



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

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Introduction

Many believe that the World Health Organization is the “legally mandated inter-governmental agency responsible for global health.” And many more believe it should be the one UN agency best equipped to keep track of the pace and pattern of contemporary developments in neglected diseases and to report on progress in a fair, timely and objective manner.

The most sensitive indicator on broad-scale health improvements is a decline in global infant mortality rates. On September 17, 2007 UNICEF released new data showing that “the global rate for the under-five population fell from 20 million annually in 1960 to 9.7 million in 2006.”¹ UNICEF went on to credit both health interventions, such as immunizations, and economic developments as the causes for this dramatic decline.

This report has to be seen in light of the fact that increased population growth rates in the developing world moved from some 2.4 billion in 1960 to an estimated 4.9 billion in 2006 (out of a total population of 6.7 billion). UNICEF stated: “we’re at the tipping point; a public health triumph has arisen, predicting further drops.”

Although the UNICEF data was not released until this September, those who believe deeply and rightly in the WHO mandate might well have expected the Organization to be ahead of the curve on data so critical to its case on neglected diseases. There still remain painful pockets of childhood mortality, mainly within failed states, and we must not insulate national leadership from responsibility and accountability to their own people. The prestigious Carter Center reports that it could have eradicated global guinea worm at this time had it not been for the leaders of these countries prohibiting it from patient treatment. Even when medications and vaccines can be made available free of charge, getting them to patients caught up in the maw of civil conflicts is a daunting task.

There is nothing in WHO’s Plan of Action which will ameliorate that situation. Governmental leaders that neglect the health needs of their own children commit human rights abuses.

Background

On January 12, 2007 Member States were asked to provide additional commentary 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 IGWG.” This was prepared by the WHO Commission on Public Health, Innovation, and Intellectual Property Rights. On July 31, using comments submitted by 15 Member States, with Germany speaking for 27 EU Members, WHO then issued “Draft global strategy and plan of action on public health, innovation and intellectual property”, a 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 recommendations of the Commission.²

The origins of the Secretariat’s authorities are drawn from WHA 59.24. The Health Assembly recognized “the focus of the strategy was to be on disease 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 exist [sic], they are inappropriate for use in countries with poor delivery systems, or unaffordable.”³

This mission statement and the focus of the strategy around which a Plan of Action has been submitted are intertwined with three themes throughout the Secretariat’s text. They form the basis of legitimacy for the Secretariat: 1) neglected diseases disproportionately affect poor 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.

Discussion

There are major disconnects between Members’ comments and the July 31 draft, particularly on issues of intellectual property and future financing needs for the 8 elements of the Plan of Action.

Thailand and the United States noted the need for the Secretariat to avoid a duplication of existing programs addressing the same issue, e.g., WHO’s Tropical Disease Research Programme. 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 went on 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.”⁴ Australia observed “it is not clear that a new forum is necessary to implement the WHA Resolution.”⁵ Japan cautioned “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.”⁶

The Secretariat didn’t take note of Kenya’s suggestion for an extension of time beyond the WHA of 2008 for a final report, as well as its comment “that the Global Strategy document as is currently prepared is inadequate and needs to be substantially revised.”⁷ Bangladesh’s requested that WHO postpone a decision until the Sixty-second WHO in 2009.

Thailand commented that WHO needed “to estimate financing requirements of the plan of action ... because each element of the Action Plan is in itself a major challenge and requires further development.”⁸ The U. S. joined in this sentiment, saying: “the IGWG should estimate funding needs for implementation of the plan of action.”⁹

For whatever reason, WHO gave no estimates for the detailed Plan of Action covering 8 separate elements in its July 31 draft. This Plan only covers treatment issues, mainly through the management of intellectual property, though the arc of AIDS disease rates continues ever upwards in the absence of prevention.

It may be asked, then, how does WHO propose to fund such a major challenge through its Regular Budget as pointed out by Thailand and the U. S.

Even if Member States were to approve the Global Strategy at the WHA in May 2008, they would be unable to vote concomitant—and substantial, increases in their assessed dues to support this activity via WHO’s Regular Budget. To do so would consume an inordinate amount of this budget’s annual \$457 million income from dues.

Rather, those Member States that have been the most active in promoting the IGWG will provide WHO with Extrabudgetary funding to pursue discreet sub-elements of the Plan of Action, such as to develop systems for the management of intellectual property, or to conduct research on products to combat Type I diseases.

But even this income stream will be insufficient to meet all 8 elements of the Plan. However, its importance lies more in the ability of special interest groups 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.

To paraphrase a recent Director General of WHO, when expressing his concerns in a formal report to Members about the use of Extrabudgetary funds: ‘they 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.’¹⁰

WHO will take on the role of a hosting organization if the Resolution is passed by the WHA in 2008, much as it does now with UNITAID. It is important to note that staff members of a WHO hosting organization “shall be members of WHO and will be considered 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.”¹¹

In the conduct of hosting arrangements, the Organization’s “principle of sovereign equality of all its Members” is diluted, making some Members more equal than others, while at the same time admitting non-members to the privileges and immunities secured by the UN Charter. The founders of that Charter could hardly have been expected to see its cherished provisions used for the commercial advantage of some Members and non-Members at the expense of all others.

Neglected Disease & the Role of the R&D Industry: An Absence of Evidence

In preparatory documents leading up to the release of the Draft Global Strategy on July 31, the considerable contributions of the R&D industry to the alleviation of pain and suffering among those least able to access medicines was largely omitted.

There are available treatments, often at zero price to patients, for each of the neglected diseases, with the possible exception of Chagas. The International Monetary Fund

reports that the expenditures for AIDS alone was \$8 billion 2004; WHO reports that they were \$8.3 billion in 2005; and UNAIDS says they reached at least \$9 billion in 2006. UNAIDS estimates for 2007 are reasonably expected to exceed \$10 billion. Expenditures for TB and malaria, while lower than AIDS, nonetheless are estimated at \$6-7 billion over this same time frame. In total, then, some \$41.8 billion have been expended on three disease entities.

In 2002, the *British Medical Journal (BMJ)* published an article entitled: “The World’s Most Neglected Diseases”. Then, on August 11, 2007 the *BMJ* published an update, written by one of the same authors of the 2002 editorial. It stated: “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.”¹²

On September 18, the European and Developing Countries Clinical Trial Partnership announced that HIV positive children can now benefit from an antiretroviral drug designed especially for them. It developed a drug called ‘Triomune Baby and Junior’, which is administered twice daily. The U. S. Food and Drug Administration recently gave its tentative approval, paving the way for it to receive Prequalification status from WHO, while making it available for distribution under the PEPFAR and Clinton Foundation programs.¹³ U. S. foreign aid funds can be used for its procurement. The drug will be manufactured by Cipla Pharmaceuticals of India. Although the three drugs which constitute this triple dose combination are covered by patents, none of the right holders challenged the FDA application process to have it certified as a true generic.

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.”¹⁴

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.”¹⁵

The IGWG didn’t recognize that global pharmaceutical companies, responding to demand, are increasingly focusing research on finding new cures and treatment for diseases that primarily affect patients in developing countries. Currently, they have under development 90 new medicines, including 11 in pediatric formulations.¹⁶

Professor Patricia Danzon of the Wharton Graduate School of Business, University of Pennsylvania, is recognized as a global authority on the pricing of drug and vaccine products in international markets. In the September 2007 issue of *Nature* she stated that “R&D costs roughly \$1 billion for each new drug approved in 2007.” She went on to raise the question of how this joint cost should be allocated among consumers to generate the greatest benefit. She then stated that “differential pricing alone will not stimulate R&D for medicines to treat diseases that occur only in developing countries, supply-side subsidies are necessary for such diseases.”¹⁷

In lieu of direct subsidies, the R&D industry has made substantial supply-side investments to ensure that these benefits have been extended to patients world-wide. For instance, SmithKlineBeachem built and now operates the Tres Cantos R&D facility in Spain, targeting its research and production capacities only on those diseases identified by WHO as products needed for ‘essential medicines’. Novartis built and operates the Institute for Tropical Diseases in Singapore, conducting basic bench research on TB, malaria and dengue for products which will be sold to any UN agency at cost.

The U. S. based Partnership for Quality Medical Donations (PQMD) recorded “the value of donated products at \$4.3 billion in 2005”¹⁸ for the developing world. This sum alone is greater than the combined annual health budgets of WHO, UNICEF and the World Bank. In 2006, Pfizer announced a collaborative effort with WHO’s TDR Programme. This will give TDR access to Pfizer’s library of medical compounds—the world’s largest. Bristol Myer-Squibb built Africa’s first pediatric AIDS hospital in Botswana. Through the Baylor Medical College, it now sponsors a Pediatric AIDS Corps, sending volunteer physicians to specialty centers in ten Southern African countries. BMS built Africa’s first AIDS laboratory in Botswana, now operated by Harvard University. Merck developed the treatment for onchocerciasis and donated ‘Ivermectin’ for as long as it was needed to combat river blindness, in whatever quantities it was needed, into perpetuity. WHO had conducted the clinical trials for ‘Ivermectin’, proving that it was safe and efficacious for human use. A World Bank evaluation showed that once people could relocate to their river-land farm sites in West Africa, 17 million hectares were returned to agriculture production, enough to feed 25 million people.

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.

Conclusion

Given the rigors of statistical measurements in demography and epidemiology, it would have been impossible for the global infant mortality rate to have declined by more than half, at the same time that the population in the developing world increased by more than the same proportion. It cannot be, then, that neglected diseases are so great a problem as to warrant implementation of the recommendations in WHO’s Plan of Action.

WHO might have informed Member States in its July 31 draft that the reason it didn’t present any financial requirements for the 8 elements in the Plan of Action was because they would have to be funded subsequently via its Extrabudgetary account. Those

Members which provided supportive comments to that draft would then provide the needed funds. Yet, as noted by a previous Director General of WHO in publicly expressing his concerns about such earmarking: “the choice of activities is determined by the donor and not by the community of Member States comprising the Organization.”

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”. Then, as now, some Members will always be more equal than others.

If UNICEF is correct in stating that we are at a tipping point in global health progress, then WHO has to step up to its global leadership position and build on the successes that have been so instrumental in the reduction of infant mortality rates. It is most difficult to see how this can be done through the centralized management of intellectual property and patent pools. History informs us that such a process stifles innovation rather than promotes it. While there might have been a case for it—if there were neglected diseases, UNICEF has put that to rest. The subordination of private capacities to WHO for the management of intellectual property and innovation can tilt all current public health progress backwards, especially if the processes of management are controlled via WHO’s Extrabudgetary account rather than through the governance principles inherent in the operation of its Regular Budget.

This public health achievement, as reported by UNICEF, was reached in the absence of the program interventions being recommended by the WHO Commission on Public Health, Innovation and Intellectual Property. As several members noted in their comments of July 31, issues of intellectual property and patents more properly lie in the domain of the WTO and WIPO. There, sovereign states have re-delegated some of their powers to enter into treaties or international trade obligations when there is reciprocity, equivalency, the rule of law, and enforceable sanctions among each of the parties.

Recommendations

WHO needs to build on the successes now in full sway, as documented by UNICEF, and become the undisputed leader in global health. Using its considerable moral powers of persuasion, WHO can stimulate an enlightened global environment wherein the R&D industry finds a continuing incentive to run its engine of innovation at flank speed in the interest of making certain that all peoples of our world benefit from its product developments. WHO needs to embrace innovation rather than to embargo it and promote more public-private partnerships. If the investment and foundation community saw that WHO was a champion of creativity, then they might well be more supportive of encouraging their governments to provide additional Regular Budget support.

End Notes

- ¹ “World Health Organization Slammed by Medical Journal”, Associated Press special to Edmonton Sun, Canada, May 7, 2007
- “Child mortality at record low; Unicef predicts further drop”, Donald M. McNeil, Jr., International Herald Tribune, September 13, 2007.
- ² WHO, Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHO, Geneva, July 31, 2007
- ³ Refer end note #2.
- ⁴ “Consultation on Elements of a global strategy and plan of action”, Comments by the European Union, via Germany as EU presidency, February 2, 2007
- ⁵ “Australian submission to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property”, Government of Australia, Canberra, February 2007
- ⁶ “Comments on Elements of a global strategy and plan of action”, Government of Japan, Tokyo
- ⁷ “Submission of Kenya to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property”, Ministry of Health, Nairobi, Kenya, April 2007
- ⁸ “Thailand’s Official Comments on the Elements of a Global Strategy and Plan of Action and Plan of Action”, Ministry of Public Health, Bangkok, Thailand, February 28, 2007
- ⁹ “U. S. Government Comments on Annexes I and II of the WHO Secretariat’s Elements of a Global Strategy and Plan of Action”, Government of the United States, Washington, D. C
- ¹⁰ See “Proposed Programme Budget for the Financial Period 1996-1997”, World Health Organization, Geneva, 1994
- ¹¹ Memorandum of Understanding among the Federal Republic of Brazil, the French Republic, the Republic of Chile, the Kingdom of Norway, the United Kingdom of Great Britain and Northern Ireland, and the World Health Organization, no date
- ¹² Yamey, Gavin, and Holtez, “Neglected Tropical Diseases”, British Medical Journal, Vol. 335, August 11, 2007
- ¹³ “New drug will give hope to HIV positive children”, Newsfood.com, September 18, 2007
- ¹⁴ “Patent Sense, Protecting intellectual property saves lives in the developing world”, Paul Herrling, Nature, Vol. 449, September 13, 2007.
- ¹⁵ Wellcome Trust, “Attention for Neglected Diseases”, Web Site, 2005
- ¹⁶ PhRMA, “Global Biopharmaceutical Spotlight, New Medicines to Fight Diseases Primarily Affecting Patients in Developing Countries”, Washington, D. C., August 2007
- ¹⁷ “At what price?”, Patricia M. Danzon, Nature, Vol. 449, September 13, 2007
- ¹⁸ The Index of Global Philanthropy, Hudson Institute, Washington, D. C., April 2007