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## The Global Governance of Communicable Diseases: The Case for Vaccine R&D\*

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*Fighting communicable diseases such HIV/AIDS, tuberculosis (TB) and malaria has become a global endeavor, with international health authorities urging the development of effective vaccines for the eradication of these global pandemics. Yet, despite the acknowledged urgency, and given the feasibility of effective vaccine development, public and private research efforts have failed to address a response adequate to the magnitude of the crisis. Members of the academic community suggest bridging this gap by devising research pull mechanisms capable of stimulating private investments, confident that competition-based market devices are more effective than public intervention in shaping scientific breakthroughs. With reference to the economics of innovation, the paper argues that, whilst such an approach would lead to a socially suboptimal production of knowledge, direct public intervention in vaccine R&D activities would represent a far more socially desirable policy option. In recognition of the current financial and political fatigue affecting the international community towards communicable disease control, the paper resorts to the theories of global public goods (GPGs) to provide governments, both in the North and in the South, with a powerful rationale for committing to a cooperative approach for vaccine R&D. The paper encourages the creation of a Global Health Research Fund to manage such exercise and proposes enshrining countries' commitments into an International Health Treaty. The paper ends by providing a number of policy recommendations.*

### I. INTRODUCTION: THE CURRENT MISMATCH BETWEEN GLOBAL HEALTH NEEDS AND GLOBAL HEALTH RESEARCH

#### A. CURRENT DISTRIBUTION OF COMMUNICABLE DISEASES

At the dawn of the twenty-first century, despite 150 years of international health cooperation and numerous high-profile health summits, communicable disease control is still lacking adequate international political action:

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forty-two million people are currently living with HIV/AIDS around the world, thirty-nine million in developing countries (the South) alone. Infection rates are also on the increase: five million new HIV/AIDS infections were reported in 2002, with over 70 percent of these occurring just in sub-Saharan Africa (WHO, 2003). Similarly, tuberculosis (TB) is responsible for the death of over two million individuals, and the infection of another seventeen million every year (WHO & UNICEF, 2002), with an incidence of infection that is thirteen times higher in developing countries than in the industrialized world (the North). Malaria also, despite having been eradicated in the North<sup>1</sup> through an overall improvement in environmental conditions, still claims over one million lives and 400 million new infections each year in the South (Harvard Malaria Initiative, 2000). The economic and social repercussions that entire regions experience as a result of these pandemics are tremendous. The United Nations (2001) estimates that AIDS alone will cause South Africa's GDP to fall by 17 percent by 2010, without taking into account falling workers' productivity, declining savings and investment, rising business costs, and decreasing life expectancy. Many other countries are also facing similar prospects, and comparable patterns are envisaged for malaria and TB (WHO & UNICEF, 2002). As well as contributing to the economic decay, social fragmentation, and political destabilisation of already volatile and strained societies, these global pandemics are also jeopardizing past and present development efforts aimed at bridging the increasing widening socio-economic divide between the North and the South.<sup>2</sup>

#### B. THE NEED FOR VACCINE R&D

Leading health organizations (International Aids Vaccine Initiative 2001; Médecins sans Frontières 2001a; WHO & UNICEF 2002) have argued with much vigor in favor of preventative immunization as representing the most effective tool in the fight against communicable diseases – the eradication of smallpox in 1977 as a result of WHO's Smallpox Eradication Programme representing the most remarkable example (see Fenner 1988 for a detailed analysis of the program's achievements). Yet, despite the success of preventative immunization and the authoritative opinion of experts, resources devoted to vaccine R&D continue to be minimal. The case of AIDS is exemplary. The annual HIV/AIDS vaccine R&D expenditure still represents just 10 per cent – about US\$400 million – of the annual global HIV/AIDS anti-retroviral R&D spending (Esparza 2000; International Aids Vaccine Initiative 2002). For malaria and TB, vaccine R&D figures are even more disconcerting. The Malaria Vaccine Initiative<sup>3</sup> estimates that the total R&D for a malaria vaccine has not exceeded US\$55 million, whilst for TB, the World Health Organization and United Nations' Children Fund (WHO & UNICEF 2002: 61) estimate that, since the early 1990s, vaccine R&D has not exceeded US\$150 million.

### C. STRUCTURE AND OBJECTIVES OF THIS STUDY

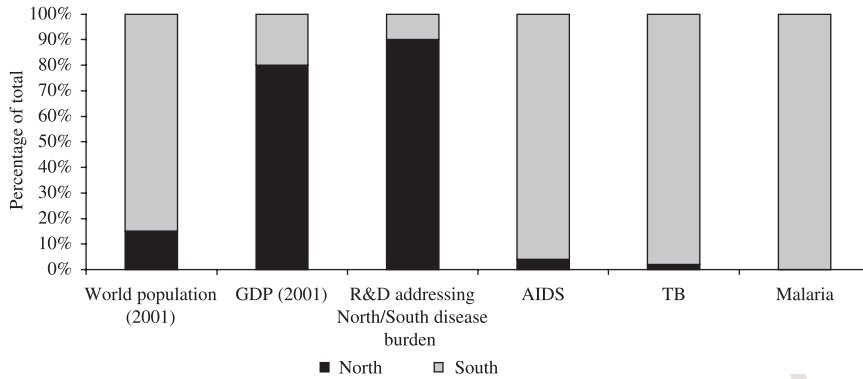
The paper will explore the possible explanations as to why vaccine R&D for major communicable diseases has been so inadequate in addressing the current health crisis. The following sections will provide an overview of current private and public research efforts in vaccine R&D, and will highlight the importance of incentives in determining R&D investments, arguing that geo-economic factors are responsible for the current lack of incentives. Through a global public goods approach, section IV provides a rationale for convincing the international community to cooperate in the fight against communicable disease control by focussing on vaccine research and development. Sections V and VI advance estimates concerning the ideal R&D resources required, and propose the creation of an Global Health Research Fund for a coordinated approach to the management of these resources. Section VII supports the creation of an International Health Treaty in an attempt to insure member states' respect of their financial obligations to the proposed fund. The paper concludes by providing a number of policy recommendations.

## II. THE CURRENT STATE OF SCIENTIFIC KNOWLEDGE

### A. HOW FAR ARE WE FROM HITTING THE TARGET?

The economics of innovation teach that, given the *de facto* uncertainty of all scientific investigation, no clear linear relationship between input and output can be assumed – the case for a cure for cancer being exemplary. Particularly with reference to the delivery of a vaccine for AIDS, malaria, and TB, experts believe science is still ten to fifteen years away from yielding the desired results (Kaufmann 2000; Malaria Vaccine Initiative 2003; WHO & UNICEF 2002). Despite this technical hurdle, it is the opinion of the very same experts that a knowledge gap alone does not explain the minimal investment geared towards vaccine R&D. To quote the authoritative opinion of the Rockefeller Foundation's deputy director, Scott Halstead, "the major impediment to basic vaccine science is not a gap in knowledge, rather a lack of serious financial commitments that precludes the yielding of tangible results" (Rabinovich, 1994). An opinion that is also shared by many other experts in the field, including Médecins sans Frontières (2001), the International AIDS Vaccine Initiative (2001, 2002), and the WHO & UNICEF (2002).

Though, if indeed a lack of incentives, as opposed to a knowledge gap, were to explain the current undermining of global efforts to fight communicable diseases, two aspects would need to be considered: (a) the type, and amount, of R&D expenditure of both profit-seeking and public non-profit agents; and (b) the influence that the distribution of the disease burden across countries exerts on global research agendas.



**Sources:** For malaria, UNDP (2002), Table 7, column 8, p. 173. For AIDS, UNAIDS and WHO (2002), p. 6. For TB, UNDP (2002), Table 7, column 9, p. 173. For GDP, World Bank (2003), Table 3, column 1, p. 239. For World Population, World Bank (2003), Table 1, column 1, p. 235. For R&D addressing North/South disease burden, MSF (2001).

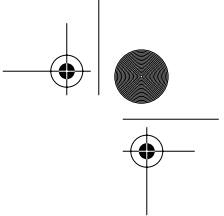
**North:** high income countries. **South:** all others. (See UNDP 2002).

**Figure 1. North/South Health and Resource Inequalities.**

#### B. THE PRIVATE FUNDING OF HEALTH-RELATED R&D

The UNDP (2001) reports that of the 1393 new drugs developed between 1975 and 1999, only sixteen (less than 1 percent) of these were relevant to tropical illnesses – including communicable diseases. The World Health Organization Commission on Macroeconomics and Health (2001: 90–91) explains that industry involvement in R&D activities concerning all major disease killers is very limited, and in the majority of cases it is simply non-existent. Similarly, the Harvard School of Public Health revealed in a recent study that, of the world's twenty-four largest drug companies, none maintain an in-house malaria research program (Medicins sans Frontieres 2001b).

This can be interpreted as a reflection of the profit-driven nature of private R&D. As Figure 1 illustrates, the bulk of the disease burden is confined to the South, also home to the highest concentration of the world's poor, where 80 percent of the world's population concentrates just 20 percent of the world's GDP. As a consequence, this low purchasing power of the South has impeded the high "social" demand for vaccine R&D to be matched by an equally high "market" demand necessary to stimulate private investment. This would explain why, of the eleven different HIV clades currently identified, private vaccine research is focussing on clade B, the clade prevalent in Europe and North America – responsible for just 4 percent of the disease burden – whilst clades A and C, prevalent in Africa and responsible for 70 percent of all HIV/AIDS infections, receive minimal



research effort (Barnet and Whiteside 2002; Kremer 2001). Moreover, the social pressure exerted over investors to treat their inventions as indivisibilities – as exemplified by the celebrated case between the South African government and the pharmaceutical industry over the AIDS anti-retroviral cocktail drug (May 2002; Seckinelgin 2002) – could cause private investors to be discouraged further from investing in a field already surrounded by much scientific uncertainty, and lacking adequate market demand.

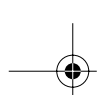
#### C. STIMULATING PRIVATE R&D: THE ROLE OF “PURCHASING COMMITMENTS”

Many economists have attempted to devise a variety of mechanisms to stimulate private investment in neglected areas of medical research. One of the most celebrated proposals, indeed welcome by many IGOs (see the World Health Organization, Commission on Macroeconomics and Health 2001; Kaul et al. 2003; UNDP, 2001) has been that of “purchasing commitments” (Kremer 2001). As described by Kremer, purchasing commitments entail a clear financial pledge by international organizations, such as UNICEF or WHO, to purchase a successful vaccine when and if developed. Kremer argues that, by committing to purchase a successful vaccine, the public sector would provide private investors with the market demand necessary to stimulate their interests, whilst it would leave the entire burden of the costs, and the risks associated with R&D activities, on the shoulders of the private sector. Although the private sector clearly necessitates of encouragement for investing in non-profitable markets, this approach presents a fundamental hurdle that deserves mentioning.

Purchasing commitments entail an entirely competitive spirit among research entities. As the economics of scientific and technological innovation teach, optimal knowledge production is reached by maximizing diffusion of all intermediate results, or rather through a highly cooperative approach to scientific inquiry (Nelson 1962). By contrast, the exclusivity of a prize, as suggested by Kremer, would force the various competing agents to maintain secret all intermediate results of their research, with an ultimate detrimental effect to vaccine knowledge production. Thus, despite the utility of encouraging private research in neglected areas of medical research, “purchasing commitments” are far from providing an ideal policy solution.

#### D. THE ROLE OF THE PUBLIC SECTOR

Back in 1962, Arrow had warned against the dangers of leaving to market forces alone the responsibility for providing the financial incentives necessary to stimulate scientific R&D since, the lack of profitable markets, indivisibilities, and scientific uncertainty, would cause private resources to be suboptimally allocated (Arrow 1962). With reference to activities with strong social implications, many classical economists, including Smith,



Malthus, Ricardo, and indeed Arrow, suggested moreover that – in the event of a market failure – the state should bare the costs of their provision (Desai, 2003). Within modern capitalist societies, the state and the market share the provision of a number of activities. With reference to scientific R&D, the public sector performs a variety of research activities through (a) a number of publicly owned infrastructures – such as academic research laboratories – and (b) by outsourcing research projects to private operators – as has been the experience of both space and military R&D programs. Especially within medical science, publicly funded R&D has played a fundamental role in major drug-lead discoveries. Publicly funded R&D has developed a number of antibiotics for many communicable diseases, drugs for treating tuberculosis, various types of chemotherapy to treat cancer, and more recently the development of anti-retrovirals for the treatment of HIV/AIDS (UNDP 2001). It is estimated that 70 percent of all drugs with therapeutic gains have been the direct result of the public sector's involvement (ibid.).

### III. THE GEO-POLITICS OF VACCINE R&D

#### A. THE NORTH-SOUTH PARADOX

If a lack of profitable markets explains the privates' disinterests towards communicable disease control, what could explain the public sector's disengagement? Figure 1 suggests that geo-political factors may be involved.

On one side of the hemisphere, the South concentrates 20 percent of the world's GDP, 90 percent of the total disease burden, and just 10 percent of the total R&D budget. In contrast, on the other side of the hemisphere, the North concentrates 80 percent of the world's GDP, 90 percent of the World's R&D budget and less than 10 percent of the world's disease burden. These conditions have conferred the North, not only the resources and the competencies necessary to address these diseases, but also the power to set the global health research agenda. Regrettably though, many governments in the North, especially European, have favored financially the R&D of non-targeted academic activities and commercial areas that would increase the international competitiveness of national firms, rather than R&D activities that would benefit humanity as a whole (European Council 2002). The result has been a paradoxical situation, in which countries affected by the diseases lack the resources and expertise necessary to combat them, whilst countries holding both the resources and the expertise to fight them, lack a direct incentive for doing so.

#### B. THE NORTH/SOUTH HEALTH DIVIDE: A MATTER OF POLITICAL WILL

The case of the Global Fund To Fight AIDS, Tuberculosis and Malaria (GFATM) is exemplary to this political and financial *fatigue* of Northern

government towards fighting communicable diseases globally. Established in 2002, under the auspices of the UN Secretary General, the fund has aimed at raising a total of US\$8 billion a year through country's voluntary donations to fight major communicable diseases – although the Fund focuses on disease prevention and cure, as opposed to vaccine research and development (Tan, Upshur & Ford 2003). Despite the apparent initial political support from the international community, the fund has suffered severe financial constraints ever since its foundation. Most countries have in fact met only partially their financial obligations to the fund, with the USA in particular having contributed just 10 percent of the US\$10 billion it agreed to donate by 2008 (see Cunningham, 2003). Far from being the exception, the Fund's lack of support follows the general trend that has distinguished Official Development Assistance (ODA) since the fall of the Berlin Wall, or rather a decreasing political and financial support to building bridges between the North/South socio-economic inequalities (World Bank 2003: 13).

Faced with this political indifference, many attempts have been made over the past thirty years to provide convincing arguments for inciting the North to play a proactive role in international cooperation, including global communicable disease control.

A most powerful rationale that has recently emerged, and has captured the interest of governments, and international governmental and non-governmental organizations, is that of global public goods (GPGs). Indeed, by looking at communicable disease control through a global public goods' lens, a persuasive justification can be developed for the North's cooperation in the fight against communicable diseases. The following section explores this rationale.

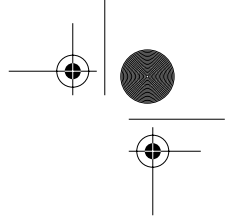
#### IV. VACCINE KNOWLEDGE AND COMMUNICABLE DISEASE CONTROL AS GLOBAL PUBLIC GOODS

##### A. GLOBAL PUBLIC GOODS (GPGs): A DEFINITION

In her pioneering work, *Providing Global Public Goods: Managing Globalisation*, Kaul (2003) defines GPGs as goods exhibiting the following characteristics:

- non-excludable benefits – entailing the technical impossibility of excluding any one individual from consuming the good (i.e., the atmosphere, judicial systems, national defense);
- and/or non-rival benefits – by which the consumption of the good by one individual does not deprive others from consuming the same good (i.e., knowledge, see below);
- and whose benefits extend to all countries, people, and generations.

To these technical properties, Kaul adds a fourth and normative aspect, namely the dependency on international cooperation for an effective provision of GPGs.



Additionally, Kaul also distinguishes between what she defines *intermediate* global public goods, and *final* global public goods, or rather, global public goods whose provision is dependent upon the production of associate goods (Kaul, 2003). For the purpose of our argument, Kaul's definition will set the frame within which it shall be argued that both the control of communicable diseases, and the knowledge necessary to develop a vaccine for their eradication, can be considered global public goods – the former, final; and the latter, intermediate.

#### B. VACCINE KNOWLEDGE AS A GPG

In 1962, Arrow postulated that knowledge could be duplicated and diffused at zero or very low costs (Arrow 1962). Although this assumption has proven wrong for the majority of technological applications (see Pavitt 1987), in the case of the chemical and pharmaceutical industries the costs of knowledge duplication and diffusion can be minimal – given adequate supporting infrastructure (Mansfield, Schwarts & Wagner 1981). Moreover, knowledge is unique in its ability to diffuse from one individual to another without depriving the original withholder from continuing to enjoy its consumption and associated benefits. As noted by Thomas Jefferson, “he who receives an idea from me, receives instructions himself without lessing me” (Stiglitz 1999).

These *de facto* non-excludable and non-rival characteristics have distinguished knowledge as a public good (Correa 2003). However, in order to qualify as a *global* public good, vaccine knowledge would have to benefit more than one group of countries, populations, and generations. At present, the scientific community is concerned that, due to the geographic variation of the HIV virus genetic make-up, country-specific vaccines may fail to prove effective globally (Kremer 2001). International cooperation for the development of a universally effective vaccine might therefore be jeopardized by the self-interest of certain countries to develop a vaccine specific to their own needs only. Also looking at communicable disease control from a global public good perspective provides a convincing argument for pursuing cooperatively the development of a universal vaccine for communicable diseases.

#### C. COMMUNICABLE DISEASE CONTROL AS A GPG

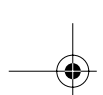
The GPG character of communicable disease control is best understood by juxtaposing it against the direct and indirect threats that the underprovision of communicable disease control poses globally. The following examples will highlight how, despite the unequal repartition of the disease burden across countries, communicable diseases bring states into a shared fate, consequently calling upon governments to act cooperatively in fighting against communicable diseases:



- *Cross border transmission* – international travel and trade are causing an increase in prevalence within industrial countries of diseases previously endemic to the South. In Switzerland, for example, new HIV infections are exhibiting similar characteristics to those fuelling the AIDS epidemic in Africa (Tenkorang & Conceição 2003). Similarly, the recent West Nile virus infections reported in the U.S., illustrate the physical boundless nature of communicable diseases (Kaul & Faust 2001);
- *Costly provision of national public goods* – the cross-border transmission of communicable diseases represents a direct negative externality for the country into which the disease enters – since the disease-importing country will have to bear the costs associated with the imported disease (i.e., prevention, treatment, vaccination, mortality, etc). This was recognized by the United States Congress in 2000, when it acknowledged in its Global AIDS and Tuberculosis Relief Act (2000), that “because of the ease of transmission of tuberculosis, its international persistence and growth pose a direct public health threat to those nations that had previously largely controlled the disease.” Indeed, by failing to achieve global eradication, even disease-free countries will still have to incur the costs associated with immunization and treatment. The case of polio is exemplary. The incomplete eradication of polio is estimated to be costing the world US\$1.5 billion a year (Aylward 2000). By contrast, it has been estimated that by achieving the eradication of smallpox, the United States recoups its contributions to the smallpox eradication programs once every twenty-six days. That is, every twenty-six days, the benefits accruing from *not* having to deal with smallpox, equal the U.S.’s total eradication costs (Tenkorang & Conceição, 2003);
- *Socio-economic repercussions* – as discussed in the introduction, HIV/AIDS is responsible for massive economic and social devastation in sub-Saharan Africa (Bell, Devarjan & Gersbach 2003). The United States assert that HIV/AIDS in Africa constitutes a national security threat not only because of cross-border HIV transmission, but because it has the potential to destabilize the region and harm the economic, political, humanitarian, and strategic interests of other countries (Fidler 2001).

#### D. THE NECESSITY OF INTERNATIONAL COOPERATION FOR COMMUNICABLE DISEASE CONTROL

The examples reported above illustrate the non-excludable and non-rival characteristics associated with communicable diseases, highlighting the strong intergenerational and social and economic implications for all countries, including those currently disease-free. In particular, they highlight the GPG character of communicable disease control, given the inherent impossibility to exclude any one country from benefiting from the direct and indirect advantages accruing from the eradication of the diseases. Three main conclusions can therefore be drawn with reference to the GPG argument:



44 *LAW & POLICY* January 2005

1. Vaccine R&D can be considered the *intermediate* GPG necessary for reaching the *final* GPG of communicable disease control.
2. The GPG character of both vaccine R&D and communicable disease control provides a strong case for public intervention in their provision.
3. The effectiveness of their provision will depend on the international community's capacity to act cooperatively, since individual efforts will not be effective unless supported by a global structure.

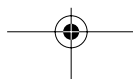
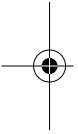
Thus, despite the different degrees of threat posed to countries by communicable diseases, the global public good character of communicable disease control brings countries into shared fate. Consequently, countries should also be brought together as partners in reforming appropriately their public policy choices. The following section proposes an ideal framework on which countries should build a cooperative approach to the financing of vaccine R&D.

## V. CREATING A GLOBAL HEALTH RESEARCH FUND

### A. A CENTRAL FUNDING ORGANIZATION

In its 2001 report, the WHO Commission on Macroeconomics and Health proposed the creation of a Global Health Research Fund (GHRF) to support basic, biomedical, and applied sciences research on health problems of the poor. Although the report provides no details as to how this fund should be structured nor managed, we support amply its creation and we suggest a number of features that should characterise the fund:

- The GHRF should act as a complementary financing mechanism to the Global Fund to Fight HIV/AIDS, Malaria and TB (GFAMT) by concentrating its mandate exclusively on vaccine research and development (hence knowledge production) – whilst the GFAMT would continue to provide financial support to outreach activities. The complementarity of the two funds would guarantee the global public good character of the vaccines developed;
- The fund would fall under the UN umbrella and, ideally, it would be coordinated by WHO in collaboration with all other UN agencies that might have a direct interest in the activities of the Fund, such as the United Nations Development Programme (UNDP), the United Nations Peoples Fund (UNFPA), and the United Nations Children Fund (UNICEF);
- WHO would be appointed as the primary coordinator of the fund, since WHO is the only global institution to benefit from the mandate to oversee international health cooperation and to guarantee the protection and promotion of global health commons. Moreover, WHO holds the ability

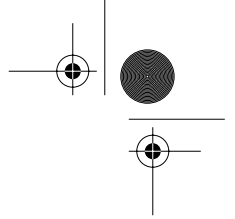


to convene a broad array of actors, develop consensus, and mobilize resources. With respect to legitimacy, the World Health Assembly is currently attended by 191 member states, all of which have equal voting rights irrespective of size of financial contribution (Buse & Walt 2000). No other health-related organization can claim near universal membership of nation states, nor does it benefit from a technical network-support as extensive as that of WHO;

- The fund would be subject to the supervision of a Health Research Council – directly accountable to the World Health Assembly – and would be composed by members representing all stakeholders with an interest in vaccine R&D. Namely, these should include WHO and other UN representatives, scientists, members of academia, NGOs, industry, and southern peoples' groups, in order to account for both scientific and non-scientific matters, keep research activity within its scope, and avoid targeted research being transformed into disciplinary research;
- The fund should also function as a catalyst and cooperate with all international research initiatives geared towards the development of a vaccine for communicable diseases, such as WHO's own vaccine research programs, the WHO/UNAIDS Initiative for Vaccine Research, the Tropical Disease Research program – co-sponsored by the WHO, UNDP, and World Bank – the International Aids Vaccine Initiative (IAVI), and the Global Alliance for Vaccine and Immunisation (GAVI);
- The fund should also aim at increasing funding to those groups obtaining more encouraging results. This evaluation would be performed by scientific peer review – a practice now common to many research-funding bodies, such as the U.S. National Institute of Health and the UK Medical Research Council. Members of the scientific community should also be encouraged to exchange information with other research groups on a constant basis. This could be effectively managed by the Global Forum for Health Research established by WHO in 1996, and through customary academic channels – such as scientific journals, conferences, academic courses, Internet, and electronic fora.

#### B. MANAGING EFFECTIVELY THE PRIVATE OUTSOURCING OF R&D

There is no requirement that public financial commitment must also be performed by public institutions. As discussed earlier, in the case of space and defense, outsourcing R&D activity to private research centres has become a common practice – especially in the United States. Though, as argued also earlier, private contractors tend to disclose the minimum information, especially if they can trade any additional or unexpected result achieved via separate contracts. This can represent a major obstacle for the achievement of optimal knowledge production. The public contracting party would therefore need to master a high degree of competence in contract dealing and a strong leadership in directing research.



## C. PRIVATELY FUNDED RESEARCH

Although the paper advocates a greater public commitment towards vaccine research, one cannot, and should not, aim at preventing private and profit-seeking agents from carrying out R&D activities in the field of immunization. Even in a residual position, the outcome of business-funded R&D could prove crucial to medical research. In the instance that the development of a successful vaccine for combating communicable diseases were the result of privately funded R&D, it would be necessary to negotiate the terms and conditions for licensing agreements – such as the type of remuneration (or compensation), and the exclusivity of the patent. Nothing should prevent the GHRF to purchase any successful vaccines through its annual budget. Alternatively, the GFATM could negotiate with patent holders the licensing right to reproduce and diffuse the vaccine via the payment of a royalty fee – issues associated with the duplication and diffusion of knowledge fall however outside the scope of argument (see Pogge (2002) for a radical proposition concerning the diffusion of essential knowledge to the developing world).

## VI. FINANCING VACCINE R&amp;D FOR COMMUNICABLE DISEASES

## A. THE COSTS OF DEVELOPING A VACCINE FOR AIDS, MALARIA AND TB

Estimates concerning the costs of drug development are very heterogeneous. Figures vary from US\$50 million (WHO & UNICEF 1996) to almost US\$900 million (Frank 2003; Tufts Center for the Study of Drug Development 2003) – though this appears to depend on whether the costs of clinical, pre-clinical, and post-approval tests are all accounted for (for a complete overview see DiMasi 1991; Frank 2003; WHO & UNICEF 1996; Miller 1998; TB Alliance 2001; Tufts Center for the Study of Drug Development 2003). The authoritative WHO Commission on Macroeconomics and Health (2001: 81) estimates that the cost of developing a vaccine for HIV/AIDS, malaria, and TB would require an ideal yearly R&D budget of US\$1.5 billion. The Commission fails though to indicate how long this commitment would be required for – ideally until successful vaccines are developed. As mentioned earlier on, experts are of the opinion that HIV/AIDS, malaria, and TB vaccines are still ten to fifteen years out of reach (Kaufmann 2000; Malaria Vaccine Initiative 2003; WHO & UNICEF 2002), an opinion that is also supported by the economics of science. Grabowski and Vernon (1994) have shown that research projects in the medical/pharmaceutical field last on average ten years.

According to these estimates therefore, the cost of developing a vaccine for AIDS, malaria, and TB would require US\$1.5 billion a year, for a potential fifteen-year period. This would total a comprehensive R&D

budget of US\$22.5 billion, a considerably large sum, compared to the current patterns of vaccine R&D expenditure – which according to estimates here provided do not exceed US\$600 million a year. Nevertheless, US\$22.5 billion is an affordable sum for most countries in the North. The fight against communicable diseases would therefore be comparable in size to the Manhattan project, though it would have a far more socially constructive objective.

#### B. A PROPOSED DISTRIBUTION OF THE FINANCIAL BURDEN

Table 1 illustrates a proposed distribution of the financial burden across countries according to the “Ability to Pay Principle” – or rather based on countries’ GDP.<sup>4</sup> The largest overall contribution would come from the North, with the United States responsible for providing the single largest contribution, followed by that of the European Union and Japan. Developing countries would also provide a substantial financial contribution.

A considerable share of the funding should also be geared towards building local knowledge in, and transferring technology to, the South through the strengthening of programmes such as those initiated by IAVI and GAVI (see <http://www.iavi.org> and <http://www.gavi.org>), which aim at training local scientists by working in close collaborations with research laboratories in the North. Empowering the South with technical competencies necessary to perform medical R&D will contribute to bridging the current North/South health gap. However, the acquisition of knowledge is a long process that requires learning capacity, absorption of competencies, and the building of local know-how (e.g., Lundvall and Johnson 1994; Pavitt 1987; Polanyi 1962).

**Table 1.** A Tentative Distribution of Requirements for Vaccine R&D

	2001 GDP	Vaccine R&D Requirements (total 15 years)*	Vaccine R&D Requirements (per year)*
	US\$ billions	US\$ billions	US\$ billions
World Total	31400.0	22.5	1.50
High Income Countries <i>of which</i>	25372.0	18.2	1.12
USA	9780.8	7.0	0.47
European Union 15	7181.7	5.1	0.34
Japan	4523.3	3.2	0.22
Low and Medium Income Countries	6025.0	4.3	0.29

Source: World Bank and elaborations

Note: \*Proposals for pledges to an International Vaccine Fund Proportional to GDP



VII. IMPLEMENTATION AND IMPLICATIONS: THE CASE FOR  
AN "INTERNATIONAL HEALTH TREATY"

A. A PROPOSED INTERNATIONAL HEALTH TREATY

How could the idea here advocated of a GHRF be implemented? Vaccine R&D is certainly not the only area where a greater international cooperation, and internationally binding legal commitments have been advocated. For many years, it has been suggested to reinforce international health law in order to overcome some of the basic hurdles that constrain the WHO mandate, namely that of voluntary compliance mechanisms (see Fidler 2001). As has been well documented, WHO has historically preferred to use recommendations and persuasion to guide member states through the adoption of appropriate public health policies. Consequently, member states' compliance with WHO recommendations have remained voluntary, leaving public-health sovereignty of states legally unfettered by WHO's actions.

Among many critics, James Love (2003; Love & Hubbard 2004) has suggested creating an international health treaty as a mechanism for inciting governments' interest in communicable disease control. In particular, Love identified in an international health treaty the most appropriate legal mechanisms for ensuring countries' commitments towards funding R&D activities, including vaccine R&D for communicable diseases. Although the paper's primary objective is to provide a science policy approach to communicable disease control, we believe that the general normative framework advocated by Love would benefit greatly the proposal of establishing a global health research fund. In particular, an international health treaty would need to focus on three main points:

- Point 1.* The Treaty would clearly stipulate that WHO member states have a legal and moral obligation not only to control communicable diseases, but also to promote the right to health both domestically and internationally, given the global public good character of communicable disease control. Member states would carry out this obligation through specific actions defined in Points 2 and 3;
- Point 2.* Member States would be required to meet the financial obligations to the GHRF – as proposed in Table 1 – and to the GFAMT in order to ensure the GPG character of communicable disease control;
- Point 3.* Member States would need to develop a coherent approach to health policy implementation by ensuring that domestic policies reflected international commitments (i.e., shift financial priorities from military to health programmes, devise tax incentives for the creation of philanthropic medical research foundations, promote international technology transfer programs, increase number of doctoral positions in the field of immunology).

An international health treaty would have the advantage to enshrine within international law the global public good character of communicable disease control and vaccine R&D, including the necessity for a cooperative approach to their provision. It would moreover provide governments with the necessary legal stimuli to meet their obligations to the GHRF.

#### VIII. CONCLUSIONS

In this paper we have applied the concept of global public goods as a powerful tool for a robust and rational approach to the cause of communicable disease control and vaccine R&D. More specifically, a GPGs-based approach has supported three main arguments:

1. The fact that both communicable disease control and vaccine knowledge require a form of global governance based on direct public intervention. This is also supported by the view that market forces alone are not the most appropriate device to provide financial investment for R&D devoted to basic human necessities;
2. The North has both direct and indirect incentives to commit its financial and technical resources to communicable disease control, even when affected just marginally by the diseases. Yet, an active involvement of developing countries will also be needed to generate appropriate capabilities in the long term and to achieve effective results on the field;
3. The distinction between *final* and *intermediate* GPGs has also allowed to make a strong case for focussing on vaccine R&D as an affective means of reaching the goal of eradicating communicable diseases – a proposition supported by ample evidence within the literature (i.e., WHO & UNAIDS 1999; WHO & UNICEF 1996, 2002).

The paper has also supported the argument in favor of the creation of a Global Health Research Fund to manage and coordinate R&D activity aimed at vaccine development, and has moreover proposed an ideal structure of the fund's mandate and operations. By reference to the economics of innovation and theories of GPGs, we have argued that the fund should be complementary to the GFATM in order to ensure the public good character of a vaccine by having the GHRF charged with the production side of knowledge, whilst the GFATM would insure its reproduction and global diffusion. The complementary role of the two funds could contribute substantially to the bridging of the North/South health divide. Although the development of a vaccine for AIDS, malaria, and TB would require US\$22.5 billion – over a third of the current total health R&D spending – this sum is realistic by all means. The financial burden could be split across countries on the basis of the ability-to-pay principle. This would be consistent with the GPG character of fighting communicable diseases, since it would require countries to contribute proportionally to their financial and



technical capabilities to produce the good of communicable disease control, as opposed to their share of the global disease burden. In recognition of the historical limitations of international law, we suggested ensuring a strong and continuous political/financial commitment by the international community by including a binding obligation to fund vaccine R&D in the proposal of an international health treaty.

Given the advocacy aspect of our argument, it might be useful to make it explicit which communities are we addressing. First, we address global civil movements, an increasingly important player in international politics. Global civil movements have already played a crucial role in steering government priorities in key areas such as environment, disarmament, and human rights (see, for example, Glasius, Kaldor & Anheier 2001, 2002, 2003). Concerning the health agenda, global movements have been particularly active in matters of knowledge diffusion, or rather access to drugs (see Shiva 2001). However, despite the present need to challenge the rules governing IPR regimes and realigning social needs with international trade law (see Coriat & Orsi 2002; Heller & Eisenberg 1998; Thurow 1997), we would urge these movements to also include in their priorities the need to increase publicly funded R&D for neglected diseases, since knowledge production is a precondition for its diffusion. As argued extensively in the paper, the current underprovision of communicable disease control is a reflection of lacking research environments, and not of diffusion mechanisms.

Second, we are addressing the academic community. In many cases, scientists hold the ability to direct strategically the priorities of their research. Governments do not have the information to direct scientific investigation unless there are scientists providing them with the technical expertise. Scientists could therefore devote increasing attention to the welfare implications and consequences of their work, and induce governments to devote more resources to global health priorities.

Last but not least, we address science policy analysts and advisors. In the last two decades there has been an increasing focus on science and technology as shapers of economic performance, rather than enhancers of social well-being. The circle of scholars of science and technology policy has been a close advisor to policymakers. If today, so much attention has been placed upon technologies for industrial innovation, and so little towards medical research for developing countries, it is due, in part, to the choices and priority setting of this community.

Whether governments will listen to a request for a change in priority setting will depend on the ability of global movements, scientific communities, and science and technology policy advisors to pursue common objectives.

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#### NOTES

1. The only high-income country with reported malaria cases is Korea (UNDP 2003: 258, Table 7, column 8).
2. North: OECD countries; South: all other countries.
3. Personal communication with Dr Walter Brandt, Senior Programme Officer, Malaria Vaccine Initiative, 17 June 2003.
4. According to the principle, the financial contribution capacity of countries is proportional to the country's GDP – membership fees to the United Nations for instance are calculated on the basis of the ability-to-pay principle.

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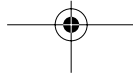
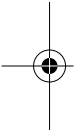
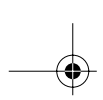
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