(Mr. UDALL) was added as a cosponsor of S. 1853, a bill to recalculate and restore retirement annuity obligations of the United States Postal Service, eliminate the requirement that the United States Postal Service pre-fund the Postal Service Retiree Health Benefits Fund, place restrictions on the closure of postal facilities, create incentives for innovation for the United States Postal Service, to maintain levels of postal service, and for other purposes.

S. 1856

At the request of Mr. DEMINT, the names of the Senator from Oklahoma (Mr. COBURN) and the Senator from South Carolina (Mr. GRAHAM) were added as cosponsors of S. 1856, a bill to prohibit Federal funding for lawsuits seeking to invalidate specific State laws that support the enforcement of Federal immigration laws.

S. 1862

At the request of Mr. LAUTENBERG, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. 1862, a bill to amend the Public Health Service Act to improve the health of children and reduce the occurrence of sudden unexpected infant death and to enhance public health activities related to stillbirth.

S. 1866

At the request of Mr. COONS, the names of the Senator from New York (Mrs. GILLIBRAND) and the Senator from Missouri (Mr. BLUNT) were added as cosponsors of S. 1866, a bill to provide incentives for economic growth, and for other purposes.

S. 1868

At the request of Mr. MENENDEZ, the names of the Senator from Texas (Mr. CORNYN) and the Senator from Colorado (Mr. BENNET) were added as cosponsors of S. 1868, a bill to establish within the Smithsonian Institution the Smithsonian American Latino Museum, and for other purposes.

S. RES. 297

At the request of Mr. MENENDEZ, the names of the Senator from Oregon (Mr. MERKLEY) and the Senator from Minnesota (Ms. KLOBUCHAR) were added as cosponsors of S. Res. 297, a resolution congratulating the Corporation for Supportive Housing on the 20th anniversary of its founding.

S. RES. 301

At the request of Mr. CASEY, the names of the Senator from New Jersey (Mr. MENENDEZ) and the Senator from Wyoming (Mr. ENZI) were added as cosponsors of S. Res. 301, a resolution urging the people of the United States to observe October 2011 as Italian and Italian-American Heritage Month.

S. RES. 302

At the request of Ms. LANDRIEU, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of S. Res. 302, a resolution expressing support for the goals of National Adoption Day and National Adoption Month by promoting national awareness of adoption and the children awaiting families, celebrating children and families involved in adoption, and encouraging the people of the United States to secure safety, permanency, and well-being for all children.

AMENDMENT NO. 939

At the request of Mr. BARRASSO, the name of the Senator from Mississippi (Mr. WICKER) was added as a cosponsor of amendment No. 939 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

AMENDMENT NO. 975

At the request of Mr. BLUNT, the name of the Senator from North Dakota (Mr. HOEVEN) was added as a cosponsor of amendment No. 975 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

AMENDMENT NO. 976

At the request of Mr. BLUNT, the names of the Senator from North Dakota (Mr. HOEVEN) and the Senator from Nebraska (Mr. JOHANNS) were added as cosponsors of amendment No. 976 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

AMENDMENT NO. 979

At the request of Mr. BEGICH, the name of the Senator from Tennessee (Mr. CORKER) was added as a cosponsor of amendment No. 979 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

AMENDMENT NO. 980

At the request of Mr. WEBB, the name of the Senator from Mississippi (Mr. WICKER) was added as a cosponsor of amendment No. 980 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

AMENDMENT NO. 1009

At the request of Mrs. HAGAN, the names of the Senator from Ohio (Mr. BROWN), the Senator from Pennsylvania (Mr. TOOMEY) and the Senator from Alaska (Ms. MURKOWSKI) were added as cosponsors of amendment No. 1009 intended to be proposed to H.R. 2354, a bill making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2012, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

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 fundamental flaw.

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 coverage.

Among the biggest reasons for this inflationary impact are the taxes that will be imposed on the American people to pay for the lost $2.6 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 be a drag on our economy, and it is going to depress wages.

I am glad to be standing here with Senator BARRASSO as we introduce the Jobs and Premium Protection Act, a bill that repeals this onerous and counterproductive tax on American workers and job creators. The President speaks about the need for Congress to do something about jobs. Well, we would go a long way toward creating the conditions for job growth by passing this legislation.

Unemployment in this country remains a full-blown crisis. Millions are out of work, and the 9-percent unemployment rate doesn't begin to capture the full extent of our jobs deficit. We need policies that will encourage businesses to invest and expand. Yet the health law's insurance tax does just the opposite. According to a recent analysis, in just the first 10 years, the insurance tax would impose $87 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 87 percent of small businesses 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 all too 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 small 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. The factories that lose orders because their customers' health care costs are going up will pay for this tax. Those searching for work will feel it too, because money that could go to new wages for new employees will instead go to pay for this tax and increased health care costs for existing employees.

This tax will hit wide swaths of the American economy, with millions of businesses and individuals impacted. A study by the National Federation of 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. I am fully committed to uprooting it in its entirety. It undermines our Constitution and it undermines 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 people of Utah and people all over the United States need a jobs agenda. Repeal of the health insurance tax through the Jobs and Premium 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.

The PRESIDING OFFICER. The Senator from Wyoming.

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 to get for the American people the health care they need, 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, to me, has been bad for patients, bad for the providers of those patients—the nurses and doctors who take care of them—and terrible for taxpayers.

That is why week after week I come to the floor to give a doctor's second opinion about the health care law, and why I am so pleased to be here with my colleague today to join in the introduction of this piece of legislation.

As people all around the country know—those who listened to the many speeches given during the debate on health care—the President and Democrats in Washington promised the American people this trillion dollar health care spending law would lower health insurance premiums. That is what the President promised, that health insurance premium costs would go down. Well, the American people have now had 19 months to review what is in the health care law, and they are finding that the President and the Washington Democrats sold them a bill of goods.

On September 27 of this year, the Kaiser Family Foundation issued its annual survey of employer-sponsored health insurance premiums. The report showed that employer-provided health insurance premiums rose—went up, not down—$1,303 for an average family last year alone. Remember—and we do—that the President repeatedly promised his health care law would reduce the average annual family premium by $2,500. Yet the exact opposite of what the President promised has occurred. The Kaiser Family Foundation report shows significant premium increases, not savings as the President promised.

Not only are premiums continuing to climb, but the President and Washington Democrats paid for their health care spending law by imposing billions of dollars in new taxes on American business and American consumers. Independent experts agree these taxes only serve to increase an individual, a family, or a small business's cost to buy medical coverage. Specifically, section 9010 of the health care law creates a new $60-plus billion tax on health insurance plans starting in 2014.

The health care law slaps this tax on all health insurance companies based on net premiums in what 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 $11.3 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.

Former Congressional Budget Office Director Douglas Holtz-Eakin released a study in March of this year estimating the health insurance tax could exceed $87 billion between 2014 and 2020. Some on the other side of the aisle want to message this tax as a ''health insurance fee.'' I would say to my friends all across this country, Do not be fooled. This new tax directly hits small business.

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 payments.

Remember, this tax only 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 this 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 and small businesses are the ones that are hit with the tax. The new tax doesn't hit large, self-insured businesses. Ultimately, uninsured 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 a premium 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 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 brunt of President's 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 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