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Part 1

CONTROLLED SUBSTANCES EXPORT REFORM ACT OF 2005

JUNE 9, 2005.—Ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 184]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 184) to amend the Controlled Substances Import and Export Act to provide authority to the Attorney General to 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 certain conditions are met, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments (stated in terms of the page and line numbers of the introduced bill) are as follows:

Page 2, line 11, strike "or II" and insert "or II,".

Page 2, line 12, strike "or IV" and insert "or IV,".

PURPOSE AND SUMMARY

The purpose of this legislation is to amend Section 1003 of the Controlled Substances Import and Export Act by allowing a controlled substance that has been exported from the United States to be subsequently exported to a third country under certain conditions and pending a permit from the Attorney General.

BACKGROUND AND NEED FOR LEGISLATION

Current law allows U.S. companies to export most controlled substances only to the immediate country where the products will be consumed. Shipment to central sites for further distribution across national boundaries is prohibited.

Foreign competitors labor under no such restrictions and can readily move approved medical products between international drug control treaty countries without limit or restriction. American manufacturers have reported that the exclusive prohibitions imposed by U.S. law on American manufacturers place them at significant disadvantage in international markets, creating incentives for these domestic companies to move production overseas, damaging local economies, and costing U.S. jobs.

H.R. 184 authorizes the Attorney General to permit carefully regulated pharmaceutical exports to countries that are parties to the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

Under the bill, the Attorney General retains full Attorney authority over all shipments of controlled substances and establishes procedures to ensure these products are used solely for legitimate medical or scientific purposes. While the Attorney General's authority over exports is undiminished, by creating new parity for U.S. companies with their international competitors, the legislation encourages domestic production and job growth.

With over 260 small U.S. pharmaceutical manufacturing exporters bringing products to market each year, H.R. 184 will help create thousands of new American jobs annually.

Enactment of H.R. 184 will also protect the jobs of thousands of current U.S. workers whose positions are jeopardized by an outdated law that encourages U.S. drug manufacturers to move production overseas. With production facilities located outside major metropolitan areas, these companies are important to the health and stability of their local economies.

HEARINGS

The Committee on Energy and Commerce has not held hearings on this legislation.

COMMITTEE CONSIDERATION

On Wednesday, April 27, 2005, the Subcommittee on Health met in open markup session and approved H.R. 184 for Full Committee consideration, without amendment, by a voice vote, a quorum being present. On Wednesday, May 4, 2005, the Full Committee met in open markup session and ordered H.R. 184 favorably reported to the House, without amendment, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 184 reported. A motion by Mr. Barton to order H.R. 184 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of Rule XIII of the rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to allow small pharmaceutical manufacturers to be more competitive in the global marketplace by reducing costs associated with regulated shipments of controlled substances intended for multiple countries.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 184, The Controlled Substances Export Reform Act of 2005 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 13, 2005.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 184, the Controlled Substances Export Reform Act of 2005.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

H.R. 184—Controlled Substances Export Reform Act of 2005

H.R. 184 would permit the Attorney General to authorize the export of certain controlled substances from the United States to a country for subsequent export to another country, if certain conditions are met. Current law allows U.S. companies to export controlled substances only to the countries where they will be used. Based on information from the Department of Justice, CBO estimates that implementing H.R. 184 would have no significant effect on the department's spending on drug enforcement activities. Enacting the bill would not affect direct spending or revenues.

H.R. 184 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contact for this estimate is Mark Grabowicz. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates the title of the bill, the "Controlled Substances Export Reform Act of 2005."

Section 2. Subsequent export of controlled substances

Section 2 amends Section 1003 of the Controlled Substances Import and Export Act by adding a new paragraph; (f). Current law under Section 1003(a)(4) for narcotic drugs and Section 1003(c)(3) for nonnarcotic controlled substances prohibits mandates that a controlled substance exported from the United States be used exclusively in the country of import. This section, notwithstanding (a)(4) and (c)(3), will allow the Attorney General to 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 certain conditions are met.

First, the country to which the controlled substance is exported from the United States must be are party to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. The country that imports the controlled substance from the country who received the controlled substances from the United States must also be a party to both treaties. Both countries must 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. The receiver of import in the first county must be a holder of such permits or licenses as may be required under the laws of that country, and a permit or license to import the controlled substance must have been issued by the country.

With respect to the second country, substantial evidence must be furnished to the Attorney General by the person who will export the controlled substance from the United States that the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of that country, and a permit or license to import the controlled substance is to be issued by the country. In addition, it must be demonstrated that the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

The controlled substance will be prohibited from being exported from the second country. 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 must deliver to the Attorney General documentation certifying that such export from the first country has occurred. Finally, the Attorney General must issue a permit to export the controlled substance from the United States.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill,

as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SECTION 1003 OF THE CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. (a) * * *

* * * * * * *

(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.

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