

KOHL and LEAHY to reintroduce an important bill for all Americans. The bill that we are reintroducing today would reduce barriers to affordable prescription drugs by eliminating one of the prominent loopholes brand name drug companies use to limit access to generic drugs.

Our bill, the Fair Prescription Drug Competition Act of 2007, would end the marketing of so-called “authorized generics” during the 180-day period Congress created exclusively for true generics to enter the market. I have spoken with my colleagues many times about this important issue.

In an effort to balance the need for returns on research facilitated by brand name prescription drug companies with the need for more affordable prescription drug options for consumers, Congress passed the Hatch-Waxman law in 1984. This law provided brand name companies with a number of incentives for investing in the research and development of new medications. These included a 20-year patent on drugs, 5 years of data exclusivity, 3 years of exclusivity for clinical trials, up to 5 years of patent extension, 6 months exclusivity for conducting pediatric testing, and a 30-month automatic stay against generic competition if the generic challenges the brand patent. Generic prescription drug manufacturers, on the other hand, received a 180-day exclusivity period, awarded to the first company to successfully challenge a brand name patent and enter the market.

This 6-month exclusivity period has been crucial to encouraging generic drug companies to make existing drugs more affordable. Challenging a brand name drug's patent takes time, money, and involves absorbing a great deal of risk. Generic drug companies rely on the added revenue provided by the 180-day exclusivity period to recoup their costs, fund new patent challenges where appropriate, and ultimately pass savings onto consumers.

Since 1984, there have been many attempts to exploit loopholes in the law in order to delay generic entry to the market and extend brand monopolies. The 2003 Medicare law addressed many of these loopholes. However, brand name manufacturers have found another loophole in current law, so-called “authorized generics.”

An authorized generic drug is a brand name prescription drug produced by the same brand manufacturer on the same manufacturing lines, yet repackaged as a generic in order to confuse consumers and shut true generics out of the market. Because it is not a true generic and does not require an additional FDA approval, an authorized generic can be marketed during the federally mandated 6-month exclusivity period for generics. This discourages true generic companies from entering the market and offering lower-priced prescription drugs.

As I have said many times, authorized generics are a sham. This practice

of re-labeling a brand product and placing it on the market to undermine the 180-day exclusivity period will only serve to reduce generic competition and lead to longer brand monopolies and higher healthcare costs over the long-term.

Brand name drug companies are expected to lose as much as \$75 billion over the next 5 years as some of their best sellers go off-patent and generic competition increases. So, not surprisingly, these big pharmaceutical companies are desperately trying to protect their market share and prevent consumers from cashing in on savings from generic drugs.

Today, generic medications comprise more than 56 percent of all prescriptions in this country, and yet they account for only 13 percent of our nation's drug costs. In fact, generic drugs provide 50 to 80 percent cost-savings over brand name drugs. These savings make a big difference in the lives of working families. That is why we must protect the true intent of Hatch-Waxman.

The bill we are introducing today eliminates the authorized generic loophole, protects the integrity of the 180 days, and improves consumer access to lower-cost generic drugs. I urge my colleagues to support this timely and important piece of legislation.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 438

*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 “Fair Prescription Drug Competition Act”.

**SEC. 2. PROHIBITION OF AUTHORIZED GENERICS.**

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

**“(o) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—**

“(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

“(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term ‘authorized generic drug’—

“(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

“(B) does not include any drug to be marketed, sold, or distributed—

“(i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

“(ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).”

Mr. LEAHY. Mr. President, I am pleased today to join Senators ROCKEFELLER, KOHL and SCHUMER in introducing legislation to end the use of so-called “authorized generics” during the 180-day period that Congress intended for true generic market exclusivity. Authorized generics are nothing more than repackaged brand name drugs purporting to be a generic, but without the benefit of a true generic's lower cost. This practice is anticompetitive and anti-consumer.

Amendments to the Hatch-Waxman Act of 1984, enacted as part of the Medicare Modernization Act (Title XI, PL 108-173) in 2003, generally grant a generic company that successfully challenges the patent of a name brand pharmaceutical company 180 days of marketing exclusivity on that generic drug. Having co-sponsored those amendments, I know that they were designed to give greater incentives for generic manufacturers to bring generic drugs quickly to the market, thus promoting competition and lowering prices for consumers.

In 2005, Senators GRASSLEY and ROCKEFELLER and I raised concerns about the practice of manufacturing authorized generics. We feared that practice could have a negative impact on competition for both blockbuster and smaller drugs, because the generic industry would be less inclined to invest in their production. According to a recent Generic Pharmaceutical Association study, our fears were well founded: Authorized generics diminish Hatch-Waxman incentives for generic firms to challenge brand name patents, resulting in higher consumer prices.

The legislation we introduce today bars brand name drug firms from producing “authorized generics.” Slapping a different name on a patented drug and calling it generic is not real competition, and it saps incentives from real generic drug makers to compete by making lower-cost generic drugs. Consumers deserve the lower costs and real choices of truly generic medicines.

I look forward to working with my colleagues on both sides of the aisle to make this good bill into a good law.

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SUBMITTED RESOLUTIONS

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**SENATE RESOLUTION 46—AUTHORIZING EXPENDITURES BY THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS**

Mrs. BOXER submitted the following resolution; from the Committee on Environment and Public Works; which was referred to the Committee on Rules and Administration:

S. RES. 46

*Resolved*, That, in carrying out its powers, duties, and functions under the Standing Rules of the Senate, in accordance with its jurisdiction under rule XXV of such rules, including holding hearings, reporting such hearings, and making investigations as authorized by paragraphs 1 and 8 of rule XXVI

of the Standing Rules of the Senate, the Committee on Environment and Public Works is authorized from March 1, 2007, through September 30, 2007; October 1, 2007, through September 30, 2008; and October 1, 2008, through February 28, 2009, in its discretion (1) to make expenditures from the contingent fund of the Senate, (2) to employ personnel, and (3) with the prior consent of the Government department or agency concerned and the Committee on Rules and Administration, to use on a reimbursable or non reimbursable basis the services of personnel of any such department or agency.

SEC. 2(a). The expenses of the committee for the period March 1, 2007, through September 30, 2007, under this resolution shall not exceed \$2,841,799, of which amount (1) not to exceed \$4,667 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946 (2 U.S.C. 72a(i))), and (2) not to exceed \$1,167 may be expended for the training of the professional staff of such committee (under procedures specified by section 202(j) of that Act).

(b) For the period October 1, 2007, through September 30, 2008, expenses of the committee under this resolution shall not exceed \$4,978,284, of which amount (1) not to exceed \$8,000 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946 (2 U.S.C. 72a(i))), and (2) not to exceed \$2,000 may be expended for the training of the professional staff of such committee (under procedures specified by section 202(j) of that Act).

(c) For the period October 1, 2008, through February 28, 2009, expenses of the committee under this resolution shall not exceed \$2,113,516, of which amount (1) not to exceed \$3,333 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946 (2 U.S.C. 72a(i))), and (2) not to exceed \$833 may be expended for the training of the professional staff of such committee (under procedures specified by section 202(j) of that Act).

SEC. 3. The committee shall report its findings, together with such recommendations for legislation as it deems advisable, to the Senate at the earliest practicable date, but not later than February 28, 2009.

SEC. 4. Expenses of the committee under this resolution shall be paid from the contingent fund of the Senate upon vouchers approved by the chairman of the committee, except that vouchers shall not be required (1) for the disbursement of salaries of employees paid at an annual rate, or (2) for the payment of telecommunications provided by the Office of the Sergeant at Arms and Doorkeeper, United States Senate, or (3) for the payment of stationery supplies purchased through the Keeper of the Stationery, United States Senate, or (4) for payments to the Postmaster, United States Senate, or (5) for the payment of metered charges on copying equipment provided by the Office of the Sergeant at Arms and Doorkeeper, United States Senate, or (6) for the payment of Senate Recording and Photographic Services, or (7) for payment of franked and mass mail costs by the Sergeant at Arms and Doorkeeper, United States Senate.

SEC. 5. There are authorized such sums as may be necessary for agency contributions related to the compensation of employees of the committee from March 1, 2007, through September 30, 2007; October 1, 2007 through September 30, 2008; and October 1, 2008, through February 28, 2009, to be paid from the Appropriations account for “Expenses of Inquiries and Investigations”.

**SENATE RESOLUTION 47—HONORING THE LIFE AND ACHIEVEMENTS OF GEORGE C. SPRINGER, SR., THE NORTHEAST REGIONAL DIRECTOR AND A FORMER VICE PRESIDENT OF THE AMERICAN FEDERATION OF TEACHERS**

Mr. DODD submitted the following resolution; which was referred to the Committee on the Judiciary:

**S. RES. 47**

Whereas George C. Springer, Sr., formerly Northeast regional director of the American Federation of Teachers (AFT), president of AFT Connecticut, and AFT vice president, was an accomplished union leader, a pillar of the civil rights community, a high school teacher and athletics coach, and a dedicated family man and devoted friend;

Whereas George Springer was known by those who worked with him as a generous mentor, a conciliator, and a skilled problem-solver;

Whereas George Springer, as president of AFT Connecticut, helped strengthen and expand the statewide organization to include not only teachers but also paraprofessionals and other school-related personnel, higher education faculty, healthcare professionals, and public employees, and united them around his vision of a shared destiny and a common commitment to quality services and professional integrity;

Whereas George Springer was an AFT vice president for 13 years and served for 4 years as the chair of the AFT's human rights and community relations committee;

Whereas George Springer cared deeply about the cause of civil rights, was a leader in the National Commission for African American Education, a board member of Amistad America, Inc., vice president of the John E. Rogers African American Cultural Center, and president of the New Britain, Connecticut chapter of the National Association for the Advancement of Colored People;

Whereas George Springer was born in the Panama Canal Zone in 1932, attended Central Connecticut State University, formerly Teachers College of Connecticut, and received a graduate degree from the University of Hartford;

Whereas George Springer was a union activist throughout his 20-year teaching career in New Britain;

Whereas George Springer succumbed on December 19, 2006, at the age of 74, after a long battle with cancer; and

Whereas George Springer is survived by his wife, Gerri Brown-Springer, 4 children, 10 grandchildren, and 4 great-grandchildren; Now, therefore, be it

*Resolved*, That the Senate honors George C. Springer, Sr. as a dedicated and pioneering leader, and a man of generous spirit who took on tough challenges with courage and compassion.

**SENATE RESOLUTION 48—AUTHORIZING EXPENDITURES BY THE COMMITTEE ON ARMED SERVICES**

Mr. LEVIN submitted the following resolution; from the Committee on Armed Services; which was referred to the Committee on Rules and Administration:

**S. RES. 48**

*Resolved*, That in carrying out its powers, duties, and functions under the Standing Rules of the Senate, in accordance with its jurisdiction under rule XXV of such rules, in-

cluding holding hearings, reporting such hearings, and making investigations as authorized by paragraphs 1 and 8 of rule XXVI of the Standing Rules of the Senate, the Committee on Armed Services is authorized from March 1, 2007, through September 30, 2007; October 1, 2007, through September 30, 2008; and October 1, 2008, through February 28, 2009, in its discretion (1) to make expenditures from the contingent fund of the Senate, (2) to employ personnel, and (3) with the prior consent of the Government department or agency concerned and the Committee on Rules and Administration, to use on a reimbursable or nonreimbursable basis the services of personnel of any such department or agency.

SEC. 2. (a) The expenses of the Committee on Armed Services for the period March 1, 2007, through September 30, 2007, under this Resolution shall not exceed \$4,073,254, of which amount—

(1) not to exceed \$75,000 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946, as amended); and

(2) not to exceed \$30,000 may be expended for the training of the professional staff of such committee (under procedures specified by section 202(j) of the Legislative Reorganization Act of 1946).

(b) For the period October 1, 2007, through September 30, 2008, expenses of the Committee on Armed Services under this Resolution shall not exceed \$7,139,800, of which amount—

(1) not to exceed \$80,000 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946, as amended); and

(2) not to exceed \$30,000 may be expended for the training of the professional staff of such committee (under the procedures specified by section 202(j) of the Legislative Reorganization Act of 1946).

(c) For the period October 1, 2008, through February 28, 2009, expenses of the Committee on Armed Services under this Resolution shall not exceed \$3,032,712, of which amount—

(1) not to exceed \$50,000 may be expended for the procurement of the services of individual consultants, or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946, as amended); and

(2) not to exceed \$30,000 may be expended for the training of the professional staff of such committee (under the procedures specified by section 202(j) of the Legislative Reorganization Act of 1946).

SEC. 3. Expenses of the Committee on Armed Services under this Resolution shall be paid from the contingent fund of the Senate upon vouchers approved by the chairman of the committee, except that vouchers shall not be required—

(1) for the disbursement of salaries of employees paid at an annual rate;

(2) for the payment of telecommunications provided by the Office of the Sergeant at Arms and Doorkeeper, United States Senate;

(3) for the payment of stationery supplies purchased through the Keeper of the Stationery, United States Senate;

(4) for payments to the Postmaster, United States Senate;

(5) for the payment of metered charges on copying equipment provided by the Office of the Sergeant at Arms and Doorkeeper, United States Senate;

(6) for the payment of Senate Recording and Photographic Services; or