distribution of medicines are well known: despite relatively low manufacturing costs, patented medicines are often very expensive and are therefore unaffordable for most people; and diseases concentrated among the poor attract little or no pharmaceutical research. As a result of both factors, the disease burden among the poor is, avoidably, very high. Many diseases of the poor are communicable and expose all of humanity to the risk of new and virulent strains. These problems are further aggravated: by patients who, often deterred by high prices, fail to complete a full course of treatment; by lack of access to competent medical staff who would ensure that medicines are taken correctly; and by counterfeiters, often attracted by high prices, who may dilute a medicine's active ingredients. In addition, competitive marketing and litigation costs reduce the return from innovation, and make it a less attractive investment.

Each of these problems has provoked ideas and initiatives by academics, NGOs, governments, and international agencies. By supporting both innovation and real access, the Health Impact Fund extends the best of these ideas into one comprehensive, unified solution that makes substantial progress toward a rational system of developing and distributing worldwide the pharmaceuticals we all need.

This book explains how the HIF would work and why the world needs it. Chapter 1 provides a summa-

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ry overview. The next four chapters examine in detail how the HIF would operate. Chapter 2 discusses the proposed mechanism for deciding how much each innovative drug would earn based on its assessed health impact. Chapter 3 shows how health impact can be measured while also examining the difficulties such measurement would have to overcome. Chapter 4 explores the HIF's governance and administrative structure. Chapter 5 considers the commitment of funding partners.

The following four chapters explore the rationale for the HIF. Chapter 6 constructs a moral argument, based on widely recognized human rights, for implementing the HIF. Chapter 7 shows how the HIF would help address the important "last mile" problem of ensuring effective distribution and use of pharmaceuticals in poor countries. Chapter 8 shows, from an economic perspective, how the HIF would usefully supplement the patent system, and Chapter 9 examines the relationship between the HIF and other proposed reforms. Chapter 10 summarizes the above and shows how this new mechanism can be brought into being.

The HIF is a work in progress, to be further perfected and completed with the help of many stakeholders. This book's objective is to show that, and how, the existing rules governing the development and distribution of new medicines can be improved upon in ways that would dramatically enhance global public health. The Health Impact Fund is a *feasible* complement to the existing regime. Governments have decisive moral reasons to implement the HIF and citizens have decisive reasons to urge their governments to do so.

Most countries are unable to institute the HIF single-handedly. But governments can make a conditional commitment to participate if enough others are also willing. Given a threshold participation of states representing about one third of global income, the founding partner states can commence the Fund at a cost of 0.03 percent of their respective gross national products. The Fund would then become operational within three years and be enhanced thereafter as experience warrants. There is little to lose, much to gain, and no time to waste.