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World Health Organization (WHO)  
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RE: Draft global strategy and plan of action on public health, innovation and intellectual property - A/PHI/IGWG/2/2 (Draft Global Strategy)<sup>1</sup>

To the WHO Secretariat, PHIIP:

These comments explain why additional means to facilitate research and development for vaccines to prevent or treat HIV infection ( the complex large molecule biologic products made from living materials) must be separate from the means pertaining to therapeutic, small molecule HIV/AIDS drugs. The important work in WHO's Draft Global Strategy and in the Commission on Intellectual Property Rights, Innovation and Public Health Report in 2006 takes the circumstances of therapeutic drugs as their exemplary focus in order to evaluate effects of intellectual property on innovation and access to care. That work resulted in several useful ideas to negotiate interlocking issues for innovation, production, licensing, low cost global access, and delivery of products in a somewhat mature market. In that market, several chemical compound therapies (and some preventives) have already been proven safe and effective since HIV was identified over 25 years ago. They can be copied generically with relative ease, skill and know-how, are subject to a variety of payment subsidies or policies, can move across borders in multiple ways and rely on relatively few patents or other property rights. Hopefully consensus on the WHO ideas will be forthcoming.

But this focus can be inapposite to the unique differences affecting the innovation needs for HIV/AIDS vaccines. These biologics require the appreciation of many more rights - not only numerous patents or patent thickets but also specialized know-how, private data, diagnostics, ownership of samples and other factors. The world is years away from the prospect of approving even the first safe and efficacious HIV vaccine, prime-boost regimen or adjuvanted products. It is unlikely one vaccine could be copied as a biosimilar or follow on biologic and shown to retain its safety, purity and potency in a quality manufacturing environment, let alone the variety of vaccines and combinations that may be needed. For the reasons articulated here, please consider establishing a wholly separate working group and set of policies to promote vital research and development of preventive and therapeutic vaccines based on their unique characteristics.

Robert Reinhard