By Mr. BARRASSO (for himself, Mr. HATCH, and Ms. SNOWE): S. 1880. A bill repeal the health care law’s job-killing health insurance tax; to the Committee on Finance.

Mr. HATCH. Mr. President, I want to thank my good friend from Wyoming, Senator Barrasso, for his work on this and other issues related to the President’s health law. He is a leading orthopedist, and I have nothing but respect for him. As a former medical liability defense lawyer defending doctors, nurses, hospitals, and other health care providers, I appreciate good doctors, and this is one good doctor. He and Dr. Coburn are two of the best people I have known and are a credit to their profession.

I thank him for his work on this and other issues related to the President’s health care law. He has been tireless in his careful analysis and fair criticism of the health spending law, and I believe we are in agreement on that bill’s flawed design.

The President and his allies repeatedly promised that the health law would decrease costs. That is not going to happen. The so-called Affordable Care Act is going to, in fact, drive up the cost of covering families.

Among the biggest reasons for this inflationary impact are the taxes that will be imposed on the American people to pay for the lost $2.5 trillion in new spending. At the top of the list of senseless cost-increasing taxes is the law’s tax on health insurance. It is not clear to me how the cost of health insurance will decrease by taxing it.

Many people probably don’t even know this tax exists. Like most of the taxes in ObamaCare, its implementation was conveniently delayed until after the 2012 Presidential election. But this tax is coming. It is going to hurt employers and employees. It is going to come on top of the $7 billion in costs on businesses and their employees. Revenue that could be spent on higher wages, new hires, and capital investment—increasing jobs and growing the economy—will instead go to pay this tax. And that is just the start. In the second decade, this tax will cost businesses and their employees $208 billion.
It is important to understand how this insurance tax will work. Starting in 2014, the health insurance companies will have to pay a tax based on their net premiums written in the fully insured market. This is the market where 97 percent of all businesses and individuals purchase their health insurance. It is the market where the self-employed and uninsured go to purchase insurance.

So who will pay this tax? Someone has to pay it. Contrary to the talking points that often come out of this administration, all of these new mandates and regulations are not free. Someone has to foot the bill. Ultimately, it will be those least able to afford it who are paying it. Primarily businesses—and their employees—will be responsible for paying this tax. When the cost of coverage goes up due to this tax, employees will pay for it in lower wages or higher health care costs.

According to a recent study, the average employee with a family plan will see his or her take-home pay reduced by $5,000 over the next decade because of this tax. The American people should remember that statistic the next time they hear their liberal supporters of the health care law talk about wage stagnation or income inequality.

The costs of this tax will be felt by citizens even beyond those small businesses and individuals impacted. A study issued by the Independent Business shows this tax alone will lead to a loss of 125,000 to 249,000 jobs between now and 2021.

The legislation we are introducing today will help to reverse this trend. Ultimately, all of Obamacare must be repealed. We are introducing new legislation that will make the health care system more affordable and will provide health care reform that works. The American people will be able to purchase health insurance products that are affordable for their budget needs and for their budget decisions.

The people of Utah and people all over the United States need a jobs agenda. Repeal of the health insurance tax through the Patient Protection Act we are introducing today would do much to address the scourge of unemployment and get our economy moving again.

Mr. President, I yield the floor.

Mr. BARRASSO. Mr. President, first, I wish to congratulate and thank my colleague, the senior Senator from Utah, Mr. HATCH, for his continued leadership on the issue of health care. As the ranking member of the Finance Committee, he has been a stalwart and strong supporter in efforts for the American people to have health care they need. And from the doctor they want, at a price they can afford, and amazing in his fight against what this body, what the House of Representatives, and what the President have forced onto people all across this country, which, under our Constitution, and it undermines personal liberty. It exacerbates our Constitution and it undermines it in its entirety. It underminds our Constitution and it underminds personal liberty. It exacerbates the Nation’s debt crisis by creating and expanding entitlement spending, and it also undermines our economy, destroying existing jobs and preventing the creation of new ones.

The health care law slaps this tax on all health insurance companies based on net premiums written in which is called the fully insured market. This means the tax an insurance company must pay is equal to the percent of their market share. The larger the insurance company’s market share, the higher their annual health insurance tax becomes. The aggregate tax in 2014 is $8 billion and climbs to $13 billion in 2015 and 2016, eventually reaching over $14 billion in 2018. After that, the law mandates the health insurance tax grow by premium inflation. More inflation, higher taxes.

The Joint Committee on Taxation makes it clear the insurance tax will be borne by consumers in the form of higher prices, by owners of firms in the form of lower profits, by employees of those firms in the form of lower wages, or by other suppliers to the firms in the form of lower payment. The Joint Committee on Taxation specifically hits health insurance companies that sell their products in the fully insured market. As we have learned, and heard earlier on the Senate floor, 87 percent of small businesses buy their health insurance in the fully insured market.

The fully insured market is also the place that uninsured individuals and the self-employed go when they need to purchase medical insurance. Insurance companies selling plans to individuals, small businesses, and their employees are the ones who are going to end up paying this unfair tax. This new punitive tax will add hundreds of dollars to family and small business insurance premiums every year.

The Wyoming Blue Cross Blue Shield Association tells me that a Wyoming family of four will see an increase because of this tax of over $300 in 2014. In 2018, that same Wyoming family of four will see over a $500 premium increase as a result of the tax. These premium increases will have been passed through to consumers as a direct result of this health care law’s tax component—what the President and the Democrats in this body have foisted on the American public.

Additionally, the Holtz-Eakin March 2011 study proves that the health insurance tax will raise premiums by as much as 3 percent or nearly $5,000 for a family of four over the next decade. What American family, I ask you, can afford to see their take-home pay reduced by $5,000 over the next decade? Thanks to the President’s new tax, the Nation’s unemployment rate stands at 9 percent. There are 14 million Americans, people across our country, unemployed and looking for work. Struggling American families cannot bear the burden of President Obama’s new tax.

A recent study by the National Federation of Independent Business found this health insurance tax will force the
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 have falsely assumed 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 premiums of plans offered by covered entities by 2 to 2½ percent.

This ill-conceived discriminatory tax must be eliminated. It must be stopped well ahead of time to impact individual, 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 VITTER—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 Pension.

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 increasing costs—the delay of generic drugs entering the market. This legislation has broad support from consumer advocates, the generics industry, and experts including: AARP, Consumer Federation of America, Consumer and Generic Protection Act.

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 $254.1 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 settlements brand and generic pharmaceutical manufacturers, however, are delaying timely public access to generic drugs, which costs consumers and taxpayers billions annually. In 2010 the Federal Trade Commission reported 31 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 that make it extremely challenging for generic drug companies to bring new affordable medicines to market. The legislation would prevent “parked exclusivities” from delaying the entry of a new, 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.—


(A) in clause (iv)(II), by adding at the end the following: 

(“v”) FIRST APPLICANT DEFINED.—As used in this subsection, the term ‘first applicant’ means an applicant 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, and such application contains a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and 

(B) by adding the following:

(“v”) FIRST APPLICANT DEFINED.—As used in this subsection, the term ‘first applicant’ means an applicant 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, and such application contains a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and 

(2) (A) in paragraph (2)(A)(vii), by adding at the end the following: 


(2) (B) in paragraph (2)(A)(vii)(IV), by striking clause (v) and (ii) and (iii).
“(I) (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) it has not entered into a disqualifying agreement described under subsection (vii)(II).

“(I) REQUIREMENTS. 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)(v)(I) or a statement described in paragraph (2)(A)(v)(IV) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(v)(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)(v)(I), 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 is invalid or unenforceable.

“(III) If an 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)(B)(vii)(IV) of such Act (21 U.S.C. 355(j)(5)(B)(vii)(IV)) is amended by striking “no action” and inserting “an action

(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)(vii)(I) 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:

“(I) by first applicant to defer commercial marketing; limitation on acceleration of deferred commercial marketing date.—

“(I) LIMITATION 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 listed drug that provides the 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 under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or to begin commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant for such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

“(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 for such drug.

“(III) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING DATE .—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355A) is amended by striking “(vi) REQUIREMENT.—The requirements described in clause (v)(II) applied to an application filed under section 505A, or section 527, (bb) 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 for such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

“(vii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING DATE .—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355A) is amended by striking “(vi) REQUIREMENT.—The requirements described in clause (v)(II) applied to an application filed under section 505A, or section 527, (bb) 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 for such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

“(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 the commercial marketing could begin on an earlier date;

“(b) 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).

“(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 subsection shall prevent the 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 “(i) (k) (k) and inserting “(i) (j) (k) (l) (m) (n) (o) (p) (q) (r) (s) (t) (u) (v) (w) (x) (y) (z) (aa) (bb) (cc) (dd) (ee) (ff) (gg) (hh) (ii) (jj) (kk) (ll) (mm) (nn) (oo) (pp) (qq) (rr) (ss) (tt) (uu) (vv) (ww) (xx) (yy) (zz) (aaa) (bbb)

(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


(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 (21 U.S.C. 355(j)(5)(B)(vii)(I)) executed after the date of enactment of this Act.

WHEREAS the United States Government enters into agreements to prevent the disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

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 entered into agreements to facilitate the advancement 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