110TH CONGRESS 1ST SESSION S.980

To amend the Controlled Substances Act to address online pharmacies.

IN THE SENATE OF THE UNITED STATES

March 23, 2007

Mrs. FEINSTEIN (for herself and Mr. SESSIONS) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend the Controlled Substances Act to address online pharmacies.

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 "Online Pharmacy Con-

5 sumer Protection Act of 2007".

SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT RELATING TO THE DELIVERY OF CON TROLLED SUBSTANCES BY MEANS OF THE INTERNET.

5 (a) IN GENERAL.—Section 102 of the Controlled
6 Substances Act (21 U.S.C. 802) is amended by adding at
7 the end the following:

"(47) The term 'Internet' means collectively the 8 9 myriad of computer and telecommunications facili-10 ties, including equipment and operating software, 11 which comprise the interconnected worldwide net-12 work of networks that employ the Transmission 13 Control Protocol/Internet Protocol, or any prede-14 cessor or successor protocol to such protocol, to com-15 municate information of all kinds by wire or radio.

"(48) The term 'deliver, distribute, or dispense
by means of the Internet' refers, respectively, to any
delivery, distribution, or dispensing of a controlled
substance that is caused or facilitated by means of
the Internet.

21 "(49) The term 'online pharmacy'—

"(A) means a person, entity, or Internet
site, whether in the United States or abroad,
that delivers, distributes, or dispenses, or offers
to deliver, distribute, or dispense, a controlled
substance by means of the Internet; and

"(B) does not include— 1 2 "(i) manufacturers or distributors 3 registered under subsection (a), (b), (c), or 4 (d) of section 303 who do not dispense 5 controlled substances; 6 "(ii) nonpharmacy practitioners who 7 are registered under section 303(f): "(iii) mere advertisements that do not 8 9 attempt to facilitate an actual transaction 10 involving a controlled substance; or "(iv) a person, entity, or Internet site 11 12 which is not in the United States and does 13 not facilitate the delivery, distribution, or 14 dispensing of a controlled substance by 15 means of the Internet to any person in the 16 United States. 17 "(50) The term 'homepage' means the first 18 page of the website of an online pharmacy that is 19 viewable on the Internet.". 20 (b) REGISTRATION REQUIREMENTS.—Section 303 of 21 the Controlled Substances Act (21 U.S.C. 823) is amend-22 ed by adding at the end the following new subsection: 23 "(i) Dispenser of Controlled Substances by MEANS OF THE INTERNET.—(1) A pharmacy that seeks 24

to deliver, distribute, or dispense by means of the Internet

a controlled substance shall obtain a registration specifi cally authorizing such activity, in accordance with regula tions promulgated by the Attorney General. In deter mining whether to grant an application for such registra tion, the Attorney General shall apply the factors set forth
 in subsection (f).

7 "(2) Registration under this subsection shall be in
8 addition to, and not in lieu of, registration under sub9 section (f).

"(3) This subsection does not apply to pharmacies
that merely advertise by means of the Internet but do not
attempt to facilitate an actual transaction involving a controlled substance by means of the Internet.".

14 (c) REPORTING REQUIREMENTS.—Section 307(d) of
15 the Controlled Substances Act (21 U.S.C. 827(d)) is
16 amended by—

(1) designating the text as paragraph (1); and
(2) inserting after paragraph (1), as so designated by this Act, the following new paragraph:

"(2) A pharmacy registered under section 303(i) shall
report to the Attorney General the controlled substances
dispensed under such registration, in such manner and accompanied by such information as the Attorney General
by regulation shall require.".

(d) ONLINE PRESCRIPTION REQUIREMENT.—Section
 309 of the Controlled Substances Act (21 U.S.C. 829) is
 amended by adding at the end the following new sub section:

5 "(e) CONTROLLED SUBSTANCES DISPENSED BY
6 MEANS OF THE INTERNET.—(1) As used in this sub7 section—

8 "(A) the term 'valid prescription' means a pre-9 scription that is issued for a legitimate medical pur-10 pose in the usual course of professional practice that 11 is based upon a qualifying medical relationship by a 12 practitioner registered by the Attorney General 13 under this part;

14 "(B) the term 'qualifying medical relation15 ship'—

16 "(i) means a medical relationship that ex-17 ists when the practitioner—

18 "(I) has conducted at least one med19 ical evaluation with the user in the phys20 ical presence of the practitioner, without
21 regard to whether portions of the evalua22 tion are conducted by other health profes23 sionals; or

24 "(II) conducts a medical evaluation of25 the patient as a covering practitioner and

1	is not prescribing a controlled substance in
2	schedule II, III, or IV; and
3	"(ii) shall not be construed to imply that
4	one medical evaluation described in clause (i)
5	demonstrates that a prescription has been
6	issued for a legitimate medical purpose within
7	the usual course of professional practice; and
8	"(C) the term 'covering practitioner' means,
9	with respect to a patient, a practitioner who con-
10	ducts a medical evaluation, without regard to wheth-
11	er the medical evaluation of the patient involved is
12	an in-person evaluation, at the request of a practi-
13	tioner who has conducted at least one in-person
14	medical evaluation of the patient and is temporarily
15	unavailable to conduct the evaluation of the patient.
16	((2) In addition to the requirements of subsections
17	(a) through (c), no controlled substance may be delivered,
18	distributed, or dispensed by means of the Internet without
19	a valid prescription.
20	"(3) Nothing in this subsection shall apply to—
21	"(A) the dispensing of a controlled substance
22	pursuant to telemedicine practices sponsored by—
23	"(i) a hospital that has in effect a provider
24	agreement under title XVIII of the Social Secu-
25	rity Act; or

1	"(ii) a group practice that has not fewer
2	than 100 physicians who have in effect provider
3	agreements under such title; or
4	"(B) the dispensing or selling of a controlled
5	substance pursuant to practices as determined by
6	the Attorney General by regulation.".
7	(e) Online Prescription Requirements.—The
8	Controlled Substances Act is amended by adding after sec-
9	tion 310 (21 U.S.C. 830) the following:
10	"ONLINE PHARMACY LICENSING AND DISCLOSURE
11	REQUIREMENTS
12	"Sec. 311. (a) IN GENERAL.—An online pharmacy
13	shall display in a visible and clear manner on its homepage
14	a statement that it complies with the requirements of this
15	section with respect to the delivery or sale or offer for sale
16	of controlled substances and shall at all times display on
17	the homepage of its Internet site a declaration of compli-
18	ance in accordance with this section.
19	"(b) LICENSURE.—Each online pharmacy shall com-
20	ply with the requirements of State law concerning the li-

20 ply with the requirements of State law concerning the li21 censure of pharmacies in each State from which it, and
22 in each State to which it, delivers, distributes, or dispenses
23 or offers to deliver, distribute, or dispense controlled sub24 stances by means of the Internet.

25 "(c) COMPLIANCE.—No online pharmacy or practi26 tioner shall deliver, distribute, or dispense by means of the
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Internet a controlled substance without a valid prescrip tion (as defined in section 309(e)) and each online phar macy shall comply with all applicable requirements of Fed eral and State law.

5 "(d) INTERNET SITE DISCLOSURE INFORMATION.—
6 Each online pharmacy site shall post in a visible and clear
7 manner on the homepage of its Internet site or on a page
8 directly linked from its homepage the following:

9 "(1) The name of the owner, street address of
10 the online pharmacy's principal place of business,
11 telephone number, and email address.

12 "(2) A list of the States in which the online 13 pharmacy, and any pharmacy which dispenses, deliv-14 ers, or distributes a controlled substance on behalf 15 of the online pharmacy, is licensed to dispense con-16 trolled substances or prescription drugs and any ap-17 plicable license number.

"(3) For each pharmacy identified on its license
in each State in which it is licensed to engage in the
practice of pharmacy and for each pharmacy which
dispenses or ships controlled substances on behalf of
the online pharmacy:

23 "(A) The name of the pharmacy.

"(B) The street address of the pharmacy.

1	"(C) The name, professional degree, and
2	licensure of the pharmacist-in-charge.
3	"(D) The telephone number at which the
4	pharmacist-in-charge can be contacted.
5	"(E) A certification that each pharmacy
6	which dispenses or ships controlled substances
7	on behalf of the online pharmacy is registered
8	under this part to deliver, distribute, or dis-
9	pense by means of the Internet controlled sub-
10	stances.
11	"(4) The name, address, professional degree,
12	and licensure of practitioners who provide medical
13	consultations through the website for the purpose of
14	providing prescriptions.
15	"(5) A telephone number or numbers at which
16	the practitioners described in paragraph (4) may be
17	contacted.
18	"(6) The following statement, unless revised by
19	the Attorney General by regulation: 'This online
20	pharmacy will only dispense a controlled substance
21	to a person who has a valid prescription issued for
22	a legitimate medical purpose based upon a medical
23	relationship with a prescribing practitioner, which
24	includes at least one prior in-person medical evalua-
25	tion. This online pharmacy complies with section

309(e) of the Controlled Substances Act (21 U.S.C.
 829(e)).'.

"(e) NOTIFICATION.—(1) Thirty days prior to offering a controlled substance for sale, delivery, distribution,
or dispensing, the online pharmacy shall notify the Attorney General, in the form and manner as the Attorney Genreal shall determine, and the State boards of pharmacy
in any States in which the online pharmacy offers to sell,
deliver, distribute, or dispense controlled substances.

10 "(2) The notification required under paragraph (1)11 shall include—

12 "(A) the information required to be posted on 13 the online pharmacy's Internet site under subsection 14 (d) and shall notify the Attorney General and the 15 applicable State boards of pharmacy, under penalty 16 of perjury, that the information disclosed on its 17 Internet site under to subsection (d) is true and ac-18 curate;

"(B) the online pharmacy's Internet site address and a certification that the online pharmacy
shall notify the Attorney General of any change in
the address at least 30 days in advance; and

23 "(C) the Drug Enforcement Administration
24 registration numbers of any pharmacies and practi25 tioners referred to in subsection (d), as applicable.

"(3) An online pharmacy that is already operational
 as of the effective date of this section, shall notify the At torney General and applicable State boards of pharmacy
 in accordance with this subsection not later than 30 days
 after the effective date of this section.

6 "(f) DECLARATION OF COMPLIANCE.—On and after 7 the date on which it makes the notification under sub-8 section (e), each online pharmacy shall display on the 9 homepage of its Internet site, in such form as the Attorney 10 General shall by regulation require, a declaration that it 11 has made such notification to the Attorney General.

12 "(g) REPORTS.—Any statement, declaration, notifi-13 cation, or disclosure required under this section shall be 14 considered a report required to be kept under this part.". 15 (f)OFFENSES INVOLVING CONTROLLED SUB-STANCES IN SCHEDULES III, IV, AND V.—Section 401(b) 16 17 of the Controlled Substances Act (21 U.S.C. 841(b)) is 18 amended-

19 (1) in paragraph (1)—

20 (A) in subparagraph (C), by striking "1
21 gram of" before "flunitrazepam";

(B) in subparagraph (D), by striking "or
in the case of any controlled substance in
schedule III (other than gamma hydroxybutyric
acid), or 30 milligrams of flunitrazepam"; and

1 (C) by inserting at the end the following: 2 "(E)(i) In the case of any controlled substance 3 in schedule III, such person shall be sentenced to a 4 term of imprisonment of not more than 10 years 5 and if death or serious bodily injury results from the 6 use of such substance shall be sentenced to a term 7 of imprisonment of not more than 20 years, a fine 8 not to exceed the greater of that authorized in ac-9 cordance with the provisions of title 18, or \$500,000 10 if the defendant is an individual or \$2,500,000 if the 11 defendant is other than an individual, or both.

"(ii) If any person commits such a violation 12 13 after a prior conviction for a felony drug offense has 14 become final, such person shall be sentenced to a 15 term of imprisonment of not more than 20 years 16 and if death or serious bodily injury results from the 17 use of such substance shall be sentenced to a term 18 of imprisonment of not more than 30 years, a fine 19 not to exceed the greater of twice that authorized in 20 accordance with the provisions of title 18, or 21 \$1,000,000 if the defendant is an individual or 22 \$5,000,000 if the defendant is other than an indi-23 vidual, or both.

24 "(iii) Any sentence imposing a term of impris-25 onment under this subparagraph shall, in the ab-

1	sence of such a prior conviction, impose a term of
2	supervised release of at least 2 years in addition to
3	such term of imprisonment and shall, if there was
4	such a prior conviction, impose a term of supervised
5	release of at least 4 years in addition to such term
6	of imprisonment";
7	(2) in paragraph (2) by—
8	(A) striking "3 years" and inserting "5
9	years";
10	(B) striking "6 years" and inserting "10
11	years";
12	(C) striking "after one or more prior con-
13	victions" and all that follows through "have be-
14	come final," and inserting "after a prior convic-
15	tion for a felony drug offense has become
16	final,"; and
17	(3) in paragraph (3) by—
18	(A) striking "2 years" and inserting "6
19	years";
20	(B) striking "after one or more convic-
21	tions" and all that follows through "have be-
22	come final," and inserting "after a prior convic-
23	tion for a felony drug offense has become
24	final,"; and

1 (C) adding at the end the following "Any 2 sentence imposing a term of imprisonment 3 under this paragraph may, if there was a prior 4 conviction, impose a term of supervised release 5 of not more than 1 year, in addition to such 6 term of imprisonment."

7 (g) OFFENSES INVOLVING DISPENSING OF CON8 TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—
9 Section 401 of the Controlled Substances Act (21 U.S.C.
10 841) is amended by adding at the end the following:

"(g) OFFENSES INVOLVING DISPENSING OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—
(1) Except as authorized by this title, it shall be unlawful
for any person to knowingly or intentionally cause or facilitate the delivery, distribution, or dispensing by means
of the Internet of a controlled substance.

17 "(2) Violations of this subsection include—

"(A) delivering, distributing, or dispensing a
controlled substance by means of the Internet by a
pharmacy not registered under section 303(i);

"(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or
dispensation by means of the Internet in violation of
subsection 309(e);

1	"(C) serving as an agent, intermediary, or other
2	entity that causes the Internet to be used to bring
3	together a buyer and seller to engage in the dis-
4	pensing of a controlled substance in a manner not
5	authorized by sections 303(i) or 309(e); and
6	"(D) making a material false, fictitious, or
7	fraudulent statement or representation in the sub-
8	mission to the Attorney General under section 311.
9	"(3) This subsection does not apply to—
10	"(A) the delivery, distribution, or dispensation
11	of controlled substances by nonpractitioners to the
12	extent authorized by their registration under this
13	title;
14	"(B) the placement on the Internet of material
15	that merely advocates the use of a controlled sub-
16	stance or includes pricing information without at-
17	tempting to propose or facilitate an actual trans-
18	action involving a controlled substance; or
19	"(C) any activity that is limited to—
20	"(i) the provision of a telecommunications
21	service, or of an Internet access service or
22	Internet information location tool (as those
23	terms are defined in section 231 of the Commu-
24	nications Act of 1934 (47 U.S.C. 231)); or

1 "(ii) the transmission, storage, retrieval, 2 hosting, formatting, or translation (or any combination thereof) of a communication, without 3 4 selection or alteration of the content of the 5 communication, except that deletion of a par-6 ticular communication or material made by an-7 other person in a manner consistent with sec-8 tion 230(c) of the Communications Act of 1934 9 (47 U.S.C. 230(c)) shall not constitute such se-10 lection or alteration of the content of the com-11 munication. 12 "(4) Any person who knowingly or intentionally vio-13 lates this subsection shall be sentenced in accordance with 14 subsection (b) of this section.". 15 (h) PUBLICATION.—Section 403(c) of the Controlled Substances Act (21 U.S.C. 843(c)) is amended by— 16 17 (1) designating the text as paragraph (1); and 18 (2) adding at the end the following: 19 ((2)(A) It shall be unlawful for any person to use 20 the Internet, or cause the Internet to be used, to advertise 21 the sale of, or to offer to sell, distribute, or dispense, a 22 controlled substance except as authorized by this title. 23 "(B) Violations of this paragraph include causing the 24 placement on the Internet of an advertisement that refers 25 to or directs prospective buyers to Internet sellers of controlled substances who are not registered under section
 303(i).

3 "(C) This paragraph does not apply to material that4 either—

5 "(i) advertises the distribution of controlled
6 substances by nonpractitioners to the extent author7 ized by their registration under this title; or

8 "(ii) merely advocates the use of a controlled 9 substance or includes pricing information without at-10 tempting to facilitate an actual transaction involving 11 a controlled substance.".

(i) INJUNCTIVE RELIEF.—Section 512 of the Controlled Substances Act (21 U.S.C. 882) is amended by
adding to the end of the section the following new subsection:

"(c) STATE CAUSE OF ACTION PERTAINING TO ON-16 LINE PHARMACIES.—(1) In any case in which the State 17 has reason to believe that an interest of the residents of 18 that State has been or is being threatened or adversely 19 affected by the action of a person, entity, or Internet site 2021 that violates the provisions of section 303(i), 309(e), or 22 311, the State may bring a civil action on behalf of such 23 residents in a district court of the United States with ap-24 propriate jurisdiction1 "(A) to enjoin the conduct which violates this 2 section;

3 "(B) to enforce compliance with this section;
4 "(C) to obtain damages, restitution, or other
5 compensation, including civil penalties under section
6 402(b); and

7 "(D) to obtain such other legal or equitable re-8 lief as the court may find appropriate.

9 ((2)(A) Prior to filing a complaint under paragraph (1), the State shall serve a copy of the complaint upon 10 the Attorney General and upon the United States Attor-11 ney for the judicial district in which the complaint is to 12 13 be filed. In any case where such prior service is not feasible, the State shall serve the complaint on the Attorney 14 15 General and the appropriate United States Attorney on the same day that the State's complaint is filed in Federal 16 17 district court of the United States. Such proceedings shall 18 be independent of, and not in lieu of, criminal prosecutions 19 or any other proceedings under this title or any other laws 20 of the United States.

"(B)(i) Not later than 120 days after the later of the
date on which a State's complaint is served on the Attorney General and the appropriate United States Attorney,
or the date on which the complaint is filed, the United

States shall have the right to intervene as a party in any
 action filed by a State under paragraph (1).

3 "(ii) After the 120-day period described in clause (i)
4 has elapsed, the United States may, for good cause shown,
5 intervene as a party in an action filed by a State under
6 paragraph (1).

7 "(iii) Notice and an opportunity to be heard with re8 spect to intervention shall be afforded the State that filed
9 the original complaint in any action in which the United
10 States files a complaint in intervention under clause (i)
11 or a motion to intervene under clause (ii).

12 "(iv) The United States may file a petition for appeal13 of a judicial determination in any action filed by a State14 under this section.

"(C) Service of a State's complaint on the United
States as required in this paragraph shall be made in accord with the requirements of Federal Rule of Civil Procedure 4(i)(1).

19 "(3) For purposes of bringing any civil action under 20 paragraph (1), nothing in this Act shall prevent an attor-21 ney general of a State from exercising the powers con-22 ferred on the attorney general of a State by the laws of 23 such State to conduct investigations or to administer oaths 24 or affirmations or to compel the attendance of witnesses 25 of or the production of documentary or other evidence. 1 "(4) Any civil action brought under paragraph (1) in 2 a district court of the United States may be brought in 3 the district in which the defendant is found, is an inhab-4 itant, or transacts business or wherever venue is proper 5 under section 1391 of title 28, United States Code. Proc-6 ess in such action may be served in any district in which 7 the defendant is an inhabitant or in which the defendant 8 may be found.

9 "(5) No private right of action is created under this10 subsection.".

(j) FORFEITURE OF FACILITATING PROPERTY IN
DRUG CASES.—Section 511(a)(4) of the Controlled Substances Act (21 U.S.C. 881(a)(4)) is amended to read as
follows:

"(4) Any property, real or personal, tangible or
intangible, used or intended to be used to commit,
or to facilitate the commission, of a violation of this
title or title III, and any property traceable thereto.".

20 (k) IMPORT AND EXPORT ACT.—Section 1010(b) of
21 the Controlled Substances Import and Export Act (21
22 U.S.C. 960(b)) is amended—

(1) in paragraph (4) by—

24 (A) striking "or any quantity of a con25 trolled substance in schedule III, IV, or V, (ex-

cept a violation involving flunitrazepam and ex-
cept a violation involving gamma hydroxy-
butyric acid)";
(B) inserting ", or" before "less than one
kilogram of hashish oil"; and
(C) striking "imprisoned" and all that fol-
lows through the end of the paragraph and in-
serting "sentenced in accordance with section
401(b)(1)(D) of this title (21 U.S.C.
841(b)(1)(E)).";
(2) by adding at the end the following:
"(5) In the case of a violation of subsection (a) of
this section involving a controlled substance in schedule
III, such person shall be sentenced in accordance with sec-
tion $401(b)(1)(E)$.
"(6) In the case of a violation of subsection (a) of
this section involving a controlled substance in schedule
IV (except a violation involving flunitrazepam), such per-
son shall be sentenced in accordance with section
401(b)(2).
"(7) In the case of a violation of subsection (a) of
this section involving a controlled substance in schedule
V, such person shall be sentenced in accordance with sec-

(3) in paragraph (3), by striking ", nor shall a
 person so sentenced be eligible for parole during the
 term of such a sentence" in the final sentence.

4 (l) EFFECTIVE DATE.—The amendments made by
5 this Act shall become effective 60 days after the date of
6 enactment of this Act.

7 (m) GUIDELINES AND REGULATIONS.—

8 (1) IN GENERAL.—The Attorney General may 9 promulgate and enforce any rules, regulations, and 10 procedures which may be necessary and appropriate 11 for the efficient execution of functions under this 12 subtitle, including any interim rules necessary for 13 the immediate implementation of this Act, on its ef-14 fective date.

15 (2)SENTENCING GUIDELINES.—The United States 16 Sentencing Commission, in determining 17 whether to amend, or establish new, guidelines or 18 policy statements, to conform the guidelines and pol-19 icy statements to this Act and the amendments 20 made by this Act, may not construe any change in 21 the maximum penalty for a violation involving a con-22 trolled substance in a particular schedule as requir-23 ing an amendment to, or establishing a new, guide-24 line or policy statement.

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