

112TH CONGRESS
2D SESSION

S. 3622

To prohibit prescription drug price-gouging during states of market shortage.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 22 (legislative day, SEPTEMBER 21), 2012

Mr. SCHUMER (for himself, Mr. MERKLEY, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To prohibit prescription drug price-gouging during states of market shortage.

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 “Protecting Patients
5 and Hospitals From Price Gouging Act”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress finds that—

8 (1) many pharmaceutical drugs are necessary to
9 maintain the health and welfare of the American
10 people;

1 (2) currently the Nation is facing a chronic
2 shortage of vital drugs necessary in surgery, to treat
3 cancer, and to fight other life-threatening illnesses;
4 and

5 (3) in order to prevent any party within the
6 chain of distribution of any vital drugs from taking
7 unfair advantage of consumers during market short-
8 ages, the public interest requires that such conduct
9 be prohibited and made subject to criminal penalties.

10 (b) PURPOSE.—The purpose of this Act is to prohibit
11 excessive pricing during market shortages.

12 **SEC. 3. DEFINITIONS.**

13 As used in this Act—

14 (1) the term “market shortage” means a situa-
15 tion in which the total supply of all clinically inter-
16 changeable versions of an FDA-regulated drug is in-
17 adequate to meet the current or projected demand at
18 the user level;

19 (2) the term “drug” means a drug intended for
20 use by human beings, which—

21 (A) because of its toxicity or other poten-
22 tiality for harmful effect, or the method of its
23 use, or the collateral measures necessary to its
24 use, is not safe for use except under the super-

1 vision of a practitioner licensed by law to ad-
2 minister such drug; or

3 (B) is limited by an approved application
4 under section 505 of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 355) to use under
6 the professional supervision of a practitioner li-
7 censed by law to administer such drug;

8 (3) the term “biologic” means a virus, thera-
9 peutic serum, toxin, antitoxin, vaccine, blood, blood
10 component or derivative, allergenic product, or anal-
11 ogous product, or arsphenamine or derivative of ars-
12 phenamine (or any other trivalent organic arsenic
13 compound), applicable to the prevention, treatment,
14 or cure of a disease or condition of human beings;
15 and

16 (4) the term “vital drug” means any drug or
17 biologic used to prevent or treat a serious or life-
18 threatening disease or medical condition, for which
19 there is no other available source with sufficient sup-
20 ply of that drug or biologic or alternative drug or
21 biologic available.

22 **SEC. 4. UNREASONABLY EXCESSIVE DRUG PRICING.**

23 (a) IN GENERAL.—

24 (1) AUTHORITY.—The President may issue an
25 Executive order declaring a market shortage for a

1 period of 6 months with regard to one or more vital
2 drugs due to a market shortage under this Act.

3 (2) UNLAWFUL ACT.—If the President issues
4 an Executive order under paragraph (1), it shall be
5 unlawful for any person to sell vital drugs at a price
6 that is unreasonably excessive and indicates that the
7 seller is taking unfair advantage of the cir-
8 cumstances related to a market shortage to unrea-
9 sonably increase prices during such period.

10 (b) AUTHORITY.—The Attorney General is author-
11 ized to enforce penalties under this Act.

12 **SEC. 5. ENFORCEMENT.**

13 (a) ENFORCEMENT.—

14 (1) IN GENERAL.—Whoever sells, or offers to
15 sell, any vital drug during a declared market short-
16 age with the knowledge and intent to charge a price
17 that is unreasonably excessive under the cir-
18 cumstances shall be guilty of an offense under this
19 section and subject to injunction and penalties as
20 provided in paragraphs (2) and (3).

21 (2) ACTION IN DISTRICT COURT FOR INJUNC-
22 TION.—Whenever it shall appear to the Attorney
23 General that any person is engaged in or about to
24 engage in acts or practices constituting a violation
25 of any provision of this section and until such com-

1 plaint is dismissed by the Attorney General or set
2 aside by a court on review, the Attorney General
3 may in his or her discretion bring an action in the
4 proper district court of the United States, the
5 United States District Court for the District of Co-
6 lumbia, or the United States courts of any territory
7 or other place subject to the jurisdiction of the
8 United States to enjoin such acts or practices, and
9 upon a proper showing a permanent or temporary
10 injunction or restraining order shall be granted with-
11 out bond in the interest of the public.

12 (3) CRIMINAL PENALTIES.—Any person acting
13 with the knowledge and intent to charge a price that
14 is unreasonably excessive under the circumstances
15 shall be guilty of an offense under this section and
16 title 18, United States Code, and subject to impris-
17 onment for a term not to exceed 3 years, fined an
18 amount not to exceed \$5,000,000, or both.

19 (b) ENFORCEMENT.—The criminal penalty provided
20 by subsection (a) may be imposed only pursuant to a
21 criminal action brought by the Attorney General or other
22 officer of the Department of Justice.

23 (c) MULTIPLE OFFENSES.—In assessing the penalty
24 provided by subsection (a) each day of a continuing viola-
25 tion shall be considered a separate violation.

1 (d) APPLICATION.—

2 (1) IN GENERAL.—This section shall apply—

3 (A) in the geographical area where the
4 vital drug market shortage has been declared;
5 and

6 (B) to all wholesalers and distributors in
7 the chain of distribution.

8 (2) INAPPLICABLE.—This section shall not
9 apply to a hospital (as defined in section 1861(e) of
10 the Social Security Act (42 U.S.C. 1395x(e)) or a
11 physician (as defined in section 1861(q) of the So-
12 cial Security Act (42 U.S.C. 1395x(q))).

13 **SEC. 6. DETERMINATION OF UNREASONABLY EXCESSIVE.**

14 (a) IN GENERAL.—The Attorney General, in deter-
15 mining whether an alleged violator's price was unreason-
16 ably excessive, shall consider whether—

17 (1) the price reasonably reflected additional
18 costs, not within the control of that person or com-
19 pany, that were paid, incurred, or reasonably antici-
20 pated by that person or company;

21 (2) the price reasonably reflected additional
22 risks taken by that person or company to produce,
23 distribute, obtain, or sell such product under the cir-
24 cumstances;

1 (3) there is a gross disparity between the chal-
2 lenged price and the price at which the same or
3 similar goods were readily available in the same re-
4 gion and during the same Presidentially declared
5 market shortage;

6 (4) the marginal benefit received by the whole-
7 saler or distributor is significantly changed in com-
8 parison with marginal earnings in the year before a
9 market shortage was declared;

10 (5) the price charged was comparable to the
11 price at which the goods were generally available in
12 the trade area if the wholesaler or distributor did
13 not sell or offer to sell the prescription drug in ques-
14 tion prior to the time a market shortage was de-
15 clared; and

16 (6) the price was substantially attributable to
17 local, regional, national, or international market con-
18 ditions.

19 (b) CONSULTATION.—Not later than 1 year after the
20 date of enactment of this Act and annually thereafter, the
21 Attorney General or designee, shall consult with represent-
22 atives of the National Association of Wholesalers, Group
23 Purchasing Organizations, Pharmaceutical Distributors,
24 Hospitals, Manufacturers, patients, and other interested
25 community organizations to reassess the criteria set forth

1 in subsection (a) in determining unreasonably excessive
2 and prepare and submit to Congress a report on the re-
3 sults of the reassessment.

4 **SEC. 7. DURATION.**

5 (a) IN GENERAL.—Any market shortage declared by
6 the President in accordance with this Act shall be in effect
7 for a period of not to exceed 6 months from the date on
8 which the President issues the Executive order.

9 (b) TERMINATION.—Any market shortage declared
10 by the President in accordance with this Act shall termi-
11 nate if—

12 (1) there is enacted a law terminating the mar-
13 ket shortage which shall be passed by Congress after
14 a national market shortage is declared; or

15 (2) the President issues a proclamation termi-
16 nating the market shortage;
17 whichever comes first.

18 (c) DECLARATION RENEWAL.—The President may
19 renew the state of market shortage declared under sub-
20 section (a), if the President declares that the severe short-
21 age continues to affect the health and well being of citizens
22 beyond the initial 6-month period.

○