

4. Governance and Administration

The HIF will be governed by a Board of Directors chosen by funding partners, exercising primary responsibility over the Fund. The Board will oversee three branches representing the core functions of the Fund: the Technical Branch, the Assessment Branch, and the Audit Branch. These will, respectively, set the standards for evaluation of health impact (Technical), determine individual products' actual impact (Assessment), and ensure correspondence between standards and evaluations (Audit).

INTRODUCTION AND SUMMARY

One important concern about the HIF is that administrative bodies are subject to influence in allocating rewards. Such bodies are liable to intense lobbying by firms with a stake in their decisions, and their officials may be corrupted by bribes or future job prospects. The governance of the HIF must therefore be carefully designed: the formulation of the assessment rules must be kept separate from their application, the assessment rules must be formulated precisely, and the application of the rules must be firmly and transparently guided in ways that leave little room for discretion. To stimulate the most cost-effective research efforts, and thus to be itself cost-effective in terms of promoting global health, the HIF must have a structure conducive to its impartial and effective operation.

GOVERNANCE

There are many important issues to be resolved concerning the governance of the HIF, including how it should be constituted, the size and composition of its board of directors, the voting mechanism of its board, and the method for selecting its new directors. It is not possible or desirable for us to try to identify a comprehensive and optimal governance mechanism at this stage, but we can identify some of its most important elements and some of the general characteristics it ought to have.

Composition of the Board of Directors

The Board of Directors will ultimately be responsible for the direction of the HIF and for the annual allocation of payments. It is clear that funding partners should be represented on the board. Because the funding expectations are based on gross national income (GNI), all countries, even the poorest ones, should be able to participate as funding partners. Other possible board members might include public health experts and *ex officio* representatives of the World Health Organization and NGOs that are active in purchasing medicines. Including individuals who do not represent funding partners is problematic since it is unlikely that the funding partners will remain committed to the HIF unless they can exercise a significant amount of control.¹

An important issue is whether the voting rights should be proportional to the size of contribution by each funding partner. Such an approach gives the greatest voting power to the countries that contribute the most. While this is attractive in some respects, it may lead to domination of the Board by a very small group of directors.

The Global Fund, which is financially supported by relatively wealthy countries, has a board that is effectively split into constituencies. Of twenty voting members, eight represent donors, seven represent developing countries (with a required geographic distribution), and five represent civil society and the private sector, notably including “one representative of an NGO who is a person living with HIV/AIDS or

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from a community living with tuberculosis or malaria.” The board also includes nonvoting members, including a WHO representative, UNAIDS, and one Swiss citizen (presumably to ensure compatibility with Swiss law; Global Fund 2007, 4). In the case of the HIF, this division into constituencies would be artificial, as funding partners are also beneficiaries. It might, however, be appropriate to require a geographical distribution which takes into account the different burdens of disease in different regions.

Size of the Board of Directors

The size of the board is intimately related to its composition. Larger boards can achieve a broader representation, but can also become more unwieldy.

Selection of the Board of Directors

Another important issue concerns how members of the board ought to be selected. First, there needs to be a process of determining candidates, which may simply allow each funding partner to nominate one candidate. It might be appropriate for other expert organizations such as the World Health Organization to nominate additional candidates.

The second step is a process of determining which candidates would be named to the Board. One approach is to allow funding partners to have voting rights in electing board members in proportion to their contribution. If regional representation were to be desired, however, there might also need to be a separate process for selecting regional members.

Board Decision-Making Mechanism

Boards have various mechanisms for making decisions, including simple majorities, supermajority rules, consensus, and other more complex rules.² In addition, voting rights might be allocated unevenly across board members to reflect, for example, financial contribution. The core decision problem of the HIF board will be the annual confirmation of estimated health impacts for each drug, since this will effectively determine how much each innovator is to be paid. Evidently, the Board cannot become in-

involved in the details of how much health impact each individual drug delivers. It will have instead to rely on estimates provided by the Assessment Branch, which is described below. Thus, the Board will exercise control more through its choice of personnel appointed to the Assessment Branch and other administrative branches of the HIF and through general oversight and internal policy making, than by involvement in detailed assessment of individual drugs. Given, however, the requirement to approve annual payments, and given that there will likely be some degree of disagreement between Board members, a consensus requirement for decisions seems problematic as it would likely create roadblocks and provide excessive veto power to individual members.

The Board’s Role in Funding Partner Relationships

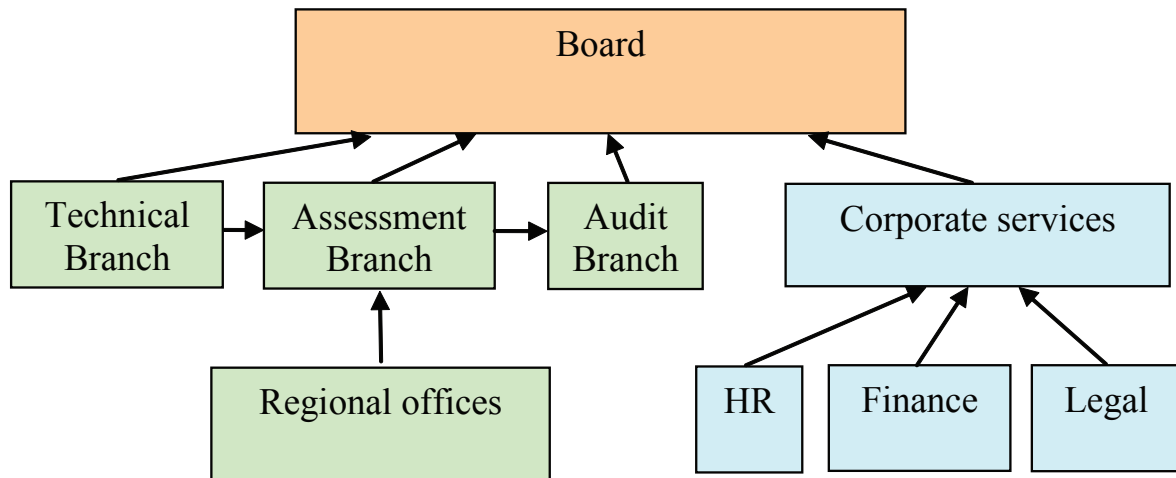
The Board will also have an important role not only in ensuring that the interests of various stakeholders are represented in the decisions and activity of the HIF, but in representing the HIF to funding partners and other stakeholders. For example, as the HIF demonstrates its effectiveness, it will perhaps wish to increase the size of its annual rewards. At that stage, the Board will be responsible for raising additional funding in a responsible manner.

One problem facing the HIF is ensuring that the financial commitments of funding partners are actually fulfilled, and therefore members of the Board will require support at the highest political levels. The fact that the HIF will be dependent on such commitments, and must be perceived to be credible for it to stimulate research investment, makes it essential that the Board members have the experience and authority necessary to represent the HIF to funding partners.

ADMINISTRATION

The HIF would need several administrative branches, including legal, financial, human resources, and other typical corporate functions. In this section, we discuss three critical divisions which would be unique to the HIF: a Technical Branch, an Assessment Branch,

Figure 1: Administrative Structure



and an Audit Branch. The Technical Branch would set the standards for how health impact would be assessed; the Assessment Branch would undertake the actual assessment following the protocol established by the Technical Branch; and the Audit Branch would monitor adherence to these protocols and the accuracy of the data reported to the Assessment Branch. The division into three branches reflects an ambition to ensure that there is a transparent, fair, and consistent process for estimating health impact.

The administrative structure of the HIF is summarized in Figure 1. The Board assumes overall responsibility for the administration of the Fund, reporting to funding partners. The health impact assessment framework is determined by the Technical Branch; this is used by the Assessment Branch in determining assessed health impact for each product on a global basis. The Audit Branch confirms the accuracy of the Assessment Branch's analyses. This enables the Board to determine the payment to each registrant. The HIF would also require other corporate services as shown. Arrows show information flow.

Health Impact Technical Branch

The Technical Branch would be responsible for designing assessment tools for use in evaluating the health impact of participating firms' interventions. This branch would not actually perform assessments, but would provide guidelines so that assessment procedures are technically sound, consistent, fair, and

predictable for registrants. Such guidelines are especially important because it is not possible for one individual, or even one team, to conduct all assessments for all drugs in all countries. Consistency of assessment across different drugs in different countries must then be achieved through clear standards that are followed in each assessment exercise. The Technical Branch will formulate such common standards by which all assessments will be performed.

The assessments to be undertaken would be similar to those performed by other expert committees for national insurers. Though these techniques are admittedly contentious and difficult, they have a track record with which many pharmaceutical innovators are already familiar, as noted in chapter 3. There are many useful sources on assessing interventions, and the Technical Branch would not be required to invent entirely new techniques. Rather, it would select the techniques appropriate for the particular purposes of the HIF and adapt them as necessary.³

The staffing requirements of this branch would be determined in part by how large the Fund is, and how many different types of drugs enter the system. The personnel required would include epidemiologists, health economists, and statisticians. They would require an understanding of the kinds of data which are available or can be collected in different countries, the kinds of data which are available through clinical trials and actual practice, and how these data vary by disease. The Technical Branch would set up protocols for health impact assessments at the initiation of the

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Fund, and would continue to modify and refine these protocols in light of experience.

Health Impact Assessment Branch

The Assessment Branch would apply the guidelines established by the Technical Branch to the actual data for each product in each country. Each year, the Assessment Branch would receive submissions from all firms having products in the system.⁴ It would also solicit reports from governments, other relevant users such as insurers and NGOs, wholesalers, pharmacies, competitors, and other interested parties. Using this data and the theoretical framework developed by the Technical Branch, the Assessment Branch would estimate the health impact of each product.

The work of the Assessment Branch will be difficult, since data on health impacts are likely to vary meaningfully between countries and between diseases in terms of accuracy, reliability, and comprehensiveness. For example, if data is available for only two percent of patients who used a drug in one country, but for forty percent of patients in another country, the accuracy of the estimate in the second country is likely to be higher. The Assessment Branch would have to rely on guidelines from the Technical Branch on how to evaluate such different data; but it would also have to rely on its own judgment, since these guidelines or policies cannot be made so detailed as to provide clear guidance on all difficult choices that it will encounter in practice.

The Assessment Branch would constitute the core of the administrative functions of the HIF. It would require personnel with expertise in epidemiology, public health, statistics, and health economics.

It would be required of the Assessment Branch that it publish its recommendations and provide detailed reasons for them, including how the Branch established the quality of evidence. This transparency would lend credibility to the system, and allow other firms to make meaningful predictions about how their products would be treated in the future. Such a transparent process is commonly followed by courts and regulatory bodies all over the world.

The Assessment Branch would be required to use the best available data to estimate health impacts,

within the guidelines specified by the Technical Branch. The honesty and integrity of the Assessment Branch is an important component of the entire system. If this Branch were not viewed as unbiased in its estimates, it could lead firms to spend more on efforts trying to influence its decisions rather than trying to reduce the burden of disease. This motivates both the creation of the Technical Branch, to reduce discretion in assessments, and the creation of the Audit Branch, to ensure that the assessments do in fact follow the guidelines. Note that by separating the actual performance of assessment from the establishment of guidelines concerning how assessments are to be performed, there would be a substantial reduction in discretion exercised in each assessment. Reducing discretion has costs, of course, and will sometimes lead mechanically to assessments that appear not to reflect the “true” situation. By reducing discretion, however, transparency is enhanced and the complexity of the assessment process is reduced, as is the opportunity for lobbying and rent-seeking by firms. Evidently, the staff of the HIF would have to satisfy strict conflict-of-interest guidelines.

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Assessment is clearly expensive and would require a significant investment of time and resources. Thus, it would be undesirable for the Assessment Branch to perform assessments on drugs with only small health impacts since the assessment costs could even exceed the health impact reward. The HIF will avoid this problem by charging an annual fee reflecting the costs of assessment to registrants, since this will deter the participation of drugs with relatively small health impact.

To help ensure fairness, there would have to be an appeal mechanism, and firms would be very likely to appeal the decisions of the Board in some cases. To the extent that the Board did not wish to be overwhelmed by such appeals, it would probably be appropriate for the costs of appeals to be borne by the

appellant (to be refunded should the appeal result in a substantial revision in the applicant's favor). This would ensure that only meritorious appeals were actually likely to be pursued; it would also ensure that scarce HIF assessment resources were not absorbed in the appeals process, since the appellant would be responsible for funding the appeal.

Health Impact Audit Branch

The Audit Branch would have the core function of ensuring that the recommendations of the Assessment Branch complied with the guidelines established by the Technical Branch. The audits would help to ensure that the recommendations of the Assessment Branch were unbiased and consistent across countries and drugs. The Audit Branch would of course report directly to the Board and would publish results of its findings annually.⁵

Such an auditing function could be performed by in-house staff, by outside experts, or both. For example, audits could be performed by independent consultants trained to evaluate health or social impact in similar contexts. Specific audits would be assigned to multiple stakeholders: academic and research institutions, and private sector partners identified through a standard request-for-proposals process.

Specific audits would be focused on evaluating a particular assessment to confirm reporting and evaluation conducted by the Assessment Branch. The frequency and level of stratification of such audits depends on system resources. Sampling techniques and new technologies for conducting such surveys (including, for example, new electronic medical record systems in parts of Africa), could substantially reduce the burden of this auditing.

One possible aid to the audit process is that firms participating in the HIF system would have an incentive to provide information about how *other* firms might have exaggerated their claims, since by reducing the payment to these other firms, each firm might increase its own payments. This kind of assistance would not only increase the amount of information available to the auditors, but would also enable it to understand how firms might exaggerate or even try to defraud the HIF.

The Audit Branch might also perform more general audits designed to evaluate the overall performance of the HIF. General audits would assess the system's capacity to generate health impact with a given level of funding, as compared with similar options available (for example, Advanced Market Commitments, direct research grants, and other initiatives discussed in chapter nine). This loosely follows the "Best Available Charitable Option" assessment framework used by the Acumen Fund.⁶

EXPENSE OF ADMINISTRATION

It is evident that performing annual health impact assessments on a variety of drugs on a global scale would be very expensive—perhaps absorbing ten percent of the annual budget of the fund. In a way, this is comparable to the administrative expenses of insurance companies, which devote substantial resources to avoiding moral hazard and fraud on the part of policyholders. The HIF is similar in many respects to a drug insurer that makes payments to drug sellers based on the estimated health impact of their products rather than on some negotiated price. While an insurance company controls its payout by monitoring drug usage, the HIF would control its payout by monitoring health impact (which, to a large extent, is determined by use).

The administrative expenses of the HIF would, however, offer some distinct benefits. The first is that they would enable the HIF to create highly desirable incentives for valuable innovation that are well aligned with public health needs. The second is that the expense of assessment would enable much better information about the medical value of different medicines in different situations. This would in turn allow for more informed treatment decisions, and hence better health.

NOTES

1. Related issues are discussed by Ngairé Woods (2000) in terms of the Board and executive of the IMF and the World Bank, which face considerable problems created by their global mandate and membership but effective financial

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- control by a smaller group of countries.
2. The GAVI Alliance operates on a presumption of consensus (e.g. consensus is strongly preferred), but falls on majority vote if necessary. The GAVI Fund, the separate entity which controls financial operations, operates on majority voting. The Global Fund has a complex supermajoritarian voting principle. To take action not based on consensus requires a two-thirds majority of both the group of eight donors and the group of developing countries and NGOs. Either group can thus block action.
 3. Examples of organizations which are required to make similar kinds of assessments include the Global Fund, NICE in the UK, CDR in Canada, and the Global Burden of Disease Project.
 4. It is likely that abbreviated assessments might be possible in some cases in some years, where the nature of the disease and the sales of the product were relatively constant.
 5. The Audit Branch could be in part modeled after the Global Fund's Technical Evaluation Reference Group, which functions independently from the Fund's operations and grant approval process and reports directly to the Board.
 6. For more on the Acumen Fund's approach, see <http://www.acumenfund.org/investments/investment-performance.html>