

112TH CONGRESS
2D SESSION

H. R. 4095

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 2012

Mr. CASSIDY (for himself and Mr. ROSS of Arkansas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 end of paragraph
4 (1) and inserting the following: “shall be dispensed
5 only pursuant to a valid prescription that is (i) a
6 written prescription of a practitioner licensed by law
7 to administer such drug, (ii) an oral prescription of
8 such practitioner which is reduced promptly to writ-
9 ing by the pharmacist, (iii) an electronic or facsimile
10 prescription issued by a practitioner licensed by law
11 to administer such drug, or (iv) the refill of any
12 such written, oral, facsimile, or electronic prescrip-
13 tion if such refilling is authorized by the prescriber
14 either in the original prescription, in the electronic
15 or facsimile prescription, or by oral order which is
16 reduced promptly to writing by the pharmacist. The
17 act of dispensing a drug contrary to the provisions
18 of this paragraph shall be deemed to be an act which
19 results in the drug being misbranded while held for
20 sale. In applying this paragraph, dispensing pursu-
21 ant to a prescription is deemed to be pursuant to a
22 valid prescription if the dispensing occurs in good
23 faith based on a reasonable belief that the prescrip-
24 tion is a valid prescription.”; and

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

1 “(6) For purposes of paragraph (1), the term
2 ‘valid prescription’ means a prescription that is
3 issued for a legitimate medical purpose in the usual
4 course of professional practice by—

5 “(A) a licensed practitioner who has con-
6 ducted at least 1 in-person medical evaluation
7 of the patient, subject to paragraph (7);

8 “(B) a covering practitioner; or

9 “(C) a practitioner engaged in the practice
10 of telemedicine.

11 “(7) For purposes of paragraph (6) and this
12 paragraph:

13 “(A)(i) The term ‘in-person medical eval-
14 uation’ means a medical evaluation that is con-
15 ducted with the patient in the physical presence
16 of the practitioner, without regard to whether
17 portions of the evaluation are conducted by
18 other health professionals.

19 “(ii) Nothing in clause (i) shall be con-
20 strued to imply that 1 in-person medical evalua-
21 tion demonstrates that a prescription has been
22 issued for a legitimate medical purpose within
23 the usual course of professional practice.

24 “(B) The term ‘covering practitioner’
25 means, with respect to a patient, a licensed

1 practitioner who conducts a medical evaluation
2 (other than an in-person medical evaluation) at
3 the request of a licensed practitioner who—

4 “(i) has conducted at least 1 in-per-
5 son medical evaluation of the patient or an
6 evaluation of the patient through the prac-
7 tice of telemedicine, within the previous 24
8 months; and

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

11 “(C) The term ‘practice of telemedicine’
12 has the meaning given that term in section 102
13 of the Controlled Substances Act.

14 “(8) For purposes of paragraphs (6) and (7),
15 an in-person medical evaluation of the patient is not
16 required if—

17 “(A) the prescribing practitioner is issuing
18 a prescription or dispensing a legend drug in
19 accordance with the Expedited Partner Therapy
20 in the Management of Sexually Transmitted
21 Diseases guidance document issued by the Cen-
22 ters for Disease Control and Prevention; or

23 “(B) the prescription, administration, or
24 dispensing is through a public health clinic or
25 other distribution mechanism approved by the

1 State health authority in order to prevent, miti-
2 gate, or treat a pandemic illness, infectious dis-
3 ease outbreak, or intentional or accidental re-
4 lease of a biological, chemical, or radiological
5 agent.

6 “(9) The Secretary may by regulation establish
7 exceptions to the requirements described in para-
8 graphs (6) through (8) with respect to a drug, based
9 on criteria established by the Secretary.”.

10 **SEC. 4. REGISTRY OF LEGITIMATE ONLINE PHARMACY**
11 **WEBSITES.**

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

15 **“SEC. 510A. REGISTRY OF LEGITIMATE ONLINE PHARMACY**
16 **WEBSITES.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) DISPENSING PHARMACY.—The term ‘dis-
19 pensing pharmacy’ means a pharmacy that dis-
20 penses, distributes, or supplies prescription drugs
21 pursuant to orders made on, through, or on behalf
22 of, an online pharmacy website.

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

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

5 “(4) INTERNET WEBSITE.—The term ‘Internet
6 website’ means the collection of digital assets, in-
7 cluding links, indexes, or pointers to digital assets,
8 accessible through the Internet that are addressed
9 relative to a common domain name.

10 “(5) LEGITIMATE ONLINE PHARMACY
11 WEBSITE.—The term ‘legitimate online pharmacy
12 website’ means an online pharmacy website that is
13 included in the Registry pursuant to a designation
14 by the Secretary under this section.

15 “(6) ONLINE PHARMACY WEBSITE.—The term
16 ‘online pharmacy website’ means an Internet website
17 that offers, sells, dispenses, or distributes, or facili-
18 tates the offering, sale, dispensing, or distribution
19 of, prescription drugs to consumers, except that an
20 Internet website shall not be considered an online
21 pharmacy website if the website does not—

22 “(A) have the capability to accept pay-
23 ment;

24 “(B) refer consumers to a separate website
25 to conduct or facilitate online payment for the

1 purpose of receiving a prescription drug without
2 a valid prescription; or

3 “(C) otherwise engage in a financial trans-
4 action for prescription drugs by means of the
5 Internet.

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

9 “(b) ESTABLISHMENT OF REGISTRY.—The Secretary
10 shall establish a Registry of Legitimate Online Pharmacy
11 Websites (referred to in this section as the ‘Registry’) for
12 the purpose of educating consumers and promoting public
13 health and safety.

14 “(c) CRITERIA.—The Secretary shall designate an
15 online pharmacy website as a legitimate online pharmacy
16 website, and include such legitimate online pharmacy
17 website on the Registry, if the Secretary determines
18 that—

19 “(1) the online pharmacy website is accredited
20 by the United States National Association of Boards
21 of Pharmacy Verified Internet Pharmacy Practice
22 Sites program; or

23 “(2) the online pharmacy website meets each of
24 the following requirements:

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

12 “(B) Each dispensing pharmacy affiliated
13 with, or that dispenses, distributes, supplies, or
14 provides prescription or other drugs on behalf
15 of the online pharmacy website, maintains a
16 valid Drug Enforcement Administration reg-
17 istration, unless such registration is not re-
18 quired by Drug Enforcement Administration
19 regulations.

20 “(C) Each dispensing pharmacy affiliated
21 with, or that dispenses, distributes, supplies, or
22 provides prescription drugs on behalf of the on-
23 line pharmacy website, dispenses, distributes,
24 supplies, provides, or offers or attempts to dis-
25 pense, distribute, supply, or provide, prescrip-

1 tion drugs only pursuant to a valid prescription
2 (as defined in section 503(b)).

3 “(D) Each dispensing pharmacy affiliated
4 with, or that dispenses, distributes, supplies, or
5 provides prescription drugs on behalf of the on-
6 line pharmacy website, complies with applicable
7 Federal and State laws and regulations applica-
8 ble to pharmacy practice.

9 “(E) The online pharmacy website promi-
10 nently displays the following information:

11 “(i) An accurate United States street
12 address of each dispensing pharmacy or
13 the corporate or other legal business entity
14 headquarters of each dispensing pharmacy.

15 “(ii) An accurate, readily accessible,
16 and responsive telephone number or other
17 secure accurate means that allows the con-
18 sumer to contact or consult with the phar-
19 macist about his or her prescription drug.

20 “(F) The online pharmacy website does
21 not make any statements, regarding the nature
22 of any dispensing pharmacy or product offered
23 via the website, that are materially misleading
24 or fraudulent.

1 “(G) The domain name registration infor-
2 mation applicable to the online pharmacy
3 website is accurate, not anonymous, and has a
4 logical nexus to a dispensing pharmacy located
5 in the United States or the corporate or other
6 legal business headquarters thereof.

7 “(H) The online pharmacy website, includ-
8 ing any operator, content owner, or domain
9 name registrant of the online pharmacy website,
10 is not affiliated with, and does not own or con-
11 trol any other online pharmacy website that vio-
12 lates the requirements under this paragraph.

13 “(I) The online pharmacy website, includ-
14 ing any operator, content owner, or domain
15 name registrant of the online pharmacy website,
16 is not affiliated with, and does not own or con-
17 trol, any other online pharmacy website that
18 violates Federal or State laws and regulations
19 applicable to pharmacy practice.

20 “(J) Information that would be considered
21 protected health information under the regula-
22 tions promulgated under section 264(c) of the
23 Health Insurance Portability and Accountability
24 Act of 1996 (commonly referred to as the
25 ‘HIPAA Privacy Rule’) is transmitted by the

1 online pharmacy website and each dispensing
2 pharmacy affiliated with, or that dispenses, dis-
3 tributes, supplies, or provides prescription
4 drugs on behalf of the online pharmacy website,
5 in accordance with the requirements of such
6 Act, including the use of Secure-Socket Layer
7 or equivalent technology for the transmission of
8 protected health information, and the online
9 pharmacy website displays its privacy policy
10 and that such policy complies with the require-
11 ments of the HIPAA Privacy Rule.

12 “(K) The online pharmacy website com-
13 plies with other requirements as determined ap-
14 propriate by the Secretary, in consultation with
15 other Federal and State agencies responsible
16 for regulating the practice of pharmacy, for
17 purposes of implementing subparagraphs (A)
18 through (J).

19 “(d) PROCESS.—

20 “(1) APPLICATION.—The Secretary shall de-
21 velop an application process through which an inter-
22 ested operator, content owner, or domain name reg-
23 istrant of an online pharmacy website may apply for
24 inclusion on the Registry. Such an application shall
25 be submitted in such form and manner as required

1 by the Secretary and shall include, at a minimum,
2 information to determine whether the online phar-
3 macy website satisfies the criteria described under
4 subsection (c). Neither the Secretary nor any private
5 entity with whom a contract is entered into under
6 subsection (e) shall charge a fee for submission of
7 an application for listing on the Registry.

8 “(2) IDENTIFICATION WITHOUT APPLICA-
9 TION.—

10 “(A) IN GENERAL.—The Secretary shall
11 take reasonable steps to identify online phar-
12 macy websites for which no application has
13 been submitted under paragraph (1) and evalu-
14 ate whether these online pharmacy websites sat-
15 isfy the criteria described under subsection (c).

16 “(B) COMPLIANCE CONFIRMED.—In cases
17 where satisfaction of the criteria described
18 under subsection (c) can be verified without the
19 receipt of an application, an online pharmacy
20 website that the Secretary determines to satisfy
21 such criteria may be designated as a legitimate
22 online pharmacy website and included on the
23 Registry and the operator, content owner, or
24 domain name registrant of such online phar-

1 macy website shall be notified of such place-
2 ment.

3 “(C) ADDITIONAL INFORMATION RE-
4 QUIRED.—In cases where satisfaction of the cri-
5 teria described under subsection (c) cannot be
6 verified without additional information or some
7 corrective action by the online pharmacy
8 website operator, content owner, or domain
9 name registrant, the online pharmacy website
10 shall not be designated as a legitimate online
11 pharmacy website or placed on the Registry
12 until the additional information is received by
13 the Secretary and the Secretary determines that
14 all applicable and necessary corrective actions
15 have been taken.

16 “(3) REGULATIONS REGARDING APPLICATION
17 PROCESS.—

18 “(A) IN GENERAL.—Not later than 180
19 days after the date of the enactment of this sec-
20 tion, the Secretary shall promulgate regula-
21 tions—

22 “(i) to establish the timeframes appli-
23 cable to informing online pharmacy website
24 operators, content owners, or domain name
25 registrants that submit an application

1 under paragraph (1) of the acceptance or
2 denial of such application;

3 “(ii) to address what information may
4 be shared with or withheld from online
5 pharmacy website operators, content own-
6 ers, or domain name registrants that sub-
7 mit such an application regarding correc-
8 tive actions that would need to be taken to
9 establish compliance with the Registry re-
10 quirements;

11 “(iii) to establish an appeal process
12 giving online pharmacy website operators,
13 content owners, or domain name reg-
14 istrants that submit such an application
15 the ability to request a second review of
16 the application to determine compliance
17 with the Registry requirements;

18 “(iv) to establish a process giving a li-
19 censed pharmacy domiciled in the United
20 States the ability to request a determina-
21 tion as to whether such pharmacy is an
22 ‘online pharmacy website’ for purposes of
23 the Registry; and

24 “(v) to address other procedural mat-
25 ters regarding the receipt and evaluation of

1 applications submitted under paragraph
2 (1) as the Secretary determines necessary.

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

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

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

18 “(4) AUTHORITY AND PROCESS FOR REMOVAL
19 FROM REGISTRY.—

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

23 “(i) upon determination that the on-
24 line pharmacy website is not in compliance

1 with the criteria as established by this sec-
2 tion;

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

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

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

17 “(C) REGULATIONS FOR APPEAL PROC-
18 ESS.—

19 “(i) IN GENERAL.—The Secretary
20 shall promulgate regulations that provide
21 the operator, content owner, or domain
22 name registrant of an online pharmacy
23 website removed from the Registry the
24 ability to appeal the removal and to pro-
25 vide information to correct matters that

1 served as basis for removal from the Reg-
2 istry. Such regulations shall provide a rea-
3 sonable time period to correct the grounds
4 for removal.

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

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

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

22 “(5) RE-INCLUSION ON REGISTRY.—Nothing in
23 this section prohibits an interested operator, content
24 owner, or domain name registrant of an online phar-
25 macy website from applying under paragraph (1) for

1 re-inclusion of the website on the Registry subse-
2 quent to the website’s removal from the Registry.

3 “(e) CONTRACTS WITH PRIVATE ENTITIES.—

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

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

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

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

23 “(D) notify the Food and Drug Adminis-
24 tration of online pharmacy websites that do not
25 satisfy such criteria; and

1 “(E) provide services to maintain the Reg-
2 istry.

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

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

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

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

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

1 “(B) On at least a monthly basis, the enti-
2 ty shall submit to the Secretary an updated list
3 of legitimate online pharmacy websites rec-
4 ommended for inclusion on the Registry.

5 “(f) USE OF REGISTRY.—

6 “(1) PUBLIC AVAILABILITY.—The Secretary
7 shall—

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

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

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

24 “(2) CONSUMER EDUCATION.—The Secretary
25 shall—

1 “(A) engage in a campaign to educate con-
2 sumers on the availability and use of the Reg-
3 istry to promote public health and safety
4 through means as determined appropriate and
5 necessary by the Secretary, which may include
6 radio, television, print media, and Internet pub-
7 lic service announcements; and

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

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

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

22 “(2) IMMUNITY FROM LIABILITY.—If an entity
23 described in paragraph (1), including the directors,
24 officers, employees, or agents of the entity, acting in
25 good faith, ceases or refuses to provide services to

1 an online pharmacy website that is not included on
2 the Registry—

3 “(A) no cause of action may be brought
4 under any Federal or State law against the en-
5 tity for such cessation or refusal; and

6 “(B) no administrative proceeding may be
7 instituted against the entity for such cessation
8 or refusal.”.

9 **SEC. 5. EFFECTIVE DATE.**

10 This Act (and the amendments made by this Act)
11 shall take effect on the date that is 180 days after the
12 date of enactment of this Act.

○