

“(A) WAITING PERIODS.—For”; and
(2) by adding at the end the following:

“(B) LIMITATION ON DENIAL OF BENEFITS.—
For purposes of paragraph (2), a group health plan may not deny benefits otherwise provided under the plan for the treatment of an injury solely because such injury resulted from the participation of the individual in a legal mode of transportation or a legal recreational activity.”.

Mr. FRIST. I ask unanimous consent the committee amendment be agreed to, the bill, as amended, be read the third time and passed, the motion to reconsider be laid upon the table, and any statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The committee amendment in the nature of a substitute was agreed to.

The bill (S. 423), as amended, was read the third time and passed.

PROVIDING FOR A CONDITIONAL ADJOURNMENT OR RECESS OF BOTH HOUSES

Mr. FRIST. I ask unanimous consent the Senate proceed to the adjournment resolution which is at the desk, provided further that the resolution be amended with the amendment at the desk, and that the resolution be agreed to, as amended, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 4079) was agreed to, as follows:

On page 1, line 2, strike from “that” through the end of page 2, line 9 and insert in lieu thereof the following:

“When the House adjourns on Wednesday, November 24, 2004, on a motion offered pursuant to this concurrent resolution by its Majority Leader or his designee, it stands adjourned until 2 p.m. on Monday, December 6, 2004, or until the time of any reassembly pursuant to section 2 of this concurrent resolution, whichever occurs first; and when the Senate recesses or adjourns from Saturday, November 20, 2004, through Wednesday, November 24, 2004, on a motion offered pursuant to this concurrent resolution by its Majority Leader or his designee, it stands recessed or adjourned until noon on Monday, December 6, 2004, or Tuesday, December 7, 2004, or until such other time as may be specified by the Majority Leader or his designee in the motion to recess or adjourn, or until the time of reassembly pursuant to section 2 of this concurrent resolution, whichever occurs first.”

The concurrent resolution (H. Con. Res. 529), as amended, was agreed to, as follows:

H. CON. RES. 529

Resolved, That the resolution from the House of Representatives (H. Con. Res. 529) entitled “Concurrent resolution providing for a conditional adjournment of the House of Representatives and a conditional recess or adjournment of the Senate.”, do pass with the following amendment:

On page 1, line 2, strike from “That” through the end of page 2, line 9 and insert in lieu thereof the following:

when the House adjourns on Wednesday, November 24, 2004, on a motion offered pursuant to this concurrent resolution by its Majority Leader or his designee, it stands adjourned until 2:00 p.m. on Monday, December 6, 2004, or until the time of any reassembly pursuant to section 2 of

this concurrent resolution, whichever occurs first; and when the Senate recesses or adjourns from Saturday, November 20, 2004, through Wednesday, November 24, 2004, on a motion offered pursuant to this concurrent resolution by its Majority Leader or his designee, it stands recessed or adjourned until noon on Monday, December 6, 2004, or Tuesday, December 7, 2004, or until such other time as may be specified by the Majority Leader or his designee in the motion to recess or adjourn, or until the time of reassembly pursuant to section 2 of this concurrent resolution, whichever occurs first.

MARINE DEBRIS RESEARCH AND REDUCTION ACT

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 792, S. 2488.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant legislative clerk read as follows:

A bill (S. 2488) to establish a program within the National Oceanic and Atmospheric Administration and the United States Coast Guard to help identify, assess, reduce, and prevent marine debris and its adverse impacts on the marine environment and navigation safety, in coordination with non-Federal entities, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. FRIST. Mr. President, I ask unanimous consent that an Inouye substitute amendment, which is at the desk, be agreed to, the bill, as amended, be read a third time and passed, the title amendment be agreed to, the motions to reconsider be laid upon the table, with no intervening action or debate, and that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 4078) was agreed to.

(The amendment is printed in today's RECORD under “Text of Amendments.”)

The bill (S. 2488), as amended, was read the third time and passed.

The title was amended so as to read: “A bill to establish a program within the National Oceanic and Atmospheric Administration and the United States Coast Guard to help identify, determine sources of, assess, reduce, and prevent marine debris and its adverse impacts on the marine environment and navigation safety, in coordination with non-Federal entities, and for other purposes.”

CONTROLLED SUBSTANCES EXPORT REFORM ACT OF 2004

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. 3028, which was introduced earlier today.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant legislative clerk read as follows:

A bill (S. 3028) to amend the Controlled Substances Import and Export Act to pro-

vide authority for the Attorney General to authorize the export of controlled substances from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied.

There being no objection, the Senate proceeded to consider the bill.

Mr. HATCH. Mr. President, I rise to introduce with my colleague, Senator BIDEN, the Controlled Substances Export Reform Act of 2004. This bill would make a minor, but long overdue, change to the Controlled Substances Act to reflect the reality of commerce in the 21st Century and to protect high-paying American jobs, while maintaining strong safeguards on exports.

Before I discuss this bill, I want to thank Senator BIDEN for working with me on this important legislation. Senator BIDEN has long been recognized as a national leader on drug-related measures, and we have a history of working together on a bipartisan basis to enact sensible reforms in this area, as evidenced by the recent enactment of our steroid precursor bill. I respect his thoughtful collaboration, and I thank him for his work on the proposal we are introducing today.

In sum, this proposed legislation will amend the Controlled Substances Act of 1970 providing greater parity for U.S. manufacturers, who wish to export their products while retaining full DEA authority over U.S. exports.

Current law places severe restrictions on exports of certain drug products from the United States. The Controlled Substances Export Reform Act proposes to amend that law to correct one small, but onerous provision that is unnecessarily threatening American jobs. This change is entirely consistent with the long-established regulatory scheme pursuant to the Federal Food, Drug and Cosmetic Act.

At present U.S. pharmaceutical manufacturers are permitted to export most controlled substances only to the immediate country where the products will be consumed. Shipments to centralized sites for further distribution across national boundaries are prohibited. This contrasts with the freedom of pharmaceutical manufacturers throughout the rest of the world to readily move approved medical products among and between international drug control treaty countries without limitation or restriction.

The unique prohibitions imposed on domestic manufacturers disadvantage U.S. businesses by requiring smaller, more frequent and costly shipments to each country of use without any demonstrable benefit to public health or safety. By imposing significant logistical challenges and financial burdens on U.S. companies, the law creates a strong incentive for domestic pharmaceutical manufacturers to move production operations overseas, threatening high-wage American jobs.

The Controlled Substances Act of 1970 permits U.S. manufacturers of Schedule I and II substances and

Schedule III and IV narcotics to export their products from U.S. manufacturing sites only to the receiving country where the drug will be used. The law prohibits export of these products if the drugs are to be distributed outside the country to which they are initially sent. The effect of this restriction is to prevent American businesses from using cost-effective, centralized foreign distribution facilities. In addition, under the current regime, unexpected cross-border demands or surges in patient needs cannot be met. Likewise, complex and time-sensitive export licensing procedures prevent the shipment of pharmaceuticals on a real time basis.

European drug manufacturers face no such constraints. They are able to freely move their exported products from one nation to another while complying with host country laws. This is entirely consistent with the scheme of regulation imposed by international drug control treaties. Only the United States imposes the additional limitation of prohibiting the further transfer of controlled substances.

Thus, while a French or British company can ship its products to a central warehouse in Germany for subsequent distribution across the European Union, an American company must incur the added costs of shipping its products separately to each individual country.

The Controlled Substances Export Reform Act would correct this imbalance and permit the highly regulated transshipment of exported pharmaceuticals placing American businesses on an equal footing with the rest of the world. Importantly, however, DEA's authority to control U.S. exports would not be diminished.

The legislation authorizes the Attorney General, or his designee, the DEA, to permit the re-export of Schedule I and II substances and Schedule III and IV narcotics to countries that are parties to the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances under tightly controlled circumstances: First, each country is required to have an established system of controls deemed adequate by the DEA. Next, only permit or license holders in those countries may receive regulated products. Third, re-exports are limited to one single cross-border transfer. Then the DEA must be satisfied by substantial evidence that the exported substance will be used to meet an actual medical, scientific or other legitimate need, and that the second country of receipt will hold or issue appropriate import licenses or permits. Fifth, in addition, the exporter must notify the DEA in writing within 30 days of a re-export. And finally, an export permit must have been issued by the DEA.

These safeguards are rigorous but fair, and represent a much-needed modernization of the law. The current restrictions on U.S. pharmaceutical exports have remained essentially un-

changed for more than thirty years. In that time, the global economy has changed dramatically. For those among us who express concerns about the outsourcing of American jobs and the competitiveness of U.S. companies, this modest change represents an opportunity to address such problems head-on.

The Controlled Substance Act's limitation on U.S. pharmaceutical exports imposes unique, unnecessary, and significant logistical and financial burdens on American businesses. The effect of this outdated policy is to create a strong incentive for domestic pharmaceutical companies to move production overseas, threatening American jobs and eliminating DEA jurisdiction over the manufacture and shipment of their products. The Controlled Substances Export Reform Act removes this unwarranted barrier to U.S. manufacturers' use of cost-effective distribution techniques while retaining full DEA control of U.S. exports and re-exports. Accordingly, I urge my colleagues to join Senator BIDEN and myself in support of this bill.

SECTION 1003

I appreciate the distinguished Senator from Delaware's work on this legislation and am pleased to join with him in correcting this small, but important provision of law.

Section 1003 of the Controlled Substances Import and Export Act currently permits U.S. pharmaceutical manufacturers to export schedule I and II drugs and schedule III and IV narcotics only to the exact country where the products will be used. While American companies are prohibited from using centralized foreign distribution facilities, our international competitors face no similar restrictions and can freely ship medicines for cross-border distribution between all international drug control treaty countries.

Mr. BIDEN. Will the Senator yield for a question?

Mr. HATCH. Yes.

Mr. BIDEN. Isn't it true that the disadvantage to U.S. businesses of requiring smaller, more frequent shipments to each country of use is substantial? When a foreign entity seeks to import a schedule I or II drug, or a schedule III or IV narcotic from the United States, they must first secure an import permit that is shared with the U.S. manufacturer and DEA. Our companies then have 60 days in which to obtain independent safety and quality testing on each separate product batch to be shipped. Upon completion of that testing, the manufacturer submits a highly detailed export permit application for DEA's approval. If DEA fails to issue the permit within 60 days, the entire process must be restarted. Because independent testing is expensive and the export process is highly paper intensive, it is not unusual for companies to struggle against the 60-day deadline only to have to begin again. Unfortunately, while we engage in this burdensome process, patients suffer without

their drugs and foreign physicians seek out substitutes to unreliable U.S. supplies.

This process was put in place long before the adoption of our international drug control treaties and the anti-diversion protections they provide. It is now outdated and unnecessary.

Mr. HATCH. Yes, the Senator is correct. In addition to the burden imposed on U.S. manufacturing exporters, the advent of the European Union has created a situation that places our foreign distributors in violation of European law. Member countries of the EU are considered borderless in terms of trade. Products introduced into the European Union are required to be available for transport and shipment among and between all member countries under their law. However, because we don't recognize the European Union as a single entity and cross-border transfers are prohibited, our distributors are placed in the position of violating European law in being forced to deny inter-country distribution of U.S. drugs.

Mr. BIDEN. Will the Senator yield for another question?

Mr. HATCH. Yes.

Mr. BIDEN. While the Controlled Substances Act restrictions made sense when they were adopted over 30 years ago, would you agree that changes in the way international pharmaceutical markets work, and in the way controlled substances are tracked, and have since rendered the requirements unnecessary? Our legislation was developed in cooperation with the Drug Enforcement Administration to ensure that all necessary anti-diversion controls remain.

Under our bill, each country is required to have an established system of controls deemed adequate by the DEA. Only DEA permit or license holders in those countries may receive regulated products. Re-exports are limited to one single cross-border transfer. The DEA must be satisfied by substantial evidence that the exported substance will be used to meet an actual medical, scientific or other legitimate need and that the second country of receipt will hold or issue appropriate import licenses or permits. The exporter must notify the DEA in writing within 30 days of a re-export, and an export permit must have been issued by the DEA.

The legislation specifically retains the Drug Enforcement Administration's authority to deny a request to export or re-export a controlled substance. A company seeking to export a drug for subsequent transfer must provide the DEA with exhaustive information on both the country of initial export and the countries to which the controlled substances would ultimately be destined. In addition, DEA must be provided follow-up notification of any cross border shipment within 30 days of that transfer. The U.S. Government will know where all drugs are being shipped and for what purpose. Without that information, U.S. pharmaceuticals will never leave our soil.

Mr. HATCH. That it is correct. The purpose and intent of this legislation is to place U.S. pharmaceutical companies on equal footing with their international competitors. Moreover, this change is entirely consistent with the long-established regulatory scheme pursuant to the Federal Food, Drug and Cosmetic Act. Eliminating the need for multiple, small shipments and the associated wasteful, small batch testing, will save U.S. companies nearly 80 percent over current export distribution costs, savings that will result in more American jobs and stronger international markets for U.S. products.

As the Senator noted, the bill has been crafted with the assistance of the Drug Enforcement Administration to ensure all necessary controls will remain in place while creating a level playing field for American business. It is simply a commonsense update to an outdated law, and I urge its passage.

Mr. FRIST. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements regarding this matter be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 3028) was read the third time and passed, as follows:

S. 3028

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

SECTION 1. REEXPORTATION OF CONTROLLED SUBSTANCES.

(a) SHORT TITLE.—This Act may be cited as the “Controlled Substances Export Reform Act of 2004”.

(b) IN GENERAL.—Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) is amended by adding at the end the following:

“(f) Notwithstanding subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II or is a narcotic drug in schedule III or IV to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:

“(1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the ‘first country’) and the country to which the controlled substance is exported from the first country (referred to in this subsection as the ‘second country’) are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

“(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.

“(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.

“(4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—

“(A) the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

“(B) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

“(5) The controlled substance will not be exported from the second country.

“(6) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

“(7) A permit to export the controlled substance from the United States has been issued by the Attorney General.”.

AUTHORIZATION TO SIGN DULY ENROLLED BILLS OR JOINT RESOLUTIONS

Mr. FRIST. Mr. President, I ask unanimous consent that during this adjournment of the Senate, the majority leader, the assistant majority leader, and the senior Senator from Virginia be authorized to sign duly enrolled bills or joint resolutions.

The PRESIDING OFFICER. Without objection, it is so ordered.

APPOINTMENTS AUTHORITY

Mr. FRIST. Mr. President, I ask unanimous consent that notwithstanding the upcoming recess or adjournment of the Senate, the President of the Senate, the President pro tempore, and the majority and minority leaders be authorized to make appointments to commissions, committees, boards, conferences, or interparliamentary conferences authorized by law, by concurrent action of the two houses or by order of the Senate.

The PRESIDING OFFICER. Without objection, it is so ordered.

ORDERS FOR NOVEMBER 24, 2004 AND DECEMBER 7, 2004

Mr. FRIST. Mr. President, I ask unanimous consent that when the Senate completes its business today, it stand adjourned until 5 p.m. on Wednesday, November 24, 2004, unless the Senate receives a message from the House that the House has agreed to the amendment of the Senate to H. Con. Res. 529, in which case the Senate shall stand adjourned until 9:30 a.m., December 7, 2004, under the provisions of H. Con. Res. 529.

I further ask that following the prayer and pledge, the morning hour be deemed to have expired, the Journal of proceedings be approved to date, the time for the two leaders be reserved, and there then be a period of morning business until the hour of 12:30, with Senators speaking for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

PROGRAM

Mr. FRIST. Mr. President, in a moment we will be adjourning until early December. When we return on Tuesday, December 7, we will be in morning business throughout the day. It is my hope that the intelligence reform conference report will be ready for consideration that afternoon.

Finally, I thank my colleagues on both sides of the aisle. We have had a challenging few days as we worked through the issues remaining before us. Just moments ago, we were able to confirm a very large number of nominations, which have been waiting for Senate action for a long period of time. I thank the Democratic leadership, in particular, for their cooperation and efforts. It took persistence from both sides of the aisle, but it was very important that neither side gave up and the Senate was able to work its will on these nominations.

I wish everybody a happy and safe Thanksgiving.

ADJOURNMENT UNTIL WEDNESDAY, NOVEMBER 24, 2004, AT 5 P.M., OR TUESDAY, DECEMBER 7, 2004, AT 9:30 A.M.

Mr. FRIST. Mr. President, if there is no further business to come before the Senate, I ask unanimous consent that the Senate stand in adjournment under the provisions of H. Con. Res. 529.

The PRESIDING OFFICER. Without objection, the Senate is adjourned until Wednesday, November 24, 2004, at 5 p.m., unless the Senate receives a message from the House agreeing to the amendment of the Senate to H. Con. Res. 529, in which case the Senate will reconvene on Tuesday, December 7, 2004, at 9:30 a.m.

There being no objection, the Senate, at 12:31 p.m., adjourned until Wednesday, November 24, 2004 at 5 p.m. or until Tuesday, December 7, 2004, at 9:30 a.m.

DISCHARGED NOMINATIONS

The Senate Committee on Health, Education, Labor, and Pensions was discharged from further consideration of the following nominations and the nominations were confirmed:

WILLIAM A. SCHAMBRA, OF VIRGINIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING SEPTEMBER 14, 2006.

DONNA N. WILLIAMS, OF TEXAS, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 6, 2006.

CYNTHIA BOICH OF CALIFORNIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 6, 2007.

DOROTHY A. JOHNSON, OF MICHIGAN, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 6, 2007, TO WHICH POSITION SHE WAS APPOINTED DURING THE LAST RECESS OF THE SENATE.

HENRY LOZANO, OF CALIFORNIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 6, 2008.

RAQUEL EGUSQUIZA, OF MICHIGAN, TO BE A MEMBER OF THE BOARD OF TRUSTEES OF THE BARRY GOLDWATER SCHOLARSHIP AND EXCELLENCE IN EDUCATION FOUNDATION FOR A TERM EXPIRING OCTOBER 13, 2005.

MARK D. GEARAN, OF NEW YORK, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR