

# Center for the Rule of Law

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## COMMENTS ON DRAFT GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY, A/PHI/IGWG/2/2

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These comments on the *Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, A/PHI/IGWG/2/2* (Draft Plan of Action) are submitted by the Center for the Rule of Law in response to the World Health Organization (WHO) call for comments in its second web-based public hearing on the work of its Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).

The Center for the Rule of Law (CRL) is an independent, non-profit center of international scholars working on issues related to the rule of law, organized under the laws of the United States as a non-profit educational foundation. Its scholars currently come from France, Italy, and the U.S. and have expertise in many fields of law, economics, and public policy, including health care regulation, intellectual property, and international trade. The Chairman of the Center, the Honorable Ronald A. Cass, is former Commissioner and Vice-Chairman of the United States International Trade Commission, Dean Emeritus of Boston University School of Law, past president of the American Law Deans Association, Senior Fellow of the International Centre for Economic Research, and has served as an adviser to the United Nations Conference on Trade and Development, Rapporteur for the Trans-Atlantic Policy Network's Intellectual Property Task Force, and consultant to numerous other government, educational, and private entities.

CRL commends the WHO for taking leadership on addressing health problems facing developing nations and for advocating increased investment in research and development targeted at treatments for diseases disproportionately affecting the least developed nations. We particularly commend the Draft Plan of Action's recommendation that developing nations invest in strengthening health care delivery infrastructure.

We have several concerns, however, about the Draft Plan of Action. These focus on the Plan's derogation of strong protections for patent rights, its ill-defined concept of "managing intellectual property," its expansion of initiatives to diseases that do not

specially affect less developed nations, and its extension of WHO initiatives into areas of core WTO and WIPO competence.

**Patent Rights and R&D Incentives.** Health care depends on the creation of treatments to promote health, their diffusion to places where the treatments are needed, and their effective delivery to patients. All three steps are essential for health, as the Draft Plan recognizes, and in many parts of the world – especially the least developed nations – critical failures in health care delivery undermine success at the other two steps.

The plan's primary focus, however, is on the first two steps, creation and diffusion of health care treatments, especially pharmaceutical-based treatments. There are, of course, legitimate concerns about improving both of those aspects of health care, particularly as they affect people in the developing world. Unfortunately, rather than supporting the institutions that have been most effective at advancing those parts of the health care enterprise, the Draft Plan suggests changes that would weaken them.

The existence of an international system of patent rights has helped promote investment in research and development of an incredible array of drugs to treat diseases that formerly afflicted extremely large populations around the world. Thirty private enterprises devoted 65 billion dollars last year to R&D activities primarily in response to the incentives of patent rights for successful innovations. Just as in other fields of endeavor, the prospect of financial rewards for success motivates investment in risky endeavors like creation of new drugs. For that reason, patent rights are safeguarded by national laws and international treaty obligations.

The Draft Plan nonetheless asks that nations shift attention away from patent protection and toward other means for promoting health-related R&D. It recommends that trade agreements not include strong patent protections or strong protections for data exclusivity related to patent-driven R&D. The plan also urges exploration of prize funds and other alternatives to patents as inducements for health-related R&D, even though such mechanisms have not been shown to improve R&D incentives.

No one doubts that there is a role for government and international agencies to play in supporting health-related R&D, and particularly for R&D related to diseases that predominantly affect less wealthy populations. Governments can contract directly with research institutes, educational institutions, and private firms to support research on the nature of such diseases and on potential treatments for them. Governments also can subsidize the dissemination of existing treatments, which both increases their availability to poor people and signals to potential investors the prospect that there will be increased financial returns for discoveries that advance treatment of these diseases. In fact,

together with private firms, governments and international agencies spend billions of dollars each year on diseases that disproportionately affect poor and developing nations, spending that has grown sharply in recent years.

The plan points to no evidence that these mechanisms have failed to support sufficient levels of R&D related to the diseases that have greatest impact on health and mortality in developing nations. In just a three year period, more than \$40 billion has been invested in R&D related to HIV/AIDS, malaria, and tuberculosis, which along with nutrition- and diarrhea-related health issues, account for the greatest share of serious health issues in developing nations. The IGWG should support the current system and urge governments and international agencies to invest in dissemination of the treatments that are being produced rather than looking to create alternative mechanisms for producing these treatments.

**Managing Intellectual Property.** In suggesting the need for investment in “education and training in the management of intellectual property,” it is unclear what the Draft Plan intends. If the plan’s language means that poor and developing countries should respect intellectual property rights and work cooperatively with those who invest in health-related R&D, that directive could be framed clearly and directly. If the Draft Plan intends something else by this phrase, it should identify the steps that are contemplated.

It is not at all apparent what steps, apart from support for investment in R&D and respect for the intellectual property rights that protect the products of health-related R&D, would serve the goals set out for the IGWG plan. Proposals for the creation of patent pools and other similar suggestions are at odds with strong protections of property rights. Unlike markets characterized by circumstances – primarily numerous interlocking patents on related technologies – that promote voluntary patent pools, the suggestion of such steps in this field seems to contemplate involuntary takings of private property. Such steps would undermine, rather than enhance, investment in health-related R&D.

**Type I Diseases.** The Draft Plan makes repeated reference to Type I diseases as well as to Type II and Type III diseases. As Type I diseases primarily affect populations in the developed world, current financing mechanisms are eminently adequate to support R&D related to these diseases. To the extent there is a need to improve health-delivery systems in less developed nations to effectively treat Type I diseases, this is a goal that WHO can and should work toward. The scope of the IGWG’s mandate, however, does not extend to examination of R&D related to Type I diseases. The Draft Plan should eliminate references to them.

**Infringement on WTO and WIPO competences.** The Draft Plan also recommends alterations of trade agreements and other international obligations within the primary competence of the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO). For example, the plan recommends “support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights,” opposes trade agreements that include “TRIPS-plus” provisions, and “encourage[s] trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health).” These recommendations are troublesome both because they expand WHO initiatives beyond the proper scope of the WHO and IGWG mandate and because they suggest actions that will reduce incentives for investment in health-related R&D.

As matters of law and process, the recommendations are improper. The TRIPS agreement sets a floor for protection of intellectual property rights, not a ceiling. Accords that derogate from these protections violate the TRIPS agreement and WTO obligations. In contrast, agreements that incorporate provisions for stronger protections of intellectual property rights – which opponents of such protections have labeled “TRIPS-plus” provisions – are fully consistent with that agreement and its obligations. By opposing TRIPS-plus provisions and supporting TRIPS-minus provisions, the Draft Plan would improperly interfere with WTO functions and undermine the protections of intellectual property rights at the core of TRIPS.

Further, the “flexibilities” incorporated in TRIPS, such as the provision for compulsory licensing of patents, are intended to be used in exceptional circumstances. Despite some claims made by advocacy groups respecting the underlying agreement and the Doha Declaration, those circumstances are narrowly tailored and do not constitute a *de facto* repeal of the protections of TRIPS. The Doha Declaration purports to interpret TRIPS but cannot legally amend the agreement except through a formal process. That process was initiated only for one minor part of the Declaration (which still lacks sufficient support from member states to effect an amendment).

The general recognition of compulsory licensing as a rare exception to both domestic and international legal obligations respecting intellectual property is at odds with the recommendations in the Draft Plan that appear to support broader use of derogations from TRIPS obligations. While advocacy groups may take a different view, their interpretation does not have the force of law and, in any event, is properly evaluated through established WTO and WIPO proceedings, not in the context of the IGWG process at issue here.

Finally, these recommendations are not only beyond the scope of WHO competence; they also are substantively ill-advised. By derogating from the established system of intellectual property rights, the recommendations would reduce incentives to invest in the very R&D that the IGWG is supposed to promote. As explained above, the current system supports an extraordinarily large and growing investment in health-related R&D. The IGWG should take care not to put that investment at risk.

### **Summary of Comments:**

- Internationally recognized patent rights promote investment in research and development, producing of an incredible array of drugs to treat diseases that formerly afflicted extremely large populations around the world. The Draft Plan points to no evidence that the patent system and related measures have failed to support sufficient levels of R&D related to the diseases that have greatest impact on health and mortality in developing nations. The IGWG should support current measures for creation of treatment products and urge governments and international agencies to invest in dissemination of these products rather than looking to create alternative mechanisms for producing these treatments.
- The Draft Plan does not clearly explain what it means in suggesting the need for investment in “education and training in the management of intellectual property.” The IGWG should take care to assure that the steps it recommends will enhance, not undermine, investment in health-related R&D.
- The scope of the IGWG’s mandate does not extend to examination of R&D related to Type I diseases. The Draft Plan should eliminate references to them.
- The Draft Plan recommends alterations of trade agreements and other international obligations within the primary competence of the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO). These recommendations expand WHO initiatives beyond the proper scope of the WHO and IGWG mandate, misconstrue legal obligations, and suggest actions that will reduce incentives for investment in health-related R&D.