

Now 30 years later, Americans again are feeling the pain at the pump. The price of oil has reached \$78 a barrel, and Americans are paying more than \$3.00 a gallon for gas. America's 20-million-barrel-a-day habit costs our economy \$800 million a day, or \$300 billion annually. Because we import 60 percent of our oil, much of it from the Middle East, our dependence on oil is also a national security issue as well. Al-Qaida knows that oil is America's Achilles heel. Osama bin Laden has urged his supporters to "Focus your operations on oil, especially in Iraq and the gulf area, since this will cause them to die off."

At a time when the energy and security stakes couldn't be higher, CAFE standards have been stagnant. In fact, because of a long-standing deadlock in Washington, CAFE standards that initially increased so quickly have remained stagnant for the last 20 years.

Since 1985, efforts to raise the CAFE standard have been stymied by opponents who have argued that Congress does not possess the expertise to set specific benchmarks and that an inflexible congressional mandate would result in the production of less safe cars and a loss of American jobs. This has been a bureaucratic logjam that has ignored technological innovations in the auto industry and crippled our ability to increase fuel efficiency.

To attempt to break this two-decade-long deadlock and start the U.S. on the path towards energy independence, I have joined with Senators LUGAR, BIDEN, SMITH, BINGAMAN, HARKIN, COLEMAN, and DURBIN to introduce the Fuel Economy Reform Act of 2006. This bill would set a new course by establishing regular, continual, and incremental progress in miles per gallon, targeting 4 percent annually, but preserving NHTSA expertise and flexibility on how to meet those targets.

Over the past 20 years, NHTSA's efforts to improve fuel economy have been encumbered with loopholes and resistance. With this bill, CAFE standards would increase by 4 percent every year unless NHTSA can justify a deviation in that rate by proving that the increase is technologically unachievable, does not materially reduce the safety of automobiles manufactured or sold in the U.S., or can prove it is not cost-effective when comparing with the economic and geopolitical value of a gallon of gasoline saved. We specifically define the grounds upon which NHTSA can determine cost-effectiveness. By flipping the presumption that has served as a barrier to action, we replace the status quo of continued stagnation with steady, measured progress.

Under this system, if the 4 percent annualized improvement occurs over ten years, this bill would save 1.3 billion barrels of oil per day—or 20 billion gallons of gasoline per year. If gasoline is just \$2.50 per gallon, consumers will save \$50 billion at the pump in 2018. By 2018, we would be cutting global warm-

ing pollution by 220 million metric tons of carbon dioxide equivalent gases.

The Fuel Economy Reform Act also would provide fairness and flexibility to domestic automakers by establishing different standards for different types of cars. Currently, manufacturers have to meet broad standards over their whole fleet of cars. This disadvantages companies like Ford and General Motors that produce full lines of small and large cars and trucks rather than manufacturers that only sell small cars.

In order to enable domestic manufacturers to develop advanced-technology vehicles, this legislation provides tax incentives to retool parts and assembly plants. This will strengthen the U.S. auto industry by allowing it to compete with foreign hybrid and other fuel efficient vehicles. It is our expectation that NHTSA will use its enhanced authority to bring greater market-based flexibility into CAFE compliance by allowing the banking and trading of credits among all vehicle types and between manufacturers.

Finally, the bill also would expand the tax incentives that encourage consumers to buy advanced technology vehicles. The bill would lift the current 60,000-per-manufacturer cap on buyer tax credits to allow more Americans to buy ultra-efficient vehicles like hybrids.

By ending a 20-year stalemate on CAFE, the Fuel Economy Reform Act will recapture the innovation that Congress and the auto industry launched in response to the OPEC crisis. In the process, we will safeguard our national security, protect our economy, reduce consumer pain at the pump, and protect our climate, environment, and public health. I urge my colleagues to join our bipartisan coalition and support the Fuel Economy Reform Act.

By Mr. ROCKEFELLER (for himself, Mr. SCHUMER, and Mr. LEAHY):

S. 3695. A bill to amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs; to the Committee on Health, Education, Labor, and Pensions.

Mr. ROCKEFELLER. Mr. President, I rise today with Senators SCHUMER and LEAHY to introduce an important piece of legislation for seniors, individual with disabilities, children, and anyone who is taking a brand name prescription drug with a generic equivalent. The bill we are introducing today would outlaw the latest in a long line of loopholes that brand name manufacturers have found to limit generic drug access to the market.

Our legislation would prohibit brand name manufacturers from introducing so-called "authorized generics" during the 180-day period that Congress intended true generics to have exclusive market rights. Some of my colleagues may be wondering what an "authorized generic" is.

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. This is a huge problem and one that is becoming even more prevalent as patents on some of the best-selling brand name pharmaceuticals start to expire.

Pravachol, Zocor and Zolofit have patents that have expired or will expire this year. Together, these drugs account for approximately \$9 billion in sales annually. In 2007, another top-selling brand name drug, Norvasc, will lose its patent protection, followed by Advair the following year.

When brand name drugs lose patent rights, this opens the door for consumers, employers, third-party payers, and other purchasers to save billions—between 50 and 80 percent on the costs of prescriptions—by using generic versions of these drugs. 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.

We have addressed this issue before. In 1984, Congress passed the Hatch-Waxman legislation to provide consumers greater access to lower cost generic drugs. The intent of this law was to improve generic competition, while preserving the ability of brand name manufacturers to discover and market new and innovative products. As part of this law, the first generic company on the market after challenging an expiring brand name patent is granted 180-days of exclusive market rights, which is just a fraction of the up to 20 years of exclusive market rights afforded brand companies.

This 6-month incentive is crucial to maintaining the balance between encouraging brand drug companies to make new drugs and 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.

This latest attempt by big drug companies to protect their profits puts billions of dollars in savings for consumers in jeopardy. 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. 3695

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

**SECTION 1. 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, recently I was pleased to introduce with Senators KOHL, GRASSLEY and SCHUMER, the Preserve Access to Affordable Generics Act of 2006, S. 3582. That bill was designed to improve the timely and effective introduction of generic pharmaceuticals into the marketplace.

It is no secret that prescription drug prices are rapidly increasing and are a source of considerable concern to many Americans, especially senior citizens and families. In a marketplace free of manipulation, generic drug prices can be as much as 80 percent lower than the comparable brand name version. Unfortunately, there are still some companies driven by greed that may be keeping low-cost, life-saving generic drugs off the marketplace, off pharmacy shelves, and out of the hands of consumers by carefully crafted anti-competitive agreements between drug manufacturers.

In 2001, and last Congress, I introduced a related bill, the Competition Act. That bill, which is now law, is small in terms of length but large in terms of impact. It ensured that law enforcement agencies could take quick and decisive action against companies seeking to cheat consumers by delaying availability of generic medicines. It gave the Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic

drugs out of the market—a practice that not only hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, but also contributes to rising medical costs.

The Drug Competition Act, which was incorporated in the Medicare Modernization Act, was a bipartisan effort to protect consumers in need of patented medicines who were being forced to pay considerably higher costs because of collusive secret deals designed. It is regrettable that we must come to the floor again today and take additional action to prevent drug companies from continuing to find and exploit loopholes.

The bill I am introducing tonight with Senators ROCKEFELLER and SCHUMER is very important. It will provide incentives for generic companies to make the investments needed to introduce low-cost generic medicines for all our citizens.

The bill assures all Americans that the original intent of the Hatch-Waxman law is carried out. That law was to provide incentives for generic companies to challenge the validity of patents on medicines and provide incentives for generic companies to manufacture low-cost medicines. That incentive was simple.

Under Hatch-Waxman law, the first generic company, called the first-filer, which successfully develops a generic version of a patented drug and meets certain other requirements, can get a 180-day exclusivity period to be the only generic company to have permission to make and sell that generic drug.

That was called an exclusivity period because that is what the Congress intended—that generic company would have the exclusive right for 180 days to make the generic version of the patented medicine.

The problem is that recently brand-name companies have been labeling their own patented drugs also as a generic version of itself, or licensing others to make it, and selling both the brand-name version and the so-called generic version. This undercuts the potential profits of the “real” generic company and denies them what the Hatch-Waxman law promised and for a long time delivered—an exclusivity period lasting up to 180 days.

When the brand-name company offers a competing “fake” generic version of the drug, that can cut the profits of the real generic manufacturer greatly—thus making it less likely that a real generic company will even want to make the product.

The Rockefeller bill prevents the brand-name company from doing that for the 180-day exclusivity period. I hope my colleagues will join me in supporting this effort.

SUBMITTED RESOLUTIONS

SENATE CONCURRENT RESOLUTION 110—COMMEMORATING THE 60TH ANNIVERSARY OF THE HISTORIC 1946 SEASON OF MAJOR LEAGUE BASEBALL HALL OF FAME MEMBER BOB FELLER AND HIS RETURN FROM MILITARY SERVICE TO THE UNITED STATES

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

S. CON. RES. 110

Whereas Robert William Andrew Feller was born on November 3, 1918, near Van Meter, Iowa, and resides in Gates Mills, Ohio;

Whereas Bob Feller enlisted in the Navy 2 days after the attack on Pearl Harbor in 1941;

Whereas, at the time of his enlistment, Bob Feller was at the peak of his baseball career, as he had been signed to the Cleveland Indians at the age of 16, had struck out 15 batters in his first Major League Baseball start in August 1936, and established a Major League record by striking out 18 Detroit Tigers in a single, 9-inning game;

Whereas Bob Feller is the first pitcher in modern Major League Baseball history to win 20 or more games before the age of 21;

Whereas Bob Feller pitched the only opening day no-hitter in Major League Baseball history;

Whereas, on April 16, 1940, at Comiskey Park in Chicago, Bob Feller threw his first no-hitter and began the season for which he was awarded Major League Baseball Player of the Year;

Whereas Bob Feller served with valor in the Navy for nearly 4 years, missing almost 4 full baseball seasons;

Whereas Bob Feller was stationed mostly aboard the U.S.S. Alabama as a gunnery specialist, where he kept his pitching arm in shape by tossing a ball on the deck of that ship;

Whereas Bob Feller earned 8 battle stars and was discharged in late 1945, and was able to pitch 9 games at the end of that season, compiling a record of 5 wins and 3 losses;

Whereas 60 years ago, amid great speculation that, after nearly 4 seasons away from baseball, his best pitching days were behind him, Bob Feller had 1 of the most amazing seasons in baseball history;

Whereas, in the 1946 season, Bob Feller pitched 36 complete games in 42 starts;

Whereas, on April 30, 1946, in a game against the New York Yankees, Bob Feller pitched his second career no-hitter;

Whereas, in 1946, Bob Feller pitched in relief 6 times, saving 4 games;

Whereas, in 1946, Bob Feller routinely threw between 125 and 140 pitches a game, a feat not often seen today;

Whereas, in 1946, Bob Feller pitched 371½ innings and had 348 strikeouts;

Whereas, in 1946, Bob Feller had an earned run average of 2.18;

Whereas, in 1946, a fastball thrown by Bob Feller was clocked at 109 mph;

Whereas Bob Feller was the winning pitcher in the 1946 All Star Game, throwing 3 scoreless innings in a 12-0 victory by the American League;

Whereas, in 1946, Bob Feller led the American League in wins, shutouts, strikeouts, games pitched, and innings;

Whereas the baseball career of Bob Feller ended in 1956, but not before pitching his