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 Africa 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 effective 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 [19 U.S.C. 2411(b)] 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 [19 U.S.C. 3511(d)].

(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.

§ 2412. Initiation of investigations

(a) Petitions

(1) Any interested person may file a petition with the Trade Representative requesting that action be taken under section 2411 of this title and setting forth the allegations in support of the request.

(2) The Trade Representative shall review the allegations in any petition filed under paragraph (1) and, not later than 45 days after the date on which the Trade Representative received the petition, shall determine whether to initiate an investigation.

(3) If the Trade Representative determines not to initiate an investigation with respect to a petition, the Trade Representative shall inform the petitioner of the reasons therefor and shall publish notice of the determination, together with a summary of such reasons, in the Federal Register.

(4) If the Trade Representative makes an affirmative determination under paragraph (2) with respect to a petition, the Trade Representative shall initiate an investigation regarding the issues raised in the petition. The Trade Representative shall publish a summary of the petition in the Federal Register and shall, as soon as possible, provide opportunity for the presentation of views concerning the issues, including a public hearing—

(A) within the 30-day period beginning on the date of the affirmative determination (or

on a date after such period if agreed to by the petitioner) if a public hearing within such period is requested in the petition, or

(B) at such other time if a timely request therefor is made by the petitioner or by any interested person.

(b) Initiation of investigation by means other than petition

(1)(A) If the Trade Representative determines that an investigation should be initiated under this subchapter with respect to any matter in order to determine whether the matter is actionable under section 2411 of this title, the Trade Representative shall publish such determination in the Federal Register and shall initiate such investigation.

(B) The Trade Representative shall, before making any determination under subparagraph (A), consult with appropriate committees established pursuant to section 2155 of this title.

(2)(A) By no later than the date that is 30 days after the date on which a country is identified under section 2242(a)(2) of this title, the Trade Representative shall initiate an investigation under this subchapter with respect to any act, policy, or practice of that country that—

(i) was the basis for such identification, and

(ii) is not at that time the subject of any other investigation or action under this subchapter.

(B) The Trade Representative is not required under subparagraph (A) to initiate an investigation under this subchapter with respect to any act, policy, or practice of a foreign country if the Trade Representative determines that the initiation of the investigation would be detrimental to United States economic interests.

(C) If the Trade Representative makes a determination under subparagraph (B) not to initiate an investigation, the Trade Representative shall submit to the Congress a written report setting forth, in detail—

(i) the reasons for the determination, and

(ii) the United States economic interests that would be adversely affected by the investigation.

(D) The Trade Representative shall, from time to time, consult with the Register of Copyrights, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and other appropriate officers of the Federal Government, during any investigation initiated under this subchapter by reason of subparagraph (A).

(c) Discretion

In determining whether to initiate an investigation under subsection (a) or (b) of any act, policy, or practice that is enumerated in any provision of section 2411(d) of this title, the Trade Representative shall have discretion to determine whether action under section 2411 of this title would be effective in addressing such act, policy, or practice.

(Pub. L. 93–618, title III, § 302, as added Pub. L. 96–39, title IX, § 901, July 26, 1979, 93 Stat. 296; amended Pub. L. 98–573, title III, § 304(d)(1), Oct. 30, 1984, 98 Stat. 3003; Pub. L. 100–418, title I, § 1301(a), Aug. 23, 1988, 102 Stat. 1168; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(b)(9)], Nov. 29, 1999, 113 Stat. 1536, 1501A–584.)

Editorial Notes

PRIOR PROVISIONS

A prior section 302 of Pub. L. 93–618, title III, Jan. 3, 1975, 88 Stat. 2043, which related to the procedure for Congressional disapproval of certain actions taken by the President to eliminate foreign import restrictions and export subsidies and which was classified to this section, was omitted in the general revision of chapter 1 of title III of Pub. L. 93–618 by Pub. L. 96–39, title IX, § 901, July 26, 1979, 93 Stat. 295.

AMENDMENTS

1999—Subsec. (b)(2)(D). Pub. L. 106–113 substituted ''Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office'' for ''Commissioner of Patents and Trademarks''.

1988—Pub. L. 100–418 amended section generally, substituting provisions relating to initiating investigations with or without petitions and discretion of Trade Representative for provisions relating to filing and determinations on petitions for investigations and investigations initiated by Trade Representative.

1984—Pub. L. 98–573 amended section generally, substituting ''United States Trade Representative'' and ''Trade Representative'' for ''Special Representative for Trade Negotiations'' and ''Special Representative'', respectively, substituting ''the reasons'' for ''his reasons'' in subsec. (b)(1), substituting ''a summary'' for ''the text'' in subsec. (b)(2), striking out the comma after ''petitioner)'' in subsec. (b)(2)(A), and inserting ''or by any interested person'' after ''petitioner'' in subsec. (b)(2)(B).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of Title 35, Patents.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 applicable to petitions filed, and investigations initiated, under this section on or after Aug. 23, 1988, and petitions filed, and investigations initiated, before Aug. 23, 1988, if by such date no decision had been made under section 2414 of this title regarding the petition or investigation, see section 1301(c) of Pub. L. 100–418, set out as a note under section 2411 of this title.

§ 2413. Consultation upon initiation of investigation

(a) In general

(1) On the date on which an investigation is initiated under section 2412 of this title, the Trade Representative, on behalf of the United States, shall request consultations with the foreign country concerned regarding the issues involved in such investigation.

(2) If the investigation initiated under section 2412 of this title involves a trade agreement and a mutually acceptable resolution is not reached before the earlier of—

(A) the close of the consultation period, if any, specified in the trade agreement, or

(B) the 150th day after the day on which consultation was commenced,

the Trade Representative shall promptly request proceedings on the matter under the formal dis-