private sector to shed somewhere between 125,000 and 249,000 jobs between now and 2021. More than half of those losses will fall on the backs of small businesses.

Two million small businesses across this country cannot afford President Obama's new tax. Twenty-six million workers, who get their insurance through their employer, cannot afford President Obama's new tax. And the 12 million people who buy health insurance plans on their own in the individual market cannot afford President Obama's new tax. That is why today we introduce legislation called the Jobs and Premium Protection Act.

I introduced this bill along with my friend, the ranking member of the Senate Finance Committee, Senator HATCH. Our legislation is simple and straightforward. It eliminates the health care law's punitive tax on every individual, family, and small business that chooses to do the right thing and buy health insurance. Unbelievably, the health care law punishes individuals and punishes small businesses, the very two groups who find buying health insurance at an affordable price extremely challenging. Why would the Federal Government implement policies that make it harder by imposing a tax on the products these individuals buy?

Some must believe that insurers will simply be able to absorb the tax. Well, experts tell us that assumption is false. Here is what the nonpartisan Joint Committee on Taxation said in a letter to Senator JOHN KYL in June of this year:

> We expect a very large portion of the insurance industry fee to be passed forward to purchasers of insurance in the form of higher premiums.

A very large portion, they say. Then they go on to say:

> Eliminating this fee would decrease the average family premium in 2016 by $300 to $400.

Isn't that what we want, to lower the cost of insurance for individuals? This is the way to do it.

Finally, the Joint Committee on Taxation letter confirms the following:

> Repealing the health insurance industry fee would reduce the premium prices of plans offered by covered entities by 2 to 2½ percent.

This ill-conceived discriminatory tax must be eliminated. It must be stopped well before it starts to impact individuals, families, and small businesses. Our bill is a critical piece of pro-business legislation. It has the support of organizations such as the National Federation of Independent Business, the U.S. Chamber of Commerce, Blue Cross Blue Shield Association, and America's health insurance plans.

I urge colleagues on both sides of the aisle who are concerned about the cost of insurance for families of America, who are shocked and surprised, some in disbelief, that what the President promised the American people—of a reduction in premiums—isn't true, and who want to try to in a little way right that wrong to do so by cosponsoring and supporting the Jobs and Premium Protection Act.

I thank the Chair and the ranking member of the Senate Finance Committee, Senator HATCH—especially Senator HATCH—for his leadership and for joining me in introducing this legislation today. The time has come to eliminate a bad policy that not only increases health insurance costs but also negatively impacts America's job creators.

By Mr. BINGAMAN (for himself, Mr. VITTER, Mr. MERKLEY, and Mr. BROWN of Ohio.

S. 1882. A bill to amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market; to the Committee on Health, Education, Labor, and Pensions.

Mr. BINGAMAN. Mr. President, I rise today with Senators VITTER, MERKLEY, and BROWN of Ohio to introduce the Fair and Immediate Release of Generic Drugs Act of 2011. The FAIR GENERxICS Act is an important step in addressing the root cause of the growing cost of healthcare—the delay of generic drugs entering the market. This legislation has broad support from consumer advocates, the generics industry, and experts including: AARP, Apotex generics manufacturer, Families USA, U.S. PIRG, Consumers Union, Consumer Federation of America, Center for Medicare Advocacy, the National Legislative Association on Prescription Drug Prices, Alliance for Retired Americans, and Community Catalyst.

According to the Kaiser Family Foundation, prices for brand-name prescription drugs have continued to outpace inflation. Overall spending on prescription drugs also has increased sharply. In 2008 spending in the U.S. for prescription drugs was $234.1 billion, nearly 6 times the $40.3 billion spent in 1990. Generic drugs can be an important source of affordable prescription drugs for many Americans. On average, generic drugs are four times less expensive than name brand drugs.

Pay-for-delay patent settlements brand and generic pharmaceutical manufacturers, however, are delaying timely public access to generic drugs, which costs consumers and taxpayers billions of dollars annually. In 2010 the Federal Trade Commission reported 31 such settlements, a 60 percent increase since 2009, and in 2011 FTC reported 28 such settlements. Many experts and consumer advocates have called for legislation to address this problem and ensure access to affordable medicines for all Americans.

The FAIR GENERxICS Act of 2011 addresses the root cause of anti-competitive pay-for-delay settlements between brand and generic pharmaceutical manufacturers—the unintended, structural flaw in the Hatch-Waxman Act that allows ''parked'' exclusivities to block generic competition. By doing so, the legislation ensures consumers will benefit from full and fair generic competition at the earliest, most appropriate time.

The legislation would prevent ''parked exclusivities'' from delaying full, fair, and early generic competition by modifying three key elements of existing law. First, the legislation would grant the right to share exclusivity to any generic filer who wins a patent challenge in the district court or is not sued for patent infringement by the brand company. The legislation also maximizes the incentive for all generic challengers to fight to bring products to market at the earliest possible time by holding generic settlers to the deferred entry date agreed to in their settlements. Finally, in order to create more clarity regarding litigation risk for pioneer drug companies and generic companies, the legislation requires pioneer companies to make a litigation decision within the 45 day window provided for in the Hatch-Waxman Act.

As a result of these changes, companies who prevail in their patent challenges and immediately come to market may be the sole beneficiary of the 180 day exclusivity period. In addition, companies will understand litigation risk before launching generic products.

Taken in concert these changes will ensure that generic markets are opened as they were originally envisioned under the Hatch-Waxman exclusivity periods; and will generate significant savings for the U.S. consumers, the Federal Government, and the American health care system.

Mr. President, 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. 1882

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 And Immediate Release of Generic Drugs Act'' or the ''FAIR Generics Act''.

SEC. 2. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING FIRST APPLICANT STATUS.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) IN GENERAL.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(A) in clause (iv)(II)—

(i) by striking item (bb); and

(ii) by redesignating items (cc) and (dd) as items (bb) and (cc), respectively; and

(B) by adding at the end the following:

''(v) FIRST APPLICANT DEFINED.—As used in this subsection, the term 'first applicant' means an applicant—

''(I)(aa) that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and

''(bb) that has not entered into a disqualifying agreement described under clause (vii)(II); or

''(II)(aa) for the drug that is not described in subclause (I) and that, with respect to the applicant and drug, each requirement described in clause (vi) is satisfied; and

''(bb) that has not entered into a disqualifying agreement described under clause (vii)(II).

''(vi) REQUIREMENT.—The requirements described in this clause are the following:

''(I) The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted.

''(II) With regard to each such unexpired patent for which the applicant described in clause (v)(II) submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against such applicant within the 45 day period specified in paragraph (5)(B)(iii); or if an action was brought within such time period, such an action was withdrawn or dismissed by a court (including a district court) without a decision that the patent was valid and infringed; or if an action was brought within such time period and was not withdrawn or so dismissed, such applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed).

''(III) If an applicant described in clause (v)(I) has begun commercial marketing of such drug, the applicant described in clause (v)(II) does not begin commercial marketing of such drug until the date that is 30 days after the date on which the applicant described in clause (v)(I) began such commercial marketing.''.

(2) CONFORMING AMENDMENT.—Section 505(j)(5)(D)(i)(IV) of such Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is amended by striking ''The first applicant'' and inserting ''The first applicant, as defined in subparagraph (B)(v)(I),''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply.

SEC. 3. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) LIMITATIONS ON AGREEMENTS TO DEFER COMMERCIAL MARKETING DATE.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)), as amended by section 2, is further amended by adding at the end the following:

''(vii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING; LIMITATION ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—

''(I) AGREEMENT TO DEFER APPROVAL OR COMMERCIAL MARKETING DATE.—An agreement described in this subclause is an agreement between a first applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, (aa) not to seek an approval of its application that is made effective on the earliest possible date under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, (bb) not to begin the commercial marketing of its drug on the earliest possible date after receiving an approval of its application that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or (cc) to both items (aa) and (bb).

''(II) AGREEMENT THAT DISQUALIFIES APPLICANT FROM FIRST APPLICANT STATUS.—An agreement described in this subclause is an agreement between an applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

''(viii) LIMITATION ON ACCELERATION.—If an agreement described in clause (vii)(I) includes more than 1 possible date when an applicant may seek an approval of its application or begin the commercial marketing of its drug—

''(I) the applicant may seek an approval of its application or begin such commercial marketing on the date that is the earlier of—

''(aa) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which the commercial marketing could begin on an earlier date; or

''(bb) 180 days after another first applicant begins commercial marketing of such drug; and

''(II) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which commercial marketing could begin on an earlier date, shall be the date used to determine whether an applicant is disqualified from first applicant status pursuant to clause (vii)(II).''.

(2) NOTIFICATION OF FDA.—Section 505(j) of such Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(11)(A) The holder of an abbreviated application under this subsection shall submit to the Secretary a notification that includes—

''(i)(I) the text of any agreement entered into by such holder described under paragraph (5)(B)(vii)(I); or

''(II) if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement; and

''(ii) the text, or a written detailed description in the event of an agreement that has not been reduced to text, of any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement described in clause (i).

''(B) The notification described under subparagraph (A) shall be submitted not later than 10 business days after execution of the agreement described in subparagraph (A)(i). Such notification is in addition to any notification required under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

''(C) Any information or documentary material filed with the Secretary pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this paragraph is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.''.

(3) PROHIBITED ACTS.—Section 301(e) of such Act (21 U.S.C. 331(e)) is amended by striking ''505 (i) or (k)'' and inserting ''505 (i), (j)(11), or (k)''.

(b) INFRINGEMENT OF PATENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(7) The exclusive remedy under this section for an infringement of a patent for which the Secretary of Health and Human Services has published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.''.

(c) APPLICABILITY.—

(1) LIMITATIONS ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—The amendment made by subsection (a)(1) shall apply only with respect to—

(A) an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply; and

(B) an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

(2) NOTIFICATION OF FDA.—The amendments made by paragraphs (2) and (3) of subsection (a) shall apply only with respect to an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 324—COMMEMORATING THE 60TH ANNIVERSARY OF THE UNITED STATES-AUSTRALIA ALLIANCE

Mr. KERRY (for himself, Mr. LUGAR, Mr. INHOFE, and Mr. WEBB) submitted the following resolution; which was considered and agreed to:

S. RES. 324

Whereas the United States Government enhanced its relationship with the Governments of Australia and New Zealand with the signing of the Australia-New Zealand-United States (ANZUS) Treaty on September 1, 1951, and subsequently engaged in annual, bilateral Australian-United States Ministerial (AUSMIN) consultations between the

Australian Ministers of Foreign Affairs and Defence and the United States Secretaries of State and Defense, including a meeting in San Francisco in September 2011 that commemorated the 60th anniversary of the United States-Australia alliance;

Whereas the alliance remains fundamental to the security of Australia and the United States and to the peace, stability, and prosperity of the Asia-Pacific region, and is one dimension of a broad and deep relationship between the two countries that encompasses robust bilateral strategic, intelligence, trade, and investment relations based on shared interests and values, a common history and cultural traditions, and mutual respect;

Whereas numerous visits by Presidents of the United States, including this week by President Barack Obama, and by the Australian Prime Minister to the United States, including in 2011 when Prime Minister Julia Gillard addressed a Joint Session of Congress, have underscored the strength and closeness of the relationship;

Whereas members of the United States and Australian armed forces have fought side-by-side in every major conflict since the First World War, with the commitment to mutual defense and security between the United States and Australia being longstanding and unshakeable, as was demonstrated by the joint decision to invoke the ANZUS Treaty in the aftermath of the September 11, 2001, terrorist attacks;

Whereas the Governments of the United States and Australia continue to share a common approach to the most pressing issues in global defense and security, including in Afghanistan, where about 1,550 Australian Defence Force personnel are deployed, and in response to natural disasters and humanitarian crises, such as in Japan following the earthquake and subsequent tsunami in March 2011;

Whereas Secretary of State Hillary Clinton recently stated, ''We are expanding our alliance with Australia from a Pacific partnership to an Indo-Pacific one, and indeed a global partnership. . . . Australia's counsel and commitment have been indispensable.'';

Whereas Secretary of Defense Leon Panetta recently remarked that ''the United States has no closer ally than Australia. . . . [We] affirm this alliance, affirm that it remains strong, and that we are determined to deepen our security cooperation even further to counter the threats and challenges that we face in the future.'';

Whereas the Governments of the United States and Australia agreed to set up a Force Posture Working Group at the November 2010 AUSMIN to examine options to align respective force postures consistent with the national security requirements of both countries and to help positively shape the regional security environment;

Whereas the United States and Australia committed in a Joint Statement on Cyberspace during the 2011 AUSMIN meeting to consult together and determine appropriate options to address any threats;

Whereas the Government of Australia is a major purchaser of United States military resources, approximately 50 percent of Australia's war-fighting assets are sourced from the United States, and the Government of Australia has plans to spend a substantial sum over the next 10-15 years to update or replace up to about 85 percent of its military equipment;

Whereas, on September 29, 2010, the Senate provided its advice and consent to ratification of the Treaty Between the Government of the United States of America and the Government of Australia Concerning Defense Trade Cooperation, signed at Sydney, Australia, September 5, 2007, which will facilitate defense trade between the two nations and enhance interoperability between military forces;

Whereas the Governments of the United States and Australia support open, transparent, and inclusive regional architectures to preserve and enhance peace, security, and prosperity in the Asia-Pacific region;

Whereas the Governments of the United States and Australia cooperate closely in regional and global forums, as evidenced by Australia's support for the United States as the host this month of the Asia-Pacific Economic Cooperation forum in 2011 and the United States' support for Australia to host the G-20 in 2014;

Whereas the United States and Australia elevated their trade relationship through the Australia-United States Free Trade Agreement that entered into force on January 1, 2005, and exports of United States goods to Australia have risen by 53 percent since that time, totaling $21,900,000,000 in 2010;

Whereas the United States is Australia's largest destination for foreign investment, helping create jobs for United States workers, with Australian companies employing more than 88,000 people directly in the United States;

Whereas the Governments and people of the United States and Australia work closely to advance and support human rights, the rule of law, and basic freedoms worldwide;

Whereas the Governments and people of the United States and Australia work jointly and separately to support democracy, economic reform, and good governance in the Pacific Islands, Southeast Asia, South and Central Asia, the Middle East, and North Africa, among other areas of the world; and

Whereas the Governments of the United States and Australia are working through their respective aid agencies (USAID and AusAID) and also exploring opportunities for collaboration across a wide variety of areas: Now, therefore, be it

Resolved, That the Senate—

(1) celebrates the 60th Anniversary of the United States-Australia alliance and takes this opportunity to reiterate the enduring significance of this historic friendship that serves as an anchor of peace, stability, and prosperity in the Asia-Pacific region and in the world;

(2) supports United States efforts to strengthen military, diplomatic, trade, economic, and people-to-people cooperation with Australia, including initiatives to positively shape the evolving strategic and economic environment that connects the Indian and the Pacific Oceans; and

(3) urges close consultation between the Governments of the United States and Australia in preparation for the East Asia Summit to be chaired by Indonesia on November 19, 2011, and encourages other, new forms of cooperation with the Government and people of Australia that strengthen regional architectures to enhance peace, security, and prosperity in the Asia-Pacific region.

SENATE RESOLUTION 325—RECOGNIZING THE 2012 WORLD CHOIR GAMES IN CINCINNATI, OHIO, AS A GLOBAL EVENT OF CULTURAL SIGNIFICANCE TO THE UNITED STATES AND EXPRESSING SUPPORT FOR DESIGNATION OF JULY 2012 AS WORLD CHOIR GAMES MONTH IN THE UNITED STATES

Mr. PORTMAN (for himself and Mr. BROWN of Ohio) submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 325

Whereas the World Choir Games, the largest choral competition in the world, takes place every 2 years, is known as the ''Olympics of choral music'', and has the goal of uniting people from all countries through singing in peaceful competition;

Whereas, from July 4 through July 14, 2012, Cincinnati, Ohio, will be first city in the United States to host the World Choir Games;

Whereas the Seventh World Choir Games are expected to include more than 400 choirs from more than 70 countries, 20,000 official participants, including performers, event officials, delegations, and international jury members, and up to 200,000 spectators;

Whereas choirs will compete in 23 different musical genres evaluated by an impartial international jury of choral music experts;

Whereas the genres of barbershop and show choir will be added as competition categories for the first time in recognition of their popularity in the United States;

Whereas the uniting of the people of the world through singing in peaceful competition in the United States in 2012 affirms the commitment of the United States to global cultural awareness, understanding, and appreciation; and

Whereas it is appropriate to designate July 2012 as World Choir Games Month in the United States: Now, therefore, be it

Resolved, That the Senate—

(1) recognizes the global significance of the Seventh World Choir Games to be hosted in Cincinnati, Ohio, from July 4 through July 14, 2012;

(2) recognizes Interkultur, the Cincinnati Organizing Committee for the Seventh World Choir Games, the Cincinnati USA Convention and Visitors Bureau, the city of Cincinnati, and the State of Ohio for their efforts to secure and host the World Choir Games;

(3) expresses appreciation to all people of the world who will participate in the World Choir Games, either in competition or as visitors, and to all of the volunteers who will welcome the participants and other visitors to the United States;

(4) supports the designation of July 2012 as World Choir Games Month in the United States; and

(5) renews the commitment of the United States to world peace and friendship and increasing global cultural understanding through singing in peaceful competition.

SENATE RESOLUTION 326—DESIGNATING THURSDAY, NOVEMBER 17, 2011, AS ''FEED AMERICA DAY''

Mr. HATCH (for himself, Mr. BROWN of Ohio, Mr. CRAPO, Mr. LEAHY, Mr. LUGAR, and Mr. UDALL of New Mexico) submitted the following resolution; which was considered and agreed to:

S. RES. 326

Whereas Thanksgiving Day celebrates the spirit of selfless giving and an appreciation for family and friends;

Whereas the spirit of Thanksgiving Day is a virtue upon which the United States was founded;

Whereas, according to the Department of Agriculture, roughly 48,000,000 people in the United States, including 16,200,000 children, continue to live in households that do not have an adequate supply of food; and