107TH CONGRESS 1ST SESSION

S. 463

To provide for increased access to HIV/AIDS-related treatments and services in developing foreign countries.

IN THE SENATE OF THE UNITED STATES

March 6, 2001

Mrs. Feinstein (for herself and Mr. Feingold) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for increased access to HIV/AIDS-related treatments and services in developing foreign countries.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Global Access to AIDS
- 5 Treatment Act of 2001".
- 6 SEC. 2. FINDINGS AND DECLARATION OF POLICY.
- 7 (a) FINDINGS.—Congress makes the following find-
- 8 ings:
- 9 (1) Since the HIV/AIDS pandemic began, it
- 10 has claimed 21,800,000 lives.

(2) Over 17,000,000 men, women, and children
have died due to AIDS in sub-Saharan Africa alone
(3) Over 36,000,000 people are infected with
the HIV virus today. Over 25,000,000 live in sub-
Saharan Africa.
(4) By 2010, approximately 40,000,000 chil-
dren worldwide will have lost one or both of their
parents to HIV/AIDS.
(5) Access to effective treatment for HIV/AIDS
is determined by issues of price, health system infra-
structure, and sustainable financing.
(6) In January 2000, the National Intelligence
Council released an intelligence estimate that framed
the HIV/AIDS pandemic as a security threat, noting
the relationship between the disease and political
and economic instability.
(7) The overriding priority for responding to
the HIV/AIDS crisis should be to emphasize and en-
courage prevention.
(8) An effective response to the HIV/AIDS pan-
demic must also involve assistance to stimulate the
development of health service delivery infrastructure
in affected States.
(9) An effective United States response to the

HIV/AIDS crisis must also focus on the development

- of HIV/AIDS vaccines to prevent the spread of the disease.
- 3 (10) The innovative capacity of the United 4 States in the commercial and public pharmaceutical 5 research sectors is unmatched in the world, and the 6 participation of both these sectors will be a critical 7 element in any successful strategy to respond to the 8 global HIV/AIDS crisis.
- 9 (b) Declaration of Policy.—Congress declares 10 that it is the policy of the United States that the United States will not seek, through negotiation or otherwise, the 11 12 revocation or revision of intellectual property or competition laws or policies that regulate pharmaceuticals or medical technologies used to treat HIV/AIDS or the most com-14 15 mon opportunistic infections that accompany HIV/AIDS in any foreign country undergoing an HIV/AIDS-related 17 public health crisis if the laws or policies of that foreign 18 country—
 - (1) promote access to the pharmaceuticals or medical technologies for affected populations; and
 - (2) provide intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in paragraph (15) of section 101(d) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

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1 SEC. 3. SENSE OF THE SENATE.

2	It is the sense of the Senate—
3	(1) to encourage the World Health Organiza-
4	tion and the Joint United Nations Programme on
5	HIV/AIDS (UNAIDS) to carry out HIV/AIDS ac-
6	tivities in foreign countries that are undergoing an
7	HIV/AIDS-related public health crisis, including ac-
8	tivities that are consistent with the policy described
9	in section 2(b); and
10	(2) that the World Health Organization and the
11	Joint United Nations Programme on HIV/AIDS
12	(UNAIDS) should lead the international organiza-
13	tion of the manufacture and distribution of pharma-
14	ceuticals or medical technologies for HIV/AIDS, in-
15	cluding the global registration of products and the
16	organization of the efficient procurement of compul-
17	sory licenses, active ingredients, and finished prod-
18	ucts for foreign countries that require such assist-
19	ance.
20	SEC. 4. PARALLEL IMPORTING AND COMPULSORY LICENS-
21	ING.
22	Section $182(d)(4)$ of the Trade Act of 1974 (19
23	U.S.C. 2242(d)(4)) is amended—
24	(1) by striking "A foreign" and inserting "(A)
25	Except as provided in subparagraph (A), a foreign";
26	and

1 (2) by adding at the end the following:

"(B)(i) With respect to a foreign country that is undergoing an HIV/AIDS-related public health crisis and that is propounding or implementing laws or policies that regulate pharmaceuticals or medical technologies used to treat HIV/AIDS, or the most common opportunistic infections that accompany HIV/AIDS, subparagraph (A) shall not apply to such country with respect to such pharmaceuticals and technologies.

"(ii) With respect to a foreign country described in clause (i), if the laws or policies of that country promote access to the pharmaceuticals or medical technologies described in such clause for affected populations within the country or within other countries undergoing an HIV/AIDS-related public health crisis, compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act shall be construed to provide adequate and effective protection of intellectual property rights for the purposes of this Act, and the President shall instruct the United States Trade Representative not to seek,

- through negotiation or otherwise, the revocation or 1 2 revision of such laws or policies."; and "(C) For purposes of this paragraph, the term 3 'foreign country that is undergoing an HIV/AIDS-5 related public health crisis' means any of the 48 for-6 eign countries of sub-Saharan Africa, and any addi-7 tional country determined to be undergoing such a 8 crisis by the President.". SEC. 5. DEVELOPMENT OF TREATMENT PROTOCOLS. 10 (a) In General.—The Director of the National In-11 stitutes of Health and the Director of the Centers for Dis-12 ease Control and Prevention shall, in collaboration with the entities described in subsection (b), conduct a needs-14 assessment and develop and implement simplified and 15 adapted protocols for the delivery of HIV/AIDS treatments in the resource poor settings of the developing world. 17 18 (b) Collaborative Entities.—The entities de-19 scribed in this subsection are— 20 (1) the Administrator of the United States 21 Agency for International Development; 22 (2) developing foreign countries that face HIV/ 23 AIDS health care crises; and
- 24 (3) appropriate international organizations.

1 SEC. 6. HEALTH CARE INFRASTRUCTURE DEVELOPMENT.

- 2 (a) IN GENERAL.—The Secretary of Health and
- 3 Human Services, acting through the Administrator of the
- 4 United States Agency for International Development,
- 5 shall—
- 6 (1) develop and implement programs to
- 7 strengthen and broaden health care systems infra-
- 8 structure, and the capacity of health care systems in
- 9 developing foreign countries to deliver HIV/AIDS
- 10 pharmaceuticals;
- 11 (2) provide assistance to foreign countries that
- the Administrator determines are ready to imple-
- ment anti-retro viral treatment programs with re-
- spect to HIV/AIDS; and
- 15 (3) provide assistance to improve access to med-
- ical education, including nursing education, in for-
- eign countries that are severely affected by the HIV/
- 18 AIDS virus.
- 19 (b) AUTHORIZATION OF APPROPRIATIONS.—There
- 20 are authorized to be appropriated to carry out this section,
- 21 \$25,000,000 for each fiscal year.
- 22 SEC. 7. INTERNATIONAL DATABASE OF HIV/AIDS PHARMA-
- 23 CEUTICALS.
- 24 The Commissioner of Food and Drugs, in consulta-
- 25 tion with the Director of the National Institutes of Health,
- 26 shall develop and maintain a database of HIV/AIDS phar-

- 1 maceuticals. Such database shall include information
- 2 about patent status, recommended protocols, price, and
- 3 quality.
- 4 SEC. 8. LOAN FORGIVENESS PROGRAM FOR INTER-
- 5 NATIONAL HIV/PHARMACEUTICAL WORK.
- 6 Title XXVI of the Public Health Service Act (42
- 7 U.S.C. 300ff–11 et seq.) is amended by adding at the end
- 8 the following:
- 9 "PART G—INTERNATIONAL ASSISTANCE
- 10 "SEC. 2695. FOREIGN HIV/AIDS ASSISTANCE LOAN REPAY-
- 11 MENT PROGRAM.
- 12 "(a) Establishment.—The Secretary shall estab-
- 13 lish a program to be known as the Foreign HIV/AIDS
- 14 Assistance Loan Repayment Program to encourage physi-
- 15 cians, nurses, physician assistants, pharmacists, nurse
- 16 practitioners, others trained in the field of public health,
- 17 and other health professionals determined appropriate by
- 18 the Secretary to provide HIV/AIDS treatment and care
- 19 in developing foreign countries.
- 20 "(b) Eligibility.—To be eligible to participate in
- 21 the Loan Repayment Program, an individual must—
- 22 "(1) have a degree in medicine, osteopathic
- 23 medicine, or other health profession, or be registered
- or certified as a nurse or physician assistant; and

1	"(2) submit to the Secretary an application for
2	a contract described in subsection (f) (relating to the
3	payment by the Secretary of the educational loans of
4	the individual in consideration of the individual serv-
5	ing for a period of obligated service).
6	"(c) Application, Contract, and Information
7	REQUIREMENTS.—
8	"(1) Summary and information.—In dis-
9	seminating application forms and contract forms to
10	individuals desiring to participate in the Loan Re-
11	payment Program, the Secretary shall include with
12	such forms—
13	"(A) a fair summary of the rights and li-
14	abilities of an individual whose application is
15	approved (and whose contract is accepted) by
16	the Secretary, including in the summary a clear
17	explanation of the damages to which the United
18	States is entitled in the case of the individual's
19	breach of the contract; and
20	"(B) information respecting meeting a
21	service obligation through private practice
22	under an agreement under subsection (f) and
23	such other information as may be necessary for
24	the individual to understand the individual's

prospective participation in the Loan Repayment Program.

"(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this section shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

"(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

"(4) RECRUITMENT AND RETENTION.—

"(A) IN GENERAL.—The Secretary shall distribute to health professions schools materials providing information on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

"(B) RETENTION.—In the case of any health professional whose period of obligated service under the Loan Repayment Program is

1	nearing completion, the Secretary shall encour-
2	age the individual to remain in a developing for-
3	eign country and to continue providing HIV/
4	AIDS-related services.
5	"(d) Considerations With Respect to Con-
6	TRACTS.—
7	"(1) In general.—In providing contracts
8	under the Loan Repayment Program—
9	"(A) the Secretary shall consider the ex-
10	tent of the demonstrated interest of the appli-
11	cants for the contracts in providing HIV/AIDS-
12	related services; and
13	"(B) may consider such other factors re-
14	garding the applicants as the Secretary deter-
15	mines to be relevant to selecting qualified indi-
16	viduals to participate in such Program, such as
17	relevant HIV/AIDS-related or international
18	health work or volunteer experiences.
19	"(2) Priority.—In providing contracts under
20	the Loan Repayment Program, the Secretary shall
21	give priority—
22	"(A) to any application for such a contract
23	submitted by an individual whose training is in
24	a health profession or specialty determined by
25	the Secretary to be needed: and

1	"(B) to any application for such a contract
2	submitted by an individual who has (and whose
3	spouse, if any, has) characteristics that increase
4	the probability that the individual will continue
5	to serve in a developing foreign country after
6	the period of obligated service pursuant to sub-
7	section (f) is completed.
8	"(e) Approval Required for Participation.—
9	An individual becomes a participant in the Loan Repay-
10	ment Program only upon the Secretary and the individual
11	entering into a written contract described in subsection
12	(f).
13	"(f) Contents of Contracts.—The written con-
14	tract between the Secretary and an individual shall
15	contain—
16	"(1) an agreement that—
17	"(A) subject to paragraph (3), the Sec-
18	retary agrees to pay on behalf of the individual
19	loans in accordance with subsection (g) or to
20	defer payment on such loans; and
21	"(B) subject to paragraph (3), the indi-
22	vidual agrees—
23	"(i) to accept loan payments on behalf
24	of the individual or a deferment in pay-
25	ments; and

1	"(ii) to serve for a time period (here-
2	inafter in this subpart referred to as the
3	'period of obligated service') equal to 2
4	years or such longer period as the indi-
5	vidual may agree to, as a provider of HIV/
6	AIDS-related health services in a devel-
7	oping foreign country;
8	"(2) a provision permitting the Secretary to ex-
9	tend for such longer additional periods, as the indi-
10	vidual may agree to, the period of obligated service
11	agreed to by the individual;
12	"(3) a provision that any financial obligation of
13	the United States arising out of a contract entered
14	into under this section and any obligation of the in-
15	dividual that is conditioned thereon, is contingent on
16	funds being appropriated for loan repayments or
17	deferments under this section;
18	"(4) a statement of the damages to which the
19	United States is entitled for the individual's breach
20	of the contract; and
21	"(5) such other statements of the rights and li-
22	abilities of the Secretary and of the individual, not
23	inconsistent with this section.
24	"(g) Payments or Deferments.—

1 "(1) IN GENERAL.—A loan repayment provided 2 for an individual under a written contract under the 3 Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the 5 individual of the principal, interest, and related ex-6 penses on government and commercial loans received 7 by the individual regarding the graduate education 8 of the individual, or the deferment of repayments on 9 such loans, which loans were made for—

"(A) tuition expenses;

- "(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or
- "(C) reasonable living expenses as determined by the Secretary.

"(2) Payments for years served.—

"(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay or defer up to \$5,000 on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay or defer for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

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1	"(i) affects the ability of the Secretary
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3	can be provided under the Loan Repay-
4	ment Program from the amounts appro-
5	priated for such contracts;
6	"(ii) provides an incentive to serve in
7	a developing foreign country with the
8	greatest such shortages; and
9	"(iii) provides an incentive with re-
10	spect to the health professional involved re-
11	maining in a developing foreign country,
12	and continuing to provide HIV/AIDS-re-
13	lated services, after the completion of the
14	period of obligated service under the Loan
15	Repayment Program.
16	"(B) Repayment schedule.—Any ar-
17	rangement made by the Secretary for the mak-
18	ing of loan repayments in accordance with this
19	subsection shall provide that any repayments
20	for a year of obligated service shall be made no
21	later than the end of the fiscal year in which
22	the individual completes such year of service.
23	"(3) Tax liability.—For the purpose of pro-
24	viding reimbursements for tax liability resulting

1	from payments or deferments under this subsection
2	on behalf of an individual—
3	"(A) the Secretary shall, in addition to
4	such payments, make payments to the indi-
5	vidual in an amount equal to 39 percent of the
6	total amount of loan repayments made for the
7	taxable year involved; and
8	"(B) may make such additional payments
9	as the Secretary determines to be appropriate
10	with respect to such purpose.
11	"(4) PAYMENT SCHEDULE.—The Secretary
12	may enter into an agreement with the holder of any
13	loan for which payments are made under the Loan
14	Repayment Program to establish a schedule for the
15	making of such payments or deferments.
16	"(h) REPORTS.—Not later than March 1 of each
17	year, the Secretary shall submit to the Congress a report
18	providing, with respect to the preceding fiscal year—
19	"(1) the total amount of loan payments or
20	deferments made under the Loan Repayment Pro-
21	gram;
22	"(2) the number of applications filed under this
23	section;

1	"(3) the number, and type of health profession
2	training, of individuals receiving loan repayments or
3	deferments under such Program;
4	"(4) the educational institution at which such
5	individuals received their training;
6	"(5) the total amount of the indebtedness of
7	such individuals for educational loans as of the date
8	on which the individuals become participants in such
9	Program;
10	"(6) the number of years of obligated service
11	specified for such individuals in the initial contracts
12	under subsection (f), and, in the case of individuals
13	whose period of such service has been completed, the
14	total number of years for which the individuals pro-
15	vided HIV/AIDS-related services in a developing for-
16	eign country (including any extensions made for pur-
17	poses of paragraph (2) of such subsection);
18	"(7)(A) the number, and type of health profes-
19	sions training, of such individuals who have
20	breached the contract under subsection (f); and
21	"(B) with respect to such individuals—
22	"(i) the educational institutions with re-
23	spect to which payments or deferments have
24	been made or were to be made under the con-
25	tract;

1	"(ii) the amounts for which the individuals
2	are liable to the United States;
3	"(iii) the extent of payment by the individ-
4	uals of such amounts; and
5	"(iv) if known, the basis for the decision of
6	the individuals to breach the contract under
7	subsection (f); and
8	"(8) the effectiveness of the Secretary in re-
9	cruiting health professionals to participate in the
10	Loan Repayment Program, and in encouraging and
11	assisting such professionals with respect to providing
12	HIV/AIDS-related services in developing foreign
13	countries after the completion of the period of obli-
14	gated service under such Program.
15	"(i) AUTHORIZATION OF APPROPRIATIONS.—There
16	are authorized to be appropriated to carry out this section,
17	\$1,000,000 for each fiscal year.".

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