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**INTELLECTUAL PROPERTY AND PUBLIC HEALTH:  
A PATIENT PERSPECTIVE ON CURRENT ISSUES**

*A submission to WHO's Second Public Hearing on Public Health Innovation and Intellectual Property  
on behalf of the Canadian Organization for Rare Disorders (CORD)*

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The Canadian Organization for Rare Disorders (CORD) supports efforts towards developing a global strategy to address the lack of safe and effective medications for many patients around the world and especially those suffering from diseases and conditions "neglected" by pharmaceutical research and development.

We are dismayed at the lack of patient engagement in these issues and urge the WHO and all stakeholders to ensure that patients and patient groups are given a central role in future discussions and provided with resources to educate and consult their communities. We recommend the following actions in response to the draft strategy.

Access and innovation are inseparable. There is probably no greater testament to the importance of strong patent protection to stimulating research into unmet needs than the "orphan drug" legislation, introduced first in the United States in 1983. In 2000, the European Union passed similar legislation that granted lower application fees and ten-year market exclusivity, and country-specific research incentives to manufacturers of drugs for rare, life-threatening or serious diseases.

The results of the Orphan Drug Act have exceeded expectations, with over 268 orphan-designated products brought to market in the USA since legislation (as compared to only 34 in the previous decade), over 300 medicines in development, and over 1600 orphan designations. In a 20-year review of the Orphan Drug Act, *Scientific American* concluded that the "Act certainly has its warts, but in a free-market economy, it is the best model devised so far to ensure that those with rare diseases can get the treatments they so desperately need."

There are many barriers to access to healthcare in developing countries, however the principal barrier is poverty. Poverty affects the availability of food, clean water, hospitals, clinics and healthcare professionals, all of which are key factors in improving health outcomes in poor countries. To assure patient safety and treatment effectiveness, medicines must be made available within a healthcare environment that includes appropriate diagnostic, monitoring, and supportive treatment and care.

A key problem for patients is the lack of quality standards (regulatory control) for treatments manufactured under a compulsory license and imported into developing countries. We urge WHO to assure all countries engaged in research and/or development of medicines provide stringent regulatory oversight for development and manufacturing processes.

We support strategies and market-based incentives to promote research into under-served needs and areas, including "pooled advance purchase commitments" for medicines such as vaccines, whereby governments, foundations, and international alliances commit to purchasing specified quantities of vaccine at contracted prices and then give it to the poorest countries at affordable prices.

We urge support for strategies to improve continued access to safe treatments. Differential pricing for new therapies may be offered to low GDP countries where healthcare systems cannot (or will not) pay. However, we must stop the "re-selling" of drugs from subsidized markets back into the developed countries, which undermines the goal of improving treatment access in poor populations and impacts ability of manufacturers to offer differential pricing.