U.S. Government Comments on Annexes I and II of the World Health Organization (WHO) Secretariat’s *Elements of a Global Strategy and Plan of Action* [Document A/PHI/IGWG/1/5](#1) for the purpose of the WHO Secretariat preparing a working document for the Intergovernmental Working Group (IGWG), as Note Verbale C.L.1.2007 requests

**GENERAL COMMENTS**

The report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), titled *Public Health, Innovation and Intellectual Property Rights*, is a carefully nuanced document that provides up-to-date thinking on a complex topic. The *Report* properly recognizes that improving the health of those who live in developing countries depends on reducing poverty and increasing wealth; improving education, nutrition, and access to clean water; reducing risky behavior; and developing the necessary health-care infrastructure - all within a stable and free political environment and respect for the rule of law.

The IGWG should concentrate on “proposing clear objectives and priorities for research and development, and estimating [their] funding needs”\(^2\) as the foundation for the medium-term framework, and its overall goal should be to develop a coherent and sustainable plan for global cooperation that considers the time and circumstances available to build the appropriate capacities within developing countries to reduce disease. Given this general observation, it would be helpful for the WHO Secretariat, in the working document it will issue in July, to identify the intended audience, as well as the anticipated actors, for each of the action plan elements. For example, sometimes it might not be practical to focus on advanced research-and-development capabilities in a particular developing country if the more immediate challenge is to provide delivery and access to currently available treatments of known efficacy. Overall, any global strategy and plan of action should consider the entire spectrum of available treatments, methods, and products, such as potable water and insecticide-impregnated nets that are not necessarily novel and innovative, but are proven, effective agents to improve public health and reduce the global burden of disease.

**ANNEX I**

2. **Prioritizing Research and Developments Needs**

To prioritize research and development, the WHO Secretariat, in collaboration with interested WHO Member States, civil society and the private sector, should develop a methodology to identify gaps in research on diseases that disproportionately affect developing countries (defined as Type II and Type III diseases in the *Report* of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)). To do so, the WHO Secretariat should identify the gaps in current research

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1 These comments do not include any consideration of the “Comments and suggested additions by Member States” as provided in the Appendix of Document A/PHI/IGWG/1/5.

2 Resolution WHA59.24, Operative Paragraph 3, Subparagraph 1.
on Type II and, in particular, Type III diseases, as well as HIV/AIDS, malaria and tuberculosis.

While promoting health research and development everywhere is a laudable goal, some countries would benefit from an emphasis on strengthening public and private health infrastructure, rather than programs for research. Therefore, the WHO Secretariat should also promote research on health systems in developing countries. Governments and their partners can improve public health, increase access to medicines and implement sound, evidence-based health policies. The WHO Secretariat also can help facilitate voluntary collaborations between public- and private-sector researchers to increase access to compound libraries to identify potential treatments for diseases that disproportionately affect developing countries.

To help begin to prioritize research needs the IGWG should focus on the following Recommendations in the CIPIH Report:

2.1 and 2.2, provided that all countries, developed and developing, focus on defining strategies for research and development, with adequate funding, for diseases that disproportionately affect developing countries. Governments and their partners should work together to take forward the benefits of that research, as well as to explore ways to build capacity in developing countries; 2.3, provided that the research on identifying gaps shows data to support the hypothesis that there is an inadequacy of research tools; 2.5, provided the focus is on increasing access through voluntary arrangements between the party that is seeking access and the party that has rights to the compound library; 2.6, but, while we support more organized sharing of information and greater coordination among all stakeholders, we would not support the creation of a standing forum; 2.11 and 2.12, provided any access to outputs is given voluntarily.

The IGWG should not consider Recommendation 2.4 as the focus of its work should be on diseases that disproportionately affect developing countries, more commonly referred to as Type II and Type III diseases.

The IGWG should engage all relevant stakeholders, particularly the Secretariats of the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), if it considers Recommendations 2.7, 2.8, 2.9 and 2.10. With specific reference to Recommendations 2.7 and 2.8, the IGWG should exercise extra caution if it considers these recommendations, because they postulate “one-size-fits all” solutions to sporadic difficulties in access to technology. Such solutions could undermine a robust research-and-development infrastructure, as would a research exemption that did not preserve or promote research-and-development investments.

3. Promoting Research and Development

The WHO Secretariat already is actively engaged in many of the activities that Paragraph Three highlights, through programs such as the Special Programme for
Research on Tropical Diseases (TDR). Member States should develop funding mechanisms for research and development for diseases that disproportionately affect developing countries, in ways that are appropriate to their national contexts. The WHO Secretariat can act as a clearinghouse for information on best-practice approaches that its Member States have applied. Member States and the WHO Secretariat should also encourage cooperation between the private and public sectors on research and development, including South-South collaboration. The WHO Secretariat already acts as an agent to improve the coordination and sharing of information relevant to research and development for Type II and III diseases, and can improve the mechanisms it uses to do so.

Member States should promote basic and applied scientific research on Type II and III diseases, and promote early-stage drug research and development in developing countries (including basic research, lead identification, lead optimization and pre-clinical trials), while complying with their international obligations.

The IGWG should engage all relevant stakeholders, including the WIPO Secretariat, if it considers Subparagraph (g).

The IGWG should consider the following Recommendations of the CIPIH:

3.1; 3.2; 3.3; 3.4; 3.5 (although it fails to take into account that advance-purchase and licensing agreements need to find a way to reflect the unpredictability in pre-identifying health emergencies); and 3.7, provided that initiatives are voluntary.

4. Building and Improving Innovative Capacity

The WHO Secretariat should engage all relevant stakeholders to provide support for the development of innovation capacity through investment by developing countries in human resources and in university and post-graduate education. The WHO should also encourage North-North and South-South partnerships and networks to support capacity building. Developing countries should strengthen their own human resources in research and development through appropriate training, and address issues relating to the migration of health professionals in a manner that respects the freedom of individuals to migrate to build a better life for themselves and their families. Developing countries should also work to strengthen their regulatory structures, including by implementing standards to ensure the protection of humans involved in biomedical and behavioral research, and to build domestic capacity to conduct safe and ethical clinical trials.

The WHO Secretariat should collaborate with the WIPO Secretariat to compile and disseminate best practices to improve health-related innovation. Examples should come from developed and developing countries alike, and should respect all international obligations.
Further, the WHO Secretariat should encourage developing countries that have indigenous traditional remedies (traditional medicine) to ensure high standards of safety and efficacy for these products, including through research on their mechanisms for action and pharmacokinetics.

The IGWG should consider the following Recommendations of the CIPIH Report:

5.1; 5.2; 5.4, provided that measures comply with international obligations, including those relating to the protection of intellectual-property rights; 5.3, provided that the IGWG engages all relevant stakeholders, including the WIPO Secretariat; 5.6; 5.7, provided that the resulting guidance documents are evidence-based; 5.8; 5.9.

The IGWG should not consider Recommendation 5.5 (see also Recommendation 4.18) as not only is there no basis to suggest a lack of compliance with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), but any discussion regarding compliance with this provision should take place in the appropriate forum, namely the WTO. The IGWG should engage all relevant stakeholders, including the WTO and WIPO Secretariats, if it considers Recommendations 5.10 and 5.11.

5. Transfer of Technology

The U.S. Government agrees that developing countries should adopt, in accordance with international obligations, including intellectual-property rights, and, where possible, develop, technologies for the discovery, development, manufacturing and delivery of vaccines, therapeutics and medical devices. With respect to technology transfer, intellectual-property protection, including patent protection, serves as a strong and effective mechanism to promote technology transfer, a significant amount of which already occurs. Developing countries should work to increase their ability to be effective partners in technology transfer, and seek fuller and better collaboration with public- and private-sector patent holders as they do so.

With respect to Article 66.2 of the TRIPS Agreement, many countries, including the United States, take seriously the obligations under this Article, and it is inappropriate for a statement to imply a lack of compliance without any substantiating evidence.

6. Management of Intellectual Property

We are unclear about the meaning of “management of intellectual property,” and ask the Secretariat to propose a standard definition for the term for this context. While countries, particularly developing countries, might work within national and/or regional institutional frameworks to promote and manage intellectual property, all activities should respect international obligations, including those related to the protection of intellectual-property rights. Countries should consider, when appropriate, alternative incentive schemes for research and development; however,
any such schemes should work in conjunction with the incentive mechanisms already contained in the patent system.

The WHO Secretariat, with the Secretariat of WIPO, could work to improve dissemination of the WIPO Secretariat’s databases on patent status. In addition, any activities the WHO Secretariat undertakes at the request of its Member States to help them strengthen education pertaining to and management of intellectual property should be done in collaboration with the WIPO Secretariat.

The WHO Secretariat, while working closely with the Secretariats of WIPO and the WTO, can provide Member States, at their request, information on monitoring and analyzing the pharmaceutical and public-health implications of relevant international agreements, it is the prerogative of Member States to determine their own public policies. Such policies should respect the Member State’s international obligations, including those related to the protection of intellectual-property rights. Accordingly, the IGWG should not consider Subsection (a) of Paragraph Six of the document.

The WHO Secretariat should not expand its work on matters better addressed by another international organization. Therefore, the IGWG should not consider Subsections (f) and (i) of Paragraph Six of the document, because they more appropriately fit within the scope and mandate of the WTO and WIPO. Finally, the WHO Secretariat should encourage communication between the national regulatory authorities for medicines and health products and intellectual-property officers, provided that any discussion recognizes the separate but equally important protections provided by the TRIPS Agreement to both undisclosed data and patentable inventions.

7. Improving Access and Delivery

Countries and aid organizations should continue to work to improve access to medicines on the WHO List of Essential Drugs, through improving product-supply chains, procurement and distribution systems, and health-care delivery, while respecting international obligations, including those related to intellectual-property rights. The WHO Secretariat should cooperate with Member States, at their request, and in collaboration with other international organizations, such as WIPO and the WTO, when providing information on the pharmaceutical and public-health implications of relevant international agreements, as it is up to each Member State to develop its health policies. While Subparagraph (j) of Paragraph Seven is important when balanced with incentives to develop new drugs, neither subparagraph (i) nor (j) are appropriate areas of action for the WHO Secretariat; thus the IGWG should not consider them.

Although the WHO Secretariat did not address the recommendations in Chapter 4 of the CIPIH Report when it developed this document, we believe the IGWG should consider the following recommendations from that Report:

4.2; 4.3; 4.4; 4.5 – 4.9; 4.11; and 4.12.
8. Ensuring Sustainable Financing Mechanisms

Paragraph Eight focuses solely on funding by donors. The question of securing sustainable funding, however, is primarily a question for Governments of developing countries themselves; donors and international organizations play a supporting role. Few Governments devote much of their health budgets to research and development. The Commission on Health Research for Development in 1990 set a target for developing countries to spend two percent of their health budgets on health research (WHO Resolution EB 120.R15 reiterates this target in Operative Paragraph One, Subparagraph One); only Argentina and Brazil met this level in 2003 (most recent available data), according to the Commission.

The references to the International Drug Purchasing Facility (UNITAID) and the International Finance Facility for Immunization (IFFIm) that the document contains are inappropriate, because neither of those organizations is directly aimed at research, the focus of this paragraph. The appropriate reference, if any, would be to the Advance Market Commitment (Paragraph Eight, subparagraph (e)), but that reference should be specific to the pilot project for a pneumococcal vaccine, and not broadened, unless the data from the pilot program demonstrate that such commitments are effective. The reference to "philanthropic organizations" should be changed to "private, not-for-profit entities," since that would also include certain university-based and other research. The term "private, not-for-profit" is also the one used by the Commission for Health Research.

Paragraph Eight focuses on raising additional funds for research organizations in developing countries. The focus, however, should be on raising more resources toward organizations that are doing research on health issues that disproportionately affect developing countries, regardless of where those institutions are located.

The U.S. Government does not support the establishment of any new "funding mechanisms" (Paragraph Eight, Subparagraph (d)), as there are several existing funding mechanisms, including public and private entities (e.g., the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services, the Bill and Melinda Gates Foundation, etc), that already make major investments in this area.

9. Establishing Monitoring and Reporting Systems

The WHO Secretariat should continue to monitor, from a public-health perspective, in consultation with other international organizations, the impact of intellectual-property rights and other health-related factors on the development of, and access to, health-care products in developing countries. Nevertheless, the WHO Secretariat

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should strive to work only in areas in which it has sufficient expertise and competency, and can add value to discussions of cross-cutting issues.

The WHO Secretariat should monitor performance and progress towards the objectives and targets of this plan of action, and report regularly on progress, and should engage the WTO and WIPO Secretariats when it conducts any monitoring of the impact of intellectual-property rights on health.

ANNEX II

Global Challenge

3. Meeting public-health needs

The Annex should include the following points:

- Public and private investment in the development of new technologies is important \( (\text{resolution WHA 59.24}) \);

- Developing countries should continue to strengthen their research-and-development capacity in new health technologies \( (\text{resolution WHA 59.24}) \);

- There is an urgent need to develop new products to address emerging health threats, such as multi-drug-resistant tuberculosis, and other infectious diseases of particular relevance to developing countries \( (\text{resolution WHA 59.24}) \); and

- Determined action should be taken to emphasize priorities in research and development to address the needs of patients, especially those in resource-poor settings \( (\text{resolution WHA 59.24}) \).

4. Making intellectual property work for health

The Annex should include the following point:

- Intellectual-property rights are important in fostering the research and development of innovative medicines, and they play an important role with regard to the development of essential medicines \( (\text{resolution 56.27}) \)

5. Making products affordable and accessible

The first bullet point does not accurately reflect Resolution 59.24, and should be amended to read as follows: “The impact of high prices of medicines on access to treatment”
Global Responsibility

1. **Discovery**

   The first bullet point should be amended to request Governments and private-sector institutions to continue promoting research to target diseases that disproportionately affect developing countries.

2. **Development**

   Regulatory frameworks and capacities for clinical trials need strengthening in developing countries. Many developed countries already have strong regulatory frameworks and a well-defined infrastructure that supports safe and ethical clinical trials.

3. **Delivery**

   A key problem in access to medicines is the delivery of those medicines to those most in need. Hence, the focus of this point should be on strengthening the delivery infrastructure in developing countries to increase the availability of and access to new products.

4. **Sustainable financing**

   Countries should consider providing tax credits to encourage research and development into medicines related to neglected or orphan diseases.