Monday, May 15, 2000

Volume 36, Issue 19; ISSN: 0511-4187

# Executive Order 13155--Access to HIV/AIDS pharmaceuticals and medical technologies

William J Clinton

## Executive Order 13155-Access to H1V/AIDS Pharmaceuticals and Medical Technologies

May 10, 2000

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act (42 U.S.C. 2421), and section 104 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b), and in accordance with executive branch policy on healthrelated intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Section 1. Policy. (a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa.

Sec. 2. Rationale: (a) This order finds that:

(1) since the onset of the worldwide HIV/ AIDS epidemic, approximately 34 million people living in sub-Saharan Africa have

been infected with the disease;

(2) of those infected, approximately 11.5 million have died;

(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and

(4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

(b) In light of these findings, this order recognizes that:

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/ AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis of HIV/AIDS in sub-Saharan Af rica should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective United States response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and remove the stigma of the disease, and should place a priority on basic health services that can be used to treat opportunistic infections, sexually transmitted infections, and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those with the disease;

(6) an effective United States response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;

(7) the innovative capacity of the United States in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these sectors will be a critical element in any successful program to respond to the

HIV/AIDS crisis in sub-Saharan Africa;

(8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;

(9) individual countries should have the ability to take measures to address the HIV/ AIDS epidemic, provided that such measures are consistent with their international obligations; and

( 10) successful initiatives will require ef fective partnerships and cooperation among governments, international organizations, nongovernmental organizations, and the private sector, and greater consideration should be given to financial, legal, and other incentives that will promote improved prevention and treatment actions.

Sec. 3. Scope. (a) This order prohibits the United States Government from taking action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit United States Government officials from evaluating, determining, or expressing concern about whether such a law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit United States Government officials from consulting with or otherwise discussing with sub-Saharan African governments whether such law or policy meets the conditions set forth in section 1(a) of this order. Moreover, this order does not prohibit the United States Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the Uruguay Round Agreements, referred to in section 101(d) of the Uruguay Round Agreements Act.

(b) This order is intended only to improve the internal management of the executive branch and is not intended to, and does not create, any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

William J. Clinton

The White House, May 10, 2000.

[Filed with the Office of the Federal Register, 8:45 am., May 11, 2000]

NOTE: This Executive order was published in the Federal Register on May 12.