



29 February 2008

Mr. Paul Hunt  
UN Special Rapporteur  
The Human Rights Centre  
University of Essex  
Colchester, Essex CO4 3SQ  
United Kingdom

Dear Mr. Hunt:

I write in response to the Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines. No doubt a great deal of time and thought was put into the document. However, once again, the debate on this topic is framed in terms of the “obligations” of those who have provided, and thankfully will continue to provide, life saving medicines.

The words of the late French economist and philosopher Frederic Bastiat are quite appropriate in the context in which this discussion has been devolving:

Sometimes the law defends plunder and participates in it. Sometimes the law places the whole apparatus of judges, police, prisons and gendarmes at the service of the plunderers, and treats the victim – when he defends himself – as a criminal.

In closing, I ask that you refer to our 2007 IGWG testimony that I prepared with the help of Dr. Leslie O. Anderson and Miss Tabettha Ralph. A copy of the testimony is attached and respectfully resubmitted. Thank you in advance for your time and consideration. All my best,

Regards,

A handwritten signature in black ink, appearing to read "B. Nedd II", with a stylized flourish at the end.

Bishop Council Nedd II, SChLJ, GCRCST  
Chairman of the Board

**Holyrood House, 1007 n. 17<sup>TH</sup> Street, Harrisburg, Pennsylvania, 17103 USA**



The Alliance for Health Education and Development

Testimony Prepared

for

The World Health Organization Intergovernmental Working  
Group on Public Health, Innovation and Intellectual Property.

Prepared by: Council Nedd II, DD, MA  
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## **Introduction**

The Alliance for Health Education and Development (AHEAD) was established with the primary goal of educating members of underserved communities about their full range of choices and options in the area of health, education and economic development.

To accomplish this goal, AHEAD employs a full range of implementation strategies including: the organization of educational outreach programs; the presentation of special events and seminars on the regional, national, and international levels; the publication of materials; and the establishment of scholarship and recruitment programs.

AHEAD's interest in this topic is twofold. First, a large part of the mission of the organization relates directly to public health and public health education. Secondly, AHEAD is affiliated with the Episcopal Missionary Church (EMC) which has several congregations in developing nations primarily in Africa.

Our mission requires that we speak out for the underserved, that we be the voice for those who may not be aware of their options, that we bring information and services and hope to those who need it. We are called to act in this issue because we believe that mankind is best served spiritually by the faith and best served physically by innovation to free us from pain and suffering caused by ill health.

The IGWG's mandate is "to prepare a global strategy and plan of action on essential health research to address conditions affecting developing countries disproportionately." While the public health crisis in the developing world is a grave situation, we must be mindful of the fact that there is no one panacea that will cure the ills of the current crisis.

Those who do not respect the hard work of individuals and institutions that have spent countless hours making pharmaceutical advances are most comfortable with the idea of infringing upon intellectual property of others. They do so routinely by downplaying the investment needed for the innovations that have so dramatically improved our lives and condition for the better in just one generation.

## **Innovation is Key**

Innovation and break-throughs in the area of pharmaceutical development have always been the key to eradication of diseases and chronic medical conditions. Remove the incentive and the "men of the mind" will cease to invent and create and by extension – save. As a philosopher once said, inventor is a term of honor and distinction, because the innovators are the ones who carry mankind forward. If mankind, acting through

governments, remove the incentives for the creators to create, it is done at mankind's peril.

Pharmaceutical innovation rests on the continuation of patent protection, which is integral at every step of the research and development process. These patent protections permit commercial rewards which in-turn, allow these institutions to continue research and further advance knowledge.

If the appropriate incentives for the creation of new medicines are eliminated, well-intentioned schemes for pirating them will be a moot point. Virtually all medicines and vaccines were developed because there was an environment in place that fostered the creation and rewarded the effort.

Pharmaceutical companies and universities are investing time and money in research and development with the goal of eradicating communicable diseases that are ravaging developing countries. Additionally, developing countries are now finding themselves in the predicament of having to address non-communicable diseases that were heretofore associated primarily with developed countries. Worldwide, people need access to medications that ensure not merely life but rather a quality of life free from relatively easily prevented chronic illnesses.

### **The Quality of Medicines Must be Maintained**

Many of the facilities in the developing world which are used for the manufacturing of pharmaceuticals do not meet the manufacturing standards established by the World Health Organization, leaving no guarantee that the generic drugs produced would be safe and effective. The effect of producing and administering substandard drugs increases resistance and forces physicians to treat with more expensive "second-line" therapies which tend to be cost prohibitive for use in most developing countries.

Anti-retro viral drug resistance develops under the best of medical conditions; however, substandard drugs accelerate resistance and mutations of the HIV/AIDS virus<sup>1</sup>

### **False Solution to Intellectual Property Issues**

#### **Patent Pools**

The discussion regarding patent pools is a bit ingenuous, as the "patent pools" which are being discussed with an eye toward implementation, are not real patent pools, but rather government mandated compulsory licensing. Contrast this with the way these types of pools are normally established. Traditionally, companies or inventors

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<sup>1</sup> Philip Stevens. "Campaign for Fighting Diseases/International Policy Network, In the Nation (Bangkok)."

*voluntarily* contribute to the pools in order to utilize other patents in the consortium, while maintaining the right to license their products outside of the pool.

### **R&D Treaty Model**

By now, all should be aware that state-driven R&D has never proven to be a remotely effective way to produce medical therapies or any type advanced technologies. Further, it is important to note that it is expensive and inefficient for governments to develop the infrastructure to conduct clinical trials. Additionally if government were to get into the business of conducting the necessary type of clinical trials, the impetus for market competition would be eliminated.

Furthermore the R&D treaty idea is fraught with operational challenges. Currently, few countries contribute to fixed R&D costs and countries not contributing to the costs would lose all incentive to enter.

### **Conclusion**

Products sold on a free and open market generally increase in quality and availability while decreasing in price. Whereas, products regulated by price controls tend to disappear from the marketplace entirely.

Pharmaceutical manufacturers spend millions of dollars and years of research to develop new drugs. The question is how long can the industry sustain this, when they are unable to recoup their costs because the price is dictated by an outside group, or worse, someone is allowed to reproduce the product ignoring the sweat equity that went into the discovery? “Ask whether you would devote your own savings or your life's work to a field in which your reward were determined, not by the value of the product you create, but by the decrees of a bureaucrat charged with cutting...costs.”<sup>2</sup>

The approaches being discussed, with regard to prescription drugs, and the current health care crisis in the developing world, are neither moral nor practical. Thankfulness and fairness should be mantra when we are talking about life-saving and life-enhancing prescription drugs.

### **Contributors**

**Council Nedd II, DD, MA**, is the Chairman of the Board of Directors and President of the Alliance for Health Education and Development, and also serves as the Bishop of the Diocese of the Chesapeake of the Episcopal Missionary Church. Bishop Nedd resides in Harrisburg, PA.

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<sup>2</sup> Robert Tracinski. “Don’t let Medicare Destroy the Drug Industry.” The Ayn Rand Institute. 13 June 2000.

**Tabetha B. Ralph, RN, BSN**, is a nurse residing in East Hartford, CT, and is completing her MSN degree and CRNP certification at Simons College in Boston, MA.

**Leslie O. Anderson, DHSc., DPH, M.Div**, is the retired Director of Health and Community Service for the Northern California Conference of Seventh Day Adventist. Dr. Anderson resides in Martinez, CA.