Background Information from Congressman Joe Pitts

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H.R. 184, The Controlled Substances Export Reform Act of 2005

On Wednesday, July 27, 2005 the House will consider S. 1395, the Senate version of H.R. 184, the Controlled Substances Export Reform Act of 2005.

Congressman Pitts originally introduced this legislation on August 8, 2004 in the 108th Congress as H.R. 4882. On January 4, 2005, Congressman Pitts reintroduced the bill as H.R. 184 in the 109th Congress. Senator Orrin Hatch (R-UT) introduced S. 1395 as the companion to Congressman Pitts' legislation. The Senate passed the legislation by unanimous consent on July 13, 2005.

▪ ISSUE SUMMARY

The Controlled Substances Act of 1970 (CSA) places severe restrictions upon exports of certain drug products from the United States. H.R. 184, the Controlled Substances Export Reform Act of 2005, would amend that law to correct one small, but onerous provision that is unnecessarily costing American jobs.

Presently, U.S. pharmaceutical manufacturers are permitted to export most controlled substances only to the immediate country where the products will be consumed. Shipment to central sites for subsequent distribution across national boundaries is prohibited. Pharmaceutical manufacturers in other nations operate under no such restriction. They move their products into and out of international drug control treaty nations at will.

While larger manufacturers with an established foreign presence may choose to manufacture off-shore using existing facilities, smaller U.S. companies and those requiring specialized manufacturing plants for niche pharmaceuticals are forced to choose between investing millions of dollars in multiple shipments and spending millions of dollars in establishing overseas manufacturing facilities. Often, neither option is feasible.

H.R. 184 would amend the CSA to provide greater parity for U.S. manufacturers while retaining full DEA authority over U.S. exports.

▪ LEGAL BACKGROUND

The Controlled Substances Act of 1970 (CSA) permits U.S. manufacturers of Schedule I and II products and Schedules III through 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. Unexpected cross-border demands or patient need surges cannot be met, nor do complex and time-sensitive export licensing procedures allow for ready 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, or re-export, of controlled substances.

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

▪ SUMMARY OF H.R. 184

H.R. 184 authorizes the Attorney General (or his designee, the DEA) to permit the subsequent export of Schedule I and II products and Schedule III and IV narcotics to countries that are parties to the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances. However, these conditions must first be met:

- 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;
- Companies may only use one subsequent shipment ("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;
- The exporter must notify the DEA in writing within 30 days of any re-export; and
- An export permit must have been issued by the DEA.

▪ JOBS IMPACT

An informal survey of impacted U.S. exporters indicates that current law jeopardizes an average of 150 new U.S. jobs each time a covered product is introduced in foreign markets. While larger manufacturers with an established foreign presence may choose to manufacture off-shore using existing facilities, smaller U.S. companies and those requiring specialized manufacturing plants are often forced to send jobs overseas because they cannot afford the extra shipping costs or the overhead involved in establishing facilities overseas.

With 260 small pharmaceutical manufacturers in the U.S and new controlled substances being introduced at record rates, thousands of jobs are at stake each year. The savings this

bill generates by removing excessive government regulation could enable these companies to keep or create more than 15,000 high paying jobs over the next five years.

H.R. 184 would save small U.S. drug manufacturers approximately 70 percent over current export costs, amounting to millions of dollars a year for each producer and adding thousands of jobs.

The impact on U.S. workers is immediate and real. One Pennsylvania firm is feeling the crunch of regulatory costs of meeting growing demand overseas. This company wants to keep jobs here, but current law increases the price of its product distribution by as much as 80 percent. This makes the cost of doing business in the U.S. steep and puts the company at a disadvantage with foreign competitors.

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