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**IMPLEMENTATION OF THE WORKPLAN FOR THE PERIOD OF 2008-2010
ENDORSED BY THE HUMAN RIGHTS COUNCIL IN RESOLUTION 9/3**

**ASSESSMENT OF ADDITIONAL GLOBAL PARTNERSHIPS IN THE AREAS OF
ACCESS TO ESSENTIAL MEDICINES, DEBT RELIEF AND TRANSFER OF
TECHNOLOGY, AS WELL AS DIALOGUE WITH MERCOSUR**

**The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Special Programme
for Research and Training in Tropical Diseases and the right to development***

Mr. James Love**

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Introduction

1. The *right to development* as a human right is a concept that has been explored in a variety of academic, policy and political fora, and has been the subject of a 1986 declaration by the UN General Assembly.¹ As a human right, the right to development has yet to attain the type of formal and enforceable status that is associated with many other human rights, but remains profoundly important.² Much of the world's population lives in a state of appalling circumstances with limited resources and opportunities, under conditions that are extraordinarily worse than those with higher incomes within and between countries. The existence of persistent under-development is both an enduring shame for the global community and an intellectual mystery. Despite enormous achievements in technology, vast investments in scholarship and development aid, endless workshops and conferences, and the creation of public and private institutions to understand and promote development, the global community has collectively failed to meet countless development benchmarks and goals.

2. This review will consider the appropriate criteria for the periodic evaluation of global partnerships for development in the context of the right to development. This evaluation addresses the United Nations Millennium Development Goal Number 8 (MDG-8), “to develop a global partnership for development.” In particular, the evaluation will consider two such partnerships: the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF); and the Special Programme for Research and Training in Tropical Diseases (TDR). Among the specific questions that have been asked are the following:

- (a) What are the areas of potential congruence and synergy of the framework and process guiding the operations of the Global Fund and TDR, and right to development?
- (b) What are the lessons learned from the mapping exercise that can aid in present efforts to develop and refine the right to development criteria in relation to Target 8E of the MDGs?
- (c) How could the right to development criteria be better reflected in the work of the Global Fund and TDR?
- (d) How could the Global Fund and TDR contribute to the realization of the right to development?

3. TDR and TGF were created at moments when there existed an interest in creating new institutions to address the needs of developing countries, and mobilizing resources and actions to address global public health.

¹Declaration on the Right to Development, adopted by General Assembly resolution 41/128 of 4 December 1986.

² *Development As a Human Right- Legal, Political, and Economic Dimensions*, edited by Bård A. Andreassen and Stephen P. Marks, Harvard School of Public Health, 2007; *Reflections on the Right to Development*, Edited by Arjun Sengupta, Archana Negi and Moushumi Basu, Sage, 2005.

I. SPECIAL PROGRAMME FOR RESEARCH AND TRAINING IN TROPICAL DISEASES (TDR)

4. TDR was created when the world was coming to grips with the recent decolonization of much of the developing world, and struggling with the conflicts, tensions and competition associated with the Cold War era.

5. TDR is the “Special Programme for Research and Training in Tropical Diseases,” described as “an independent global program of scientific collaboration that helps coordinate, support and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged.”³ TDR was initiated by WHO and co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP) and the World Bank. According to its charter,⁴ TDR has “the two interdependent objectives of developing improved tools for the control of tropical diseases and strengthening the research capability of affected countries themselves.”

6. The founding of TDR closely followed and was influenced by the creation of two other research partnerships. In 1971, the World Bank and UNDP founded the Consultative Group on International Agricultural Research (CGIAR). In 1972, the Programme of Research, Development and Research Training in Human Reproduction, also known as HRP, was created by the World Health Organization, the World Bank and UNDP. TDR was the third major global research partnership initiative in the early 1970s, and its governance structure shared some characteristics of the earlier efforts; it created a body that provides roles to a variety of stakeholders, including multilateral institutions, significant donors, developing country governments, and leading researchers in both developed and developing countries.

7. Two US-based philanthropic organizations--the Rockefeller and Ford Foundations--played an instrumental role in the creation of the CGIAR. The founding resolution to create the CGIAR was the “Statement of Objectives, Composition, and Organizational Structure.” This committed the CGIAR to:

- (a) examine the needs of developing countries for specialized efforts in agriculture;
- (b) harmonize international, regional, and national efforts to finance and undertake agricultural research;
- (c) provide finance for high priority agricultural research activities; and
- (d) undertake a continuing review of priorities.

8. On May 1, 1974, the UN General Assembly passed the “Declaration on the Establishment of a New International Economic Order.”⁵ This Declaration set out a list of grievances and demands by developing countries. The Declaration stated that “Current events have brought into sharp focus the realization that the interests of the developed countries and those of the

³ <http://underweight/tdr/svc/about> (accessed April 29, 2009).

⁴ Memorandum of Understanding on the Administrative and Technical Structures of the Special Programme for Research and Training in Tropical Diseases (1978; amended 1988, 2003, 2006 and 2008), TDR/CP/78.5/Rev.2008.

⁵ A/RES/S-6/3201

developing countries can no longer be isolated from each other, that there is a close interrelationship between the prosperity of the developed countries and the growth and development of the developing countries, and that the prosperity of the international community as a whole depends upon the prosperity of its constituent parts.” Among other things, the Declaration called for more equitable sharing of the benefits of technological progress by “Giving to the developing countries access to the achievements of modern science and technology, and promoting the transfer of technology and the creation of indigenous technology for the benefit of the developing countries in forms and in accordance with procedures which are suited to their economies;”⁶ The Declaration also called for the “regulation and supervision of the activities of transnational corporations,” on the basis of “the full sovereignty” of countries.

9. In May 1974, the World Health Assembly adopted Resolution WHA27.52, a brief document that called for “Intensification of research on tropical parasitic diseases.” Among the significant donors who supported a new initiative on tropical diseases were the Norwegian development authorities and the Wellcome Trust, a private charity. In the WHA resolution, members requested the Director General of the WHO to:

- (a) intensify WHO activities in the field of research on the major tropical parasitic diseases (malaria, onchocerciasis, schistosomiasis, the trypanosomiases, etc.), taking into consideration that such activities be carried out in endemic areas whenever possible and feasible;
- (b) define the priorities in research on the problem of tropical parasitic diseases in the various regions of the world, bearing in mind the primary needs of the developing countries;
- (c) extend cooperation with national institutions and other governmental and nongovernmental organizations in regard to the coordination of research in this field;
- (d) enlist extra budgetary resources on a wider scale for these purposes; and
- (e) submit a report on progress in the implementation of the resolution to the World Health Assembly in 1976.

A. Governance Structure for TDR

10. In 1978, the WHO and other parties entered into a “Memorandum of Understanding on the Administrative and Technical Structures of the Special Programme for Research and Training in Tropical Diseases,” referred to hereafter as the MoU/ATS/TDR. The agreement was subsequently amended in 1988, 2003 and 2006.

11. The TDR structure includes a Standing Committee, made up of the sponsoring agencies (WHO, as well as its co-sponsors UNICEF, UNDP, and the World Bank), a Joint Coordinating Board (JCB), and a Scientific and Technical Advisory Committee (STAC).

12. The JCB has the authority to review all of TDR's activities, determine TDR's budgets, approve arrangements for financing, and review planning documents. The JCB also undertakes

⁶ Ibid, paragraph 4 p.

ongoing evaluations of programs. The specific functions of the JCB are set out in Article 2.1 of the MoU/ATS/TDR.

13. The rules for the composition of the JCB are set out in Articles 1.2 and 2.2. Article 1.2 defines the cooperating parties:

1.2 Cooperating Parties are;

1.2.1 those governments contributing to Special Programme Resources; those governments providing technical and/or scientific support to the Special Programme; and those governments whose countries are directly affected by the diseases dealt with by the Special Programme;

1.2.2 those intergovernmental and other non-profit making organizations contributing to Special Programme Resources or providing technical and/or scientific support to the Special Programme.

14. Article 2.2 sets out the representation from different groups of cooperating parties. The JCB shall consist of 342 members from among the Cooperating Parties as follows:

2.2.1 Twelve government representatives selected by the contributors to the Special Programme Resources;

2.2.2 Twelve government representatives selected by the WHO Regional Committees from among those countries directly affected by the diseases dealt with by the Special Programme, or from among those providing technical or scientific support to the Special Programme;

2.2.3 Six members, designated by the JCB itself, from among the remaining Cooperating Parties;

2.2.4 The four Agencies which comprise the Standing Committee.

Members of the JCB shall serve for a period of three years and may be reappointed. Other Cooperating Parties may, at their request, be represented as observers upon approval by the JCB.

15. TDR describes a cooperating party as “any government plus any organisation, other than private 'for-profit', which provides technical or financial support and collaboration to TDR and applies for such status.” The applications are reviewed by the WHO Legal Department.

16. While for-profit pharmaceutical companies would not qualify directly, they may participate through a trade association, such as the International Federation of Pharmaceutical Manufacturers Association (IFPMA), or a partnership such as Medicines for Malaria Venture (MMV), which do qualify as non-profit entities.

17. Among the current cooperating parties are such entities as MMV, DNDi, the Bill and Melinda Gates Foundation, the Wellcome Trust, the Canadian International Development Research Centre (IDRC), the Oswaldo Cruz Foundation (known as Fiocruz), the London School of Hygiene and Tropical Medicine, the International Federation of Pharmaceutical Manufacturers

& Associations (IFPMA), and other several academic institutions. All cooperating parties are free, at their own expense, to attend the JCB as observers.

18. While under the rules there are six seats on JCB that could be occupied by a non-governmental cooperating party, these positions have historically been occupied by governments. According to TDR, recently there are proposals to give some seats to non-government cooperating parties on the JCB. If this happens, they will be selected by the other members of the JCB.

B. Focus and role of TDR

19. In its own official history,⁷ TDR describes four phases:

Phase I (1975–1986): Heroic goals

Phase II (1987–1997): Innovations in field research

Phase III (1998–2006): The partnership decade

Phase IV (2007–future): Research that makes a difference

20. Among the context for “Heroic goals,” TDR singles out the 1978 “Declaration of Alma-Ata,”⁸ issued at an International Conference on Primary Health Care, organized by the WHO. The Alma-Ata declaration said “the existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable,” and called for “urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world.”

21. By its own account, TDR began its work with enormous challenges and “heroic goals” that were clearly linked to development, scientific progress, and access to treatment and care. However, the TDR aspirations were not unlimited. TDR initially focused on a limited group of eight neglected tropical diseases: malaria, leprosy, schistosomiasis, visceral and cutaneous leishmaniasis, onchocerciasis, lymphatic filariasis and the two diseases caused by parasitic trypanosomatid protozoans—Chagas disease in the Americas, and human African trypanosomiasis (HAT), popularly known as sleeping sickness in Africa. AIDS, which was not diagnosed until 1981, and was not named until 1982, and tuberculosis, which then was not considered a major public health challenge, were not among the original TDR targets. Over time TDR has somewhat expanded its mandate in terms of diseases and conditions, for example, to address issues from a social and multi-disciplinary context, to undertake projects that encompass coinfections of TB and HIV, syphilis and other sexually transmitted diseases (STDs), and the treatment of pneumonias and diarrhoeas. However, TDR has not aspired more generally to address the development of treatments for diseases which are common in both developed and

⁷ *Making A Difference, 30 Years of Research and Capacity Building in Tropical Diseases*. (NLM classification:WC 680) doi: 10.2471/TDR.07.978-924-1595575.

⁸ http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf

developing countries, but do not have effective or appropriate treatments in resource poor settings.⁹

22. Since its creation, TDR has focused on an extremely wide range of research, policy and implementation issues, including: studying the impact of target diseases, as well as their social, cultural, economic and environmental context; advancing scientific understanding of diseases; evaluating diagnostics and treatments and their modes of delivery; and promoting or directly subsidizing the development of diagnostic devices, preventative and prophylactic interventions, pharmaceutical drugs, vaccines and other medical technologies. TDR has also issued reports and conducted training in the area of medical ethics, and invested in efforts to enhance capacity for undertaking research and policy analysis in developing countries. TDR had a relatively small budget given the nature of the challenges; but due to a low level of engagement by others, TDR found itself doing many different things, often accumulating responsibilities by default.

C. TDR and Intellectual Property Rights

23. Since its inception, TDR has struggled with limited resources, a lack of private pharmaceutical industry investment in new products, and weak leverage to induce the sharing of knowledge, materials and technology. TDR has seen it useful to develop friendly relations with the pharmaceutical industry, and to avoid taking positions that would alienate companies and undermine collaborations. This has, in some cases, extended to views on intellectual property right issues; and TDR has often aligned itself with conventional industry views,¹⁰ during periods where conventional views are challenged by key public health groups as contrary to the values set out in a growing number of declarations and resolutions insisting on policies that promote access to medicines for all.

24. In interviews, TDR says it follows standard WHO policy on the licensing of intellectual property rights to the private sector which provides that intellectual property rights should be exploited in a manner consistent with WHO's public sector objectives, including specifically to ensure:

- (a) the wide availability of any resulting product to the public; and
- (b) its availability to the public sector of developing countries in sufficient quantities to meet demand and at a preferential price.

25. TDR was asked to provide copies of clauses in licenses that deal with access concerns, but declined to do so. TDR notes that disclosure of any agreement would require the consent of both parties, and claims the WHO has the consistent policy not to make its agreements public. The secrecy of such agreements makes it difficult to evaluate the assertions that such agreements

⁹ This includes cases where medical infrastructure is weak or non-existent, or where cold chain storage of perishable medicines is lacking.

¹⁰ Traditionally, pharmaceutical companies involved in research and development for new products have favored systems of strong monopoly rights to sell new products. Enforced through a plethora of intellectual property rules, these rights including patents, rights in pharmaceutical test data for purposes of drug registration, and various *sui generis* systems of marketing exclusivity associated with the development or testing of products. In recent years, some companies have been more open to alternative systems that de-link R&D rewards from the prices of products, and which do not preclude competition in the supply of generic versions of products.

adequately address concerns regarding upstream and downstream access to inventions.

II. 1998: THE RISE OF NEW ACTORS IN GLOBAL NEGLECTED DISEASE RESEARCH

26. In 1998, a number of new initiatives were undertaken that would dramatically change both the landscape of neglected disease research, and the role of non-government actors.

A. The Global Forum for Health Research

27. In 1998, the Global Forum for Health Research (GFHR) was created. The mission of the Global Forum is to play a leadership role in catalysing global research applied to the health problems of the poor, through:

- (a) engaging current and future high-level decision-makers from high-, middle- and low-income countries;
- (b) brokering coherence and partnerships between global players in research and innovation;
- (c) promoting relevant research on health and health equity;
- (d) advocating increased resources for relevant research and innovation by all sectors;
- (e) encouraging the use of evidence in policy- and decision-making;
- (f) stimulating the dissemination of research findings in ways that will enable their utilization.

28. The driving forces beyond the new Global Forum were the Rockefeller Foundation and the World Bank, and European and Canadian development funding agencies. The institution sought to give a more direct role and engagement for private pharmaceutical companies, and would play a role in promoting a new public private partnership for malaria research. The Rockefeller Foundation was drawing upon its work in the area of agricultural biotechnology, where it had sought partnerships and engagements with the private sector.¹¹

B. MSF and BMGF

29. In 1998, Médecins Sans Frontières (MSF) and the Bill and Melinda Gates Foundation (BMGF) began to focus on research for neglected diseases. These two institutions would, in quite different ways, change the public health landscape.

30. The BMGF dedicated billions of dollars in new money to address the challenges of global health—including diseases such as malaria and tuberculosis, which were the subject of attention

¹¹ See Gordon Conway, *The Double Green Revolution: Food for All in the Twenty-first Century*, Cornell University Press, 1998, and Gordon Conway, *The Rockefeller Foundation and Plant Biotechnology*, Rockefeller Foundation, June 24, 1999

by TDR and its sponsoring agencies.

31. MSF began a highly visible campaign on global neglected diseases in 1998. At a major international meeting on neglected diseases held in Paris in October 1999, it was announced that MSF had won the Nobel Peace Prize for its humanitarian work in conflict areas. Speaking to the press on that day, MSF called for a global treaty to support R&D for neglected diseases.

32. Collectively, the high visibility and competition between the BMGF and MSF, the vast resources of the BMGF, and the ability of MSF to mobilize media attention and donor resources, created new possibilities to greatly expand efforts to find new treatments for diseases primarily affecting the poorest people living in developing countries.

33. While the BMGF and MSF share a common interest in developing treatments for tropical diseases, they differ on other issues, and these contrasts represent important policy divides within the global health community. In particular, the BMGF has historically been seen as supportive of a global regime of strong exclusive rights for intellectual property. The problem of neglected diseases was initially seen by the BMGF as a consequence of unequal income distribution, rather than a flaw in the global system to stimulate R&D investments. Early BMGF projects included highly visible work to promote incentives that closely paralleled the incentives at work in areas where disease burdens were similar in high and low income countries, through special subsidies on sales of products that would treat neglected diseases. The Gates Foundation also funded a number of projects that emphasized the importance of strong intellectual property rights protection. Access concerns were to be addressed through greater subsidies for drug, vaccine and medical device purchases, sometimes combined with systems of price discrimination within and between countries. Such views were widely shared by many larger pharmaceutical companies, and embraced by a number of governments and private actors seeking funds from the BMGF. To promote new policies, BMGF often focused on high level fora, such as meetings of the G8 or the World Economic Forum at Davos, to engage governments and corporate leaders.

34. MSF and a number of other public health and development NGOs have sought more fundamental challenges to the current intellectual property rules, often promoting generic competition as necessary for obtaining low cost products, the broader use of flexibilities in intellectual property agreements, and measures to promote greater access to knowledge, materials and technology by researchers. MSF is among the groups that have advocated a multilateral treaty to address the need for adequate sustainable research funding for neglected diseases and other priorities.

C. The Expansion of Public-Private Partnerships

35. TDR describes the period from 1998 and 2006 as “the partnership decade.” This included an expansion of partnerships with new sponsors, such as UNICEF, and the creation of broader networks with public health groups and research networks. TDR also more actively embraced new partnership agreements with private pharmaceutical, vaccine and medical device companies for product development, and increasingly gave Product Development Partnerships (PDPs) a strong policy voice.

36. Among the early projects encouraged by TDR was the Medicines for Malaria Venture, a collaboration suggested by the IFPMA, and initially supported by the Rockefeller Foundation:

Medicines for Malaria Venture (MMV)¹²

37. The form MMV has chosen to fulfill its mission is that of a public-private partnerships, which has become one of the preferred ways to ensure that progress can be made in addressing healthcare issues which neither the public nor the private sector can solve on their own. MMV is among the first of these public-private partnerships established to tackle a major global disease. The initiative arose from discussions between the World Health Organization (WHO) and the representative body of the pharmaceutical industry, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Early partners in these exploratory discussions were the Global Forum for Health Research, the Rockefeller Foundation, the World Bank, the Swiss Agency for Development and Cooperation, the Association of the British Pharmaceutical Industry and the Wellcome Trust. The combination of the pharmaceutical industry, with its knowledge and expertise in drug discovery and development, and the public sector, with its depth of expertise in basic biology, clinical medicine, field experience and above all its public remit, constitutes the rationale for MMV.

38. In a short period of time, a number of other new partnerships were explored and eventually launched, sometimes, but not always, with an early involvement by TDR. The new “product development partnerships” (known today as PDPs) are highly diverse in terms of governance structures, transparency, and policies on issues such as the management of intellectual property rights, access to medicines, and technology transfer to developing countries.

Examples of Product Development Partnerships

39. These includes:

- (a) BIO Ventures for Global Health;
- (b) Drugs for Neglected Diseases Initiative (DNDi);
- (c) Foundation for Innovative New Diagnostics (FIND);
- (d) Global Alliance for Tuberculosis Drug Development;
- (e) Institute for One World Health;
- (f) International Aids Vaccine Initiative (IAVI);
- (g) International Partnership for Microbiocides;
- (h) Medicines For Malaria Venture (MMV);
- (i) Pediatric Dengue Vaccine Initiative;
- (j) Program for Appropriate Technology in Health (PATH)

¹² Website of MMV, http://www.mmv.org/rubrique.php?id_rubrique=11, visited March 29, 2009.

40. As the PDPs have grown in number, size and importance in terms of setting policy norms and funding priorities, TDR has shifted from the lead focal point to one of several entities working in the neglected diseases field, and is often eclipsed by the newer PDPs in terms of setting global priorities and standards.

41. In general, the new PDPs are accountable to donors, but not to governments. This change has shifted the locus of policy-making away from UN bodies and toward a new environment, where donors connect with PDPs on the putative basis of performance in advancing research and product development goals but also to promote the broader values and norms advanced by specific PDPs.

42. The norm setting activities of the PDPs can and often do extend into the broader debates about access to medicines. Key officials from MMV, One World Health, the TB Alliance, DNDi, and other PDPs are often outspoken on broader policy debates involving intellectual property, openness or technology transfer. For example, in 2007, One World Health publicly criticized developing countries for issuing compulsory licenses on drug patents, claiming it would harm investments in new drugs for neglected diseases.¹³ MMV, a partnership with the pharmaceutical industry, frequently defends strong patent rights. On the other hand, DNDi, a non-profit PDP which also works with major drug companies on the development of new products, often pushes companies harder on access, intellectual property rights and technology transfer issues.

D. The Role of the BMGF in Funding Research for Neglected Diseases

43. Private donors have always played a role in supporting and shaping research priorities and policies for neglected diseases. Notable earlier examples would include institutions such as the Rockefeller Foundation and the Wellcome Trust. The new role of the BMGF is, however, historically unprecedented. Even before receiving \$37 billion in new funds from Warren Buffet, the BMGF was the dominant funder of global health initiatives. In the area of neglected disease research, no one comes close. Today, every one of the leading international PDPs working in the area of neglected diseases receives a significant portion of its budget from the BMGF. The amount of such funding exceeds 90 percent of the budgets for several groups. In return for funding, PDPs report they are asked to engage in frequent reporting on program operations, and to consider BMGF suggestions regarding board members and key staff.

44. The BMGF is not only the leading private funding institution for research and development, but also supports a number of advocacy efforts to shape public policy on topics such as intellectual property rights, incentives for product development, and pricing or access. In addition, the BMGF funds much of the academic and private think tank work on this topic. Recently the BMGF has begun to fund the work of journalists.¹⁴

¹³ “Drug companies' patents are under attack. Will this really help the poor?” *The Economist*, June 7, 2007. “Even experts devoted to the cause of helping the poor get access to drugs see the trend as worrying. 'Brazil is not Rwanda, which cannot afford to pay,' says Tadataka Yamada of the Gates Foundation, a giant charity. Victoria Hale, head of One World Health, an innovative non-profit pharmaceutical firm, reckons that compulsory licensing could prove “the last blow” that pushes the drug industry away from looking for cures for diseases of the poor world, which are already woefully neglected.”

¹⁴ Press Release, December 1, 2008, “The NewsHour with Jim Lehrer to expand coverage of important global health issues with support from \$3.5 million Gates Foundation grant to WETA.”
http://www.pbs.org/newshour/aboutus/press_releases/2008/gates_12-1.html

45. The BMGF is now spending billions every year on global health initiatives. The benefits of this largess are enormous, as resources have dramatically expanded, and the field is attracting talented and influential researchers, managers, analysts and advocates. The BMGF has itself assembled a highly respected and skilled staff, and has developed many innovative approaches to global health challenges. However, as is recognized by the BMGF itself, there are also significant risks of the spectacular concentration of money and power in a single agency accountable to two people, Bill and Melinda Gates.

46. Among the risks that stand out are the dangers of “group think,” a lack of competition for ideas, and a reduction in the role and influence of democratically elected national governments, on topics that are important for development. The WHO malaria chief Dr. Arata Kochi elaborated on these risks, in a memorandum later reported in the *New York Times*: Donald G. McNeil Jr., “Gates Foundation’s Influence Criticized,” *New York Times*, February 16, 2008:

- (a) The chief of malaria for the World Health Organization has complained that the growing dominance of malaria research by the Bill and Melinda Gates Foundation risks stifling a diversity of views among scientists and wiping out the world health agency’s policy-making function;
- (b) In a memorandum, the malaria chief, Dr. Arata Kochi, complained to his boss, Dr. Margaret Chan, the director general of the W.H.O., that the foundation’s money, while crucial, could have “far-reaching, largely unintended consequences”;
- (c) Many of the world’s leading malaria scientists are now “locked up in a ‘cartel’ with their own research funding being linked to those of others within the group,” Dr. Kochi wrote. Because “each has a vested interest to safeguard the work of the others,” he wrote, getting independent reviews of research proposals “is becoming increasingly difficult”;
- (d) He argued, that the foundation’s determination to have its favored research used to guide the health organization’s recommendations “could have implicitly dangerous consequences on the policy-making process in world health.”

47. The unprecedented level of funding from the BMGF has also created a crowding out effect, as some important private and public sector donors have turned away from funding innovation for neglected diseases, which is now perceived as being adequately resourced by the BMGF. The crowding out has led to more concentration and less competition among donors.

E. TDR's Fourth External Review

48. Since its inception, TDR has a reputation for attracting a talented and motivated staff, and has worked well with the broader scientific community. Over its first 30 years, TDR has made a number of valuable contributions in both the field of neglected disease research and the development of health systems and products. These contributions are impressive in light of TDR's modest funding support. TDR has been criticized in the past, however, for not having

provided sufficient leadership to do more, particularly given the lack of progress in treatment for many of the diseases targeted by it.¹⁵

49. The contrast between TDR's early role in setting the agenda for neglected disease research, and the situation today, is marked. In the beginning, TDR played a central role. Today it exists in a considerably different environment, with other influential players. The question today is not so much "will TDR provide adequate leadership?" but rather, "what should be TDR's role, given the expanding leadership role of other institutions?" TDR's Fourth External Review,¹⁶ which was conducted over the period of 2005 to 2006, gave the following evaluation:

- (a) TDR has been extremely successful in the past. It worked with industry partners to shape the development of new products, including eflornithine for African trypanosomiasis, praziquantel for schistosomiasis, and various drug combination and formulation innovations for malaria. TDR also sponsored the critical studies establishing the efficacy of insecticide-impregnated bednets for control of malaria. Its more recent successes include the registration of miltefosine for visceral leishmaniasis, facilitation of the sequencing of the *Anopheles gambiae* genome, and provision of evidence for artemisinin-based combination treatments for malaria control policy. Its important social science intervention research includes developing a strategy for managing malaria "close to home", and contributions in the use of ivermectin for community control of onchocerciasis in areas with high loiasis. Most importantly, it has played a major role in building individual and institutional research capacity in the developing world;
- (b) Today, TDR continues to be moderately successful, but its influence has waned because of the very changed external landscape. There are many more players and initiatives in neglected diseases research. There are huge new funding sources such as the Bill & Melinda Gates Foundation, the Wellcome Trust, the United States National Institutes of Health, and others; there are PPPs involved in product development; there are other organizations (e.g., Council on Health Research for Development and Global Forum for Health Research) that focus on various research-related issues, including advocacy for health research in developing countries; and there is more research and training conducted in, and by, disease-endemic countries themselves;
- (c) Thus, the future role of TDR at the time of our review was unclear. There was a danger of TDR becoming marginalized as large infusions of funds went elsewhere, for example into product-developing PPPs such as the Medicines for Malaria Venture, which had been created with TDR's help.

¹⁵ Press Release, December 1, 2008, "The NewsHour with Jim Lehrer to expand coverage of important global health issues with support from \$3.5 million Gates Foundation grant to WETA."
http://www.pbs.org/newshour/aboutus/press_releases/2008/gates_12-1.html

¹⁶ Daar AS, Whyte SR, Abdullah MS, Ching-Li H, Hoffman SL, et al. (2008) "TDR Thirty Years On: Taking Stock and Envisioning the Future for the Special Programme for Research and Training in Tropical Diseases", *PLoS Negl Trop Dis* 2(11): e314. doi:10.1371/journal.pntd.0000314

50. Robert Ridley, the Director of TDR since June 2004, has taken issue with this evaluation:¹⁷ “[b]ecause TDR works through partners in a way that promotes their achievements, the achievements of TDR as an organization are often under-valued. TDR was judged by the Fourth External Review to be moderately successful from 1998 to 2005, largely due to the reduced global significance of the Programme with the arrival and excitement of new funds and new global initiatives. Paradoxically, we believe that when the history of this period is written, and particularly when judged against its budget, TDR’s role will be seen to have been highly significant and successful in terms of its public health impact.”

51. TDR has further described¹⁸ its response to recent developments: “As new players have come into the product development field, TDR, as a conscious part of its new strategy, has moved to activities that will complement the work of the many PDP’s rather than compete with them. It has done this by focusing in product development on diseases not adequately covered by PDP’s. It has done this by emphasizing its potential to work with stakeholders, especially developing country stakeholders, to develop research agendas in relevant areas through its stewardship function. It has done this by emphasizing the need to build capacity for innovation and research leadership in developing countries through its empowerment function. It has done this by more strongly emphasizing research post product development to assess how best to utilize products and interventions in resource poor settings and how best to scale up their access at the periphery of the health system.”

52. The importance of TDR’s role in incubating and supporting the rise of new actors varies considerably across projects, and in some cases has been quite significant. However, it is widely acknowledged that the great expansion of activity in this area within the past decade was stimulated by private non-profit entities and governments seeking to build a new and expanded platform for drug development. These new entities are less accountable to governments, and more accountable to donors, particularly the most active private donor, the BMGF.

III. THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA (TGF)

53. The driving force behind the creation of TGF was a dramatic and eventful debate over the fate of persons living with HIV/AIDS in developing countries.

54. The human immunodeficiency virus (HIV) is a communicable diseases that can lead to acquired immune deficiency syndrome (AIDS), a life threatening condition associated with the failure of immune systems. Patients do not die directly from AIDS, but from infections that attack patients with weakened immune systems. For example, tuberculosis and pneumonia, and influenza are major causes of AIDS related death. Some forms of cancer also more prevalent in persons living with HIV, including Kaposi sarcoma, non-Hodgkin lymphoma, Hodgkin disease and cancers of the lung, mouth, cervix, and digestive system.¹⁹

55. There is no cure for AIDS. Patients who are infected with HIV are treated with various regimes of antiretroviral (ARV) drugs. In 1996, health professionals and researchers discovered

¹⁷ Ridley RG, Ndumbe P, Korte R (2008), “Two Years after the Fourth External Review: TDR Moves Forward with a New Vision and Strategy”, *PLoS Negl Trop Dis* 2(11): e307. doi:10.1371/journal.pntd.0000307

¹⁸ Comments from Robert Ridley, April 30, 2009.

¹⁹ <http://www.cancer.gov/cancertopics/types/aids/>.

that HIV/AIDS could often be effectively controlled with combinations of at least three ARV drugs, an approach referred to as highly active antiretroviral therapy (HAART).

A. The Crisis in Access

56. The debate over access to AIDS drugs in developing countries first gained prominence in 1999. A series of stunning reports of the extent of the pandemic in Africa,²⁰ combined with evidence that high prices for medicines were blocking access to treatment in developing countries led to a mobilization by treatment advocates. A series of protests by AIDS activists in the US²¹ and Europe, and a dramatic Seattle World Trade Organization (WTO) ministerial conference in December 1999,²² first focused attention on the role of intellectual property rights in blocking access to AIDS drugs.²³ These protests lead to changes in U.S. Trade policy,²⁴ including on May 10, 2000, Presidential Executive Order 13155, on “Access to HIV/AIDS Pharmaceuticals and Medical Technologies,” which in the context of intellectual property rights, acknowledged the right of countries to “adopt measures necessary to protect public health.” The executive order prohibited US government agencies from bringing trade pressures on countries in Sub-Saharan Africa for taking measures consistent with the WTO TRIPS Agreement “that promotes access to HIV/AIDS pharmaceuticals or medical technologies.”²⁵

57. While there was growing recognition among policy-makers that developing countries in Africa and elsewhere could challenge the efforts by patent owners to block generic competition, much patent owner resistance to such actions remained, and considerable official skepticism existed over the feasibility and sustainability of providing treatment to AIDS patients in resource-poor settings. By 2000, the best generic prices were more than \$1,000 per year for any

²⁰ Lawrence Altman, “Parts of Africa Showing H.I.V. in 1 in 4 Adults,” *New York Times*, June 24, 1998. Donald McNeil, Jr., “AIDS Stalking Africa's Struggling Economies,” *New York Times*, Nov. 15, 1998. Lawrence K. Altman, “In Africa, a Deadly Silence About AIDS Is Lifting,” *New York Times*, July 13, 1999. “U.N.: AIDS orphans portend catastrophic future in Africa,” *CNN*, December 6, 1999. The crisis was not unforeseen. See for example, Barton Gellman, “Death Watch: The Global Response to AIDS in Africa: World Shunned Signs of the Coming Plague,” *Washington Post*, July 5, 2000. Gellman's report begins with a discussion of a CIA analysis: Interagency Intelligence Memorandum 91-10005, “The Global AIDS Disaster,” which in 1991 predicted 45 million deaths from AIDS by 2000.

²¹ Merrill Goozner, “Third World Battles For Aids Drugs,” *Chicago Tribune*, April 28, 1999. Lisa Richwine, “Groups Say U.S. Hurts World Access To AIDS Drugs”, *Reuters*, April 11, 1999. Sabin Russell, “New Crusade To Lower AIDS Drug Costs, Africa's needs at odds with firms' profit motive”, *San Francisco Chronicle*, May 24, 1999. Charles R. Babcock and Ceci Connolly, “AIDS Activists Badger Gore Again,” *Washington Post*, June 18, 1999. Bob Davis, “Gore Hopes New AIDS Pact Will Help Shake Protesters,” *Wall Street Journal*, August 12, 1999.

²² Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power, Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health*, AMB Publishers, 2009. Susan K. Sell, *Private power, public law: the globalization of intellectual property rights*, Cambridge University Press, 2003.

²³ Mark Milano, “Zapping for Drugs,” *the Body*, Fall 2006. Greg Behrman, *The invisible people: how the U.S. has slept through the global AIDS pandemic, the greatest humanitarian catastrophe of our time*, Simon and Schuster, 2004.

²⁴ Sabin Russell, “Poor Nations Given Hope on AIDS Drugs: New policy would lower prices,” *San Francisco Chronicle*, December 3, 1999.

²⁵ 65 FR 30521, May 12, 2000.

medically approved HAART regime, and policy makers argued that donor funds should only be spent on prevention, rather than treatment.²⁶

B. 2001

58. The debate was radically changed in January 2001, when an Indian generic AIDS drug manufacturer offered to sell an acceptable HAART treatment regime for less than a dollar per day.²⁷ This offer set the stage and raised the stakes for a highly publicized trial between 39 pharmaceutical companies and the Republic of South Africa,²⁸ that captured the attention of the news media worldwide.²⁹

59. In April of 2001, in a speech in Abuja, Nigeria, UN Secretary-General Kofi Annan, long the target of lobbying by AIDS activists, endorsed “the creation of a Global Fund, dedicated to the battle against HIV/AIDS and other infectious diseases.”³⁰ Annan's leadership in creating TGF was later cited by the Nobel Peace Prize Committee. In making his announcement, Annan noted “. . . there has been a worldwide revolt of public opinion. People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.”³¹

60. In November 2001, the World Trade Organization (WTO) Ministerial Conference issued the landmark Doha Declaration on TRIPS and Public Health³², which famously stated that the WTO TRIPS Agreement on Intellectual Property Rights “can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.”

²⁶ For an insightful report of this debate, see: Barton Gellman, “An Unequal Calculus of Life and Death,” *Washington Post*, December 27, 2000.

²⁷ Donald G. McNeil, “Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa,” *New York Times*, February 7, 2001. Rachel Zimmerman and Jesse Pesta, “Drug Industry Jolted by Cipla AIDS Drug Offer,” *Wall Street Journal*, February 8, 2001. Daniel Pearl and Alix Freedman, “Altruism, Politics and Bottom Line Intersect at Indian Generics Firm,” *Wall Street Journal*, March 12, 2001.

²⁸ In The High Court Of South Africa (Transvaal Provincial Division), Case number: 4183/98. In the matter between: The Pharmaceutical Manufacturers' Association Of South Africa, (and 39 companies identified by name) v. The President of The Republic of South Africa, The Honourable Mr N.R. Mandela N.O., et al. The suit was originally filed on February 18, 2008. For background on the pressures put on South Africa by the U.S. Government, see: Report on steps taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(C) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997 required by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105 277), US Department of State, February 5, 1999.

²⁹ The law suit was dropped by the pharmaceutical industry on April 19, 2001. The following are some of the news reports appearing on the day the lawsuit was dropped by the 39 pharmaceutical companies. Rachel Swarns, “Drug Firms Drop South African AIDS Case,” *New York Times*. “Drugs Firms Drop AIDS Case,” *BBC*. Karen DeYoung, “Makers of AIDS Drugs Drop Patent Lawsuit,” *Washington Post*. Cris McGreal, “Shamed and humiliated - the drugs firms back down,” *The Guardian*. “Drug firms drop case against SA medicine laws,” *Business Day*.

³⁰ Secretary-General Proposes Global Fund For Fight Against HIV/AIDS And Other Infectious Diseases at African Leaders Summit, Press Release, April 26, 2001. SG/SM/7779/Rev.1, AFR/313/Rev.1, AIDS/7/Rev.1.

³¹ *Ibid.*

³² WT/MIN(01)/DEC/2, Declaration on the TRIPS agreement and public health, Adopted on 14 November 2001.

C. 2002

61. In 2002, TGF was created, initially at a much lower level of funding than proposed by UN Secretary-General Kofi Annan, with the capacity to implement treatment programs in many countries. TGF was originally part of the WHO, but would operate through its own unique, still-evolving governance structure (see discussion below), and would be spun off into its own Swiss Foundation status.

D. PEPFAR and UNITAID

62. Two other significant programs were created for several very similar purposes. On January 28, 2003, during his annual State of the Union address, President George W. Bush announced he would support spending \$15 billion to treat AIDS patients.³³ In making the announcement, President Bush made reference to the fact that drugs that were previously priced at \$12,000 per year were now available for less than \$300 per year--a sign that the US decision to fund treatment was based in part on the possibility of buying medicines from generic suppliers operating in India and China. This was later confirmed by Mitch Daniels, then-Director of the Office of Budget and Management, who said the change in policy by the Bush Administration in favor of US funding for AIDS treatment came when the price fell below \$1 per day.³⁴ The Bush program was called the US President's Emergency Plan for AIDS Relief (PEPFAR), and was passed by the US Congress on May 27, 2003.³⁵ In 2006, France, Brazil, Chile, Norway and the United Kingdom created UNITAID, an international drug purchase facility that was to be financed with sustainable, predictable resources. The basis for the contributions was a tax on airline tickets.

E. Managing TGF

63. In 2002, the title, purpose, principles and scope of TGF were set out in a 22 page "Framework Document of the Global Fund to Fight AIDS, Tuberculosis and Malaria."³⁶ The Framework Document set out an ambitious multi-stakeholder structure that gave voices to developed and developing countries, to donors and patients, and to other institutions that were

³³ See, State of The Union Address of the President to the Joint Session of Congress, January 28, 2003. "There are whole countries in Africa where more than one-third of the adult population carries the infection. More than four million require immediate drug treatment. Yet across that continent, only 50,000 AIDS victims - only 50,000 - are receiving the medicine they need. . . . A doctor in rural South Africa describes his frustration. He says, 'We have no medicines..many hospitals tell [people], 'You've got AIDS. We can't help you. Go home and die.' In an age of miraculous medicines, no person should have to hear those words. AIDS can be prevented. Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from \$12,000 a year to under \$300 a year, which places a tremendous possibility within our grasp.....tonight I propose the Emergency Plan for AIDS Relief - a work of mercy beyond all current international efforts to help the people of Africa. . . .I ask the Congress to commit \$15 billion over the next five years, including nearly \$10 billion in new money, to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean."

³⁴ In a 2003 meeting with Mitch Daniels, Jr. Ralph Nader and myself, Mr. Daniels said that when prices were more than \$1,000 per year, OMB could not justify spending money on AIDS treatment, given competing development and health priorities. When the price fell below \$1 per day, he felt they could not justify not spending money on AIDS drugs.

³⁵ Public Law 108-25. May 27, 2003.

³⁶ http://www.theglobalfund.org/documents/TGF_Framework.pdf

involved in providing treatment.

64. Starting with a very small staff, the TGF was faced with enormous challenges in creating governance structures, raising funds, and administering grants and contracts for a variety of programs to prevent and treat the covered diseases. Any evaluation of TGF has to recognize and applaud the speed at which institutions, structures and procedures were established, and treatment programs were rolled out often in very challenging environments.

65. The Framework Document called for a Country Coordination Mechanism (CCM) to be established for each country. Among the responsibilities of the CCMs proposals for funding to TGF.

66. The CCMs were on paper to play a key role in ensuring transparency, accountability and legitimacy of the grants in a particular country, subject to oversight from TGF. Civil society was to be given at least 40 percent of the membership of the CCMs, and multilateral institutions like the World Bank, or various UN agencies were also given seats. The majority of the CCM members were from a mixture of national and subnational government agencies. The TGF management of the CCM mechanism was initially quite modest. In 2006 there was a single person responsible for providing technical assistance and resources to 136 CCMs. Today this has grown to just eight persons -- one person for every 17 CCMs.

67. According to interviews³⁷ at TGF, in the beginning, the CCMs were frequently “a rubber stamp” for grant proposals. TGF staff have been committed to strengthening the CCMs, and today many are performing the functions anticipated by the original Framework Document.

68. In a commendable way, TGF comes across as idealistic and committed to not only delivering services, but in creating durable, transparent, accountable and effective national structures to manage the programs. The TGF is also committed to developing sounder methods of evaluating programs. In some cases, these goals are in tension, as TGF often defers to local institutions on matters that undermine the ability of TGF to manage programs. This includes, for example, an acknowledged inability of TGF to synchronize fiscal periods, or to standardize reporting in ways that would improve program management and evaluation. There is some debate at TGF about how to improve the gathering of data and strengthen management oversight, without placing undue burdens on recipients of grants, and without imposing undue conformity on programs delivering services.³⁸

F. Sustainability of Treatment

69. An important challenge for TGF is to address the sustainability of treatment. According to some officials, TGF is expected to shift the costs of providing treatment to developing countries,

³⁷ March 30 and 31, 2009.

³⁸ Global Fund to Fight AIDS, TB and Malaria Has Improved Its Documentation of Funding Decisions but Needs Standardized Oversight Expectations and Assessments, GAO, May 2007.

over time. In the meantime, TGF has to secure sustainable funding³⁹ and address a looming crisis in the prices for second generation products.⁴⁰

70. The Framework Document calls for TGF to support proposals that “respect intellectual property rights, such as TRIPS, and encourage efforts to make quality drugs and products available at the lowest possible prices for those in need.” There is strong evidence that intellectual property rights, economies of scale and scope and competition are important factors in the prices for second generation HIV/AIDS drugs. Today the overwhelming proportion of HIV/AIDS patients receiving treatment through TGF received a three drug HAART regime based upon d4T+3TC+NVP. This regime is now available in a fixed dose combination from several generic suppliers for less than \$100 per year, including in several African markets where patents are not enforced by patent owners. Prices are higher for all other treatment regimes, and are particularly higher for products that came to the market after 1996, the year that Brazil changed its patent law, and for which there is a sufficiently large market for generic suppliers of medicines.⁴¹ Over time, experts say it will be necessary to migrate patients to newer generation products, raising concerns over the affordability and sustainability of TGF treatment commitment.⁴²

71. There are several related developments that present additional risks to the supply of affordable medicines. The creation of TGF has created new incentives for pharmaceutical companies to patent newer treatments for HIV/AIDS, TB or malaria in developing country markets, including sub Saharan Africa.⁴³ The WTO TRIPS Agreement provisions on patents became binding on India and other major developing country manufacturers of medicines in 2005, a policy and political change that will present barriers to the competitive supply of generic medicines.⁴⁴ Also, since the 2001 WTO Doha Declaration on TRIPS and Public Health, there

³⁹ In an April 2, 2009 email exchange, TGF Board Member Asia Russell indicated a major challenge is “getting donors to give what they promised so that country programs can grow.”

⁴⁰ Médecins Sans Frontières, “WHO Sticks Head in Sand Over High Cost of Newer AIDS Drugs, Must Act to Ensure Long-Term Quality Care for People With HIV/AIDS,” *The Body*, August 14, 2006.

⁴¹ UNITAID/EB8/2008/11/1, Annex 1, Cost Benefit Analysis for UNITAID Patent Pool, 20 June 2008.

⁴² Ibid.

⁴³ Ibid.

⁴⁴ One possible area of flexibility concerns Least Developed Countries. In Article 66 of the TRIPS, Least Developed Country (LDC) members of the WTO are given the opportunity to request extensions of their obligations, in order to address their “special needs and requirements . . . their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.” The WTO’s Council for TRIPS is required, upon a “duly motivated request by a least-developed country Member,” to grant such an extension. In the 2001, Paragraph 7 of the Doha Declaration on TRIPS and Public Health extended the deadline for LDCs to implement pharmaceutical product patents to 2016. Despite these measures, today nearly all sub-Saharan Africa countries have patents on pharmaceutical products. In 2005, a joint WHO-UNICEF “Workshop on IP coherence in procurement” held in Copenhagen agreed to develop a “model declaration” to allow LDCs to invoke the provisions of Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, and to not enforce patents and exclusive marketing rights in relation to pharmaceutical products. These non-enforcement declarations are often used outside of a formal legislative framework, and are accepted by some donor agencies. Their status may be less clear in the European Union, however, where medicines in transit from India to Africa have been seized on the grounds that they infringe on patents. For further discussions, see Carlos Correa, *Implications of the Doha Declaration on the Trips Agreement and Public Health*, WHO; 2002; Carlos Correa, *Trade Related Aspects of Intellectual Property Rights, A Commentary on the TRIPS Agreement*, Apr 2007; ICTSD, “TRIPS Council Agrees On Extensions For LDCs On Pharmaceutical Patents,” July 2002, <http://ictsd.net/ip/39211/>;

have been a series of new developments in trade policy that effectively create barriers for access to medicine for all. Among these are bilateral trade agreements that impose restrictive intellectual property rules on medicines, and unilateral trade pressures against countries that use TRIPS flexibilities such as the use of compulsory licenses on patents.⁴⁵ A European Union Directive on the enforcement of intellectual property rights has been used to seize legitimate medicines in transit from India to developing country markets, including a shipment of second generation AIDS drugs en route from India to Nigeria via the Netherlands.⁴⁶ TGF has yet to respond to such developments, even when they clearly present risks to the longer run prospects for access to affordable medicines.

72. An additional and related concern is the fact that TGF does not have a long run sustainable source of funding. Even if funding remains fixed in the face of the financial crisis, if the cost of medicines increases sharply, and the number of patients needing treatments increases, as is expected, TGF and other related initiatives like PEPFAR and UNITAID will find it impossible to meet the needs of patients.

73. There are several important developments outside of TGF that are relevant to the sustainability of HIV/AIDS, TB and Malaria treatment in developing countries. The World Health Organization is engaged in a negotiation over innovation and access to medicines, including in particular for diseases and conditions that disproportionately concern developing countries, such as AIDS, TB and Malaria. In May of 2008 the WHO adopted a Global Strategy and Plan of Action (GS/PoA) for Public Health, Innovation and Intellectual Property Rights. This document called for the use of the collective management of intellectual property rights through upstream and downstream patent pools, and called for discussions regarding a new biomedical R&D treaty, the use of voluntary and non-voluntary licensing of patents to promote competition and affordable prices, and the de-linking of R&D incentives from drug prices, through such mechanisms as medical innovation prizes.

74. Related to the WHO GS/PoA and particularly relevant to TGF are two new proposals that, taken together, offer the possibility of more sustainable access to medicines for HIV/AIDS, TB and Malaria. One was the decision in the summer of 2008 by UNITAID to consider the development of a patent pool for medicines, in order to enhance competition among generic

Frederick M. Abbott, Rudolf V. Van Puymbroeck, *Compulsory licensing for public health: a guide and model documents for implementation of the Doha Declaration paragraph 6 decision*, World Bank Publications, 2005; Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, Oxford University Press US, 2009; Brook Baker, "Processes and issues for improving access to medicines: willingness and ability to utilise TRIPS flexibilities in non-producing countries," DFID HSRC, 2004.

⁴⁵ Jakkrit Kuanpoth, "TRIPS-Plus Intellectual Property Rules: Impact on Thailand's Public Health," *The Journal of World Intellectual Property*, 15 Aug 2006, Volume 9 Issue 5, Pages 573 -591. Sisule F. Musungu, Susan Villanueva, Roxana Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks*, South Centre.2004. Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Quaker United Nations Office, 2004. Susan K. Sell, "TRIPS-Plus Free Trade Agreements and Access to Medicines," *Liverpool Law Review* Volume 28, Number 1, April, 2007.

⁴⁶ Andrew Jack, Frances Williams, Michael Steen, "Dutch seizure of HIV drugs highlights patent friction", *Financial Times*, March 5 2009. Thiru Balasubramaniam, "India: Intervention at WTO TRIPS Council on public health dimension of the TRIPS Agreement," *Knowledge Ecology Notes*, March 9, 2009.

suppliers of second generation AIDS drugs and pediatric formulations.⁴⁷ The second is a March 2009 proposal by Bangladesh, Barbados, Bolivia and Suriname (3B+S) for “A Prize Fund to Support Innovation and Access for Donor Supported Markets Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Use.” The 3B+S proposal regarding donor supported markets involves (1) setting aside a fixed fraction of the drug budgets of TGF, PEPFAR and or UNITAID into a prize fund to reward products for their impacts on health outcomes, and (2) linking eligibility for the prize fund payments to the open licensing of patents for generic competition, such as that proposed in the UNITAID patent pool.

75. There is now support for the approach set out in the 3B+S donors market proposal by some large pharmaceutical companies, but also opposition from others, particularly as regards to the open licensing element of the proposal, which many public health NGOs say is critical in assuring sustainable access to affordable products.

IV. EVALUATION OF TDR AND TGF IN TERMS OF THE RIGHT TO DEVELOPMENT

76. There is much to admire in the operations of TDR and TGF. Both institutions have attracted highly qualified and idealistic staff that are devoted to the health and welfare of poor persons living in developing countries. Both institutions respect human rights and promote development. Both institutions also can be found wanting in certain areas.

77. TDR has accomplished many things with few resources, but for several years did not mobilize sufficient resources to accomplish its own goals regarding the eradication or treatment of tropical diseases. Because of its limited resources, TDR has found itself saddled with an unhelpful dependency on the pharmaceutical industry in important areas of medical R&D, and may not have adequate leverage to negotiate intellectual property rights agreements that protect upstream research and downstream access. TDR's role has been challenged and often eclipsed by new private sector actors, including the BMGF, which have a tendency to lessen TDR's ability to set global norms, or to shape policy.

78. TGF has done an impressive job of building the capacity and delivering treatment and care for HIV/AIDS, TB and malaria. But TGF has not responded to threats to the sustainability of treatment.

79. Table 1 presents an evaluation using the current formulation of the criteria on the right to development.⁴⁸ In nearly all areas, both TDR and TGF score well.

⁴⁷ Press Release: <http://www.unitaid.eu/en/NEWS/UNITAID-moves-towards-a-patent-pool-for-medicines.html>. See also: “Access to medicines and IPR: UNITAID moving towards a Patent Pool?” UNITAID Second Consultative Forum (Dakar, Senegal, 6 December 2008) Jorge Bermudez Executive-Secretary, UNITAID: http://www.unitaid.eu/images/test/2e_cf_unitaid_unitaid%20jb_patent%20pool_61208.pdf.

⁴⁸ Current formulation of criteria – (A/HRC/8/WG.2/TF/2, 31 January 2008, Annex 2)

Table 1: Application of Current Formulation of Right to Development Criteria to TDR and TGF

Structural/Institutional Framework	TDR	TGF
(a) Contributes to creating an enabling environment for sustainable development and the realization of all human rights;	Overall, yes.	Overall, yes.
(b) Draws on all relevant international human rights instruments, including those relating to the RTD, in elaborating the content of development strategies and tools for monitoring and evaluating their implementation;	Not all instruments. For example, TDR was not initially aware of the RTD. However, the TDR approach to issues <i>is</i> broadly and consciously consistent with core human rights concepts. TDR has published an excellent human rights analysis of neglected diseases, authored by Paul Hunt.	Not all instruments, but TGF is generally quite sensitive to human rights issues. It was not specifically aware of the RTD, but is organized in ways that are consistent with many core RTD ideas.
(c) Promotes good governance, democracy and the rule of law and effective anti-corruption measures at the national and international levels;	Yes.	Yes, although implementation at the national level is uneven.
(d) Follows a human rights-based approach to development, and integrates the principles of equality, non-discrimination, participation, transparency, and accountability in its development strategies;	Yes.	Yes.
(e) Establishes priorities that are responsive to the needs of the most vulnerable and marginalized segments of the population, with positive measures to realize their human rights;	Yes.	Yes.
(f) Recognizes mutual and reciprocal responsibilities among the partners, taking into account their respective capacities and resources and the special vulnerability of Least Developed Countries;	Yes.	Yes.
(g) Ensures that human rights obligations are respected in all aspects of the relationship between the partners, through harmonization of policies;	Not completely. TDR does not insist on deep harmonization of approaches with its partners.	Not completely.

Process	TDR	TGF
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Process	TDR	TGF
(h) Ensures that adequate information is freely available to enable effective public scrutiny of its policies, working methods and outcomes;	In general, TDR is transparent, and provides much public information, including through the extensive publications and documents available on the TDR web page. There are some areas where TDR could be more transparent, however. These include those are intellectual property right issues and contractual agreements with pharmaceutical companies regarding pricing and access to medicines. TDR does not disclose the details of such agreements.	In general, TGF is transparent, and is aware that this is important. People working at TGF spoke quite freely about controversial issues, and candidly about the strengths and weaknesses of TGF performance on a wide range of issues. Where there are weaknesses in transparency, it is mostly due to a lack of capacity or systems to obtain quality information, an issue that pits management needs against burdens on recipients of grants.
(i) Promotes gender equality and the rights of women;	Yes.	Yes.
(j) Provides for the meaningful consultation and participation of all stakeholders, including affected populations and their representatives, as well as relevant civil society groups and experts, in processes of elaborating, implementing and evaluating development policies, programmes and projects;	Yes.	Yes.
(k) Respects the right of each state to determine its own development policies in accordance with international law, and the role of national parliaments to review and approve such policies.	Mostly. In some cases, TDR focuses on “international standards” that a country has not necessarily agreed to be legally bound, such as the standards for drug quality.	Largely. There are tensions with donors on some issues relating to intellectual property rights.
(l) Includes fair institutionalized mechanisms of mutual accountability and review, through which the fulfillment by all partners of their agreed commitments is monitored and publicly reported, responsibility for action is indicated, and effective remedies are provided;	TDR does undertake fair institutionalized mechanisms of mutual accountability and review, and is responsive to criticisms in areas where it seeks such reviews. The scope of independent reviews appear to be limited in some topics,	TGF is conscious that this is important, and the Geneva based organization is struggling to address the monitoring of programs in 136 countries. The early focus on TGF work was to expand program activities.

Process	TDR	TGF
	such as those relating to the management of intellectual property, or the pricing of products developed by private sector partners.	Recently more attention and resources have been devoted to monitoring functions, but more needs to be done. Detailed grant related information is available on TGF webs.
(m) Monitors and evaluates progress in achieving development strategies by carrying out systematic assessments of the human rights impact of its policies and projects based on appropriate indicators and contributes to strengthening the capacity to collect and disseminate timely data, which should be disaggregated sufficiently to monitor the impacts on vulnerable population groups and the poor;	TDR certainly monitors elements of its progress in achieving development goals, and is sensitive to human rights and development concerns. TDR tends to be weak in the area of economic analysis.	TGF does monitor its progress in achieving development strategies and human rights concerns, but is constrained somewhat by the poor quality of data in some areas, and the shortcomings of some reporting mechanisms, which cannot by policy impose significant burdens on grant recipients.

Outcome/Obligations	TDR	TGF
(n) Ensures that developing countries, through their own efforts and through international assistance and cooperation, have the human and financial resources to implement successfully, development strategies based on these criteria;	TDR has contributed significantly in the area of the development of human resources in developing countries. TDR has been less effective in mobilizing financial resources adequate to implement successful development strategies.	In the short and medium term, yes. Longer-term sustainability is less certain.
(o) Establishes, as needed, safety nets, to provide for the needs of vulnerable populations in time of natural, financial or other crisis;	In some cases, yes.	Yes.
(p) Achieves the constant improvement of the well-being of populations and all individuals, on the basis of their active, free, and meaningful participation in development and in the fair distribution of the benefits, in accordance with article 2, paragraph 3, of the Declaration on the Right to Development;	Yes.	Yes.
(q) Contributes to development that is sustainable and equitable, with a view to ensuring continually increasing opportunities for all and a fair distribution of resources.	Yes.	Yes.

80. The current criteria capture well, the degree to which TDR and TGF operate in an ethical manner, and the degree to which both institutions are focused on efforts to address the specific needs of marginalized and vulnerable populations living in developing countries. But the present criteria do not capture well, the failures to address clear needs to confront the challenges of sustainable resource mobilization, the management of intellectual property rights in a manner consistent with access to medicine for all, or the need for new access friendly business models to reward drug developers.

81. In recent years there have been a number of areas where risks to access to medicines are important considerations, or where new mechanisms to address the challenges of innovation and access to medicine are discussed. These include contentious discussions at the World Health Organization regarding the use of limitations and exceptions to patent rights, a possible biomedical R&D treaty and efforts to reform the incentive systems for drug development so that incentives are no longer linked to high drug prices,⁴⁹ the creation of a patent pool at UNITAID to

⁴⁹ One account that captures the tensions in the negotiations is Riaz K. Tayob, "WHO IPR and innovation working group begins work." *Suns*, November 6, 2007. See also: Lisa Forman, "Desk Review Of The Intergovernmental Working Group On Public Health, Innovation And Intellectual Property From A Right To Development

facilitate open competition for second generation AIDS drugs, the Dutch seizure of generic AIDS medicines in transit to developing countries, proposals in the WHO and WIPO to promote greater transparency of patent landscape information, and the WIPO negotiations on a “Development Agenda” and on limitations and exceptions to patent rights to address access to medicines. The following table reports the response of TDR and TGF to these events.

Table 2: Response of TDR and TGF to selected recent innovation + access to medicine negotiations, proposals and developments

Criteria	TDR	TGF
1. Express support or offer analysis of biomedical R&D Treaty	No	No
2. Evaluate proposals to separate R&D incentives from drug prices	Participation in January workshop on innovation inducement prizes	No
3. Express Visible Support for UNITAID Patent Pool?	No	No
4. Core activities funded via sustainable funding mechanisms	No	No
5. Express criticism or concern over EU seizures of generic medicines in transit to developing countries	No. However, WHO has issued a short statement.	No
6. Promote transparency of patent landscape or patent licensing policies	No	No
7. Participate in WIPO Development Agenda Debate	No	No
8. Participate in WIPO Patent Committee Discussions on Limitations and Exceptions to Patent Rights	No	No

Perspective,” A/HRC/12/WG.2/TF/CRP.5. 27 March 2009; Statement On Behalf Of Oxfam By Sir John Sulston, to the WHO Executive Board on Thursday, January 26, 2006. AGENDA ITEM 4.10, Global Framework on essential health research and development; Open letter from scientists in support of World Health Organisation resolution proposed by Brazil and Kenya, submitted 25th January 2006 to members of WHO Executive Board, In reference to: EB117/Conf. Paper No.3, Global Framework on essential health research and development (Draft resolution proposed by Brazil and Kenya) AGENDA ITEM 4.10; Francis Williams, WHO to decide on medical R&D, FT, January 30 2006. For background on the debate over incentive systems, see: An Annotated Bibliography of Scholarly and Technical Articles and Books on Innovation Prizes, *KEI Research Note* 2008:2, and updates to more recent papers here: <http://www.keionline.org/content/view/82/>

82. In light of the importance of these issues, it may be useful to consider additional sub-criteria for the right to development, in the area of innovation and access to medicine.

Table 3: Supplementary Criteria for Right to Development, Applied to TDR and TGF

Criteria	TDR	TGF
9. Has the institution made reasonable medium and long-term projections regarding the resources necessary to accomplish its objectives?	TDR was created more than 30 years ago, and has yet to provide long term projections of the resources reasonably necessary to address the costs of research and development for new products for the treatment and eradication of identified tropical diseases. TDR recently issued a 2008-13 business plan and is assessing its needs in relation to better contributing to GS/PoA.	No
10. Has the institution secured sustainable funding sufficient to accomplish its objectives?	No	No
11. If access to knowledge goods (including new medicines, vaccines, diagnostics, compound libraries, data, research tools, etc) is important for success, is there a feasible strategy to obtain sustainable access at affordable prices, consistent with resource constraints?	TDR recognizes the benefits of new knowledge goods being available and accessible in an equitable manner consistent with public health objectives, but has not been fully supportive to efforts to make such access sustainable, in some cases defending a status quo that pits access and innovation against each other.	Current policies rely on non-enforcement of rights by patent owners, and ignore longer-term challenges of obtaining access to second-generation HIV/AIDS drugs.
12. Are policies regarding intellectual property rights transparent, and consistent with human rights?	Policies are not transparent. Compromises regarding access are not consistent with “access to medicine for all.”	Patent landscape for relevant products is not transparent. Licensing practices are not sufficiently transparent. There is inadequate progress on the transparency of pricing of products.

<p>13. If current business models fail to promote development and undermine human rights, does the institution encourage and support efforts to evaluate or promote new business models that are better for development and human rights?</p>	<p>See Table 2</p>	<p>See Table 2</p>
<p>14. Does the institution play the role anticipated and needed, regarding the establishment of global norms and accountable leadership, in the core areas of operations?</p>	<p>The role of private sector actors, including in particular the BMGF, presents enormous challenges in terms of the regulatory and leadership role for TDR in the field of neglected diseases. TDR has sought to remain sufficiently independent of any single donor, in order to provide some space for norm setting and regulatory roles.</p>	<p>TGF is now the second largest of three large institutional efforts to provide treatment for persons living with HIV/AIDS. The governance structure of TGF and the wide geographic areas of operation and scope of actions are definite assets regarding the ability of TGF to establish global norms in some areas. TGF has been innovative in the delivery of treatment and care. In some cases, policy innovation has come from other entities, such as UNITAID, which has a less diverse and less representative governance structure.</p>
<p>15. Is the institution independent and flexible enough to respond to new challenges and opportunities?</p>	<p>TDR is undertaking serious evaluations of its future role given changes in the policy landscape. TDR does not seem sufficiently open or positioned to challenge corporate interests on matters concerning intellectual property rights, access or business models.</p>	<p>Probably yes, although tensions remain regarding the interests of some donor countries in protecting domestic pharmaceutical industries.</p>

Annex I

List of acronyms

3B+S	Bangladesh, Barbados, Bolivia and Suriname
AIDS	acquired immune deficiency syndrome
ARV	antiretroviral
BIO	Ventures for Global Health
CCM	Country Coordinating Mechanism
CGIAR	Consultative Group on International Agricultural Research
DNDi	Drugs for Neglected Diseases Initiative
FIND	Foundation for Innovative New Diagnostics
Fiocruz	Oswaldo Cruz Foundation
GFHR	Global Forum for Health Research
GMGF	Bill and Melinda Gates Foundation
GS/PoA	Global Strategy and Plan of Action
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
HRP	The Programme of Research, Development and Research Training in Human Reproduction
IAVI	International Aids Vaccine Initiative
IDRC	International Development Research Centre
IFPMA	International Federation of Pharmaceutical Manufacturers Association
JCP	Joint Coordinating Board
MDG	Millennium Development Goal
MMV	Medicines for Malaria Venture
MoU/ATS/TDR.	Memorandum of Understanding on the Administrative and Technical Structures of the Special Programme for Research and Training in Tropical Diseases
MSF	Médecins Sans Frontières
PATH	Program for Appropriate Technology in Health
PDPs	Product Development Partnerships
PEPFAR US	President's Emergency Plan for AIDS Relief
PPP	Public Private Partnership
STAC	Scientific and Technical Advisory Committee
TDR	Special Programme for Research and Training in Tropical Diseases
TGF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNITAID	UNITAID
UN	United Nations
WHA	World Health Assembly
WHO	Director General of the World Health Organization
WTO	World Trade Organization

Annex II

Membership of current TDR Joint Coordinating Board (JCB)

The JCB consists of 34 members. Membership was formerly for a three-year period but those selected for membership from 2009 onwards will serve for a period of four years. JCB members may be reappointed. As of January 2009, the JCB consists of the following members:

Chair Professor Rolf Korte, Germany (JCB30 and 31, June 2007 and 2008)

Vice Chair Professor Rodrigo Correa-Oliveira, Brazil (JCB31, June 2008)

12 governments selected by TDR resource contributors

1. Belgium
2. Canada
3. China
4. India
5. Japan
6. Malaysia
7. Nigeria
8. Spain
9. Constituency: Germany and Luxembourg
10. Constituency: Netherlands and Sweden
11. Constituency: Norway and Switzerland
12. Constituency: United Kingdom of Great Britain and Northern Ireland and United States of America

12 governments selected by WHO Regional Committees

1. Chad (AFRO)
2. Comoros (AFRO)
3. Brazil (AMRO)
4. Costa Rica (AMRO)
5. Libyan Arab Jamahariya (EMRO)
6. Syrian Arab Republic (EMRO)
7. Bulgaria (EURO)
8. Uzbekistan (EURO)
9. Bhutan (SEARO)
10. Thailand (SEARO)
11. Papua New Guinea (WPRO)
12. Viet Nam (WPRO)

6 other cooperating parties selected by the JCB

1. Cuba
2. Ghana
3. Iran, Islamic Republic of
4. Panama
5. United Arab Emirates
6. Zambia

WHO Regional Offices include: AFRO: Regional Office for Africa; AMRO: Regional Office for the Americas; EMRO: Regional Office for the Eastern Mediterranean; EURO: Regional Office for Europe; SEARO: Regional Office for South-East Asia; WPRO: Regional Office for the Western Pacific

Annex III

Functions, composition and operation of the Scientific and Technical Advisory Committee (STAC)

4. THE SCIENTIFIC AND TECHNICAL ADVISORY COMMITTEE (STAC)

4.1 Functions

The STAC shall have the following functions:

4.1.1 Review, from a scientific and technical standpoint, the content, scope and dimensions of the Special Programme, including the diseases covered and approaches to be adopted.

4.1.2 Recommend priorities within the Special Programme, including the establishment and disestablishment of Scientific Working Groups, and all scientific and technical activities related to the Programme.

4.1.3 Provide the JCB and the Executing Agency with a continuous independent evaluation of the scientific and technical aspects of all activities of the Special Programme.

For these purposes the STAC may propose and present for consideration such technical documents and recommendations as it may deem appropriate.

4.2 Composition

The STAC shall be comprised of 15-18 scientists and other technical personnel who will serve in their personal capacities to represent the broad range of biomedical and other disciplines required for Special Programme activities. Members of STAC, including the Chairman, will be selected on the basis of scientific or technical competence by the Executing Agency, in consultation with the Standing Committee and with the endorsement of the JCB.

4.2.1 Members of the STAC, including the Chairman, shall be appointed to serve for a period of three years, and will be eligible for further reappointment. To maintain continuity of membership, the expiration of the initial terms of office of members of STAC will be staggered.

4.3 Operation

4.3.1 The STAC shall meet at least once each year.

4.3.2 The Executing Agency shall provide the Secretariat to STAC including sustained scientific, technical and administrative support.

4.3.3 Costs of the STAC shall be borne by the Special Programme Resources.

The STAC shall prepare an annual report on the basis of a full review of all technical and scientific aspects of the Special Programme. This report, containing its findings and recommendations, shall be submitted to the Executing Agency and to the Standing Committee. The Executing Agency shall submit its comments on the report to the Standing Committee. The

Standing Committee shall then transmit the report, including the comments of the Executing Agency, together with its own observations and recommendations, to the JCB, not less than forty-five days before the JCB's annual session. The Chairman of the STAC, or in his absence a member of the STAC deputized to act for him, shall attend all sessions of the JCB.
