II

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protecting Patients and Hospitals From Price Gouging Act".

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds that—

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

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

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

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

SEC. 3. DEFINITIONS.

As used in this Act—

(1) the term ''market shortage'' means a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level;

(2) the term ''drug'' means a drug intended for use by human beings, which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the super-

vision of a practitioner licensed by law to administer such drug; or

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

(3) the term ''biologic'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings; and

(4) the term ''vital drug'' means any drug or biologic used to prevent or treat a serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or biologic or alternative drug or biologic available.

SEC. 4. UNREASONABLY EXCESSIVE DRUG PRICING.

(a) IN GENERAL.—

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

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

(2) UNLAWFUL ACT.—If the President issues an Executive order under paragraph (1), it shall be unlawful for any person to sell vital drugs at a price that is unreasonably excessive and indicates that the seller is taking unfair advantage of the circumstances related to a market shortage to unreasonably increase prices during such period.

(b) AUTHORITY.—The Attorney General is authorized to enforce penalties under this Act.

SEC. 5. ENFORCEMENT.

(a) ENFORCEMENT.—

(1) IN GENERAL.—Whoever sells, or offers to sell, any vital drug during a declared market shortage with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances shall be guilty of an offense under this section and subject to injunction and penalties as provided in paragraphs (2) and (3).

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

plaint is dismissed by the Attorney General or set aside by a court on review, the Attorney General may in his or her discretion bring an action in the proper district court of the United States, the United States District Court for the District of Columbia, or the United States courts of any territory or other place subject to the jurisdiction of the United States to enjoin such acts or practices, and upon a proper showing a permanent or temporary injunction or restraining order shall be granted without bond in the interest of the public.

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

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

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

(d) APPLICATION.—

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

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

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

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

SEC. 6. DETERMINATION OF UNREASONABLY EXCESSIVE.

(a) IN GENERAL.—The Attorney General, in determining whether an alleged violator's price was unreasonably excessive, shall consider whether—

(1) the price reasonably reflected additional costs, not within the control of that person or company, that were paid, incurred, or reasonably anticipated by that person or company;

(2) the price reasonably reflected additional risks taken by that person or company to produce, distribute, obtain, or sell such product under the circumstances;

(3) there is a gross disparity between the challenged price and the price at which the same or similar goods were readily available in the same region and during the same Presidentially declared market shortage;

(4) the marginal benefit received by the wholesaler or distributor is significantly changed in comparison with marginal earnings in the year before a market shortage was declared;

(5) the price charged was comparable to the price at which the goods were generally available in the trade area if the wholesaler or distributor did not sell or offer to sell the prescription drug in question prior to the time a market shortage was declared; and

(6) the price was substantially attributable to local, regional, national, or international market conditions.

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

in subsection (a) in determining unreasonably excessive and prepare and submit to Congress a report on the results of the reassessment.

SEC. 7. DURATION.

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

(b) TERMINATION.—Any market shortage declared by the President in accordance with this Act shall terminate if—

(1) there is enacted a law terminating the market shortage which shall be passed by Congress after a national market shortage is declared; or

(2) the President issues a proclamation terminating the market shortage;

whichever comes first.

(c) DECLARATION RENEWAL.—The President may renew the state of market shortage declared under subsection (a), if the President declares that the severe shortage continues to affect the health and well being of citizens beyond the initial 6-month period.

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