sure that they are included in this reauthorization of the State high-risk pool. I thank her for her comments. I think they were well taken. And I have already spoken to the author of the legislation, and he assures me that he is in agreement with the proposition that the gentlewoman has brought to our attention.

Mrs. CHRISTENSEN. I thank the gentleman for agreeing to take this up in conference.

Mr. DINGELL. Mr. Speaker, this bill extends Federal grant funding for State high risk pools first authorized under the Trade Adjustment Assistance Act of 2005. High risk pools provide coverage for those who are otherwise medically uninsurable, for example, individuals with preexisting conditions or catastrophic illnesses such as cancer or multiple sclerosis. Today, 32 States operate high risk pools but these pools are far from an ideal solution. Many pools exclude coverage for certain benefits such as prescription drugs or maternity care. Other pools have waiting lists or closed enrollment. Still others exclude pre-existing conditions from coverage.

Because of these limitations, Congress established parameters around eligibility for Federal grant funding of high risk pools. The intent was to ensure that Federal funding was used to improve access and coverage under these pools. Unfortunately, in the first round of grants, half of the States that received funding used the money solely to lower insurance company assessments that fund high risk pools rather than to actually improve the pools for individual beneficiaries.

I am particularly pleased that H.R. 3204 includes bonus grants for supplemental consumer benefits. This legislation would require States to use up to 50 percent of their grant funds to improve the risk pools for consumers by lowering premiums, reducing waiting lists, or improving benefits.

Many of the bills relating to health insurance coverage and access in this Congress—such as Association Health Plans—are partisan and have little chance of passage. But I am pleased to support this legislation which is the product of a bipartisan effort to improve access to coverage under high risk pools.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. CULBERSON). The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and pass the bill, H.R. 3204, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

CONTROLLED SUBSTANCES EXPORT REFORM ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 1395) to amend the Controlled Substances Import and Export Act to provide 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.

The Clerk read as follows:

S. 1395

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 2005''.

(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.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Georgia (Mr. DEAL) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Georgia (Mr. DEAL).

GENERAL LEAVE

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on S. 1395.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

There was no objection.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, S. 1395, the Controlled Substances Export Reform Act of 2005, is simply about allowing companies to better compete in the global marketplace.

Under the Controlled Substances Import and Export Act, a company is not allowed to export controlled substances to one country and then send it to a third country. Companies that export controlled substances must make a large number of long-distance, small shipments to individual countries, incurring large shipping costs. Due to this restriction, American manufacturers are less competitive than their foreign competitors, which results in high-paying U.S. jobs being sent overseas.

S. 1395 will enable U.S. companies to export products more efficiently by allowing them to send a large shipment to one nation overseas and from there to distribute smaller shipments to other countries. All subsequent transfers of controlled substances would still be subject to strict oversight by the DEA and will require a permit from the Attorney General to prevent any potential abuse.

Both the Committee on Energy and Commerce and the Committee on the Judiciary have reported the House companion legislation to this bill earlier this year. I would like to thank the gentleman from Pennsylvania (Mr. PITTS), a member of the Committee on Energy and Commerce, for his work on this issue.

I urge my colleagues to support this needed legislation.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, before yielding to my friend from Guam, I would like to make a couple of opening comments. The Controlled Substances Import and Export Reform Act is commonsense legislation that would lift unnecessary barriers to the export of controlled substances.

I was pleased to join my colleague on the Committee on Energy and Commerce, the gentleman from Pennsylvania (Mr. PITTS), as a sponsor of this legislation.

Our bill expands the U.S. role in an important export while maintaining safeguards to prevent illegal diversion of controlled substances. The key provisions of this bill create a regulatory mechanism by which U.S. exporters can ship controlled substances efficiently from one country to another,

enabling those companies to compete on a global scale.

The Drug Enforcement Administration worked with us on this legislation to ensure sufficient protections for consumers and safeguards against illegal activity. I thank the gentleman from Pennsylvania (Mr. PITTS) and his staff for their work on this bill. I am pleased to support its passage.

Mr. Speaker, I yield such time as she may consume to the gentlewoman from Guam (Ms. BORDALLO).

Ms. BORDALLO. Mr. Speaker, I wish to speak very briefly on H.R. 3204.

The cost of providing health care in the territories is relatively high, and corresponding insurance rates are high due to the number of factors, including high levels of chronic disease in small populations over which to spread risk.

H.R. 3204 authorizes Federal seed funding and additional grants to the 50 States and the District of Columbia for the purposes of initiating and operating high-risk pools, but, Mr. Speaker, unfortunately, it fails to include the U.S. territories. I want to thank my colleague, the gentlewoman from the Virgin Islands (Mrs. CHRISTENSEN), who was here speaking on my behalf earlier. I also want to thank the gentleman from Georgia (Mr. DEAL) and the gentleman from Ohio (Mr. BROWN).

I respectfully request the gentleman's assistance and the attention of our colleague, the gentleman from Ohio (Mr. BROWN) in working to add the territories as eligible recipients of this funding as this bill moves through the rest of the legislative process and in any conference with the Senate on this reauthorization.

□ 1215

Mr. BROWN of Ohio. Mr. Speaker, I thank the gentlewoman from Guam, and I will work with the gentleman from Georgia (Mr. DEAL) and the gentlewoman from Guam (Ms. BORDALLO) and the congressional Representatives from other U.S. territories to secure the inclusion of U.S. territories in the conference report on the prior legislation reauthorizing the State high-risk pool grant funding; and I thank the gentlewoman from Guam and also the gentlewoman from the Virgin Islands (Mrs. CHRISTENSEN) in joining us on the floor.

Mr. Speaker, I reserve the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Pennsylvania (Mr. PITTS), the author of the House companion bill to the legislation that we are considering now.

Mr. PITTS. Mr. Speaker, as a sponsor of this legislation in the House, I rise in strong support of S. 1395. This bipartisan legislation would reform laws that govern the export of American-made pharmaceutical products, which our chairman, the gentleman from Georgia (Mr. DEAL), has explained.

This really is a jobs bill that will benefit small businesses, particularly small pharmaceutical companies employing between 100 and 250 highly paid workers. Current law puts U.S. companies, particularly these small manufacturers, at significant disadvantage with their foreign competitors. Larger manufacturers, with an established foreign presence, may choose to manufacture offshore. Foreign firms do not have to worry about it. They readily export approved medical products between international drug control treaty countries without limit or restriction.

To compete, smaller U.S. companies, or those requiring specialized manufacturing plants for niche pharmaceuticals, are forced to choose between spending millions of dollars on export costs or spending millions of dollars in establishing overseas manufacturing facilities. This cost hurts smaller companies like Cephalon, back home in Pennsylvania.

The bottom line is our law ties the hands of American companies, forces them to do business elsewhere or not to do business at all. This legislation would authorize the Attorney General to permit carefully regulated pharmaceutical exports to international drug convention partner companies. The DEA would retain full authority over all shipments of controlled substances, and the bill establishes strict procedures to ensure these products are used solely for legitimate medical purposes.

Mr. Speaker, this legislation keeps jobs and capital right here at home, and removes one of the barriers to prevent the success of these small companies. I urge support of the bill; and I thank my colleague, the gentleman from Ohio (Mr. BROWN), for the bipartisan effort, and I thank Chairman Deal for his leadership on the issue.

Mr. Speaker, as the sponsor of this legislation in the House I rise in strong support of S. 1395, the Controlled Substances Export Reform Act of 2005.

This bipartisan legislation would reform laws that govern the export of American-made pharmaceutical products.

This is a jobs bill that will benefit small businesses, particularly small pharmaceutical companies employing between 100 and 250 highly paid workers.

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 currently prohibited.

Current law puts U.S. companies, particularly small manufacturers, at a significant disadvantage with their foreign competitors.

Larger manufacturers with an established foreign presence may choose to manufacture off-shore using existing facilities.

Foreign firms don't have to worry about it.

They readily export approved medical products between international drug control treaty countries without limit or restriction.

To compete, smaller U.S. companies and those requiring specialized manufacturing plants for niche pharmaceuticals are forced to choose between spending millions, of dollars on export costs or spending millions of dollars in establishing overseas manufacturing facilities.

This cost harms smaller companies, like Cephalon, back home in Pennsylvania.

The bottom line: Our law ties the hands of American companies and forces them to do business elsewhere—or to not do business at all.

This legislation authorizes the Attorney General to permit carefully regulated pharmaceutical exports to international drug convention partner countries.

The Drug Enforcement Administration (DEA) would retain its full authority over all shipments of controlled substances.

It establishes strict procedures to ensure these products are used solely for legitimate medical purposes.

Once enacted it would save small companies nearly 75 percent on export costs.

It would enable them to compete in the long-term in the global market. And it would help them keep jobs and capital right here at home.

An informal review of impacted U.S. exporters indicates that current law, with the cost of compliance, jeopardizes between 100–250 new U.S. jobs each time a covered product is introduced in foreign markets.

Small businesses create new jobs; they strengthen communities; they drive innovation.

The law should help them thrive, not put them at a disadvantage with foreign competitors or large corporations.

We need to make sure that we treat them fairly and give them every opportunity to succeed.

This bill removes just one of the barriers that prevent their success.

I urge support for this bill.

And continued support for our Nation's small businesses.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I yield such time as he may consume to the gentleman from Georgia (Mr. NORWOOD) for closing.

Mr. NORWOOD. Mr. Speaker, I thank the gentleman for yielding me this time, and I think it is pretty obvious that all is said that needs to be said, so I will be very, very brief.

I just simply want to rise in support of the Controlled Substances Export Reform Act of 2005. This is very commonsense legislation; and I thank my good friend, the gentleman from Pennsylvania (Mr. PITTS), for spearheading this in the House and would hope that all Members would vote for it.

Mr. CANNON. Mr. Speaker, as America strives to adapt to a world of rapidly changing international trade, preserving and expanding U.S. manufacturing and production capabilities becomes ever more important. This is particularly true in Utah where current restrictions on exports of the medicines we produce have discouraged industry growth and threatened workers' jobs.

The Controlled Substances Export Reform Act currently allows U.S. pharmaceutical companies to export most controlled substances only to the exact country where their product will be used. Shipment of U.S. medicines to central sites for further cross-border distribution, even when conducted under the watchful

eyes of the U.S. Drug Enforcement Administration and Department of Justice, is prohibited for U.S. exporters. This contrasts with the freedom of drug manufacturers throughout the rest of the world to readily move their products among and between international drug control treaty countries without limit or restriction.

These limitations put U.S. manufacturers at a disadvantage by requiring more frequent and costly shipments to each individual country of use. We are effectively discouraging domestic manufacturing while encouraging U.S. drug exporters to move production overseas.

Utah, with a small but growing pharmaceutical manufacturing industry, is committed to maintaining a strong domestic base so that U.S. businesses can compete on a level playing field with our international competitors. But this industry faces an uncertain future unless we do something.

S. 1395, the Controlled Substances Export Reform Act of 2005, is the companion legislation to H.R. 184 that Rep. JOE PITTS and I introduced in the House, and that passed the House Judiciary and Energy and Commerce Committees. This legislation advances that goal by permitting the carefully regulated international transshipment of exported U.S. pharmaceuticals. The bill retains full DEA control over all drug exports and establishes strict permitting requirements to ensure drug safety while removing an unnecessary barrier to U.S. production and the growth of well-paid jobs.

Mr. Speaker, on behalf of the 500 Utah workers whose jobs may be endangered by current law, and on behalf of the many more workers we stand to gain by updating an outdated statute, I am pleased to support S. 1395 and I urge the measure's immediate adoption.

Mr. DEAL of Georgia. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. CULBERSON). The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and pass the Senate bill, S. 1395.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the Senate bill was passed.

A motion to reconsider was laid on the table.

PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 544) to amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

The Clerk read as follows:

S. 544

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Patient Safety and Quality Improvement Act of 2005''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) in section 912(c), by inserting '', in accordance with part C,'' after ''The Director shall'';

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(4) in section 938(1) (as so redesignated), by striking ''921'' and inserting ''931''; and

(5) by inserting after part B the following:

''PART C—PATIENT SAFETY IMPROVEMENT

''SEC. 921. DEFINITIONS.

''In this part:

''(1) HIPAA CONFIDENTIALITY REGULATIONS.—The term 'HIPAA confidentiality regulations' means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

''(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'identifiable patient safety work product' means patient safety work product that—

''(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

''(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

''(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

''(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'nonidentifiable patient safety work product' means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

''(4) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

''(5) PATIENT SAFETY ACTIVITIES.—The term 'patient safety activities' means the following activities:

''(A) Efforts to improve patient safety and the quality of health care delivery.

''(B) The collection and analysis of patient safety work product.

''(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

''(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

''(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

''(F) The provision of appropriate security measures with respect to patient safety work product.

''(G) The utilization of qualified staff.

''(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

''(6) PATIENT SAFETY EVALUATION SYSTEM.—The term 'patient safety evaluation system' means the collection, management, or analysis of information for reporting to or by a patient safety organization.

''(7) PATIENT SAFETY WORK PRODUCT.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

''(i) which—

''(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

''(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

''(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

''(B) CLARIFICATION.—

''(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

''(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

''(iii) Nothing in this part shall be construed to limit—

''(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

''(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

''(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

''(8) PROVIDER.—The term 'provider' means—

''(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

''(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

''(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

''(B) any other individual or entity specified in regulations promulgated by the Secretary.

''SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

''(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local