

**The World Health Organization Secretariat's
Draft Global Strategy and Plan of Action on
Public Health, Innovation and Intellectual Property**

By Jeremiah Norris

Introduction

On January 12, 2007 Member States were asked to provide additional comments on the document prepared by the Intergovernmental Working Group (IGWG), entitled “Elements of a global strategy and plan of action—progress to date in the Intergovernmental Working Group”. This was prepared by World Health Organization’s (WHO) Commission on Intellectual Property Rights, Innovation and Public Health. On July 31, using comments submitted by 15 Member States, WHO then issued “Draft global strategy and plan of action on public health, innovation and intellectual property, report by the Secretariat.” Subsequently, the IGWG will submit to the Sixty-first World Health Assembly, through the Executive Board, a global strategy and plan of action to provide a medium-term framework based on the recommendations of the Commission.ⁱ

This analysis will be in two parts. The first will examine the substance of comments offered by key Member States as a result of WHO’s invitation of January 12. These were intended to inform the draft global strategy submitted by WHO on July 31. There are major disconnects between these two sets of documents, wherein the requests of some Member States have been unrecognized by WHO, while those of other Members have been given undue attention.

The second part will examine resolution WHA 59.24, the origins of the Commission’s institutional legitimacy, in which the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and reducing the high incidence of communicable diseases in those countries is an overriding

priority. Thus, “the focus of the strategy was to be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available—either because no treatment exists or because, where treatment [sic] exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable.”ⁱⁱ

Part I: The Disconnects Between Members’ Comments and the July 31 Draft

Only Brazil, Kenya, Thailand, Germany (on behalf of 27 Members of the EU), Japan, Australia, and the United States submitted extensive comments, running up to 20 pages. The others were cursory, e.g., Malaysia’s and Egypt’s each ran to $\frac{3}{4}$ of a page.

Brazil and Thailand are recognized as leaders by the activist community in using the WHO to move their agenda to disenfranchise the research based industry of its intellectual property on the pretext of public health concerns for the poor. Groups such as Oxfam and Medecins Sans Frontieres either have publicly endorsed Brazil and Thailand’s threats to issue compulsory licenses, or have actively engaged in promoting the expropriation of patents from right holders. Although these NGOs are not Member States of WHO, the Organization has issued statements in support of their actions in the absence of examining the merits of each case with relevant Members’ authorities.

Brazil commented that “necessary legislative steps ... to allow compulsory licensing for exports consistent with the flexibilities of TRIPS” should be permitted, and “access to drugs cannot depend on the decisions of private companies.” It went on to comment that “it supports research on affordable and technologically appropriate products to combat Type I diseases in developing countries, and that a larger proportion of health research and development budgets of developed countries [should] be devoted to the health needs of developing countries.” Brazil also recommends that “the Plan of Action should examine concrete measures that can be implemented to comply with the requirements for the protection of undisclosed test data against unfair commercial use, as set out by TRIPS that do not involve the granting of property rights or the needs to remunerate the party concerned.” Brazil recommends that “the attention of the Working Group be drawn to IP issues that have a bearing on all aspects of access to medicines and health, such as pricing, affordability, access to data in the public domain.” Lastly, Brazil recommends that “the promotion of patent pools should be considered in light of the implications that such initiatives might enhance access to research and to medicines of developing countries.”

In the context of comments that were non-supportive of the draft plan of action, Brazil stated that its “suggestions for deletions have generally not been incorporated by the Secretariat ... Delegations to the Working Group have not had an opportunity to comment on the text as it appears in Annex I ... Comments made during the debate with the Working Group have not been incorporated in the body of the text ... and the recommendation of the IGWG to work within national and/or regional frameworks to promote and manage IP is too broad and requires even more clarification.”ⁱⁱⁱ

Kenya believes that Member States should consider a set of legally binding obligations to support a needs-driven R&D agenda and as the legally mandated inter-governmental agency responsible for global health, “WHO has the full legitimacy to take on this new responsibility.”

Kenya’s non-supportive comments covered a variety of issues. For instance, “The Global Strategy document as is currently prepared is inadequate and needs to be substantially revised. It is basically a reiteration of principles noted in WHA Resolution 59.24 and previous resolutions. Kenya believes that merely reiterating the recommendations of the Commission and then framing them as areas of action in the Plan of Action will not be sufficient. It is not possible to finalize discussion during the next Working Group meeting. Kenya would support a reasonable extension of time during the 2008 WHA.”^{iv}

Thailand believes that on the subject of the ‘management of intellectual property’, the IGWG must prevent specific aspects of the system, such as test data exclusivity, “me-too” patents, and patent linkages.” On manufacturing standards, Thailand does not support the WHO GMP requirements. Rather, it says “developing countries should start with their own national GMP and gradually move towards WHO GMP.” In terms of financing the 8 elements, Thailand recommends that developed countries “devote a larger or appropriate share of health R&D to the health needs of developing countries.”

Thailand’s non-supportive comments included the need to “estimate financing requirements of the plan of action; utilize existing [funding mechanisms] for research and development for neglected diseases, while avoiding duplication of existing programs; and [because each element of] the Action Plan is in itself a major challenge and requires further development, [there should be collaboration] where appropriate with WIPO and WTO and other international bodies, taking in account their mandates.”^v

The positive comments of Brazil, Kenya and Thailand found substantial expression in the July 31 draft, and as noted above, Brazil's non-supportive comments did not, nor did the comment from Thailand to avoid duplication of existing programs, such as WHO's Tropical Disease Research Programme. The Secretariat disregarded Kenya's comment for an extension of time in WHA 2008, and Bangladesh's request to postpone a decision until the Sixty-second WHA in 2009.^{vi} In addition, the non-supportive comments from Germany, on behalf of 27 Member States of the EU, Australia, Japan, and the U. S. were also ignored.

For instance, Germany requested the Secretariat to bear in mind that "it is of the utmost importance for the plan of action to stick to the WHO mandate and respect the work carried out in other international organizations, such as WIPO and WTO." It goes on to suggest that when WHO uses the term 'management of intellectual property', this should be in line with work already done or being carried out by WIPO and WTO in particular." Germany believes that there are already comprehensive preliminary inventories on the transfer of technology issue and the EU would be interested in "getting an evaluation of such transfers." It stated strongly the importance "to flag up developing country governments responsibilities for investing in their own healthcare systems."^{vii}

Australia observed "it is not clear that a new forum is necessary to implement the WHA Resolution on WHO's role and responsibilities in health research, and that existing arrangements should be assessed before making any decisions to establish a new forum." It further states that "any work to strengthen education and funding in the management of intellectual property must be done in close cooperation with WIPO and WTO."^{viii}

Japan cautions "that restricting the contents of bilateral trade agreements is beyond the mandate of WHO." It went on to affirm that the "appropriate protection of intellectual property is a factor indispensable to the development of industry, including the pharmaceutical industry." When the IGWG discusses a funding mechanism for sustainable financing, Japan "believes it is important to promote research and development efficiently, utilizing existing mechanisms such as TDR at WHO/Geneva."^{ix}

Lastly, in building and improving innovative capacity, Japan recommends that this subject "is appropriate to discuss in WIPO".

For its part, the United States Government emphasized that it "believes in promoting R&D and commends the IWGW to review how the WHO Secretariat already is actively engaged in many of the activities suggested

through programs such as [its] Special Programme for Research in Tropical Diseases (TDR) [in Geneva].”^x

The USG offered several other comments which were substantially ignored in the July 31 draft by the Secretariat:

- The IGWG should not consider the Recommendation on Type 1 diseases;
- It is unclear about the meaning of ‘management of intellectual property’, and Requested the Secretariat to propose a standard definition;
- Any activities pertaining to the management of intellectual property should be done in collaboration with the WIPO Secretariat;
- The WHO Secretariat should not expand its work on matters better addressed by other international organizations, such as WIPO and WTO, on intellectual property;
- The USG does not support the establishment of any new funding mechanisms, as there are several existing funding mechanisms, including public and private entities;
- In the section on sustainable financing, this focuses solely on funding by donors.
- The USG calls attention to the 1990 Commission on Health Research for Development which set a target for developing countries to spend 2% of their health budgets on health research. To date, only Brazil and Argentina have complied;
- With respect to Article 66.2 of TRIPS, many countries, including the US, take seriously its obligations, and it is inappropriate for a statement to imply a lack of compliance without any substantive evidence;
- The WHO Secretariat should cooperate with WIPO and WTO when providing information on the pharmaceutical and public-health implications of relevant international organizations;
- The IGWG should estimate funding needs for implementation of the plan of action, and identify its intended audience;
- While promoting health R&D everywhere is a laudable goal, some countries would benefit from an emphasis on strengthening public and private health infrastructure.

Part II: Mission Statement, Focus of the Strategy and Thematic Presentations

The Secretariat set out a clear mission statement in the first line of its Draft Global Strategy in which the Health Assembly recognized “the growing burden of diseases and conditions disproportionately affecting developing countries ... and reducing them is an overriding priority.” Subsequently, the Secretariat fixed its primary focus on “disease conditions of significant public health importance in developing countries for which an adequate treatment ... is not available—either because no treatment exists or because, where treatment exist [sic], they are inappropriate for use in countries with poor delivery systems, or unaffordable.”^{xi}

The mission statement and the focus of a strategy around which a Plan of Action has been proposed are intertwined with three themes throughout the Secretariat’s texts. They form the basis for the legitimacy of the Commission: 1) neglected diseases disproportionately affect poorer countries; 2) the international patent system, and concomitantly—price, is a barrier to access of medicines for the poor; and 3) there is a dearth of R&D on these diseases. However, WHO failed to provide to Member States any countervailing evidence by which they could weight the veracity of these themes against authoritative publications, many by WHO/Geneva:

Neglected Diseases

According to WHO, there are ten neglected diseases:^{xii}

Tropical Diseases

- Trypanosomiasis
- Chagas disease
- Schistosomiasis
- Leishmaniasis
- Lymphatic filariasis
- Onchocerciasis

Other Diseases

- HIV/AIDS
- Tuberculosis
- Malaria
- Diarrhoeal diseases

In 2007, *The Lancet* reported that in the year 2000 the number of disability-adjusted life years for tropical diseases was 0.9% of the total, and global mortality was 0.3%. By 2002, WHO recorded a 0.1% mortality rate for trypanosomiasis and leishmaniasis and zero for the remaining tropical diseases. There was a striking decrease in mortality from schistosomiasis, which WHO recorded at 200,000 in 1995.^{xiii}

While the Other Diseases record higher rates of mortality, there are available treatments, often at zero prices, for each of them, with the possible exception of Chagas. The International Monetary Fund (IMF) reports that expenditures for AIDS alone was \$8 billion in 2004^{xiv}; WHO reports that they were \$8.3 billion in 2005, and UNAIDS says they reached at least \$9 billion in 2006, while estimates for 2007 are reasonably expected to exceed \$10 billion. Expenditures on TB and malaria, while lower than on AIDS, nonetheless are estimated at \$6-7 billion over this same time frame. In total, then, since 2004 some \$41.8 billion have been expended on three disease entities.

If these are neglected diseases, then the Commission and the IGWG have to develop a new definition for the global health community.

The WHO Commission has not kept track of the pace and pattern of contemporary developments in neglected diseases. In 2002, the British Medical Journal published an editorial entitled: “The world’s most neglected diseases.” On August 11, 2007 the BMJ published an update, written by one of the same authors of the 2002 editorial. The update stated that “The long held belief that it is not economically feasible to develop drugs ... specifically for tropical diseases has been shattered. Product development partnerships have been established for at least six neglected diseases in the past seven years without commercial markets or conventional business models, and several new drugs and vaccines are in the pipeline. We can expect to see eight or nine new drugs for neglected tropical diseases within the next five years.”^{xv}

On September 18, 2007 the European and Developing Countries Clinical Trials Partnership (EDCTP) announced that HIV positive children can now benefit from an anti-retroviral drug designed especially for them. The Partnership developed a drug called ‘Triomune Baby and Junior’. It is administered twice daily. “The US Food and Drug Administration recently gave its tentative approval for the drug, paving the way for it to receive prequalification status from the World Health Organization and making it available for distribution under the President’s [Bush] Emergency Plan for AIDS Relief (PEPFAR) and Clinton Foundation programmes.”^{xvi} The drug will be manufactured by Cipla Pharmaceuticals of India.

The drug industry has formed other partnerships with the public sector, generating pipelines of early-stage potential medicines for certain neglected diseases. These include “the Global Alliance for TB Drug Development, the Drugs for Neglected Diseases Initiative (DNDi), and the Medicines for Malaria Venture. In 2004, 63 new drugs were being pursued by this approach.”^{xvii}

The most sensitive indicator on progress in reducing neglected diseases is a decline in infant mortality rates. On September 13, 2007 UNICEF released new data, showing that the global mortality for the under-five population fell from 20 million annually in 1960 to 9.7 million in 2006. This decline has to be viewed in light of increased population growth rates in the developing world, moving from less than 2.8 billion in 1960 to an estimated 5 billion at risk in 2006 (out of a total global population of 6.7 billion). UNICEF stated: a “public health triumph has arisen, predicting further drops.”^{xviii}

These rapid declines in infant mortality rates occurred in an environment which had no need for WHO to sanction the confiscation of intellectual property rights or require it to manage an international patent pool.

Global biopharmaceutical companies, responding to demand, are increasingly focusing new research on finding new cures and treatments for diseases that primarily affect patients in developing countries. Currently, they have under development these medicines: ^{xix}

• African Trypanosomiasis	1
• Dengue	5
• HIV Vaccines	19
• ARVs	22*
• Leishmaniasis	2
• Malaria	20
• Onchocerciasis	1
• Schistosomiasis	1
• Tuberculosis	19

* Including 11 in pediatric formulations

On September 1, U. S. drug reviewers at the FDA gave a boost to Merck’s experimental HIV vaccine ahead of a key advisory panel meeting, saying “the benefits outweigh the risks.” ^{xx} In mid-September, however, Merck closed down this clinical trial because it had failed to yield the expected results. Nonetheless, it still has a number of trials testing other cell-mediated immunity vaccines against HIV infection. Earlier, in 2006, Merck developed the world’s first vaccine against cervical cancer, which is now approved for sale in 85 countries, and pending approval in 40 more. This disease has rapidly become one of the leading causes of death among women in the developing world.

The largest cause of morbidity and mortality within neglected diseases is HIV/AIDS. If the WHA 59.24 is the operative rationale for this

Commission, then its Plan of Action to improve “adequate treatment” is misdirected and can have little effect on ameliorating this disease in the absence of prevention. “Factually speaking, HIV is one of the most preventable viral infections known in the history of pandemics. HIV is more preventable than the common cold or hepatitis. The reality is that the great majority—90% plus—of new HIV infections occurs through consensual sex between adults.”^{xxi}

All elements of the Plan address R&D issues directed at treatment, e.g., develop mechanisms to manage intellectual property; support capacity building in the management of intellectual property; provide support for the flexibilities of TRIPS; promote competition to ensure that pricing of medicines is consistent with public health policies; and, monitor the impact of intellectual property rights and other factors on innovation.

Even if a future Commission achieved 100% effectiveness on implementing this Plan of Action as proposed by the WHO Secretariat, it would have a marginal effect subsequently on dampening the rate of new HIV infections due to an almost total lack of prevention interventions as a fundamental requirement for treatment initiatives.

The draft global strategy on public health, innovation and intellectual property places a fix on all that is wrong on treatment failures. Yet, all could be made right if only intellectual property became a public good under WHO auspices. It disregards the most obvious manifestations of the HIV/AIDS global battle. “The prime mover of the epidemic is not inadequate antiretroviral medications, poverty, or bad luck, but our inability to accept the gothic dimensions of a disease that is transmitted sexually. Only when we cease to dodge this fact will effective HIV-control programs be established. Until then, it is no exaggeration to say that our polite behavior is killing us.”^{xxii}

International Patent System and Price

In 2001, the *Journal of the American Medical Association* published a landmark study on patents in the developing world. It found that patents on antiretroviral medicines for HIV/AIDS in Africa suggest that the poorest WTO members often have few or zero patents on these medicines. It is wrong, the authors stated, to categorically equate the mere existence of patents with a barrier to accessing AIDS treatment, because the relationship between patents and access is a complex and nuanced one. For instance, it depends on non-market factors such as the medically accepted guidelines for ARV treatment; offers by pharmaceutical firms to discount or donate medicines, notwithstanding

patent status; and—above all, the availability of international aid finance to purchase drugs. ^{xxiii}

In May 2004, the U. S. FDA offered to Fast Track any ARV from any country and certifies it as a true generic. In conformity with US laws and requirements, the FDA was compelled to seek comment from the patent holders who could challenge the applications from abroad. None did so. Today, several ARVs manufactured in India and South Africa have been designated by the FDA as true generics and are now listed on WHO's prequalification program. PEPFAR states that 70% of all ARV use among its programs is from either of these two countries, and they are being procured with US foreign aid monies. ^{xxiv}

During the World Health Assembly in May 2006, WHO released a report on the pricing of drugs. A major finding: “taxes and duties levied on medicines, as well as the mark-up applied, frequently contribute more to the final price than the actual manufacturers’ price.” WHO went on to comment: “There is evidence that some governments procure medicines efficiently, but charge markedly higher prices to patients, e.g., in Indonesia’s public sector, patients paid 11 times the procurement price.” ^{xxv}

Shortly thereafter, in July, the director for WHO’s HIV division publicly stated: “Africa has been hardest hit by the AIDS epidemic ... it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, and supply chains that don’t exist.” ^{xxvi}

WHO followed-up its May 2006 study in July 2007 during a meeting in Vienna, Austria to launch Pharmaceutical Pricing and Reimbursement Information (PPRI), a project sponsored by the European Commission and the Austrian government. WHO, using new data developed since the May 2006 study was released, stated: “The mark-up on generic products can be considerably more than on originator products. Some countries have set prices to patients at levels which have the purpose of, for example, protecting the industry [local], providing revenues for hospitals or funding the development of national health services.” ^{xxvii}

When claims are presented that drug pricing is a barrier to access for the poor, they assume that there is a consistency in price setting between producer and recipient countries. Cross national comparisons by the Wharton School of Business prove that this contention is entirely invalid. Its studies show that when generics are included in pricing studies and compared with price per gram of active ingredient, Japan and Switzerland are more expensive than the United States. Comparing price

per standard unit (a rough measure of dose, which differs across countries) show that Canada, Germany, Switzerland and Sweden are more expensive than the U.S. And many governments, such as Japan, Denmark, the U.K., and France subsidize the R&D components of their pharmaceutical and vaccine industries, making international comparisons difficult. The Wharton studies conclude: policy or regulatory conclusions cannot be drawn from price comparisons alone. ^{xxviii}

The same author for the study mentioned above, Professor Patricia Danzon, published a more recent article on pricing in the September 2007 issue of *Nature*. She stated that “R&D costs roughly \$1 billion for each new drug approved in 2007 ... [this can benefit patients globally] raising the question of how this joint cost should be allocated among consumers to generate the greatest benefit.” ^{xxix} She went on to write that “differential pricing alone will not stimulate R&D for medicines to treat diseases that occur only in developing countries, supply-side or demand-side subsidies are necessary for such diseases.” ^{xxx}

In lieu of direct subsidies, the R&D industry has made substantial investments to ensure that these benefits have been extended to patients world-wide. The items mentioned below do not account for direct product donations. For instance, the U. S. based Partnership for Quality Medical Donations (PQMC) recorded that “the value of donated products was \$4.2 billion in 2005 from American pharmaceutical corporations.” ^{xxxi}

R&D Investments on Neglected Diseases

Of the 15 responses sent in by Members, only two mentioned the existence of WHO’s Tropical Disease Research Programme (TDR), though it has been in operation since 1974, expending to date some \$1.3 billion. Many of the respondents called for public-private collaboration on R&D for neglected diseases without recognizing that TDR was established for this purpose. Brazil, the 10th largest economy in the world, and an outspoken proponent for implementation of the proposed Action Plan, has made a single contribution “of \$100,000 in support of TDR’s research efforts” over the past 33 years. ^{xxxii}

TDR does—and has been doing, much of what the Commission is recommending. On June 17, 2002 a WHO press release announced that through collaboration with the Government of India, a German biopharmaceutical company and TDR, “scientists have developed a new treatment for the 500,000 people who develop visceral leishmaniasis each year.” In clinical trials it cured 95% of treated patients. The new drug, miltefosine, could save most of the 60,000 who die from the disease every year, according to WHO. ^{xxxiii}

GlaxoSmithKline has built the Tres Cantos R&D facility in Spain, dedicated to diseases identified by WHO “as neglected”. Novartis developed a Tropical Disease Research Institute in Singapore, targeting dengue, malaria and tuberculosis. For any product subsequently developed in this facility, Novartis will sell to UN agencies at ‘no cost’.

In October 2006, Pfizer announced a collaborative effort with TDR. This will give TDR access to Pfizer’s library of medical compounds—the world’s largest.^{xxxiv} Although this was announced last year, the Secretariat has failed to take notice of it, though several Member States requested it to review the current situation with libraries for medical compounds.

Merck developed the treatment for onchocerciasis and donated Ivermectin for as long as it was needed, in whatever quantities it was needed, into perpetuity. A World Bank evaluation of this program showed that once people could return to their river-land farm sites in West Africa, 17 million hectares were returned to agriculture production, enough to feed 25 million people.

Since 1968, when Merck developed oral rehydration salts (ORS) for the treatment of diarrheal diseases, UNICEF records that the death rate among children plummeted by almost half. *The Lancet* proclaimed ORS as “possibly the most important advance of this 21 [last] century.”^{xxxv} Today, ORS—which costs pennies to make in any home kitchen, is the preferred treatment for millions of poor children suffering from this disease.

Pfizer built the first Infectious Disease Institute in Uganda, now producing well-trained physicians and other healthcare cadres in the treatment of HIV/AIDS. Bristol Myer-Squibb (BMS) and the Baylor Medical College built the first Pediatric AIDS Hospital in all of Africa, located in Botswana. Through Baylor, they now sponsor a Pediatric AIDS Corps, sending volunteer physicians to specialty centers of excellence in ten Southern African countries. And BMS built an AIDS Laboratory in Botswana, the first on the continent, now operated by Harvard University.

The Societal Value of Innovation

The Founding Fathers of the United States valued so highly the concept of intellectual property rights that they enshrined it in the Constitution of 1789 as Article One. Section 8 of this Article reads: “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and

discoveries.” Section 8 reads further: the Congress reserves the right “to regulate commerce with foreign nations.”^{xxxvi}

These rights have been re-delegated down through time to such Executive branches of government as the Department of Commerce, the Food and Drug Administration, and the Interstate Commerce Commission. However, they have never been re-delegated to an extraterritorial power or supranational state. The consent of Congress is given as part of its power to enter into treaties or international trade obligations, such as NAFTA or GATT, when there is reciprocity, equivalency, and enforceable sanctions among each of the parties. In all cases, though, Congress has insisted on the full maintenance of its sovereign rights to regulate commerce.

It is unlikely that the Congress will ever re-delegate its rights to regulate commerce to WHO, as many of the elements in its Plan of Action require such authorities. One reason would be that WHO has no enforcement powers. On the other hand, both the WTO and WIPO do have such powers. This may be why several Member States in their comments to WHO recommended that it work closely with these organizations to implement the Plan of Action.

In the Draft Global Strategy, innovation and intellectual property rights have been cast in an unfavorable light. Without the protections guaranteed by the U. S. Constitution, the world’s largest benefactor on international health funding, the Bill and Melinda Gates Foundation, would be without its vast resources for re-distribution. In 2007, its commitment will reach approximately \$3 billion, a sum greater than the combined health financing from the World Bank and the Regular Budget of WHO. The beneficiaries of this largesse are the least advantaged people in our world, most particularly those who are receiving immunizations through the Foundation’s grant of \$1.5 billion to GAVI.

All of the ARVs in use today in the developing world are products of the patent system. Many are produced in India and supplied to Africa at very low cost. While it is legal for India to produce these drugs for its domestic markets, it is illegal for them to be exported. Still, none of the R&D companies have presented a legal challenge to prohibit this practice.

Of the many reasons which justify patent protection, one least considered is that nature does not distinguish between the biology of diseases of the poor and the rich, nor does it isolate diseases solely within specific national borders. The therapeutic molecules or pathways that are targeted by drugs for neglected diseases might also be relevant for

treating diseases that affect people in more affluent regions. Thus, there are cross benefits for our global society which can emanate from basic research on neglected diseases. For instance, “the Novartis Institute for Tropical Diseases in Singapore takes all molecules that have activity against dengue virus and systematically tests them against the West Nile and hepatitis C viruses, which belong to the same family as dengue and cause disease also in developed countries.”^{xxxvii} A portion of the financial returns generated in the developed world can then be a component of the Institute’s non-profit initiatives in the developing world.

An Absence of Evidence

The disconnects in the Secretariat’s July 31 draft strategy are so obvious that it seems almost unkind to draw attention to them. Any panel of independent experts would have to conclude that there is an absence of evidence, empirical and otherwise, that can support WHO’s justification for this Commission, either in terms of its mission, its focus or the three themes embedded in both. If diseases which disproportionately affect the poor, or price/patents, or a dearth of R&D on these diseases isn’t the issue, then what is?

Alone or taken together, these three issues generate enormous populous sentiments and are evocative of a deeper and much more pervasive attitude among those in the activist community who operate at the highest levels of generality and lowest levels of specificity. This community is distinct from the civil society NGOs which are dedicated to policy making and education or work directly with people who have HIV. They labor unselfishly in some of the world’s most difficult environments, largely unnoticed by the media. For instance, in the late 1980s, NGO organizations in Brazil such as Grupo Pela Vida “supported an invigorated public health response to the disease on the part of the national government.” Their efforts forced the government to make AIDS a priority. It is with thanks to NGO groups like this that the world was alerted to an epidemic it had preferred to ignore.

Activists, on the other hand, believe that the research based industry is an enemy of the poor, except when it produces private intellectual property which can be expropriated to serve the activists’ definition of the common good. Its oxygen for sustainability is ever wide-spread media coverage, wherein the press performs little due diligence. A copy drug from India morphs into a true generic when reported to media outlets. No need to check if this designation would make a difference in patient care. Activists are proponents of advocacy on behalf of some at the expense of science on behalf of all. Though some 96 different therapies have been developed by industry for HIV/AIDS treatment since the first

drug was approved in 1988, activists all too often fail to acknowledge this scientific accomplishment as the single reason why 2 million, mostly poor and disadvantaged patients, have had an extended life span. They much prefer instead to demonize the research based industry while at the same time promoting policies for its socialization.

None of the respondents could cite any statistics on disease incidence rates, though all quickly stated the problem. The subject of price was discussed in broad terms, such as “too high”, without relating it to a more possibly advantageous economic value relative to clinical outcome. Only one (Spain) alluded to an extensive, private investment on R&D in its country, specifically on diseases identified by WHO as those affecting the poor. None mentioned that a complete annual therapy for schistosomiasis costs .21 cents (US), or that millions of people, mainly children, receive an annual free treatment for onchocerciasis, preventing blindness in most of those treated.

Nor is there any commentary citing UNICEF data showing that childhood deaths from diarrheal diseases were reduced from 5 million to less than 3 million due to ORS.

None offered to explain why governments of the affected countries were neglecting the diseases that were causing so much suffering among their own people. In March 2007, the Carter Center informed the president of Nigeria that it could treat all of his nation’s schistosomiasis cases, mainly among children, for a total of \$4 million. The president gave the Center permission to raise the required funds from private foundations and corporations outside of Nigeria—without one comment from him that in a country exporting 2.4 million barrels of oil per day this neglected health problem could easily be financed from local resources.

Yet, even when they supported the Commission, IWGW respondents stated that their recommendations could only be implemented with the active collaboration of WIPO or WTO. Some went so far as to comment that such issues as intellectual property and patents were outside the remit of WHO.

Almost all respondents placed the responsibility onto developed countries for the funding of R&D activities in the developing world, while Brazil, Thailand and Kenya sanctioned an expropriation of intellectual property from the former. Only one, the USG, raised the issue of past international commitments through the WHO on the funding of research activities. For instance, in 1990 the WHO “Commission on Health Research and Development set a target of for

developing countries to spend two percent of their health budgets on health research. To date, only Brazil and Argentina have complied.”^{xxxviii}

More recently, at the 2002 Abuja Conference in Nigeria, developing countries signed on to a commitment that pledged them to the allocation of 15% of their national budgets for public health activities. This pledge was renewed at the G8 Summit in Gleneagles, Scotland in 2005. None have complied thus far.

Despite failing to meet the two percent target, African leadership in Nigeria and Ghana “is taking the lead in an intercontinental effort to create a new, indigenous agenda for health research, relevant to policy-making and action—and to apply the results of proven science.”^{xxxix} On September 20, 2007 Nigeria announced that “it may become the first country in Africa to locally extract active ingredients from *Artemisia Annus* for the production of Artemisinin-based anti-malaria drugs, including combination therapies.” (40) Neither Ghana nor Nigeria is awaiting a WHO Commission to lead this effort.

WHO has launched several new initiatives in the past, such as Health for All by the Year 2000; Roll Back Malaria; the Commission on the Social Determinants of Ill Health; the Commission on Macroeconomics and Health; and in 2003, its ‘3 by 5’ plan on AIDS treatment. It takes on impossible goals and, as was the case with Health for All, fails to report on donor expenditure of \$99 billion between 1977 – 2000.

In subsequent official publications, seldom can a reference be found that would detail progress or outcomes, reinforcing the notion among skeptics that while WHO can use its authorities to launch new initiatives, it has only a limited ability to stay a course of action over any period of time. It proposes the improbable use of supranational powers. For instance, in June the Globalization Knowledge Network submitted its final report to the WHO Commission on Social Determinants of Ill Health. In order to meet the Millennium Development Goals and provide debt relief, a global redistribution proposal is offered, one that is “based on a per capital income of \$3 per day ... and no taxes on those within this ‘ethical poverty line’ and a 25 percent tax on all people above it.”^{xl}

In the respondents’ recommendations that developed countries assume the financial responsibility for funding health R&D, there is the assumption that foreign aid has a significant impact on the most critical indicator of a nation’s health: infant mortality. In May 2007, the IMF released a report on Health Aid and Infant Mortality. It found that “despite the vast empirical literature considering the effects of foreign aid

on growth, there is little systematic empirical evidence on how overall aid affects health, and none on how health aid affects health.”^{xli}

Research and development in medicine is a complex technological endeavor in any society. Its fundamental basis is uncompromising evidence drawn from rigorous research. In the May issue of *The Lancet*, researchers found that “when developing evidence-based guidelines, the World Health Organization routinely forgets one key ingredient: evidence.”^{xlii}

In an interview with a Canadian newspaper after publication of this article in *The Lancet*, its editor commented: “This is a pretty seismic event ... it undermines the very purpose of WHO.” In response to his comment, a WHO official noted “that, in many cases, evidence simply did not exist.”^{xliii}

Nor does it exist, as this analysis demonstrates, to support an institutional rationale for the Commission on Intellectual Property Rights.

Along with a lack of evidence, WHO contradicts itself—within the same report. In April 2006, a draft Report of the WHO’s Commission on Intellectual Property Rights was released. On page 16, WHO stated: “deaths from communicable diseases are projected to fall 13% by 2015.” By the time a reader reaches page 193, a vast change has occurred: “the burden of infectious diseases that disproportionately affect developing countries continues to increase.”^{xliv}

Since diseases which affect the poor are minimal against total disease rates, and patents aren’t an issue, nor is there a lack of R&D on these diseases, the downstream objective of those who are promoting the Commission’s work is to strike at the heart of the pharmaceutical industry’s global franchise: chronic disease therapies, or Type 1 diseases. Through WHO, they plan to have these therapies listed on its Essential Drugs and Medicines Programme, thus declaring them as “essential medicines” for the poor. Developing countries can then issue compulsory licenses and produce these drugs with the imprimatur of WHO and UN agencies.

The recent Compulsory License by Thailand for Plaviv, a heart medication, and the threat by India for Glivec, a therapy for a rare cancer disease, are the opening salvos in this upcoming campaign. Medecins Sans Frontieres, the Clinton Foundation, WHO, UNAIDS, the World Bank, and the media were all quick to endorse Thailand and India’s claim that price is the barrier prohibiting the poor from access.

Price is no barrier if it is one negotiated by an activist organization for drugs from a preferred supplier. On May 18, *Drug Week* released a laudatory statement, praising the Clinton Foundation for its landmark price negotiations with Indian firms. The foundation's published price for lopinavir/r is \$695 per person per year. However, for the past five years, the right holder has been offering this same drug with assured attributes of quality, safety and efficacy to 69 poor countries at \$500 per person per year.^{xlv} In the press release, the foundation doesn't explain why it is paying 28% more in order to provide the poor with access to a drug of indeterminate quality. The mere source of the drug imputes a therapeutic benefit to patients, notwithstanding its questionable quality.

The Minister of Health in Thailand has an interesting perspective on patented vs. copy drugs. His government is now considering the revocation of its compulsory license for Efavirenz. In a May 24 article in *The Bangkok Post*, he said: Who wants to buy generic drugs for treating patients if the original drug is more affordable."^{xlvi}

The work of the Commission and the IGWG is a costly distraction for the research based industry, forcing it to expend ever-increasing amounts of human and fiscal resources to defend themselves against indefensible imagery: the poor. These resources could be better allocated against what industry does best: new product development. Equally important, the Commission's work would be an expensive duplication of initiatives long underway, both by industry and by the donor community, e.g., the Tropical Disease Research Institute in Singapore and WHO's TDR Programme.

The WHO Commission can only succeed if five variables are operationally harmonized with the active collaboration of WIPO and the WTO. When any one variable fails, the Commission's work would be rendered moot. Thus, WHO can only succeed with this Commission if:

- The research based industries can be encouraged to continue the development of new products for expropriation;
- Donor countries assume the responsibility for sustainable financing of R&D capacity building in developing countries, and support involuntary tax systems, such as UNITAID and the 25 percent tax on all incomes above \$3 a day proposed by WHO's Commission on Social Determinants of Health;

- Governments in the developing world provide subsidies to maintain the production and pricing structure of expropriated drugs against competitive drugs of the same strength and dosage forms in the market;
- Countries which execute compulsory licenses actually produce drugs to equivalent standards as the right holders, and can control pricing from manufactures to patients;
- And, the poor continued to be denied the principles of consumer choice and Informed Consent, as guaranteed in the UN's Universal Declaration on Human Rights.

A voluntary membership organization has no authorities to control these variables, save the fifth item—which WHO has so far ignored in AIDS treatment. But it can act as a 'Trojan Horse' for the activist community, extending a moral approbation that deputizes it to erect non-tariff barriers to the free flow of health and medical goods in international commerce. The intervention by activists is no guarantee for lower prices. It only guarantees that the price is from one of its approved producers, e.g. India through such organizations as the Clinton Foundation.

If the WHO Commission and the activist community were interested in the real needs of the poor, then they would press the research based industries to get on with the heavy lifting and develop new products, especially those which will be in demand for multi-drug resistant TB, AIDS—and the oncoming tsunami of chronic diseases, which left inadequately treated will cause massive macroeconomic distortions in the developing world, e.g., early retirements, disabilities, and long term care in fixed base facilities.

It is far beyond time to leave rhetoric and ideology aside and recognize and deal with the actual causes of access to medicines for the most disadvantaged. No UN membership organization built on the guaranteed equality of all can long sustain its institutional authorities by providing commercial advantage to some through the disenfranchisement of others and still expect to secure within the wider community of nations a harbor of respect and dignity. WHO's sponsorship of this Commission out-sources Constitutional authorities to supporters in the activist community who serve well their own interests; it is now time for both to serve those they have long purported to represent.

Unmet Demand as a Justification for this Plan of Action

The inability of the R&D industry to meet the enormous demand, particularly for AIDS therapies, is often cited as the reason why its innovative capacities and intellectual property need to be declared as public goods. UNAIDS, which publishes annual data on AIDS infection rates, stated that India had 5.7 million cases, or 0.9% of the population. This eclipsed South Africa as the highest case rate in the world. In Cambodia, UNAIDS said the infection rate was 1.6 percent of the population.

In June 2007, India refuted the UNAIDS findings and “dramatically reduced its estimate of people infected to a range of 2.7 – 3.1 million, or 0.36% of the population. Cambodia reduced its infection rate from 1.6% to 0.6%.”^{xlvii} UNAIDS has now accepted these new projections.

While it is difficult for the R&D industry to make accurate demand forecasts for products when the UNAIDS data is so inaccurate, it is impossible for proponents of the WHO Commission to base their justification for assuming greater control over the innovative capacities and intellectual property of this industry on the false assumptions of unmet demand.

What Can a Commission Do that Now Isn't Being Done?

In 2005, the London School of Economics and Political Science released a report on “a dramatic sea-change in research into ten so-called neglected diseases ... could result in at least eight new drugs being developed by 2010 [through] Public – Private Partnerships (PPPs). PPPs now conduct the majority of neglected disease drug projects, have the majority of drugs in clinical trials and are likely to have registered several products within the next few years.”^{xlviii}

GSK and Novartis have funded and built R&D facilities in Spain and Singapore only for those diseases identified by WHO as priorities, or specifically for dengue, TB and malaria. WHO's TDR Programme has been in effect since 1974, expending at least \$1.3 billion on neglected diseases. In TDR's Budget Review for the 2001-2002 Biennium, its managers stated: “TDR's strong scientific reputation, its ability to draw upon a network of leaders in biomedical and social sciences in both industrialized and disease endemic countries, and its growing linkages with private sector partners, in particular, those in the pharmaceutical

world, mean that the Programme is in a vitally important position to make a difference in generating new knowledge and tools to prevent and control tropical diseases and relieve the suffering of those affected by them.”^{xlix} Subsequent to this statement, TDR collaborated with a German research firm to develop a drug for viral leishmaniasis.

Several of the global R&D firms have had major bench research efforts underway on malaria, TB, AIDS, and dengue fever for the past few decades, with billions being devoted to product development for diseases which have no commercial markets to justify a return on investment. The U.S. military has been working on a vaccine for malaria since the first shovel of dirt was removed from the Panama Canal in 1906.

Canada is a good example of what can happen if WHO tries to ‘force-fit’ a round peg into a square hole with this Commission. In May 2004, the government gave a grant of \$100 million to its generic industry to produce ARV and malaria products for Africa. It even passed a law that would force pharmaceutical companies to offer some patented drugs to generic producers if impoverished countries requested them. The law was intended to take advantage of an agreement signed by Canadian officials at a WTO meeting in Doha in 2001: the issuance of a Compulsory License in cases of national health emergencies. Canada became the first country to implement that international generics agreement through legislation. The UN’s Special Envoy for AIDS to Africa called it a “stunning breakthrough.”¹

By August 2006, “not a single drug has gone out of Canada under the legislation”, commented the director of the Nobel Prize winning group’s Campaign for Access to Essential Medicines. “That’s an undeniable fact”, he added.ⁱⁱ

Canadian generic manufacturers complained that even with the \$100 million subsidy from the government, and a Compulsory License, they were unable to produce these drugs at a profit. In an update by *The Globe and Mail of Canada* on August 9, 2007, it commented that [still] “not one pill has been exported”.ⁱⁱⁱ

Yet, pharmaceutical firms in Sub-Saharan Africa are producing them at a profit. Though Africa has long been considered a charity case by donors, in 2006 its pharmaceutical industry “earned \$4 billion in revenues ... with estimates of reaching \$6.9 billion by 2012.” In four countries alone (Kenya, South Africa, Nigeria and Tanzania) their medical equipment market was an additional \$1.87 billion. In each of these countries,

analysis showed a high potential for growth opportunities within the healthcare industry.^{liii}

If research and product development for communicable diseases is of great interest to the WHO Commission, it may be useful to review data on this issue. In WHO's Financial Performance for 2002-2003, it budgeted \$88.9 million for these activities against an income of \$75.8 million. Yet, WHO expended only \$66.8 million. In a budget note, WHO explained that "expenditures were below budget due to lower than planned spending in research in developing countries on the burden of communicable diseases upon poor or marginalized populations."^{liv} A footnote also explained that its TDR Programme had expended more on research than did the WHO itself, calling into question the need for it to implement the Plan of Action outside of an extant institutional capacity.

The Importance of Costing-out the 8 Elements in the Plan of Action

What will the Plan of Action cost? The WHO Secretariat offers no clues to this question. New initiatives by UN organizations, such as UNITAID, are launched without any benefit-cost analysis being undertaken. For instance, "several affluent countries [the U. K., Norway, Italy, Canada, and Russia] have announced donations totaling \$1.5 billion to buy new vaccines that will help eradicate pneumococcal diseases in the world's poorest children."^{lv} This new program is called the Advanced Market Commitment (AMC), and it is operated through the GAVI Alliance, with UNICEF as one of its members. G8 leaders and the Bill and Melinda Gates Foundation have made commitments to its founding and operation. None of the sponsors or GAVI has estimated the transaction costs involved in the operation of AMC. Thus, it is unknown if the provision of vaccines to those in need will be less or more expensive under the AMC than at present.

In a July issue of *The Lancet*, it was found that in the AMC "only a quarter of the money will be spent on covering the costs of vaccines [for these diseases]—three quarters will go towards extra profits for vaccines that are already profitable. By commercializing vaccines for poor people, the AMC approach is making the culture of the GAVI Alliance more commercially oriented than it previously was."^{lvi}

The AMC assumes that a supply side model would find equal traction on the demand side in recipient countries. As in any market environment, control and influence of day to day activities flow to those who represent the majority of buyers and sellers. In countries like Brazil, India, Egypt, Nigeria and Kenya, mandatory, employer-based health insurance (often

state-sponsored) is a growing factor in health expenditures. It is a highly regulated market and medical products which enter it for consumers' use are established in existing national statutes which set price parameters and access criteria, usually from a centralized governmental authority. Ministries of public health, and the patients they represent, constitute a rapidly declining minority share of this market.

The penetration of this environment requires sophisticated market intelligence. Careers rise and fall on forecasting that proves accurate or inaccurate. This intelligence is not shared between companies, either in the same market, or across markets. Rather, it is highly proprietary—and most likely will remain so.

A prior study on potential revenue projections and the cost of investing in a market intelligence capacity, especially in the face of possible second or third competitors, and the demand from recipient countries for such a program, would have informed AMC proponents beforehand of these constraints. Otherwise, the AMC is a supply side mechanism in an expensive search for a market.

Conclusion

Since there is a near lack of evidence to support neglected diseases, price and patents as the principles underlying the formation of this Commission by WHO—then what is its purpose!

Several Member States have called upon WHO to detail expected financial support costs for the 8 Elements of the Action Plan, all of which address treatment rather than prevention, e.g., develop mechanisms to manage intellectual property, etc. WHO has ignored these requests. It may be asked, then, how does WHO propose to fund such a major challenge through its Regular Budget?

It doesn't.

Each of the 8 Elements cut across many other jurisdictional boundaries, e.g., WIPO, WTO, while intersecting with multiple national drug regulatory authorities that always take their sovereignty seriously. Member States, while perhaps prone to approve the Global Strategy at the Sixty-first World Health Assembly, would be unable to vote concomitant increases in their dues to support this activity via the Regular Budget. The likely costs to fund all 8 Elements would consume an inordinate amount of Members' Dues, now totaling \$457 million per annum (if all paid their assessments). This explains why the Secretariat

didn't want to respond to Members' requests on detailed budget estimates for the Plan of Action.

Rather than a reliance on the Regular Budget, those Member States that have been most active in promoting the IWGW, as well as the activist community, will provide WHO with Extrabudgetary funding to pursue discreet sub-elements of the Plan of Action, e.g., developing countries to set research priorities; developed countries to devote a larger proportion of their health R&D budgets to the health needs of developing countries; develop systems in developing countries for the management of intellectual property; conduct research on appropriate products to combat Type I diseases; and as Brazil has recommended: pursue "necessary legislation steps to allow compulsory licensing for exports consistent with the flexibilities of TRIPS".

While this will be insufficient to meet all 8 Elements, the importance of their funding lies more in their ability to use all of the institutional authorities and legitimacies of WHO without the burden of having to be held accountable and responsible to its governance structure—which is tethered only to the Regular Budget.

The use of Extrabudgetary funds for the Plan of Action will serve as the Trojan Horse for the implementation of the Commission's activities. It will ride in on the institutional legitimacies of the Organization's Regular Budget. Then: Extrabudgetary funds will be earmarked, the choice of sub-activities within the 8 Elements will be determined by the donors and not the community of Member States comprising the Organization, and the management of these funds will escape the jurisdiction of the Executive Board and the Health Assembly.

In the current biennium, WHO's Regular Budget is \$915 million. Its Extrabudgetary account is closing in on \$3 billion. In any human endeavor, money talks and people tend to listen. The Regular Budget has morphed into a license for staff to hunt for new funds from special interest groups. Such funding goes into the Extrabudgetary account where it is shielded from the governance provisions of WHO.

WHO will take on the role of a hosting organization, much as it does now with UNITAID. In return, UNITAID pays WHO a \$425,000 annual fee, in addition to a broad range of administrative fees and commissions for products being procured by non-members, such as the Clinton Foundation which pays WHO a commission of 1% for processing its procurements. WHO charges UNITAID 13% for technical support activities. These fees and commissions are dedicated to WHO's

Extrabudgetary account and thus removed from the governance of Member States.

Subsection 2.2 of UNITAID's MoU states that "the hosting arrangement and the operations of the Secretariat shall in all respects be administered in accordance with the WHO Constitution, WHO's Financial and Staff Regulations and Rules, Manual provisions, and applicable policies, procedures and practices and with the terms of the MoU."^{lvii} Although WHO is only one member of ten on the Executive Board of UNITAID, this subsection concedes all operational authority over UNITAID to WHO, making it a wholly owned subsidiary of the UN's health agency.

Subsection 3.2, Secretariat as WHO Staff, further explains that "all staff assigned to the Secretariat, including WHO staff seconded to WHO for assignments to the UNITAID Secretariat, shall be staff members of WHO and will be considered by WHO as WHO officials for the purpose of the application of the privileges and immunities accorded under international law for the free exercise of these functions."^{lviii} The UNITAID funds which are managed and disbursed by WHO will be used to procure products that are consistent with WHO technical guidelines. For ARVs, these guidelines are accompanied by a public Disclaimer, stating that they are not warranted for safety and/or efficacy if used in the treatment of AIDS.

The Clinton Foundation will work with manufacturers and national governments to organize the markets for HIV/AIDS commodities to lower the prices of medicines and diagnostics. One of the immunities provided to the Foundation will be coverage under the International Organization Act, wherein it is protected from suit in any jurisdiction. This removes the moral incentive to procure and negotiate for drugs of known quality, safety and efficacy.

The rationale behind the formation of this Commission is diluted in the face of contrary evidence showing that neglected diseases, price and patents aren't the problems in access to healthcare services. The Commission is an expensive duplication of extant activities, some within WHO itself (TDR). If WHO becomes the hosting agent for this Commission through its Extrabudgetary account on behalf of special interest groups, it would forfeit its role as "the legitimate inter-governmental authority on global health matters".

Either WHO is a membership organization in which "the principle of sovereign equality of all its Members" is sustained, or it is a "pay to play" mercantile enterprise, wherein it ought then to be subjected to all the rules and regulations governing the movement of goods in international

commerce. The Commission will make some Members more sovereign than others and admits non-members to the privileges and immunities that were granted under the WHO Constitution—when all activities were supported only by the Regular Budget (Members' Dues) in strict adherence to its governance structure.

WHO: A Dual Institutional Personality

According to UNICEF, when announcing the significant drop in global infant mortality rates, “we feel we’re at a tipping point.”^{lix} All of the progress now being made on a voluntary basis with public-private partnerships, on R&D into neglected diseases, on the building of research capacities for these diseases in Singapore, Spain, Uganda, Nigeria and Botswana, on the work of WHO’s TDR Programme in cooperation with industry, and on the dramatic downturn in mortality from tropical diseases—these positive interventions can be short-circuited by an involuntary process in the management of intellectual property rights and patent pools if they are subordinated to WHO, permitting it to define the global capacity for contributions to a healthier world. Its past experiences in such failed programs as Health for All by the Year 2000, and the more recent ‘3 by 5’ initiative for AIDS, are examples of the disappointments awaiting us. We will never learn from that history if we remain in a suspended state of amnesia about it.

WHO and its allies continue to talk about the need for more resources, though they are unable to define what is needed to implement the 8 elements of the Plan of Action. However, “the problem is that development and long-run growth are less about resources than about the environment for generating and sustaining private sector investment. Two key aspects of this environment are decent public institutions or governance ... and incentives that encourage the private sector to export, especially manufactured products.”^{lx}

The Plan of Action is aloof from this environment. It is a supply-driven, public sector model of development, with the demand side being described as fragile institutional structures which are simply ‘Waiting for Godot’ to come down that long road from the colonial office and infuse them with meaning and purpose. To make its case, WHO was required to ignore the reality of transformational events within recipient countries. But they can only be set aside at peril. African voices will insist on being heard.

It is possible that with the present structure of WHO, it is incapable of executing the proposed Plan of Action because it will have to be financed through its Extrabudgetary Account rather than its Regular Budget. The

former now outweighs the latter by a factor of 3. Yet, the governance of WHO as an institution is firmly locked into the processes of the Regular Budget.

Thus, WHO has two institutional personalities: the minor one is controlled by dues paying Members through the Regular Budget, while the major one is a 'pay to play' Extrabudgetary Account. This "is earmarked, where the choice of activities is determined by the donor and not by the community of Member States comprising the Organization, and where the management of these funds generally escapes the jurisdiction of the Executive Board and the Health Assembly."^{lxi} WHO's Regional Directors are elected by the countries they represent rather than by WHO/Geneva. The designated funds in the Extrabudgetary Account are controlled by them, with the central authority in Geneva playing a pass-through role.

A house so divided cannot possibly undertake the proposed Plan of Action and execute it with a fealty which upholds "the principle of sovereign equality of all its Members."^{lxii} If UNICEF is correct in stating that we are at a tipping point in global health development, then WHO's past record on global programming achievements indicates strongly that the subordination of private capacities for intellectual property to it can tilt all current progress backwards.

A Cautionary Note

On October 10, the U. S. Department of Health and Human Services help on open hearing for Civil Society to comment on the IGWG's July 31 report. Richard Holbrooke, president of the Global Business Coalition on HIV/AIDS, TB and Malaria wrote an Op Ed piece in The Washington Post the previous day. He quoted Dr. Anthony Fauci, the famed director of the National Institutes of Allergy and Infectious Diseases at the NIH as saying: "For every one person that you put on therapy, six new people get infected. So, we're losing that game." Mr. Holbrooke ended his article by stating: "If current policies are not changed, we will face uncontrollable growth in the costs of treatment of the victims of a disease that should be, as Bill Clinton has said, completely preventable."^{lxiii}

There is absolutely nothing in WHO's Plan of Action that addresses this situation; yet it contains everything that denies its existence. Instead of holding governments responsible for neglecting the diseases which affect their own people, especially in oil-rich states, WHO sanctions that policy by placing the onus for care and treatment onto the pharmaceutical industry. WHO is promoting a target of moving 10 million people into AIDS treatment by 2010 in the absence of understanding the cost and

medical care consequences to global society. Even if WHO held complete control over all 8 elements of the Action Plan, this would be insufficient to effect the grim outcome that awaits us in the absence of prevention.

Recommendations

The Secretariat's current presentation of a Global Strategy and Action Plan represents the special interests of some Members and Non-members, while disregarding all others. In terms of its three themes, the Secretariat set aside known facts to reach an outcome which was predetermined. It ignored authoritative documentation on the presence of neglected tropical diseases. For instance, "over the past two decades there have been significant achievements in the control of a handful of important tropical infections ... as a result of aggressive regional vertical interventions, there is the possibility that some neglected tropical infections could be eventually controlled to the point of eliminating some areas of endemicity."^{lxiv} And, the Action Plan's 8 elements concentrate on issues of treatment to the detriment of prevention. If such a Commission were ever able to gain greater control over industry's innovative capacities and intellectual property by declaring them as public goods, it is difficult to determine how this would diminish the arc of HIV/AIDS infections, still in ascendancy, in the absence of prevention programming.

Lastly, as the UNICEF report of September 13 showed, the world's most sensitive indicator on health progress, infant mortality rates, has fallen to a record low. This achievement was reached without an active WHO Commission on Public Health, Innovation and Intellectual Property. In the face of this reality on what has been done, why risk all on what might be done by an untried entity?

This presentation by WHO is unworthy of an Organization that many believe is the "legally mandated inter-governmental agency responsible for global health".

As several Members stated, though their views were not in the July 31 report, intellectual property and innovation are societal issues which are too serious to be left in the hands of WHO alone. Japan commented that "it is necessary to consult with other international organizations with specialized expertise in the area of intellectual property ... and we think it is appropriate to discuss matters of building innovative capacity in WIPO."^{lxv}

It is recommended, therefore, that:

1. the Secretariat table the Global Strategy and Action Plan until such time that it can be re-written in a fair and objective manner which represents the interest of the community of Member States comprising the Organization;
2. an inventory be undertaken to catalogue extant activities, both public and private, in R&D activities targeted on neglected diseases, e.g., TDR, and the private research facilities in Spain and Singapore;
3. WHO sponsor a benefit-cost analysis to determine if its implemented Plan of Action would dampen incentives for local and foreign investment in the Sub-Saharan African pharmaceutical industry, now in its ascendancy;
4. the Global Strategy be re-written to provide a balance of interventions between prevention and treatment, particularly in HIV/AIDS;
5. and, upon completion of the above, that any subsequent action taken to fund the Commission's ongoing work will direct expenditures only through WHO's Regular Budget.

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- lxi Proposed Programme Budget for the Financial Period 1996-1997, p. 1, World Health Organization, Geneva, 1994
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- lxv Refer to endnote #9