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To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of Internet pharmacies.

IN THE SENATE OF THE UNITED STATES

DECEMBER 15, 2011

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of Internet 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 Safe-
5 ty Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

8 (1) consumers in the United States are targeted
9 by organized international crime networks that use
10 Internet websites to sell illegal and often dangerous

1 drugs under the guise of being legitimate online
2 pharmacies;

3 (2) illegal online drug sellers offer products that
4 do not meet the safety standards established by
5 United States laws, and recent reports from the Na-
6 tional Association of Boards of Pharmacy show that
7 92 to 95 percent of Internet websites offering to sell
8 prescription medications online are illegitimate and
9 operate in clear violation of United States laws en-
10 acted to protect patients;

11 (3) criminals are attracted to the high profit
12 margin of business through illegitimate online drug
13 sales, as counterfeit drug sales alone are estimated
14 to have generated \$75,000,000,000 in 2010, an in-
15 crease of 92 percent from 2005;

16 (4) the World Health Organization estimates
17 that 50 percent of the prescription medicines sold
18 online by Internet websites that hide their physical
19 address are counterfeit;

20 (5) research by The Partnership at
21 Drugfree.org found that 1 in 6 consumers in the
22 United States, a total of about 36,000,000 Ameri-
23 cans, has bought or currently buys prescription
24 medication online without a valid prescription;

1 (6) the prevalence of illegal online drug sellers,
2 and their sale of counterfeit or otherwise illegitimate
3 medicines, is a growing public health threat;

4 (7) people have been seriously injured or killed
5 by products sold by illegal online drug sellers;

6 (8) the accessibility of controlled substances
7 and other drugs without a valid prescription by ille-
8 gal online drug sellers contributes to a growing pre-
9 scription drug abuse problem in the United States
10 that is endangering teenagers and public health;

11 (9) the anonymous and unregulated nature of
12 the Internet contributes to the counterfeit drug
13 trade and enables counterfeit medicines to reach
14 United States consumers through illegitimate online
15 drug sellers posing as legitimate pharmacies;

16 (10) counterfeit drugs that are sold through il-
17 legal online drug sellers are manufactured by crimi-
18 nals who deliberately and fraudulently misrepresent
19 the product in order to trick consumers into think-
20 ing they are purchasing a legitimate and safe medi-
21 cine;

22 (11) these counterfeit drugs are frequently
23 manufactured in unsanitary conditions and may con-
24 tain the wrong ingredients, lack active ingredients,

1 have insufficient or contaminated active ingredients,
2 or contain too many active ingredients;

3 (12) counterfeit drugs obtained from illegal on-
4 line drug sellers have been found to contain harmful
5 ingredients including arsenic, boric acid, brick dust,
6 cement powder, chalk dust, floor polish, leaded road
7 paint, nickel, shoe polish, and talcum powder;

8 (13) United States citizens deserve access to
9 safe and legitimate online pharmacies and protection
10 from illegal Internet websites that sell counterfeit or
11 otherwise illegitimate medication;

12 (14) while the Ryan Haight Online Pharmacy
13 Consumer Protection Act of 2008 (Public Law 110-
14 425) has helped to prevent illegitimate online sales
15 of prescribed controlled substances, illegal online
16 sellers continue to sell other types of prescription
17 drugs and stronger laws are needed to stop them;
18 and

19 (15) greater education and awareness regarding
20 illegal online drug sellers will help to protect the
21 United States drug supply chain from infiltration by
22 unregulated and counterfeit products.

23 **SEC. 3. VALID PRESCRIPTIONS.**

24 Section 503(b) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 353(b)) is amended—

1 (1) in paragraph (1), in the matter following
2 subparagraph (B), by striking “shall be dispensed”
3 and all that follows through “the pharmacist.” and
4 inserting the following: “shall be dispensed only pur-
5 suant to a valid prescription that is (i) a written
6 prescription of a practitioner licensed by law to ad-
7 minister such drug; (ii) an oral prescription of such
8 practitioner which is reduced promptly to writing by
9 the pharmacist; (iii) an electronic prescription issued
10 by a practitioner licensed by law to administer such
11 drug; or (iv) the refill of any such written, oral, or
12 electronic prescription if such refilling is authorized
13 by the prescriber either in the original prescription,
14 electronic prescription, or by oral order which is re-
15 duced promptly to writing by the pharmacist.”; and

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

17 “(6) In this paragraph:

18 “(A) The term ‘valid prescription’ means a
19 prescription that is issued for a legitimate med-
20 ical purpose in the usual course of professional
21 practice by—

22 “(i) a licensed practitioner who has
23 conducted at least 1 in-person medical
24 evaluation of the patient, subject to para-
25 graph (7);

1 “(ii) a covering practitioner; or

2 “(iii) a practitioner engaged in the
3 practice of telemedicine.

4 “(B)(i) The term ‘in-person medical eval-
5 uation’ means a medical evaluation that is con-
6 ducted with the patient in the physical presence
7 of the practitioner, without regard to whether
8 portions of the evaluation are conducted by
9 other health professionals.

10 “(ii) Nothing in clause (i) shall be con-
11 strued to imply that 1 in-person medical evalua-
12 tion demonstrates that a prescription has been
13 issued for a legitimate medical purpose within
14 the usual course of professional practice.

15 “(C) The term ‘covering practitioner’
16 means, with respect to a patient, a licensed
17 practitioner who conducts a medical evaluation
18 (other than an in-person medical evaluation) at
19 the request of a licensed practitioner who—

20 “(i) has conducted at least 1 in-per-
21 son medical evaluation of the patient or an
22 evaluation of the patient through the prac-
23 tice of telemedicine, within the previous 24
24 months; and

1 “(ii) is temporarily unavailable to con-
2 duct the evaluation of the patient.

3 “(D) The term ‘practice of telemedicine’
4 has the meaning given that term in section 102
5 of the Controlled Substances Act.

6 “(7) For purposes of paragraph (6), an in-per-
7 son medical evaluation of the patient is not required
8 if—

9 “(A) the prescribing practitioner is issuing
10 a prescription or dispensing a legend drug in
11 accordance with the Expedited Partner Therapy
12 in the Management of Sexually Transmitted
13 Diseases guidance document issued by the Cen-
14 ters for Disease Control and Prevention; or

15 “(B) the prescription, administration, or
16 dispensing is through a public health clinic or
17 other distribution mechanism approved by the
18 State health authority in order to prevent, miti-
19 gate, or treat a pandemic illness, infectious dis-
20 ease outbreak, or intentional or accidental re-
21 lease of a biological, chemical, or radiological
22 agent.

23 “(8) The Secretary may by regulation establish
24 exceptions to the requirements described in para-

1 graph (6) with respect to a drug, based on criteria
2 established by the Secretary.”.

3 **SEC. 4. REGISTRY OF LEGITIMATE ONLINE PHARMACY**
4 **WEBSITES.**

5 Chapter V of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 351 et seq.) is amended by inserting after
7 section 510 the following:

8 **“SEC. 510A. REGISTRY OF LEGITIMATE ONLINE PHARMACY**
9 **WEBSITES.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) DISPENSING PHARMACY.—The term ‘dis-
12 pensing pharmacy’ means a pharmacy that dis-
13 penses, distributes, or supplies prescription drugs
14 pursuant to orders made on, through, or on behalf
15 of, an online pharmacy website.

16 “(2) DOMAIN NAME.—The term ‘domain name’
17 has the meaning given that term in section 45 of the
18 Lanham Act (15 U.S.C. 1127).

19 “(3) FINANCIAL TRANSACTION PROVIDER.—
20 The term ‘financial transaction provider’ has the
21 meaning given that term in section 5362(4) of title
22 31, United States Code.

23 “(4) INTERNET WEBSITE.—The term ‘Internet
24 website’ means the collection of digital assets, in-
25 cluding links, indexes, or pointers to digital assets,

1 accessible through the Internet that are addressed
2 relative to a common domain name.

3 “(5) LEGITIMATE ONLINE PHARMACY
4 WEBSITE.—The term ‘legitimate online pharmacy
5 website’ means an online pharmacy website that is
6 included in the Registry pursuant to a designation
7 by the Secretary under this section.

8 “(6) ONLINE PHARMACY WEBSITE.—The term
9 ‘online pharmacy website’ means an Internet website
10 that offers, sells, dispenses, or distributes, or facili-
11 tates the sale, dispensing, or distribution of prescrip-
12 tion or other drugs to consumers.

13 “(7) PRESCRIPTION DRUG.—The term ‘pre-
14 scription drug’ means a drug that is subject to sec-
15 tion 503(b)(1).

16 “(b) ESTABLISHMENT OF REGISTRY.—The Secretary
17 shall establish a Registry of Legitimate Online Pharmacy
18 Websites (referred to in this section as the ‘Registry’) for
19 the purpose of educating consumers and promoting public
20 health and safety.

21 “(c) CRITERIA.—The Secretary shall designate an
22 online pharmacy website as a legitimate online pharmacy
23 website, and include such legitimate online pharmacy
24 website on the Registry, if the Secretary determines
25 that—

1 “(1) the online pharmacy website is accredited
2 by the United States National Association of Boards
3 of Pharmacy Verified Internet Pharmacy Practice
4 Sites program; or

5 “(2) the online pharmacy website meets each of
6 the following requirements:

7 “(A) Prescription drugs ordered, sold, dis-
8 pensed, distributed, supplied, or provided
9 through or by the online pharmacy website are
10 sold, dispensed, distributed, supplied, or pro-
11 vided solely by dispensing pharmacies that are
12 domiciled in the United States and that main-
13 tain pharmacy licensure, a permit, or registra-
14 tion in good standing in all United States juris-
15 dictions where such dispensing pharmacies pro-
16 vide services or are required to maintain such
17 licensure, permit, or registration.

18 “(B) Each dispensing pharmacy affiliated
19 with, or that dispenses, distributes, supplies, or
20 provides prescription or other drugs on behalf
21 of the online pharmacy website, maintains a
22 valid Drug Enforcement Administration reg-
23 istration, unless such registration is not re-
24 quired by Drug Enforcement Administration
25 regulations.

1 “(C) Each dispensing pharmacy affiliated
2 with, or that dispenses, distributes, supplies, or
3 provides prescription drugs on behalf of the on-
4 line pharmacy website, dispenses, distributes,
5 supplies, provides, or offers or attempts to dis-
6 pense, distribute, supply, or provide, prescrip-
7 tion drugs only pursuant to a valid prescription
8 (as defined in section 503(b)).

9 “(D) Each dispensing pharmacy affiliated
10 with, or that dispenses, distributes, supplies, or
11 provides prescription drugs on behalf of the on-
12 line pharmacy website, complies with applicable
13 Federal and State laws and regulations applica-
14 ble to pharmacy practice.

15 “(E) Each dispensing pharmacy affiliated
16 with, or that dispenses, distributes, supplies, or
17 provides prescription or other drugs on behalf
18 of the online pharmacy website, does not dis-
19 pense, distribute, supply, provide, offer or at-
20 tempt to dispense, distribute, supply, or pro-
21 vide, advertise, or promote prescription or other
22 drugs that have not been approved by the Food
23 and Drug Administration.

24 “(F) The online pharmacy website promi-
25 nently displays the following information:

1 “(i) An accurate United States street
2 address of each dispensing pharmacy or
3 the corporate or other legal business entity
4 headquarters of each dispensing pharmacy.

5 “(ii) An accurate, readily accessible,
6 and responsive telephone number or other
7 secure accurate means that allows the con-
8 sumer to contact or consult with the phar-
9 macist about his or her prescription drug.

10 “(G) The online pharmacy website does
11 not make any statements, regarding the nature
12 of any dispensing pharmacy or product offered
13 via the website, that are materially misleading
14 or fraudulent.

15 “(H) The domain name registration infor-
16 mation applicable to the online pharmacy
17 website is accurate, not anonymous, and has a
18 logical nexus to each dispensing pharmacy or
19 the corporate or other legal business head-
20 quarters of each dispensing pharmacy.

21 “(I) The online pharmacy website, includ-
22 ing any operator, content owner, or domain
23 name registrant of the online pharmacy website,
24 is not affiliated with, and does not own or con-

1 trol any other online pharmacy website that vio-
2 lates the requirements under this paragraph.

3 “(J) The online pharmacy website, includ-
4 ing any operator, content owner, or domain
5 name registrant of the online pharmacy website,
6 is not affiliated with, and does not own or con-
7 trol any other online pharmacy website that vio-
8 lates Federal or State law.

9 “(K) Information that would be considered
10 protected health information under the regula-
11 tions promulgated under section 264(c) of the
12 Health Insurance Portability and Accountability
13 Act of 1996 (commonly referred to as the
14 ‘HIPAA Privacy Rule’) is transmitted by the
15 online pharmacy website and each dispensing
16 pharmacy affiliated with, or that dispenses, dis-
17 tributes, supplies, or provides prescription
18 drugs on behalf of the online pharmacy website,
19 in accordance with the requirements of such
20 Act, including the use of Secure-Socket Layer
21 or equivalent technology for the transmission of
22 protected health information, and the online
23 pharmacy website displays its privacy policy
24 and that such policy complies with the require-
25 ments of the HIPAA Privacy Rule.

1 “(L) The online pharmacy website com-
2 plies with other requirements as determined ap-
3 propriate by the Secretary, in consultation with
4 other Federal and State agencies responsible
5 for regulating the practice of pharmacy.

6 “(d) PROCESS.—

7 “(1) APPLICATION.—The Secretary shall de-
8 velop an application process through which an inter-
9 ested operator, content owner, or domain name reg-
10 istrant of an online pharmacy website may apply for
11 inclusion on the Registry. Such an application shall
12 be submitted in such form and manner as required
13 by the Secretary and shall include, at a minimum,
14 information to determine whether the online phar-
15 macy website satisfies the criteria described under
16 subsection (c). The Secretary shall not charge a fee
17 for submission of an application.

18 “(2) IDENTIFICATION WITHOUT APPLICA-
19 TION.—

20 “(A) IN GENERAL.—The Secretary shall
21 take reasonable steps to identify online phar-
22 macy websites for which no application has
23 been submitted under paragraph (1) and evalu-
24 ate whether these online pharmacy websites sat-
25 isfy the criteria described under subsection (c).

1 “(B) COMPLIANCE CONFIRMED.—In cases
2 where satisfaction of the criteria described
3 under subsection (c) can be verified without the
4 receipt of an application, an online pharmacy
5 website that the Secretary determines to satisfy
6 such criteria may be designated as a legitimate
7 online pharmacy website and included on the
8 Registry and the operator, content owner, or
9 domain name registrant of such online phar-
10 macy website shall be notified of such place-
11 ment.

12 “(C) ADDITIONAL INFORMATION RE-
13 QUIRED.—In cases where satisfaction of the cri-
14 teria described under subsection (c) cannot be
15 verified without additional information or some
16 corrective action by the online pharmacy
17 website operator, content owner, or domain
18 name registrant, the online pharmacy website
19 shall not be designated as a legitimate online
20 pharmacy website or placed on the Registry
21 until the additional information is received by
22 the Secretary and the Secretary determines that
23 all applicable and necessary corrective actions
24 have been taken.

1 “(3) REGULATIONS REGARDING APPLICATION
2 PROCESS.—

3 “(A) IN GENERAL.—The Secretary shall
4 promulgate regulations—

5 “(i) to establish the timeframes appli-
6 cable to informing online pharmacy website
7 operators, content owners, or domain name
8 registrants that submit an application
9 under paragraph (1) of the acceptance or
10 denial of such application;

11 “(ii) to address what information may
12 be shared with or withheld from online
13 pharmacy website operators, content own-
14 ers, or domain name registrants that sub-
15 mit such an application regarding correc-
16 tive actions that would need to be taken to
17 establish compliance with the Registry re-
18 quirements;

19 “(iii) to establish an appeal process
20 giving online pharmacy website operators,
21 content owners, or domain name reg-
22 istrants that submit such an application
23 the ability to request a second review of
24 the application to determine compliance
25 with the Registry requirements; and

1 “(iv) to address other procedural mat-
2 ters regarding the receipt and evaluation of
3 applications submitted under paragraph
4 (1) as the Secretary determines necessary.

5 “(B) LIMITATION REGARDING APPEALS
6 PROCESS.—The appeals process established
7 under subparagraph (A)(iii) shall in no case re-
8 quire the Secretary—

9 “(i) to disclose information that may
10 impede an ongoing or potential criminal or
11 regulatory investigation; or

12 “(ii) to provide an opportunity for ap-
13 peal in cases where the Secretary deter-
14 mines, in the Secretary’s sole discretion,
15 that the violation of a Registry require-
16 ment is materially significant, such a viola-
17 tion is not likely to be curable, or the ap-
18 plicant has engaged in a pattern of viola-
19 tions of Federal or State law.

20 “(4) AUTHORITY AND PROCESS FOR REMOVAL
21 FROM REGISTRY.—

22 “(A) IN GENERAL.—The Secretary shall
23 have the authority to remove an online phar-
24 macy website from the Registry—

1 “(i) upon determination that the on-
2 line pharmacy website is not in compliance
3 with the criteria as established by this sec-
4 tion;

5 “(ii) upon determination that the on-
6 line pharmacy website was mistakenly in-
7 cluded in the Registry; or

8 “(iii) for good cause as determined by
9 the Secretary based on credible evidence.

10 “(B) PROCESS.—If the Secretary deter-
11 mines that an online pharmacy website shall be
12 removed from the Registry under subparagraph
13 (A), the Secretary shall provide notice to the
14 operator, content owner, or domain name reg-
15 istrant of the online pharmacy website of the
16 determination, the date of the removal of the
17 website from the Registry, and the reasons for
18 removal.

19 “(C) REGULATIONS FOR APPEAL PROC-
20 ESS.—

21 “(i) IN GENERAL.—The Secretary
22 shall promulgate regulations that provide
23 the operator, content owner, or domain
24 name registrant of an online pharmacy
25 website removed from the Registry the

1 ability to appeal the removal and to pro-
2 vide information to correct matters that
3 served as basis for removal from the Reg-
4 istry. Such regulations shall provide a rea-
5 sonable time period to correct the grounds
6 for removal.

7 “(ii) LIMITATION REGARDING AP-
8 PEALS PROCESS.—The appeals process es-
9 tablished under clause (i) shall in no case
10 require the Secretary—

11 “(I) to disclose information that
12 may impede an ongoing or potential
13 criminal or regulatory investigation;
14 or

15 “(II) to provide an opportunity
16 for appeal in cases where the Sec-
17 retary determines, in the Secretary’s
18 sole discretion, that the violation of a
19 Registry requirement is materially sig-
20 nificant, such a violation is not likely
21 to be curable, or the applicant has en-
22 gaged in a pattern of violations of
23 Federal or State law.

24 “(e) CONTRACTS WITH PRIVATE ENTITIES.—

1 “(1) IN GENERAL.—The Secretary may enter
2 into contracts with the United States National Asso-
3 ciation of Boards of Pharmacy or other private enti-
4 ties to—

5 “(A) review applications submitted under
6 subsection (d)(1) and evaluate whether the on-
7 line pharmacy website satisfies the criteria de-
8 scribed under subsection (c);

9 “(B) on an ongoing basis, review and iden-
10 tify online pharmacy websites for which no ap-
11 plication has been submitted under subsection
12 (d)(1) and evaluate whether these online phar-
13 macies satisfy the criteria described under sub-
14 section (c);

15 “(C) make recommendations to the Sec-
16 retary as to whether an online pharmacy
17 website, either through application or through
18 identification under subparagraph (B), satisfies
19 the criteria under subsection (c);

20 “(D) notify the Food and Drug Adminis-
21 tration of online pharmacy websites that do not
22 to satisfy such criteria; and

23 “(E) provide services to maintain the Reg-
24 istry.

1 “(2) CONTRACTING.—In contracting with enti-
2 ties under this subsection, the Secretary—

3 “(A) may waive such provisions of the
4 Federal Acquisition Regulation, except for pro-
5 visions relating to confidentiality of informa-
6 tion, as necessary for the efficient implementa-
7 tion of this subsection and for selecting such
8 entities; and

9 “(B) shall select entities that have dem-
10 onstrated a history of competency in reviewing,
11 evaluating, and determining the legitimacy of
12 online pharmacy websites, based on standards
13 approved by the United States National Asso-
14 ciation of Boards of Pharmacy.

15 “(3) TERMS OF CONTRACT.—A contract with
16 an entity under this subsection shall include such
17 terms and conditions as specified by the Secretary,
18 including the following:

19 “(A) The entity shall monitor the Internet
20 on an ongoing basis in order to sufficiently
21 maintain a current list of legitimate online
22 pharmacy websites for consideration by the Sec-
23 retary.

24 “(B) On at least a monthly basis, the enti-
25 ty shall submit to the Secretary an updated list

1 of legitimate online pharmacy websites rec-
2 ommended for inclusion on the Registry.

3 “(f) USE OF REGISTRY.—

4 “(1) PUBLIC AVAILABILITY.—The Secretary
5 shall—

6 “(A) make the Registry available to Inter-
7 net advertising services, financial transaction
8 providers, domain name registries, domain
9 name registrars, other domain name authori-
10 ties, information location tool service providers,
11 and others as determined necessary and appro-
12 priate by the Secretary to promote public health
13 and safety;

14 “(B) make the Registry available to con-
15 sumers and other interested persons through
16 publication on the Internet website of the Food
17 and Drug Administration; and

18 “(C) specify the Registry criteria used to
19 designate legitimate online pharmacy websites
20 on the Internet website of the Food and Drug
21 Administration.

22 “(2) CONSUMER EDUCATION.—The Secretary
23 shall—

24 “(A) engage in a campaign to educate con-
25 sumers on the availability and use of the Reg-

1 istry to promote public health and safety
2 through means as determined appropriate and
3 necessary by the Secretary, which may include
4 radio, television, print media, and Internet pub-
5 lic service announcements; and

6 “(B) make consumer education materials
7 available, on the Internet website of the Food
8 and Drug Administration and in a consumer-
9 friendly form and manner, regarding how to
10 safely purchase drugs over the Internet.

11 “(g) REFUSAL OF SERVICE; IMMUNITY.—

12 “(1) REFUSAL OF SERVICE.—A domain name
13 registry, domain name registrar, other domain name
14 authority, financial transaction provider, information
15 location tool service provider, or Internet advertising
16 service, acting in good faith based on the Registry,
17 may cease or refuse to provide services to an online
18 pharmacy website that is not included on the Reg-
19 istry.

20 “(2) IMMUNITY FROM LIABILITY.—An entity
21 described in paragraph (1), including the directors,
22 officers, employees, or agents of such entity, that,
23 acting in good faith, ceases or refuses to provide
24 services to an online pharmacy website that is not

1 listed on the Registry shall not be liable to any party
2 under any Federal or State law for such action.

3 “(3) IMMUNITY FROM SUIT.—No cause of ac-
4 tion shall lie in any court or administrative agency
5 against any entity described in paragraph (1), in-
6 cluding the directors, officers, employees, or agents
7 of such entity, that, acting in good faith, ceases or
8 refuses to provide services to an online pharmacy
9 website that is not included on the Registry.”.

10 **SEC. 5. FUNDING.**

11 There is authorized to be appropriated such sums as
12 may be necessary to carry out this Act (and the amend-
13 ments made by this Act).

14 **SEC. 6. EFFECTIVE DATE.**

15 This Act (and the amendments made by this Act)
16 shall take effect on the date that is 180 days after the
17 date of enactment of this Act.

○