THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 17 2000

The Honorable Janice D. Schakowsky
House of Representatives
Washington, D.C. 20515

Dear Ms. Schakowsky:

Thank you for your letter to President Clinton suggesting that the Administration use its authorities to provide the World Health Organization (WHO) with royalty-free rights to health care products for which the United States holds the rights to such inventions. The President has asked that I respond to you and your colleagues on behalf of the Administration.

We share your concern about the global HIV/AIDS crisis and are committed to assisting foreign governments and international organizations in addressing their health care needs. Recent developments in AIDS treatments provide hope for helping those already living with HIV and for preventing new infections by interrupting maternal to child transmission. The challenge of making treatments a viable option for those who need them is one that eludes simple answers. The United States will continue to work with its partner nations, multilateral organizations, industry, and affected communities to improve access to treatment.

The AIDS crisis in developing countries is a public health problem involving much broader issues than access to anti-viral drugs. The question of the supply of drug products must be considered in the context of the equally important issues of medical infrastructure, public health programs, treatment monitoring and compliance, and emergence of drug-resistant HIV strains. Therefore, the Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH), welcomes and is pursuing further discussions with the WHO on what can be done to assist developing countries with health care needs.

The intellectual property aspects of this matter are complex and I would like to share with you some background and analysis developed by the NIH.

Programmatic Background

As you know, in the early 1980s Congress enacted the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act (with later amendments, including the Federal Technology Transfer Act of 1986) to encourage the transfer of basic research findings to the marketplace. The

primary purpose of these laws is economic development: specifically, to provide appropriate and necessary incentives to the private sector to invest in federally funded discoveries and to enhance U.S. global competitiveness. To implement these mandates, the DHHS has designated NIH as lead agency for technology transfer for the Public Health Service (PHS).

While NIH respects and is sensitive to the economic development intent of the authorizing legislation, it carries out this mandate in accordance with its public health mission. For example, the NIH licensing strategy gives preference to nonexclusive licenses so that market competition and broad distribution are fostered. Exclusive licenses are granted when such rights are believed to be necessary to ensure product development. In regard to inventions developed with NIH funding, the Bayh-Dole Act gives NIH grantees and contractors authority to retain title to patents and to license inventions that arise from the NIH funding.

As you have pointed out, the United States Government has a royalty-free license to practice an invention it owns on its own behalf and on behalf of a foreign government or international organization pursuant to a treaty or other agreement with the United States. This royalty-free license provides the Government with no-cost use of a technology it invented or funded. It does not provide rights or access to a licensee's final product. The Government use contemplated by this provision has been interpreted generally to include research use, although its full scope has not been determined. To our knowledge, the Government use license has never been employed to facilitate direct competition with a commercial licensee.

Granting Rights to WHO

In principle, the U.S. Government can license patent rights to the WHO. However, there is an important distinction between having rights to a compound and having rights to the fully developed product. NIH does not license drugs that are ready for marketing, but rather early-stage biomedical technologies that in most cases require further research, development and testing. The distinction between final product and "raw technology" is important because others may well have filed for patents on non-NIH technologies that are required for the production of the final product. Therefore, even with NIH-granted rights, WHO or a contract manufacturer of such products may infringe patents belonging to others. Because it is the rule rather than the exception that multiple patents cover final drug products, NIH's granting of rights to the early compound or invention would be unlikely to significantly improve access to drugs.

It should also be noted that NIH can only license or otherwise grant rights to patents in countries in which the agency or its grantees have sought and obtained patent protection. Presently, NIH holds patent rights in selected countries to technologies that have contributed to the development of drugs reported as AIDS/HIV-related treatments. In those countries where NIH or its grantees have neither sought nor obtained patent protection, NIH has no intellectual property rights to be licensed or otherwise granted.

In summary, I am committed to a multilateral approach to improve access to treatment, including continuing the discussions with WHO that we have recently initiated. In addition, we understand that WHO is undertaking a feasibility study to review what they have done in this area and what their appropriate role should be vis a vis government scientific institutions worldwide. We are assisting the WHO in this effort.

I appreciate the opportunity to share information with you on this issue.

Sincerely,

Donna E. Shalala