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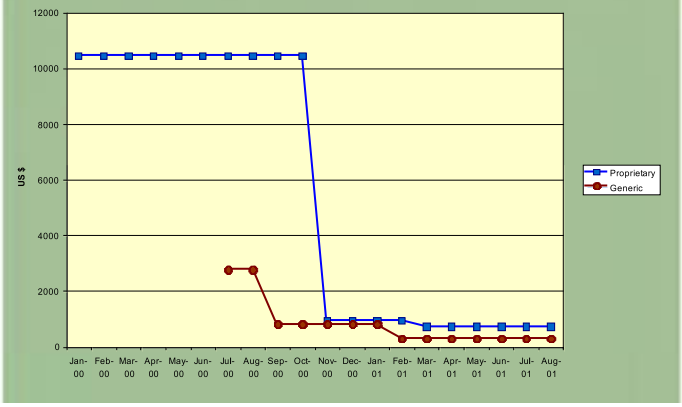

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A Global Health Innovation System (GHIS)

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Executive Summary

This paper describes a Global Health Innovation System (GHIS) based on research in innovations systems theory. This system would define how concerned countries and institutions could more effectively contribute to health care innovations, especially for the poor in developing countries. Such a system is needed because of the very rapid recent changes in global health innovation. Since the turn of the millennium, the Era of Partnerships has emerged. This era is characterized by the rise of product-development public-private partnerships and is also marked by increased networking, a trend that would benefit from greater coordination and the adoption of a range of best practices. With a comprehensive and compelling GHIS current resources could be allocated more efficiently and additional resources could be mobilized more readily.

By integrating innovation with health systems and widened perspectives, the GHIS would help overcome a set of critical health failures: failures of science, failures of the market, and failures of public health systems. It would do so by providing valuable guidance in the planning and management of innovation at the global, regional, national, institutional, and sector levels. The paper concludes by demonstrating how a GHIS could address the health failures by applying the lessons of innovation studies in a structured framework.

Introduction

There is a growing consensus about the need to develop and deliver new health technologies for diseases affecting the poor in developing countries. New funds, new organizations, and new approaches are revitalizing the public sector. Spurred by a better understanding of the market and its limitations when addressing the needs of the poor, there is a greater awareness of the public sector's essential role in promoting access to health technologies. This revitalization is relatively young, but in some areas it is moving very quickly. For example, global procurement mechanisms for vaccines, drugs, and other materials have been set up, and public-private product development partnerships (PDPs) in developed countries and some developing countries have been established.

No global model, however, has yet been put forward to plan, coordinate, conduct, and support efforts. Now is the time to construct such a global model. How do the new parts relate to each other? How do the new components relate to the old parts? And how do they relate to things occurring outside health? We must consider the big picture to determine how all of the parts can work together most effectively. Funds are limited but there is the prospect and need for more, so it is essential to find cost effective policies, strategies that can mobilize those funds. What are those policies and strategies and how do we develop them? To answer these questions, we need a global model or system. The problem has been succinctly summarized by Prof. Barry Bloom, "*There've been lots of creative ideas and lots of*

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new people, but there's one missing piece. There's no architecture of global health."[1]

Fortunately, existing research can guide our pursuit of the answers to these questions. Having carefully studied how new technologies reach markets, innovation systems theory has already contributed greatly to our understanding of the architecture of global health. Our quest to improve health care innovation should therefore include the work of scholars of innovation, and in this paper we build on innovation theory to address the health problems of the poor in developing countries. Based on widely-accepted scholarship that clearly lays out how all the players in health innovation—firms, governments, research institutes, non-governmental organizations (NGOs), citizens, and donors—can work together most effectively to assure access to urgently needed health technologies in developing countries, we argue for the creation of a Global Health Innovation System (GHIS) – the missing architecture.

The History of Health Innovation

Health innovation includes not only technologies but also better systems and policies. Since Schumpeter's analysis[2], scholars have argued that advances in human health and well-being are determined both by technological innovation and by how institutions handle new technologies. Understanding the history of health care innovation, therefore, requires us to consider both technologies and policies.

Since the 19th century, we see four major periods of health technology innovation: the Era of the Public Sector, the Era of the Private Sector, the Era of Public Sector Reawakening, and the Era of Partnerships. Our analysis is based in part on the work of Stokes [3], which we have adapted to the field of health technology innovation. The Era of the Public Sector is the period from the mid-19th century to World War I. The Era of the Private Sector is the period from World War I to the fall of the Berlin Wall. The years from the fall of the Berlin Wall to the dawn of the 21st century, we refer to as the Era of Public Sector Reawakening. The birth of the 21st century marks the beginning of the Era of Partnerships. The transitions from era to era take place in response to broader world changes, particularly the struggle between capitalism and socialism and the emergence of globalization.

The Era of the Public Sector is epitomized by the work of Pasteur. Working within the university, he was able to develop a number of human and animal health technologies that were widely adopted and greatly improved medical practice. His initial discoveries and technological innovations, such as disproving spontaneous generation and developing the rabies vaccine, were made possible largely by public sector institutions, such as l'Ecole Normale in Paris. The explosive demand for rabies vaccination led Pasteur in 1888 to create the Pasteur Institute in Paris, a private, state-approved institute recognized by the President of France. In 1891, Pasteur dispatched Albert Calmette to Saigon, (today Ho Chi Minh City), Vietnam, where he founded the first Institute outside France. Other disciples set up establishments modeled on the Paris Institute in several developing countries. Invariably, these were public institutions closely associated with national governments. Of course, Pasteur had no choice: no private sector pharmaceutical or vaccine industry existed in the second half of the 19th century, so he had to create production facilities and structures himself.[4]

The Era of the Private Sector emerged in Germany when chemical companies applied their manufacturing skills to medicines[5]. They soon recognized the high investment returns of these technologies and established research capabilities to create new and even more profitable products. During this Era, the public sector became less involved in activities that brought new medicines and vaccines into wide use. To some degree, this was due to less support for science in the Socialist east and to the shift to funding "basic" research in the capitalist West, which left it to industry to translate such research into products. This was the established "linear paradigm" described in Vanevar Bush's report to the President of the United States at the end of World War II: "*Science the Endless Frontier*"[6].

The Era of Public Sector Reawakening began in the 1970s, when several development organizations (foundations and governments) established after World War II became concerned about health in developing countries, especially the absence of health

technologies. Around this time, the World Health Organization (WHO) established its Special Programmes: the Human Reproduction Programme (HRP), the Tropical Disease Research and Training Programme (TDR), and the Diarrheal Disease Control Program (CDD). Each of these programs sought to develop or apply new technologies and strategies for the pressing health needs of people in developing countries. With support from the Ford and Rockefeller Foundations, The Population Council in New York and the Program for Appropriate Technology in Health (PATH) in Seattle also created programs to begin product research and development to address health needs in developing countries. The United States government dramatically increased funding for the NIH, which led to the unprecedented growth of biomedical research there and in collaborating centers around the world. But in the health field, collaboration between the public and private sectors during this period was uncommon and viewed with suspicion. In other fields, particularly in engineering schools and land grant colleges, a tradition of public-private collaboration went back to the late 19th century, especially in the United States [7]. In health research and development, however, neither sector understood the other, and collaboration was difficult, at best. For example, private-sector representatives were excluded from almost all WHO meetings, and universities and companies rarely interacted, in part because no clear legal framework allowed public institutions to manage IP rights.

The passage of such legislation as the Bayh-Dole Act in the U.S. in 1980 [8], the fall of the Berlin Wall on 9 November 1989, and the collapse of the Soviet Union on Christmas Day, 1991, made it possible to view the relationship between the public and private sectors more objectively. It became more acceptable for academics in the West to work closely with pharmaceutical companies; conversely, pharmaceutical companies saw the benefits of closer collaboration with universities and nonprofit research centers. Beginning in the 1990s and flowering in the early part of the 21st century, a number of new initiatives were launched that have since become known as product development public-private partnerships (PDPs) [9, 10]. They seek to accelerate the development of health products for use in developing countries. Examples include the founding of the International AIDS Vaccine Initiative (IAVI) in 1996, the Aeras Foundation in 1997 to develop TB vaccines, and the Medicines for Malaria Venture in 1999 (MMV) [10].

These developments led to the current *Era of Partnerships*. It began to be understood that for-profit pharmaceutical companies in wealthy industrialized countries would not address the needs of the poor in developing countries without incentives from government or other public sector agencies. On the other hand, the private sector had certain skills and abilities that the public sector lacked, including the ability to manufacture large numbers of products to very high standards.

The Era of Partnerships

We are in the very first years of the new Era of Partnerships, and, among many issues, we need to understand better how the public and private sectors can partner most effectively. Ignorance is mutual. While the public sector faces such challenges as managing IP rights for the public's benefit, IP management practices are well-established in the private sector[11]. The private sector, on the other hand, is eager to learn how to handle the special needs of poor populations in both developed and developing countries[12]. The ground is moving under everyone's feet: a number of developing countries are beginning to reap the fruits of substantial investments in biotechnology over the last 25 years. These countries, such as Brazil, China, India, South Africa and others, are now known as Innovative Developing Countries (IDCs)[13, 14]. India is becoming a global center for both vaccine and drug production and is also rapidly increasing its capability to undertake research and development. It already has extensive capabilities in clinical assessment[15]. China is also very rapidly expanding its research capabilities[16].

Early evidence collected and analyzed by Mary Moran and other investigators shows that PDPs have the promise to develop and introduce new health technologies for developing countries[12]. Numerous questions, however, still need answers. To be sure, the new Era of Partnerships has seen a

range of proposals to encourage or create initiatives promoting health technology innovation for the poor. These include double-bottom-line venture capital funds (where both profits and social benefit are measured); France's airline solidarity contribution [17]; humanitarian licensing practices at research universities[18]; fast-track regulatory approval vouchers[12]; global procurement funds such as GAVI and the Global Fund to Fight AIDS, TB, and Malaria; advance market commitments[19]; and others. We do not know, however, which of these are most cost-effective, which are synergistic, and which may cross-react to produce unwanted side-effects[20].

The Era of Partnerships is structured by technological innovation, the legacy of the geopolitical struggle between capitalism and socialism, and globalization. This last factor has affected many aspects of health worldwide. Jet travel can transmit diseases from one part of the world to another in a matter of hours. Pharmaceutical firms are now global companies, marketing their products to over 100 countries. Because of the very large profits they have made off of critically needed health products—especially by the poor—these companies have been admired and criticized. Globalization has led university investigators to collaborate through worldwide research systems, which has made science a global undertaking. All of these aspects of globalization are profoundly affecting how knowledge is produced and how health technology innovation occurs [21] [22].

We do not yet know how this new Era of Partnerships can operate most effectively in the field of health innovation. Insistent questions have arisen about how to best regulate new drugs and vaccines, how to manage patents and other forms of IP for new health applications, and how to fund research in academia and industry. Many more such questions will continue to arise as we learn more about the new structure, limitations, and possibilities of the new Era of Partnerships.

We do know, however, one thing for certain: this new era requires a global perspective. The WHO Commission on Intellectual Property Rights and Innovation has recently called for a global plan to make the most of this new era[23]:

> *"It is important that all the contributions of all stakeholders are taken into account so that their respective energies can be mobilized towards the achievement of a common goal… For this purpose, the need is to develop a Global Plan of Action which would provide a medium term framework for action by these partners, including the setting of clear objectives and priorities and a realistic estimation of funding needs if these are to be achieved. … Viewed across the field, there are few or no available mechanisms at present to advise on appropriate priorities for resource allocation between R&D on different diseases, the balance between resources needed for R&D and delivery for each disease or the means to monitor and evaluate the impact of resources devoted to treatment and delivery. Such a Plan would also provide an important basis for measuring progress towards the achievement of these goals."*

If health technology innovation is to contribute to alleviating death and disease among the poor worldwide, its operations must be global. It must be able to identify the nature and causes of so-called "health failures" and to propose strategies to cope with them. And these strategies must involve all countries—from industrialized to least developed countries. In short, the Global Plan of Action called for by the WHO Commission should be a part of a Global Health Innovation System (GHIS).

The GHIS as a Response to "Health Failures"

A Global Health Innovation System is warranted because of a number of "health failures." We identify three kinds of these: science failures, market failures, and public health failures.

Science failures occur when we lack the knowledge to make tools or mechanisms to address health problems. For example, we do not know how to make safe and effective drugs or vaccines against such important diseases as dengue, avian flu, tuberculosis, and all parasitic diseases (malaria, leishmaniases, and trypanosomiases, etc.). To address this failure globally, we need more basic and applied research, which requires not only increased funding but also enhanced strategies for developing new products that will be accessible to the poor in developing countries. Some of the most promising strategies involve PDPs

and funding agencies in industrialized countries to address scientific issues of interest to developing countries (e.g., the genome projects for tropical pathogens and their vectors [24], [25]).

Market failures occur when the costs of vaccines, drugs, or other health interventions bar the poor from access, when the cost of developing or producing new drugs is very high, or when their delivery requires costly structures, such as sophisticated tertiary health care units. Examples of these kinds of products are antiretrovirals, combination therapies against malaria, and regimens for fighting drug-resistant tuberculosis. To address these failures, we must either provide much greater funding for such mechanisms as the Global Fund to Fight AIDS, Tuberculosis, and Malaria, or we need to find more efficient ways to produce these products and lower their cost to consumers. We can address such market failures by a number of means, including procurement funds and funding PDPs. Other options include increasing the health budgets of national governments or stretching health expenditures through government negotiations with drug suppliers to reduce the costs of pharmaceuticals. One example of an innovative financing system is the Provisional Contribution on Financial Movement (CPMF) that Brazil established in the 1990s to finance health care, which generated revenue of 1.5% GDP for several years and helped deliver antiretrovirals to millions [26] [27].

Public health failures occur when good governance or sound priorities are lacking. Corruption, crises, war, or cultural and religious factors can block access to cheap and readily available interventions. Resistance to immunization by religious or cultural factors, for example, has made polio eradication more difficult. Obesity and tobacco consumption are other examples. To address these public health failures, we need more education, better leadership within civil society, and the strengthening of human rights. Recent innovations that are helping to address these public health failures include National Immunization Days[28], the WHO Tobacco Convention, educational TV campaigns, and better management and budgeting practices, as in the Tanzania Essential Health Interventions Project, TEHIP [29].

These failures point to a broad based "failure of policy": the global, national, and institutional policies needed to effectively address these failures are lacking. A sound GHIS would fill this need, and we believe that innovation systems studies can provide valuable guidance about how to make it work most effectively.

What We Can Learn from Innovation Systems Studies

Over the last three decades, innovation studies have taught us much about the essential elements of effective innovation systems. We highlight four: the role of the firm, the role of governments, the value of networks, and the need for adequate and sustained financing.

1. **The role of the firm.** Private firms are the key actors in innovation. While historically some innovation, such as the development and production of early vaccines, took place through state-owned or parastatal organizations, they are of much less importance today [30]. A new technology has very little chance to reach the market without the sponsorship or partnership of a firm. This insight helps us to understand from another point of view why public-private partnerships are necessary. Lall has examined this issue with respect to developing countries and shows that firms are also essential there [31].
2. **The role of government and the public sector.** After the fall of the Soviet Union, some argued that the government should not be involved in directing or stimulating innovation (this was a component of the "Washington Consensus"[32]). A number of economists, however, have demonstrated that the government is in fact a necessary and essential partner in innovation. Korea is often cited as the prime example[33]. We believe that while the government cannot determine innovation, it does have an essential role to play in setting ground rules and providing funding and other incentives.
3. **The value of networks.** Innovation studies show that the most effective firms and organizations are those with the most dynamic networks. Whether in the public or private sector, these organizations reach out to actors in the key areas in which they work. They build collaborative part-

nerships or exchange information. Conversely, organizations operating within limited networks are less innovative and successful[34].

4. **Adequate and sustained financing.** Acquiring innovation capabilities is a long- term process of 10-30 years that requires long-term funding at high levels. By contrast, the pace of technological innovation is very rapid[35], imposing extra challenges to developing countries.

While most innovation studies focus on developed countries, innovation in developing countries has also received some attention. One focus has been on whether or not developing countries can innovate. Viotti argues that developing countries do not innovate but learn, and he divides them into two categories: active learning and passive learning[36]. Defining innovation as the development and commercialization of truly new technologies, he argues, by that definition, developing countries are not currently capable of innovation. But it seems that some developing countries—the IDCs—may be poised to make truly innovative contributions. India, for example, has already moved into the first frontier of innovation in information technology. Nevertheless, the vast majority of the world's innovators are in developed countries. Developing countries must therefore devote a larger proportion of their innovation activities to learning from others. And given the four major lessons described above, developing countries should also work to stimulate innovative firms, provide long-term sustained funding to develop innovation capabilities, and promote the establishment of networks not only among themselves but also with leading centers in developed countries[37].

In sum, a GHIS should help to involve firms and government, create and sustain networks, and mobilize and maintain adequate financing. It must also facilitate networks with nodes in both developed and developing countries.

Promising Developments

As documented by the work of DiMasi[38] and Towse[39], the resources necessary to develop new drugs and vaccines are substantial: between $400-$1,285 million (in year 2000 dollars). As Towse and Glickman[40] point out, the funds available to current PDPs are insufficient to develop a range of new technologies successfully. Every effort must therefore be made to achieve the highest level of cost effectiveness when allocating resources to develop new and improved health technologies. But where can guidance for such efforts be found? The GHIS would help to meet this need.

Certain types of health innovation systems are already emerging. For example, PDPs are setting up global systems to promote the development of new drugs or vaccines. With both public and private sector collaborators in developed and developing countries, they are addressing all of the issues associated with developing and introducing new technologies. This includes research and development, market development in individual developing countries, international trade issues, manufacturing issues, intellectual property rights, and regulatory matters[41].

In addition, several developing countries are beginning to build collaboration networks. For example, Brazil, China, Cuba, India, Nigeria, Russia, South Africa, Thailand, and Ukraine have formed a network to boost production of antiretrovirals and other health products[13]. These networks must address all the issues related to the development and introduction of new technologies, including the critical area of intellectual property rights. It is not clear whether these networks will succeed: they are in very early stages of development.

Within some developing countries, such as Brazil, India, and South Africa, networks have been created to facilitate the development and introduction of new health technologies that meet their citizen's needs. All of these countries strongly emphasize forming and promoting public private partnerships. In Brazil, for example, it used to be very difficult to partner with private companies. Due to the Law on Innovation enacted in December 2004, a new, enabling environment strongly encourages such partnerships [42].

Other efforts to develop focused global health innovation systems include the Bill and Melinda Gates foundation's promotion of an HIV Enterprise, which will provide a worldwide coordinated strategy to address the need for new HIV vaccines[43],

and Dr. Gerald Keusch has proposed the formation of a network to link medical research councils and universities around the world in concerted strategies to develop new health technologies[44].

Each of these initiatives (PDPs, developing country health innovation programs, and international networks) are either relatively new or have yet to be fully launched. Unfortunately, there is little if any cross learning among these various initiatives, and there is a lot of repetition and duplication. One initiative addressing the need for cross links is the Centre for the Management of IP in Health R&D in Oxford England (MIHR). MIHR is attempting to identify and disseminate best practices for IP management in order to insure access to new health technologies by the poor in developing countries (www.mihr.org). WHO is promoting another cross-linking initiative, the WHO Developing Countries' Vaccine Regulators Network, created in September 2004. Including Brazil, China, Cuba, India, Indonesia, Russia, South Africa, South Korea, and Thailand, it brings together national regulatory authorities to prepare standard approaches for the review and approval of vaccines and drugs needed in developing countries[45]. Brazil and Kenya have proposed to the World Health Assembly a treaty concerning health R&D. The proposed treaty would result in the establishment of a global mechanism for priority setting in health R&D. It would also set non-enforceable targets based on GNP for support of health R&D in priority areas for the poor. The treaty would allow member states to modify laws and policies concerning intellectual property in ways that would enhance access by the poor. Finally, the treaty would establish various operating institutions (possibly within WHO) for the management of priority setting, oversight of financial contributions, monitoring of activities under the treaty, and other matters. This treaty and a resolution concerning it will be considered at the World Health Assembly in May 2006. If the resolution is approved, the treaty might go into effect in 2009 following preparatory work[46]. Representing potentially important contributions to the creation of a GHIS, these valuable efforts should be promoted.

A Framework for a GHIS

We propose a framework for the GHIS based largely on the work of Lall[47]. The Framework identifies six components of health technology innovation[48]:

- Development and expansion of national health delivery systems, including an attractive, domestic, private-sector market for health products;
- Development of manufacturing capability for health products;
- The drug and vaccine regulatory system;
- The IP regulatory system;
- Development of R&D capability by the public and private sectors;
- Development of international trade systems for health products, including global procurement funds.

Because these innovation components are dynamically linked, successfully developing and introducing new technologies requires concerted attention to each of the six components [49]. Progress in one requires progress in all, and failure in one may impede progress in all. National innovation policies and the crafting of global policy interventions and norms must be considered. And to create strategies for product development and introduction, we must also attend to the roles of the public and private sectors in each of the six components. These roles of the public and private sectors for any given technology development will necessarily be inadequate if they are considered independently of one another. For national policies, moreover, the relative emphasis given to the components will differ according to the kind of country: developed, IDC, or low-income.

The framework can be used to develop not only strategies for particular technology innovation initiatives but also strategies for national health innovation. Indeed, the value of such a framework is readily apparent. When a country wishes to accelerate progress in science and technology, its strategy must encompass all six components. Likewise, if it wants to develop comprehensive financing strategies or capacity building strategies, it must address all six components. The ministry of science and technology, for example,

cannot develop a comprehensive innovation strategy on its own. It must work with the ministry of health, the ministry of industry, and the ministry of trade.

The Framework applies equally to the operation of international networks, such as the HIV Enterprise. Such enterprises will have to address issues with respect to each of the six components, as will PDPs.

Using the Innovation Components to Address the Health Failures

By focusing on the six components of innovation, effective innovation policies can be developed. But different actors and different countries have different roles to play in accelerating health innovations and addressing health failures. We have therefore mapped the six components of health innovation against the three kinds of health failure (i.e., science failures, market failures, and public health failures). *Science failures* can be addressed primarily through considering drug regulation, IP, and research and development issues. *Market failures* are primarily addressed by working on the components of innovation for domestic markets and international markets. *Public health failures* can also be addressed by looking at why domestic markets, which include national health service delivery systems and the private sector's delivery of health services, do not work efficiently. Understanding how international markets work, such as those for tobacco (an example where we want to innovate by reducing the use of the technology and tobacco consumption), will also move us towards solutions. We argue, however, that addressing science failures, market failures, and public health failures requires addressing all six components of innovation.

This health innovation assessment and the identification of the three areas of health failure lead us to propose a comprehensive matrix to illustrate how various countries and institutions within those countries can contribute to addressing health failures through innovation. There are roles for industrialized countries, for IDCs, and for the least developing countries. Table 1 provides this matrix and illustrates how different agencies and organizations in both the public and private sectors in different kinds of countries can be brought together to help address health failures.

The matrix of Table 1 articulates two dimensions:

(i) The vertical (column) "diagnostics/therapeutics" axis:
- *Diagnostics*: Lists the three kinds of **failures** (interventions do not exist, interventions exist but are too expensive, cost-effective interventions are available but do not reach the poor)
- *Therapeutics*: Lists the appropriate type of **innovation** required to cope with each kind of failure (new products, new processes, new strategies/policies)

(ii) The horizontal (row) player axis:
- *Players*: Displays the three categories of **countries** whose national innovation systems are responsible for the development & implementation of the innovations and interventions (industrialized, IDCs, Least-Developed Countries).

The cells of the matrix display examples of health actions, where each country category intervenes appropriately to cope with each kind of health failure. For these actions to take place, the countries and institutions will need to address the four elements of an effective innovation system: the role of the firm, the role of the public sector, the value of networks, and sustained funding.

Developing the GHIS

The new millennium continues to bring major changes to the world. In health these changes—new funds, new organizations, and new opportunities to develop the health technologies needed in developing countries—have helped give birth to the Era of Partnerships for health innovation.

Most of the partnerships, however, have focused missions and concentrate their activities on develop-

Table 1: Coping with health failures: An example of a Health Innovation -- Country Category matrix

		Health Failures		
		Science failure (knowledge/learning gap)	**Market failure (resources gap)**	**Public Health failure (best practices gap)**
Actions by National Innovation Systems	**Industrialized Countries**	Public funding of R&D of interest to developing countries (e.g. NIH genome projects of tropical pathogens)	Drug procurement mechanisms (e.g. Stop TB Partnership Global Drug Facility, GDF)	Drug donation programs (e.g. Merck Mectizan); Donor support to health systems (e.g. Rotary International & poliomyelitis vaccination)
		Private sector participation at PDPs; Big Pharma institutes dedicated to neglected diseases (e.g. Novartis Institute for Tropical Diseases, Singapore; GSK drug discovery unit in Tres Cantos, Spain)	Differential drug pricing (e.g. Novartis' antimalarial Coartem® in endemic countries sells as Riamet® in industrialized countries)	Actions through Global Conventions (e.g. Tobacco Convention against smoking; UN Framework Convention on Climate Change to monitor impact of climate changes on insect-borne diseases)
	Innovative Developing Countries	Health innovation networks (e.g. South/South: WHO Developing Countries Vaccine Regulators Network; e.g. North-South: genomics/bioinformatics networks for the study of tropical pathogens)	Innovative financing systems (e.g. Provisional Contribution on Financial Movement, or CPMF taxation, imposed by Brazil to buy antiretrovirals)	Pressure from health sector and civil society (e.g. Brazil Constitution's "Health is the citizen's right and the State's obligation and responsibility")
		"Bayh-Dole"-like laws to foster academia-industry partnerships (e.g. Innovation Law, Brazil)	Negotiating price reductions (e.g. Brazil/Abbott deal to lower price on antiretroviral drug Kaletra)	National Immunization Days; cash transfer programs to reduce poverty and inequality (e.g. The Bolsa Familia Project in Brazil)
	Least Developed Countries	South-South networking with IDCs (e.g. collaboration between Brazil and lusophone Africa in the strengthening of public health schools and R&D institutes)	Funding mechanisms (e.g. The Global Fund to Fight AIDS, Tuberculosis and Malaria; The Global Alliance for Vaccines and Immunization)	Better priority setting (e.g. The Tanzania Essential Health Interventions Project, TEHIP)
		Participation at clinical trial platforms (e.g. European & Developing Countries Clinical Trials Partnership, EDCTP)	Regional production of generic drugs; Popular Pharmacies ("Boticas Populares") that sell generic and essential drugs at a reduced price to poor people	Innovative approaches in relation to educational campaigns, empowerment of women, fighting corruption
		New products, methods	**New processes**	**New strategies or policies**
		Health Innovations needed		

ing specific interventions or products. Although an important component of a future GHIS, their compartmentalized mandates are no substitute for the global architecture called for by Professor Bloom.

We believe that a new architecture for health innovation is possible, necessary, and urgently required. It should be based on the lessons provided by innovation studies, effectively addressing each of the six innovation components and the three different health failures by identifying appropriate roles for each country and public- or private-sector organization.

A GHIS does not exist today and so we do not know what exact form it would assume. But without changes from the status quo, it is likely that 10 or 20 years from now we will have only a few new products on the market: most will be stuck in the pipeline. To open the floodgates to new innovation, we need a widely accepted, understood, and cost effective GHIS. We propose that its architecture should be integrated to become more than the mere sum of its parts: the innovation systems of PDPs, developing countries, developed countries, and international networks. One may think of it as an overarching system that discusses, shapes, and provides a long-term strategic vision, a system that offers best practices and policies adapted to the particular needs and environments of all the participating organizations.

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