107TH CONGRESS 2D SESSION

S. 812

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

1 TITLE I—GREATER ACCESS TO

2 **AFFORDABLE PHARMA-**

3	\mathbf{CEU}	TICA	\LS
5			

- 4 SEC. 101. SHORT TITLE.
- 5 This title may be cited as the "Greater Access to Af-
- 6 fordable Pharmaceuticals Act of 2002".
- 7 SEC. 102. FINDINGS; PURPOSES.
- 8 (a) FINDINGS.—Congress finds that—
- 9 (1) prescription drug costs are increasing at an 10 alarming rate and are a major worry of American
- families and senior citizens;
- 12 (2) enhancing competition between generic drug 13 manufacturers and brand-name manufacturers can 14 significantly reduce prescription drug costs for
- 15 American families;
- (3) the pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals, but competition must be
- 20 further stimulated and strengthened;
- 21 (4) the Federal Trade Commission has discov-22 ered that there are increasing opportunities for drug 23 companies owning patents on brand-name drugs and 24 generic drug companies to enter into private finan-
- cial deals in a manner that could restrain trade and

- greatly reduce competition and increase prescription drug costs for consumers;
 - (5) generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals;
 - (6) the Congressional Budget Office estimates that—
 - (A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between \$8,000,000,000 and \$10,000,000,000 each year; and
 - (B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of \$15 to \$30 on each prescription;
 - (7) generic pharmaceuticals are widely accepted by consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than

- doubled during the last decade, from approximately
 1 percent to 43 percent, according to the Congressional Budget Office;
 - (8) expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs;
 - (9) Congress should ensure that measures are taken to effectuate the amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (98 Stat. 1585) (referred to in this section as the "Hatch-Waxman Act") to make generic drugs more accessible, and thus reduce health care costs; and
 - (10) it would be in the public interest if patents on drugs for which applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) were extended only through the patent extension procedure provided under the Hatch-Waxman Act rather than through the attachment of riders to bills in Congress.
 - (b) Purposes.—The purposes of this title are—
 - (1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and

1	(2) to ensure fair marketplace practices and
2	deter pharmaceutical companies (including generic
3	companies) from engaging in anticompetitive action
4	or actions that tend to unfairly restrain trade.
5	SEC. 103. FILING OF PATENT INFORMATION WITH THE
6	FOOD AND DRUG ADMINISTRATION.
7	(a) FILING AFTER APPROVAL OF AN APPLICA-
8	TION.—
9	(1) In General.—Section 505 of the Federal
10	Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as
11	amended by section $9(a)(2)(B)(ii)$ is amended in
12	subsection (c) by striking paragraph (2) and insert-
13	ing the following:
14	"(2) Patent information.—
15	"(A) IN GENERAL.—Not later than the
16	date that is 30 days after the date of an order
17	approving an application under subsection (b)
18	(unless the Secretary extends the date because
19	of extraordinary or unusual circumstances), the
20	holder of the application shall file with the Sec-
21	retary the patent information described in sub-
22	paragraph (C) with respect to any patent—
23	"(i)(I) that claims the drug for which
24	the application was approved; or

1	"(II) that claims an approved method
2	of using the drug; and
3	"(ii) with respect to which a claim of
4	patent infringement could reasonably be
5	asserted if a person not licensed by the
6	owner engaged in the manufacture, use, or
7	sale of the drug.
8	"(B) Subsequently issued patents.—
9	In a case in which a patent described in sub-
10	paragraph (A) is issued after the date of an
11	order approving an application under subsection
12	(b), the holder of the application shall file with
13	the Secretary the patent information described
14	in subparagraph (C) not later than the date
15	that is 30 days after the date on which the pat-
16	ent is issued (unless the Secretary extends the
17	date because of extraordinary or unusual cir-
18	cumstances).
19	"(C) Patent information.—The patent
20	information required to be filed under subpara-
21	graph (A) or (B) includes—
22	"(i) the patent number;
23	"(ii) the expiration date of the patent;
24	"(iii) with respect to each claim of the
25	patent—

1	"(I) whether the patent claims
2	the drug or claims a method of using
3	the drug; and
4	"(II) whether the claim covers—
5	"(aa) a drug substance;
6	"(bb) a drug formulation;
7	"(cc) a drug composition; or
8	"(dd) a method of use;
9	"(iv) if the patent claims a method of
10	use, the approved use covered by the claim;
11	"(v) the identity of the owner of the
12	patent (including the identity of any agent
13	of the patent owner); and
14	"(vi) a declaration that the applicant,
15	as of the date of the filing, has provided
16	complete and accurate patent information
17	for all patents described in subparagraph
18	(A).
19	"(D) Publication.—On filing of patent
20	information required under subparagraph (A)
21	or (B), the Secretary shall—
22	"(i) immediately publish the informa-
23	tion described in clauses (i) through (iv) of
24	subparagraph (C); and

1	"(ii) make the information described
2	in clauses (v) and (vi) of subparagraph (C)
3	available to the public on request.
4	"(E) CIVIL ACTION FOR CORRECTION OR
5	DELETION OF PATENT INFORMATION.—
6	"(i) In General.—A person that has
7	filed an application under subsection $(b)(2)$
8	or (j) for a drug may bring a civil action
9	against the holder of the approved applica-
10	tion for the drug seeking an order requir-
11	ing that the holder of the application
12	amend the application—
13	"(I) to correct patent information
14	filed under subparagraph (A); or
15	"(II) to delete the patent infor-
16	mation in its entirety for the reason
17	that—
18	"(aa) the patent does not
19	claim the drug for which the ap-
20	plication was approved; or
21	"(bb) the patent does not
22	claim an approved method of
23	using the drug.
24	"(ii) Limitations.—Clause (i) does
25	not authorize—

1	"(I) a civil action to correct pat-
2	ent information filed under subpara-
3	graph (B); or
4	"(II) an award of damages in a
5	civil action under clause (i).
6	"(F) NO CLAIM FOR PATENT INFRINGE-
7	MENT.—An owner of a patent with respect to
8	which a holder of an application fails to file in-
9	formation on or before the date required under
10	subparagraph (A) or (B) shall be barred from
11	bringing a civil action for infringement of the
12	patent against a person that—
13	"(i) has filed an application under
14	subsection (b)(2) or (j); or
15	"(ii) manufactures, uses, offers to sell,
16	or sells a drug approved under an applica-
17	tion under subsection (b)(2) or (j).".
18	(2) Transition Provision.—
19	(A) FILING OF PATENT INFORMATION.—
20	Each holder of an application for approval of a
21	new drug under section 505(b) of the Federal
22	Food, Drug, and Cosmetic Act (21 U.S.C.
23	355(b)) that has been approved before the date
24	of enactment of this Act shall amend the appli-
25	cation to include the patent information re-

1 quired under the amendment made by para-2 graph (1) not later than the date that is 30 3 days after the date of enactment of this Act 4 (unless the Secretary of Health and Human 5 Services extends the date because of extraor-6 dinary or unusual circumstances). 7 (B) NO CLAIM FOR PATENT INFRINGE-8 MENT.—An owner of a patent with respect to 9 which a holder of an application under sub-10 section (b) of section 505 of the Federal Food, 11 Drug, and Cosmetic Act (21 U.S.C. 355) fails 12 to file information on or before the date re-13 quired under subparagraph (A) shall be barred 14 from bringing a civil action for infringement of 15 the patent against a person that— 16 (i) has filed an application under sub-17 section (b)(2) or (j) of that section; or 18 (ii) manufactures, uses, offers to sell, 19 or sells a drug approved under an applica-20 tion under subsection (b)(2) or (j) of that 21 section. 22 (b) FILING WITH AN APPLICATION.—Section 505 of 23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 24 355) is amended—

(1) in subsection (b)(2)—

1	(A) in subparagraph (A), by striking
2	"and" at the end;
3	(B) in subparagraph (B), by striking the
4	period at the end and inserting "; and"; and
5	(C) by adding at the end the following:
6	"(C) with respect to a patent that claims
7	both the drug and a method of using the drug
8	or claims more than 1 method of using the drug
9	for which the application is filed—
10	"(i) a certification under subpara-
11	graph (A)(iv) on a claim-by-claim basis;
12	and
13	"(ii) a statement under subparagraph
14	(B) regarding the method of use claim.";
15	and
16	(2) in subsection (j)(2)(A), by inserting after
17	clause (viii) the following:
18	"With respect to a patent that claims both the drug and
19	a method of using the drug or claims more than 1 method
20	of using the drug for which the application is filed, the
21	application shall contain a certification under clause
22	(vii)(IV) on a claim-by-claim basis and a statement under
23	clause (viii) regarding the method of use claim.".

1	SEC. 104. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-
2	ENTS.
3	(a) Abbreviated New Drug Applications.—Sec-
4	tion $505(j)(5)$ of the Federal Food, Drug, and Cosmetic
5	Act (21 U.S.C. 355(j)(5)) is amended—
6	(1) in subparagraph (B)—
7	(A) in clause (iii)—
8	(i) by striking "(iii) If the applicant
9	made a certification described in subclause
10	(IV) of paragraph (2)(A)(vii)," and insert-
11	ing the following:
12	"(iii) Subclause (IV) Certification
13	WITH RESPECT TO CERTAIN PATENTS.—If
14	the applicant made a certification de-
15	scribed in paragraph (2)(A)(vii)(IV) with
16	respect to a patent (other than a patent
17	that claims a process for manufacturing
18	the listed drug) for which patent informa-
19	tion was filed with the Secretary under
20	subsection (c)(2)(A),"; and
21	(ii) by adding at the end the fol-
22	lowing: "The 30-month period provided
23	under the second sentence of this clause
24	shall not apply to a certification under
25	paragraph (2)(A)(vii)(IV) made with re-
26	spect to a patent for which patent informa-

1	tion was filed with the Secretary under
2	subsection (c)(2)(B).";
3	(B) by redesignating clause (iv) as clause
4	(v); and
5	(C) by inserting after clause (iii) the fol-
6	lowing:
7	"(iv) Subclause (IV) Certification
8	WITH RESPECT TO OTHER PATENTS.—
9	"(I) In general.—If the appli-
10	cant made a certification described in
11	paragraph (2)(A)(vii)(IV) with respect
12	to a patent not described in clause
13	(iii) for which patent information was
14	published by the Secretary under sub-
15	section $(c)(2)(D)$, the approval shall
16	be made effective on the date that is
17	45 days after the date on which the
18	notice provided under paragraph
19	(2)(B) was received, unless a civil ac-
20	tion for infringement of the patent,
21	accompanied by a motion for prelimi-
22	nary injunction to enjoin the applicant
23	from engaging in the commercial
24	manufacture or sale of the drug, was
25	filed on or before the date that is 45

days after the date on which t	the no-
tice was received, in which ca	se the
approval shall be made effective-	
4 "(aa) on the date of a	a court
action declining to grant	a pre-
6 liminary injunction; or	
7 "(bb) if the court has	grant-
8 ed a preliminary injunctio	n pro-
9 hibiting the applicant fro	m en-
gaging in the commercial	manu-
facture or sale of the drug-	_
2 "(AA) on issuance	e by a
court of a determination	ination
4 that the patent is inv	alid or
is not infringed;	
6 "(BB) on issuance	e by a
7 court of an order re	voking
8 the preliminary injunc	tion or
9 permitting the applic	ant to
0 engage in the comm	mercial
1 manufacture or sale	of the
2 drug; or	
3 "(CC) on the date	e spec-
4 ified in a court order	under
section 271(e)(4)(A) of	of title

1	35, United States Code, if
2	the court determines that
3	the patent is infringed.
4	"(II) Cooperation.—Each of
5	the parties shall reasonably cooperate
6	in expediting a civil action under sub-
7	clause (I).
8	"(III) Expedited notifica-
9	TION.—If the notice under paragraph
10	(2)(B) contains an address for the re-
11	ceipt of expedited notification of a
12	civil action under subclause (I), the
13	plaintiff shall, on the date on which
14	the complaint is filed, simultaneously
15	cause a notification of the civil action
16	to be delivered to that address by the
17	next business day."; and
18	(2) by inserting after subparagraph (B) the fol-
19	lowing:
20	"(C) Failure to bring infringement
21	ACTION.—If, in connection with an application
22	under this subsection, the applicant provides an
23	owner of a patent notice under paragraph
24	(2)(B) with respect to the patent, and the
25	owner of the patent fails to bring a civil action

1 against the applicant for infringement of the 2 patent on or before the date that is 45 days 3 after the date on which the notice is received, 4 the owner of the patent shall be barred from 5 bringing a civil action for infringement of the 6 patent in connection with the development, 7 manufacture, use, offer to sell, or sale of the 8 drug for which the application was filed or ap-9 proved under this subsection.". 10 (b) OTHER APPLICATIONS.—Section 505(c)) of the 11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) 12 (as amended by section 9(a)(3)(A)(iii)) is amended— 13 (1) in paragraph (3)— 14 (A) in subparagraph (C)— 15 (i) by striking "(C) If the applicant made a certification described in clause 16 (iv) of subsection (b)(2)(A)," and inserting 17 18 the following: 19 "(C) CLAUSE (iv) CERTIFICATION WITH 20 RESPECT TO CERTAIN PATENTS.—If the appli-21 cant made a certification described in sub-22 section (b)(2)(A)(iv) with respect to a patent 23 (other than a patent that claims a process for 24 manufacturing the listed drug) for which patent

1	information was filed with the Secretary under
2	paragraph (2)(A),"; and
3	(ii) by adding at the end the fol-
4	lowing: "The 30-month period provided
5	under the second sentence of this subpara-
6	graph shall not apply to a certification
7	under subsection (b)(2)(A)(iv) made with
8	respect to a patent for which patent infor-
9	mation was filed with the Secretary under
10	paragraph (2)(B)."; and
11	(B) by inserting after subparagraph (C)
12	the following:
13	"(D) CLAUSE (iv) CERTIFICATION WITH
14	RESPECT TO OTHER PATENTS.—
15	"(i) In general.—If the applicant
16	made a certification described in sub-
17	section (b)(2)(A)(iv) with respect to a pat-
18	ent not described in subparagraph (C) for
19	which patent information was published by
20	the Secretary under paragraph (2)(D), the
21	approval shall be made effective on the
22	date that is 45 days after the date on
23	which the notice provided under subsection
24	(b)(3) was received, unless a civil action
25	for infringement of the patent, accom-

1	panied by a motion for preliminary injunc-
2	tion to enjoin the applicant from engaging
3	in the commercial manufacture or sale of
4	the drug, was filed on or before the date
5	that is 45 days after the date on which the
6	notice was received, in which case the ap-
7	proval shall be made effective—
8	"(I) on the date of a court action
9	declining to grant a preliminary in-
10	junction; or
11	"(II) if the court has granted a
12	preliminary injunction prohibiting the
13	applicant from engaging in the com-
14	mercial manufacture or sale of the
15	drug—
16	"(aa) on issuance by a court
17	of a determination that the pat-
18	ent is invalid or is not infringed;
19	"(bb) on issuance by a court
20	of an order revoking the prelimi-
21	nary injunction or permitting the
22	applicant to engage in the com-
23	mercial manufacture or sale of
24	the drug; or

1	"(cc) on the date specified
2	in a court order under section
3	271(e)(4)(A) of title 35, United
4	States Code, if the court deter-
5	mines that the patent is in-
6	fringed.
7	"(ii) Cooperation.—Each of the
8	parties shall reasonably cooperate in expe-
9	diting a civil action under clause (i).
10	"(iii) Expedited notification.—If
11	the notice under subsection (b)(3) contains
12	an address for the receipt of expedited no-
13	tification of a civil action under clause (i),
14	the plaintiff shall, on the date on which the
15	complaint is filed, simultaneously cause a
16	notification of the civil action to be deliv-
17	ered to that address by the next business
18	day."; and
19	(2) by inserting after paragraph (3) the fol-
20	lowing:
21	"(4) Failure to bring infringement ac-
22	TION.—If, in connection with an application under
23	subsection (b)(2), the applicant provides an owner of
24	a patent notice under subsection (b)(3) with respect
25	to the patent, and the owner of the patent fails to

1 bring a civil action against the applicant for in-2 fringement of the patent on or before the date that 3 is 45 days after the date on which the notice is received, the owner of the patent shall be barred from 5 bringing a civil action for infringement of the patent 6 in connection with the development, manufacture, 7 use, offer to sell, or sale of the drug for which the 8 application was filed or approved under subsection (b)(2).". 9

(c) Effective Date.—

10

11

12

13

14

15

16

17

18

19

20

21

- (1) IN GENERAL.—The amendments made by subsections (a) and (b) shall be effective with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section.
- (2) Transition Provision.—In the case of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed before the date of enactment of this Act—
- 23 (A) a patent (other than a patent that 24 claims a process for manufacturing a listed 25 drug) for which information was submitted to

1	the Secretary of Health and Human Services
2	under section 505(b)(1) of the Federal Food,
3	Drug, and Cosmetic Act (as in effect on the day
4	before the date of enactment of this Act) shall
5	be subject to subsections (c)(3)(C) and
6	(j)(5)(B)(iii) of section 505 of the Federal
7	Food, Drug, and Cosmetic Act (as amended by
8	this section); and
9	(B) any other patent (including a patent
10	for which information was submitted to the
11	Secretary under section 505(c)(2) of that Act
12	(as in effect on the day before the date of en-
13	actment of this Act)) shall be subject to sub-
14	sections $(e)(3)(D)$ and $(j)(5)(B)(iv)$ of section
15	505 of the Federal Food, Drug, and Cosmetic
16	Act (as amended by this section).
17	SEC. 105. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG
18	APPLICANTS.
19	(a) In General.—Section 505(j)(5) of the Federal
20	Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
21	amended by section 4(a)) is amended—
22	(1) in subparagraph (B)(v), by striking sub-
23	clause (II) and inserting the following:
24	"(II) the earlier of—

1	"(aa) the date of a final de-
2	cision of a court (from which no
3	appeal has been or can be taken,
4	other than a petition to the Su-
5	preme Court for a writ of certio-
6	rari) holding that the patent that
7	is the subject of the certification
8	is invalid or not infringed; or
9	"(bb) the date of a settle-
10	ment order or consent decree
11	signed by a Federal judge that
12	enters a final judgment and in-
13	cludes a finding that the patent
14	that is the subject of the certifi-
15	cation is invalid or not in-
16	fringed;"; and
17	(2) by inserting after subparagraph (C) the fol-
18	lowing:
19	"(D) Forfeiture of 180-day period.—
20	"(i) Definitions.—In this subpara-
21	graph:
22	"(I) APPLICATION.—The term
23	'application' means an application for
24	approval of a drug under this sub-
25	section containing a certification

1	under paragraph (2)(A)(vii)(IV) with
2	respect to a patent.
3	"(II) FIRST APPLICATION.—The
4	term 'first application' means the first
5	application to be filed for approval of
6	the drug.
7	"(III) Forfeiture event.—
8	The term 'forfeiture event', with re-
9	spect to an application under this sub-
10	section, means the occurrence of any
11	of the following:
12	"(aa) Failure to mar-
13	KET.—The applicant fails to
14	market the drug by the later of—
15	"(AA) the date that is
16	60 days after the date on
17	which the approval of the
18	application for the drug is
19	made effective under clause
20	(iii) or (iv) of subparagraph
21	(B) (unless the Secretary ex-
22	tends the date because of ex-
23	traordinary or unusual cir-
24	cumstances); or

1	"(BB) if 1 or more civi
2	actions have been brough
3	against the applicant for in-
4	fringement of a patent sub-
5	ject to a certification under
6	paragraph (2)(A)(vii)(IV) or
7	1 or more civil actions have
8	been brought by the appli-
9	cant for a declaratory judg
10	ment that such a patent is
11	invalid or not infringed, the
12	date that is 60 days after
13	the date of a final decision
14	(from which no appeal has
15	been or can be taken, other
16	than a petition to the Su-
17	preme Court for a writ or
18	certiorari) in the last of
19	those civil actions to be de
20	cided (unless the Secretary
21	extends the date because or
22	extraordinary or unusua
23	circumstances).

1	"(bb) Withdrawal of AP-
2	PLICATION.—The applicant with-
3	draws the application.
4	"(cc) Amendment of cer-
5	TIFICATION.—The applicant, vol-
6	untarily or as a result of a settle-
7	ment or defeat in patent litiga-
8	tion, amends the certification
9	from a certification under para-
10	graph (2)(A)(vii)(IV) to a certifi-
11	cation under paragraph
12	(2)(A)(vii)(III).
13	"(dd) Failure to obtain
14	APPROVAL.—The applicant fails
15	to obtain tentative approval of an
16	application within 30 months
17	after the date on which the appli-
18	cation is filed, unless the failure
19	is caused by—
20	"(AA) a change in the
21	requirements for approval of
22	the application imposed
23	after the date on which the
24	application is filed; or

1	"(BB) other extraor-
2	dinary circumstances war-
3	ranting an exception, as de-
4	termined by the Secretary.
5	"(ee) Failure to Chal-
6	LENGE PATENT.—In a case in
7	which, after the date on which
8	the applicant submitted the ap-
9	plication, new patent information
10	is submitted under subsection
11	(c)(2) for the listed drug for a
12	patent for which certification is
13	required under paragraph (2)(A),
14	the applicant fails to submit, not
15	later than the date that is 60
16	days after the date on which the
17	Secretary publishes the new pat-
18	ent information under paragraph
19	(7)(A)(iii) (unless the Secretary
20	extends the date because of ex-
21	traordinary or unusual cir-
22	cumstances)—
23	"(AA) a certification
24	described in paragraph
25	(2)(A)(vii)(IV) with respect

1	to the patent to which the
2	new patent information re-
3	lates; or
4	"(BB) a statement that
5	any method of use claim of
6	that patent does not claim a
7	use for which the applicant
8	is seeking approval under
9	this subsection in accord-
10	ance with paragraph
11	(2)(A)(viii).
12	"(ff) Unlawful con-
13	DUCT.—The Federal Trade Com-
14	mission determines that the ap-
15	plicant engaged in unlawful con-
16	duct with respect to the applica-
17	tion in violation of section 1 of
18	the Sherman Act (15 U.S.C. 1).
19	"(IV) Subsequent applica-
20	TION.—The term 'subsequent applica-
21	tion' means an application for ap-
22	proval of a drug that is filed subse-
23	quent to the filing of a first applica-
24	tion for approval of that drug.

1	"(ii) Forfeiture of 180-day pe-
2	RIOD.—
3	"(I) IN GENERAL.—Except as
4	provided in subclause (II), if a for-
5	feiture event occurs with respect to a
6	first application—
7	"(aa) the 180-day period
8	under subparagraph (B)(v) shall
9	be forfeited by the first applicant;
10	and
11	"(bb) any subsequent appli-
12	cation shall become effective as
13	provided under clause (i), (ii),
14	(iii), or (iv) of subparagraph (B),
15	and clause (v) of subparagraph
16	(B) shall not apply to the subse-
17	quent application.
18	"(II) Forfeiture to first
19	SUBSEQUENT APPLICANT.—If the sub-
20	sequent application that is the first to
21	be made effective under subclause (I)
22	was the first among a number of sub-
23	sequent applications to be filed—
24	"(aa) that first subsequent
25	application shall be treated as

1	the first application under this
2	subparagraph (including sub-
3	clause (I)) and as the previous
4	application under subparagraph
5	(B)(v); and
6	"(bb) any other subsequent
7	applications shall become effec-
8	tive as provided under clause (i),
9	(ii), (iii), or (iv) of subparagraph
10	(B), but clause (v) of subpara-
11	graph (B) shall apply to any such
12	subsequent application.
13	"(iii) Availability.—The 180-day
14	period under subparagraph (B)(v) shall be
15	available to a first applicant submitting an
16	application for a drug with respect to any
17	patent without regard to whether an appli-
18	cation has been submitted for the drug
19	under this subsection containing such a
20	certification with respect to a different pat-
21	ent.
22	"(iv) Applicability.—The 180-day
23	period described in subparagraph (B)(v)
24	shall apply to an application only if a civil
25	action is brought against the applicant for

1	infringement of a patent that is the subject
2	of the certification.".
3	(b) APPLICABILITY.—The amendment made by sub-
4	section (a) shall be effective only with respect to an appli-
5	cation filed under section 505(j) of the Federal Food,
6	Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date
7	of enactment of this Act for a listed drug for which no
8	certification under section $505(j)(2)(A)(vii)(IV)$ of that
9	Act was made before the date of enactment of this Act,
10	except that if a forfeiture event described in section
11	505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of
12	an applicant, the applicant shall forfeit the 180-day period
13	under section $505(j)(5)(B)(v)$ of that Act without regard
14	to when the applicant made a certification under section
15	505(j)(2)(A)(vii)(IV) of that Act.
16	SEC. 106. FAIR TREATMENT FOR INNOVATORS.
17	(a) Basis for Application.—Section 505 of the
18	Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
19	is amended—
20	(1) in subsection (b)(3)(B), by striking the sec-
21	ond sentence and inserting "The notice shall include
22	a detailed statement of the factual and legal basis of
23	the applicant's opinion that, as of the date of the no-
24	tice, the patent is not valid or is not infringed, and
25	shall include, as appropriate for the relevant patent,

a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation."; and

(2) in subsection (j)(2)(B)(ii), by striking the second sentence and inserting "The notice shall include a detailed statement of the factual and legal basis of the opinion of the applicant that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation."

- 1 (b) Injunctive Relief.—Section 505(j)(5)(B) of 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3 355(j)(5)(B)) (as amended by section 4(a)(1)) is 4 amended—
- 5 (1) in clause (iii), by adding at the end the fol-6 lowing: "A court shall not regard the extent of the 7 ability of an applicant to pay monetary damages as 8 a whole or partial basis on which to deny a prelimi-9 nary or permanent injunction under this clause."; 10 and
- 11 (2) in clause (iv), by adding at the end the following:
- 13 "(IV) Injunctive relief.—A court shall 14 not regard the extent of the ability of an appli-15 cant to pay monetary damages as a whole or 16 partial basis on which to deny a preliminary or 17 permanent injunction under this clause.".

18 SEC. 107. BIOEQUIVALENCE.

- 19 (a) In General.—The amendments to part 320 of
- 20 title 21, Code of Federal Regulations, promulgated by the
- 21 Commissioner of Food and Drugs on July 17, 1991 (57
- 22 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
- 23 as an exercise of authorities under sections 501, 502, 505,
- 24 and 701 of the Federal Food, Drug, and Cosmetic Act
- 25 (21 U.S.C. 351, 352, 355, 371).

- 1 (b) Effect.—Subsection (a) does not affect the au-
- 2 thority of the Commissioner of Food and Drugs to amend
- 3 part 320 of title 21, Code of Federal Regulations.
- 4 (c) Effect of Section.—This section shall not be
- 5 construed to alter the authority of the Secretary of Health
- 6 and Human Services to regulate biological products under
- 7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301)
- 8 et seq.). Any such authority shall be exercised under that
- 9 Act as in effect on the day before the date of enactment
- 10 of this Act.

11 SEC. 108. REPORT.

- 12 (a) IN GENERAL.—Not later than the date that is
- 13 5 years after the date of enactment of this Act, the Fed-
- 14 eral Trade Commission shall submit to Congress a report
- 15 describing the extent to which implementation of the
- 16 amendments made by this title—
- 17 (1) has enabled products to come to market in
- a fair and expeditious manner, consistent with the
- rights of patent owners under intellectual property
- 20 law; and
- 21 (2) has promoted lower prices of drugs and
- greater access to drugs through price competition.
- 23 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
- 24 authorized to be appropriated to carry out this section
- 25 \$5,000,000.

1	SEC. 109. CONFORMING AND TECHNICAL AMENDMENTS.
2	(a) Section 505.—Section 505 of the Federal Food,
3	Drug, and Cosmetic Act (21 U.S.C. 355) is amended—
4	(1) in subsection (a), by striking "(a) No per-
5	son" and inserting "(a) In General.—No person";
6	(2) in subsection (b)—
7	(A) by striking "(b)(1) Any person" and
8	inserting the following:
9	"(b) Applications.—
10	"(1) Requirements.—
11	"(A) IN GENERAL.—Any person";
12	(B) in paragraph (1)—
13	(i) in the second sentence—
14	(I) by redesignating subpara-
15	graphs (A) through (F) as clauses (i)
16	through (vi), respectively, and adjust-
17	ing the margins appropriately;
18	(II) by striking "Such persons"
19	and inserting the following:
20	"(B) Information to be submitted
21	WITH APPLICATION.—A person that submits an
22	application under subparagraph (A)"; and
23	(III) by striking "application"
24	and inserting "application—";
25	(ii) by striking the third through fifth
26	sentences; and

1	(iii) in the sixth sentence—
2	(I) by striking "The Secretary"
3	and inserting the following:
4	"(C) GUIDANCE.—The Secretary"; and
5	(II) by striking "clause (A)" and
6	inserting "subparagraph (B)(i)"; and
7	(C) in paragraph (2)—
8	(i) by striking "clause (A) of such
9	paragraph" and inserting "paragraph
10	(1)(B)(i)";
11	(ii) in subparagraphs (A) and (B), by
12	striking "paragraph (1) or"; and
13	(iii) in subparagraph (B)—
14	(I) by striking "paragraph
15	(1)(A)" and inserting "paragraph
16	(1)(B)(i)"; and
17	(II) by striking "patent" each
18	place it appears and inserting
19	"claim"; and
20	(3) in subsection (c)—
21	(A) in paragraph (3)—
22	(i) in subparagraph (A)—
23	(I) by striking "(A) If the appli-
24	cant" and inserting the following:

1	"(A) CLAUSE (i) OR (ii) CERTIFICATION.—
2	If the applicant"; and
3	(II) by striking "may" and in-
4	serting "shall";
5	(ii) in subparagraph (B)—
6	(I) by striking "(B) If the appli-
7	cant" and inserting the following:
8	"(B) CLAUSE (iii) CERTIFICATION.—If the
9	applicant"; and
10	(II) by striking "may" and in-
11	serting "shall";
12	(iii) by redesignating subparagraph
13	(D) as subparagraph (E); and
14	(iv) in subparagraph (E) (as redesig-
15	nated by clause (iii)), by striking "clause
16	(A) of subsection (b)(1)" each place it ap-
17	pears and inserting "subsection
18	(b)(1)(B)(i)"; and
19	(B) by redesignating paragraph (4) as
20	paragraph (5); and
21	(4) in subsection (j)—
22	(A) in paragraph (2)(A)—
23	(i) in clause (vi), by striking "clauses
24	(B) through ((F)" and inserting "sub-

1	clauses (ii) through (vi) of subsection
2	(b)(1)";
3	(ii) in clause (vii), by striking "(b)
4	or''; and
5	(iii) in clause (viii)—
6	(I) by striking "(b) or"; and
7	(II) by striking "patent" each
8	place it appears and inserting
9	"claim"; and
10	(B) in paragraph (5)—
11	(i) in subparagraph (B)—
12	(I) in clause (i)—
13	(aa) by striking "(i) If the
14	applicant" and inserting the fol-
15	lowing:
16	"(i) Subclause (i) or (ii) certifi-
17	CATION.—If the applicant"; and
18	(bb) by striking "may" and
19	inserting "shall";
20	(II) in clause (ii)—
21	(aa) by striking "(ii) If the
22	applicant" and inserting the fol-
23	lowing:
24	"(i) Subclause (III) certifi-
25	CATION.—If the applicant"; and

```
(bb) by striking "may" and
 1
 2
                           inserting "shall";
 3
                           (III) in clause (iii), by striking
                       "(2)(B)(i)" each place it appears and
 4
                      inserting "(2)(B)"; and
 5
                           (IV) in clause (v) (as redesig-
 6
 7
                      nated by section 4(a)(1)(B), by strik-
                      ing "continuing" and inserting "con-
 8
 9
                      taining"; and
10
                       (ii) by redesignating subparagraphs
11
                  (C) and (D) as subparagraphs (E) and
12
                  (F), respectively.
13
        (b) Section 505A.—Section 505A of the Federal
   Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
14
15
    amended—
16
             (1)
                    in
                          subsections
                                         (b)(1)(A)(i)
                                                        and
17
        (c)(1)(A)(i)—
18
                  (A) by striking "(c)(3)(D)(ii)" each place
19
             it appears and inserting "(c)(3)(E)(ii)"; and
                  (B) by striking "(j)(5)(D)(ii)" each place
20
             it appears and inserting "(j)(5)(F)(ii)";
21
22
             (2)
                    in
                          subsections
                                        (b)(1)(A)(ii)
                                                        and
23
        (c)(1)(A)(ii)—
24
                  (A) by striking "(c)(3)(D)" each place it
25
             appears and inserting "(c)(3)(E)"; and
```

1	(B) by striking "(j)(5)(D)" each place it
2	appears and inserting " $(j)(5)(F)$ ";
3	(3) in subsections (e) and (l)—
4	(A) by striking "505(c)(3)(D)" each place
5	it appears and inserting " $505(c)(3)(E)$ "; and
6	(B) by striking " $505(j)(5)(D)$ " each place
7	it appears and inserting " $505(j)(5)(F)$ "; and
8	(4) in subsection (k), by striking
9	" $505(j)(5)(B)(iv)$ " and inserting " $505(j)(5)(B)(v)$ ".
10	(c) Section 527.—Section 527(a) of the Federal
11	Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is
12	amended in the second sentence by striking " $505(c)(2)$ "
13	and inserting " $505(c)(1)(B)$ ".
14	TITLE II—IMPORTATION OF
14 15	PRESCRIPTION DRUGS
15	PRESCRIPTION DRUGS
15 16 17	PRESCRIPTION DRUGS SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS.
15 16 17	PRESCRIPTION DRUGS SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS. (a) IN GENERAL.—Chapter VIII of the Federal
15 16 17 18	PRESCRIPTION DRUGS SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS. (a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
15 16 17 18	PRESCRIPTION DRUGS SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS. (a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the fol-
115 116 117 118 119 220	PRESCRIPTION DRUGS SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS. (a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:
115 116 117 118 119 220 221	PRESCRIPTION DRUGS. SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS. (a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following: "SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

1	"(2) Pharmacist.—The term 'pharmacist'
2	means a person licensed by a State to practice phar-
3	macy, including the dispensing and selling of pre-
4	scription drugs.
5	"(3) Prescription drug.—The term 'pre-
6	scription drug' means a drug subject to section
7	503(b), other than—
8	"(A) a controlled substance (as defined in
9	section 102 of the Controlled Substances Act
10	(21 U.S.C. 802));
11	"(B) a biological product (as defined in
12	section 351 of the Public Health Service Act
13	(42 U.S.C. 262));
14	"(C) an infused drug (including a peri-
15	toneal dialysis solution);
16	"(D) an intravenously injected drug; or
17	"(E) a drug that is inhaled during surgery.
18	"(4) QUALIFYING LABORATORY.—The term
19	'qualifying laboratory' means a laboratory in the
20	United States that has been approved by the Sec-
21	retary for the purposes of this section.
22	"(5) Wholesaler.—
23	"(A) IN GENERAL.—The term 'wholesaler'
24	means a person licensed as a wholesaler or dis-

1	tributor of prescription drugs in the United
2	States under section 503(e)(2)(A).
3	"(B) Exclusion.—The term 'wholesaler'
4	does not include a person authorized to import
5	drugs under section $801(d)(1)$.
6	"(b) Regulations.—The Secretary, after consulta-
7	tion with the United States Trade Representative and the
8	Commissioner of Customs, shall promulgate regulations
9	permitting pharmacists and wholesalers to import pre-
10	scription drugs from Canada into the United States.
11	"(c) Limitation.—The regulations under subsection
12	(b) shall—
13	"(1) require that safeguards be in place to en-
14	sure that each prescription drug imported under the
15	regulations complies with section 505 (including
16	with respect to being safe and effective for the in-
17	tended use of the prescription drug), with sections
18	501 and 502, and with other applicable require-
19	ments of this Act;
20	"(2) require that an importer of a prescription
21	drug under the regulations comply with subsections
22	(d)(1) and (e); and
23	"(3) contain any additional provisions deter-
24	mined by the Secretary to be appropriate as a safe-

1	guard to protect the public health or as a means to
2	facilitate the importation of prescription drugs.
3	"(d) Information and Records.—
4	"(1) In general.—The regulations under sub-
5	section (b) shall require an importer of a prescrip-
6	tion drug under subsection (b) to submit to the Sec-
7	retary the following information and documentation:
8	"(A) The name and quantity of the active
9	ingredient of the prescription drug.
10	"(B) A description of the dosage form of
11	the prescription drug.
12	"(C) The date on which the prescription
13	drug is shipped.
14	"(D) The quantity of the prescription drug
15	that is shipped.
16	"(E) The point of origin and destination of
17	the prescription drug.
18	"(F) The price paid by the importer for
19	the prescription drug.
20	"(G) Documentation from the foreign sell-
21	er specifying—
22	"(i) the original source of the pre-
23	scription drug; and

1	"(ii) the quantity of each lot of the
2	prescription drug originally received by the
3	seller from that source.
4	"(H) The lot or control number assigned
5	to the prescription drug by the manufacturer of
6	the prescription drug.
7	"(I) The name, address, telephone number,
8	and professional license number (if any) of the
9	importer.
10	"(J)(i) In the case of a prescription drug
11	that is shipped directly from the first foreign
12	recipient of the prescription drug from the
13	manufacturer:
14	"(I) Documentation demonstrating
15	that the prescription drug was received by
16	the recipient from the manufacturer and
17	subsequently shipped by the first foreign
18	recipient to the importer.
19	"(II) Documentation of the quantity
20	of each lot of the prescription drug re-
21	ceived by the first foreign recipient dem-
22	onstrating that the quantity being im-
23	ported into the United States is not more
24	than the quantity that was received by the
25	first foreign recipient.

1	"(III)(aa) In the case of an initial im-
2	ported shipment, documentation dem-
3	onstrating that each batch of the prescrip-
4	tion drug in the shipment was statistically
5	sampled and tested for authenticity and
6	degradation.
7	"(bb) In the case of any subsequent
8	shipment, documentation demonstrating
9	that a statistically valid sample of the ship-
10	ment was tested for authenticity and deg-
11	radation.
12	"(ii) In the case of a prescription drug
13	that is not shipped directly from the first for-
14	eign recipient of the prescription drug from the
15	manufacturer, documentation demonstrating
16	that each batch in each shipment offered for
17	importation into the United States was statis-
18	tically sampled and tested for authenticity and
19	degradation.
20	"(K) Certification from the importer or
21	manufacturer of the prescription drug that the
22	prescription drug—
23	"(i) is approved for marketing in the
24	United States; and

1	"(ii) meets all labeling requirements
2	under this Act.
3	"(L) Laboratory records, including com-
4	plete data derived from all tests necessary to
5	ensure that the prescription drug is in compli-
6	ance with established specifications and stand-
7	ards.
8	"(M) Documentation demonstrating that
9	the testing required by subparagraphs (J) and
10	(L) was conducted at a qualifying laboratory.
11	"(N) Any other information that the Sec-
12	retary determines is necessary to ensure the
13	protection of the public health.
14	"(2) Maintenance by the secretary.—The
15	Secretary shall maintain information and docu-
16	mentation submitted under paragraph (1) for such
17	period of time as the Secretary determines to be nec-
18	essary.
19	"(e) Testing.—The regulations under subsection (b)
20	shall require—
21	"(1) that testing described in subparagraphs
22	(J) and (L) of subsection (d)(1) be conducted by the
23	importer or by the manufacturer of the prescription
24	drug at a qualified laboratory:

1	"(2) if the tests are conducted by the
2	importer—
3	"(A) that information needed to—
4	"(i) authenticate the prescription drug
5	being tested; and
6	"(ii) confirm that the labeling of the
7	prescription drug complies with labeling re-
8	quirements under this Act;
9	be supplied by the manufacturer of the pre-
10	scription drug to the pharmacist or wholesaler;
11	and
12	"(B) that the information supplied under
13	subparagraph (A) be kept in strict confidence
14	and used only for purposes of testing or other-
15	wise complying with this Act; and
16	"(3) may include such additional provisions as
17	the Secretary determines to be appropriate to pro-
18	vide for the protection of trade secrets and commer-
19	cial or financial information that is privileged or
20	confidential.
21	"(f) Registration of Foreign Sellers.—Any es-
22	tablishment within Canada engaged in the distribution of
23	a prescription drug that is imported or offered for impor-
24	tation into the United States shall register with the Sec-

- 1 retary the name and place of business of the establish-
- 2 ment.
- 3 "(g) Suspension of Importation.—The Secretary
- 4 shall require that importations of a specific prescription
- 5 drug or importations by a specific importer under sub-
- 6 section (b) be immediately suspended on discovery of a
- 7 pattern of importation of the prescription drugs or by the
- 8 importer that is counterfeit or in violation of any require-
- 9 ment under this section or poses an additional risk to the
- 10 public health, until an investigation is completed and the
- 11 Secretary determines that the public is adequately pro-
- 12 tected from counterfeit and violative prescription drugs
- 13 being imported under subsection (b).
- 14 "(h) APPROVED LABELING.—The manufacturer of a
- 15 prescription drug shall provide an importer written au-
- 16 thorization for the importer to use, at no cost, the ap-
- 17 proved labeling for the prescription drug.
- 18 "(i) Prohibition of Discrimination.—
- 19 "(1) IN GENERAL.—It shall be unlawful for a
- 20 manufacturer of a prescription drug to discriminate
- against, or cause any other person to discriminate
- against, a pharmacist or wholesaler that purchases
- or offers to purchase a prescription drug from the
- 24 manufacturer or from any person that distributes a

1 prescription drug manufactured by the drug manu-2 facturer.

"(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

- "(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or
- "(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.
- "(j) CHARITABLE CONTRIBUTIONS.—Notwith-21 standing any other provision of this section, section 22 801(d)(1) continues to apply to a prescription drug that 23 is donated or otherwise supplied at no charge by the man-24 ufacturer of the drug to a charitable or humanitarian or-

1	ganization (including the United Nations and affiliates)
2	or to a government of a foreign country.
3	"(k) Waiver Authority for Importation by In-
4	DIVIDUALS.—
5	"(1) Declarations.—Congress declares that
6	in the enforcement against individuals of the prohi-
7	bition of importation of prescription drugs and de-
8	vices, the Secretary should—
9	"(A) focus enforcement on cases in which
10	the importation by an individual poses a signifi-
11	cant threat to public health; and
12	"(B) exercise discretion to permit individ-
13	uals to make such importations in cir-
14	cumstances in which—
15	"(i) the importation is clearly for per-
16	sonal use; and
17	"(ii) the prescription drug or device
18	imported does not appear to present an
19	unreasonable risk to the individual.
20	"(2) Waiver authority.—
21	"(A) IN GENERAL.—The Secretary may
22	grant to individuals, by regulation or on a case-
23	by-case basis, a waiver of the prohibition of im-
24	portation of a prescription drug or device or
25	class of prescription drugs or devices, under

1	such conditions as the Secretary determines to
2	be appropriate.
3	"(B) GUIDANCE ON CASE-BY-CASE WAIV-
4	ERS.—The Secretary shall publish, and update
5	as necessary, guidance that accurately describes
6	circumstances in which the Secretary will con-
7	sistently grant waivers on a case-by-case basis
8	under subparagraph (A), so that individuals
9	may know with the greatest practicable degree
10	of certainty whether a particular importation
11	for personal use will be permitted.
12	"(3) Drugs imported from canada.—In
13	particular, the Secretary shall by regulation grant
14	individuals a waiver to permit individuals to import
15	into the United States a prescription drug that—
16	"(A) is imported from a licensed pharmacy
17	for personal use by an individual, not for resale,
18	in quantities that do not exceed a 90-day sup-
19	ply;
20	"(B) is accompanied by a copy of a valid
21	prescription;
22	"(C) is imported from Canada, from a sell-
23	er registered with the Secretary;
24	"(D) is a prescription drug approved by
25	the Secretary under chapter V;

1	"(E) is in the form of a final finished dos-
2	age that was manufactured in an establishment
3	registered under section 510; and
4	"(F) is imported under such other condi-
5	tions as the Secretary determines to be nec-
6	essary to ensure public safety.
7	"(l) Studies; Reports.—
8	"(1) By the institute of medicine of the
9	NATIONAL ACADEMY OF SCIENCES.—
10	"(A) Study.—
11	"(i) In General.—The Secretary
12	shall request that the Institute of Medicine
13	of the National Academy of Sciences con-
14	duct a study of—
15	"(I) importations of prescription
16	drugs made under the regulations
17	under subsection (b); and
18	"(II) information and docu-
19	mentation submitted under subsection
20	(d).
21	"(ii) Requirements.—In conducting
22	the study, the Institute of Medicine shall—
23	"(I) evaluate the compliance of
24	importers with the regulations under
25	subsection (b);

1	"(II) compare the number of
2	shipments under the regulations
3	under subsection (b) during the study
4	period that are determined to be
5	counterfeit, misbranded, or adulter-
6	ated, and compare that number with
7	the number of shipments made during
8	the study period within the United
9	States that are determined to be
10	counterfeit, misbranded, or adulter-
11	ated; and
12	"(III) consult with the Secretary,
13	the United States Trade Representa-
14	tive, and the Commissioner of Patents
15	and Trademarks to evaluate the effect
16	of importations under the regulations
17	under subsection (b) on trade and
18	patent rights under Federal law.
19	"(B) Report.—Not later than 2 years
20	after the effective date of the regulations under
21	subsection (b), the Institute of Medicine shall
22	submit to Congress a report describing the find-
23	ings of the study under subparagraph (A).
24	"(2) By the comptroller general.—

1	"(A) STUDY.—The Comptroller General of
2	the United States shall conduct a study to de-
3	termine the effect of this section on the price of
4	prescription drugs sold to consumers at retail.
5	"(B) Report.—Not later than 18 months
6	after the effective date of the regulations under
7	subsection (b), the Comptroller General of the
8	United States shall submit to Congress a report
9	describing the findings of the study under sub-
10	paragraph (A).
11	"(m) Construction.—Nothing in this section limits
12	the authority of the Secretary relating to the importation
13	of prescription drugs, other than with respect to section
14	801(d)(1) as provided in this section.
15	"(n) AUTHORIZATION OF APPROPRIATIONS.—There
16	are authorized to be appropriated such sums as are nec-
17	essary to carry out this section.
18	"(o) Conditions.—This section shall become effec-
19	tive only if the Secretary of Health and Human Services
20	certifies to the Congress that the implementation of this
21	section will—
22	"(A) pose no additional risk to the public's
23	health and safety, and
24	"(B) result in a significant reduction in the cost
25	of covered products to the American consumer.".

1	(b) Conforming Amendments.—The Federal
2	Food, Drug, and Cosmetic Act is amended—
3	(1) in section 301(aa) (21 U.S.C. 331(aa)), by
4	striking "covered product in violation of section
5	804" and inserting "prescription drug in violation of
6	section 804"; and
7	(2) in section 303(a)(6) (21 U.S.C. 333(a)(6),
8	by striking "covered product pursuant to section
9	804(a)" and inserting "prescription drug under sec-
10	tion 804(b)".
11	SEC. 202. CLARIFICATION OF STATE AUTHORITY RELATING
12	TO MEDICAID DRUG REBATE AGREEMENTS.
13	Section 1927 of the Social Security Act (42 U.S.C.
	Section 1927 of the Social Security Act (42 U.S.C. 1396r-8) is amended by adding at the end the following:
13	
13 14	1396r-8) is amended by adding at the end the following:
13 14 15	1396r-8) is amended by adding at the end the following: "(l) Rule of Construction.—Nothing in this sec-
13 14 15 16	1396r-8) is amended by adding at the end the following: "(l) Rule of Construction.—Nothing in this section shall be construed as prohibiting a State from—
13 14 15 16 17	1396r-8) is amended by adding at the end the following: "(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from— "(1) directly entering into rebate agreements
13 14 15 16 17	1396r-8) is amended by adding at the end the following: "(l) Rule of Construction.—Nothing in this section shall be construed as prohibiting a State from— "(1) directly entering into rebate agreements (on the State's own initiative or under a section
13 14 15 16 17 18	1396r-8) is amended by adding at the end the following: "(1) Rule of Construction.—Nothing in this section shall be construed as prohibiting a State from— "(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on,
13 14 15 16 17 18 19 20	1396r-8) is amended by adding at the end the following: "(I) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from— "(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection)
13 14 15 16 17 18 19 20 21	1396r-8) is amended by adding at the end the following: "(l) Rule of Construction.—Nothing in this section shall be construed as prohibiting a State from— "(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection) that are similar to a rebate agreement described in

- residents of a State who are not otherwise eligible for medical assistance under this title; or
- "(2) making prior authorization (that satisfies
 the requirements of subsection (d) and that does not
 violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State
 program under this title) a condition of not participating in such a similar rebate agreement.".

10 SEC. 203. TEMPORARY STATE FISCAL RELIEF.

- (a) Temporary Increase of Medicaid FMAP.—
- 12 (1)PERMITTING MAINTENANCE OF 13 YEAR 2001 FMAP FOR LAST 2 CALENDAR QUARTERS 14 OF FISCAL YEAR 2002.—Notwithstanding any other 15 provision of law, but subject to paragraph (5), if the 16 FMAP determined without regard to this subsection 17 for a State for fiscal year 2002 is less than the 18 FMAP as so determined for fiscal year 2001, the 19 FMAP for the State for fiscal year 2001 shall be 20 substituted for the State's FMAP for the third and 21 fourth calendar quarters of fiscal year 2002, before 22 the application of this subsection.
 - (2) PERMITTING MAINTENANCE OF FISCAL YEAR 2002 FMAP FOR FISCAL YEAR 2003.—Notwithstanding any other provision of law, but subject to

11

23

24

- paragraph (5), if the FMAP determined without regard to this subsection for a State for fiscal year 2003 is less than the FMAP as so determined for fiscal year 2002, the FMAP for the State for fiscal year 2002 shall be substituted for the State's FMAP for each calendar quarter of fiscal year 2003, before the application of this subsection.
 - (3) GENERAL 1.35 PERCENTAGE POINTS INCREASE FOR LAST 2 CALENDAR QUARTERS OF FISCAL YEAR 2002 AND FISCAL YEAR 2003.—Notwithstanding any other provision of law, but subject to paragraphs (5) and (6), for each State for the third and fourth calendar quarters of fiscal year 2002 and each calendar quarter of fiscal year 2003, the FMAP (taking into account the application of paragraphs (1) and (2)) shall be increased by 1.35 percentage points.
 - (4) Increase in Cap on Medicaid Payments to territories.—Notwithstanding any other provision of law, but subject to paragraph (6), with respect to the third and fourth calendar quarters of fiscal year 2002 and each calendar quarter of fiscal year 2003, the amounts otherwise determined for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under

- subsections (f) and (g) of section 1108 of the Social Security Act (42 U.S.C. 1308) shall each be increased by an amount equal to 2.7 percent of such amounts.
 - (5) Scope of application.—The increases in the FMAP for a State under this subsection shall apply only for purposes of title XIX of the Social Security Act and shall not apply with respect to—
 - (A) disproportionate share hospital payments described in section 1923 of such Act (42 U.S.C. 1396r-4); or
 - (B) payments under title IV or XXI of such Act (42 U.S.C. 601 et seq. and 1397aa et seq.).

(6) State eligibility.—

(A) IN GENERAL.—Subject to subparagraph (B), a State is eligible for an increase in its FMAP under paragraph (3) or an increase in a cap amount under paragraph (4) only if the eligibility under its State plan under title XIX of the Social Security Act (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) is no more restrictive than the eligibility under such plan (or waiver) as in effect on January 1, 2002.

- 1 STATE REINSTATEMENT OF ELIGI-2 BILITY PERMITTED.—A State that has re-3 stricted eligibility under its State plan under 4 title XIX of the Social Security Act (including 5 any waiver under such title or under section 6 1115 of such Act (42 U.S.C. 1315)) after Jan-7 uary 1, 2002, but prior to the date of enact-8 ment of this Act is eligible for an increase in its 9 FMAP under paragraph (3) or an increase in 10 a cap amount under paragraph (4) in the first calendar quarter (and subsequent calendar 12 quarters) in which the State has reinstated eli-13 gibility that is no more restrictive than the eli-14 gibility under such plan (or waiver) as in effect 15 on January 1, 2002.
 - (C) Rule of Construction.—Nothing in subparagraph (A) or (B) shall be construed as affecting a State's flexibility with respect to benefits offered under the State medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)).
- 24 (7) Definitions.—In this subsection:

11

16

17

18

19

20

21

22

1	(A) FMAP.—The term "FMAP" means
2	the Federal medical assistance percentage, as
3	defined in section 1905(b) of the Social Secu-
4	rity Act (42 U.S.C. 1396d(b)).
5	(B) STATE.—The term "State" has the
6	meaning given such term for purposes of title
7	XIX of the Social Security Act (42 U.S.C. 1396
8	et seq.).
9	(8) Repeal.—Effective as of October 1, 2003,
10	this subsection is repealed.
11	(b) Additional Temporary State Fiscal Re-
12	LIEF.—
13	(1) IN GENERAL.—Title XX of the Social Secu-
14	rity Act (42 U.S.C. 1397–1397f) is amended by
15	adding at the end the following:
16	"SEC. 2008. ADDITIONAL TEMPORARY GRANTS FOR STATE
17	FISCAL RELIEF.
18	"(a) In General.—For the purpose of providing
19	State fiscal relief allotments to States under this section,
20	there are hereby appropriated, out of any funds in the
21	Treasury not otherwise appropriated, \$3,000,000,000.
22	Such funds shall be available for obligation by the State
23	through June 30, 2004, and for expenditure by the State
24	through September 30, 2004. This section constitutes
25	budget authority in advance of appropriations Acts and

- 1 represents the obligation of the Federal Government to
- 2 provide for the payment to States of amounts provided
- 3 under this section.
- 4 "(b) Allotment.—Funds appropriated under sub-
- 5 section (a) shall be allotted by the Secretary among the
- 6 States in accordance with the following table:

"State	Allotment (in dollars)
Alabama	\$33,918,100
Alaska	\$8,488,200
Amer. Samoa	\$88,600
Arizona	\$47,601,600
Arkansas	\$27,941,800
California	\$314,653,900
Colorado	\$27,906,200
Connecticut	\$41,551,200
Delaware	\$8,306,000
District of Columbia	\$12,374,400
Florida	\$128,271,100
Georgia	\$69,106,600
Guam	\$135,900
Hawaii	\$9,914,700
Idaho	\$10,293,600
Illinois	\$102,577,900
Indiana	\$50,659,800
Iowa	\$27,799,700
Kansas	\$21,414,300
Kentucky	\$44,508,400
Louisiana	\$50,974,000
Maine	\$17,841,100
Maryland	\$44,228,800
Massachusetts	\$100,770,700
Michigan	\$91,196,800
Minnesota	\$57,515,400
Mississippi	\$35,978,500
Missouri	\$62,189,600
Montana	\$8,242,000
Nebraska	\$16,671,600
Nevada	\$10,979,700
New Hampshire	\$10,549,400
New Jersey	\$87,577,300
New Mexico	\$21,807,600
New York	\$461,401,900
North Carolina	\$79,538,300
North Dakota	\$5,716,900
N. Mariana Islands	\$50,000
Ohio	\$116,367,800
Oklahoma	\$30,941,800
Oregon	\$34,327,200
Pennsylvania	\$159,089,700
Puerto Rico	\$3,991,900
Rhode Island South Carolina	\$16,594,100
South Caronna South Dakota	\$38,238,000
	\$6,293,700
Tennessee	\$81,120,000
Texas Utah	\$159,779,800
	\$12,551,700
Vermont Virgin Islands	\$8,003,800
Virgin Islands	\$128,800 \$44,288,300
Virginia Washington	
Washington West Virginia	\$66,662,200 \$19,884,400
West Virginia Wisconsin	\$19,884,400
Wyoming	\$3,776,400
8	, ,
Total	\$3,000,000,000

- 1 "(c) Use of Funds.—Funds appropriated under
- 2 this section may be used by a State for services directed
- 3 at the goals set forth in section 2001, subject to the re-
- 4 quirements of this title.
- 5 "(d) Payment to States.—Not later than 30 days
- 6 after amounts are appropriated under subsection (a), in
- 7 addition to any payment made under section 2002 or
- 8 2007, the Secretary shall make a lump sum payment to
- 9 a State of the total amount of the allotment for the State
- 10 as specified in subsection (b).
- 11 "(e) Definition.—For purposes of this section, the
- 12 term 'State' means the 50 States, the District of Colum-
- 13 bia, and the territories contained in the list under sub-
- 14 section (b).".
- 15 (2) Repeal.—Effective as of January 1, 2005,
- section 2008 of the Social Security Act, as added by
- 17 paragraph (1), is repealed.
- 18 (c) Emergency Designation.—The entire amount
- 19 necessary to carry out this section is designated by Con-
- 20 gress as an emergency requirement pursuant to section

- 1 252(e) of the Balanced Budget and Emergency Deficit
- $2\ \ Control\ Act\ of\ 1985\ (2\ U.S.C.\ 902(e)).$

Passed the Senate July 31, 2002.

Attest:

Secretary.

 $^{\rm 107TH~CONGRESS}_{\rm 2D~SESSION}~S.\,812$

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.