Legislative Bulletin.....November 13, 2012

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H.R. 6190 – Asthma Inhalers Relief Act of 2012 (Burgess, R-TX)

<u>Order of Business</u>: The bill is scheduled to be considered on Tuesday, November 13, 2012, under a motion to suspend the rules requiring two thirds majority vote for passage.

Summary: H.R. 6190 directs the Administrator of the Environmental Protection Agency (EPA) to permit the sale and distribution of remaining inventories of over-the-counter (OTC) chlorofluorocarbon (CFC) epinephrine inhalers until August 1, 2013. It also requires the EPA to issue No Action Assurance letters to any requesting distributor or seller expressing that the EPA will not initiate any enforcement action against the sale or distribution of CFC epinephrine inhalers until August 1, 2013. Lastly, it expresses that the FDA is not prevented from ensuring the safety and effectiveness of these inhalers.

Pursuant to Title VI of the Clean Air Act¹, the manufacture and sale of CFC epinephrine has been banned for purposes of reducing ozone-depleting substances since December 31, 2011. There are an estimated 1.2 million OTC epinephrine inhalers currently in storage. House Energy and Commerce Committee report #112-673 states that prior to the ban, the Food and Drug Administration estimated 1.7 to 2.3 million consumers purchased 4.5 million inhalers annually.

The FDA has <u>stated</u> that epinephrine users can still continue to use any unused OTC CFC epinephrine purchased before the December 31, 2011 deadline as long as it has not expired.

Additional Background: These inhalers (commonly marketed as Primatene Mist) use CHC propellants to administer epinephrine to those with asthma. They have been sold

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¹ This 1990 amendment to the Clean Air Act (P.L. 101-549) implemented the 1989 Montreal Protocol on Substances that Deplete the Ozone Layer international environmental treaty designed to reduce emissions of ozone-depleting substances. CFC inhalers were exempt from the law's phase out of CFC manufacture and sale in the United States until 2008. The FDA and EPA extended this 2008 phase out of inhalers until December 31, 2011.

over-the-counter for more than 40 years. According to reports, Armstrong Pharmaceuticals, Inc is the last company to manufacture such inhalers and has over 1.2 million in storage with a potential market value of between \$15 to \$18 million. Requests by manufacturers and other related trade associations to sell the remaining OTC inventories have been denied by the EPA.

Opponents of the bill, including some medical organizations, claim it amounts to providing Armstrong Pharmaceuticals, Inc. a regulatory preference since it will likely benefit only one company that has remaining inventory of inhalers in storage as well as a lack of medical guidelines that recommend CFC epinephrine for asthma treatment. Additionally, they cite that other OTC non-CFC epinephrine-related products are planning to enter the market.²

Supporters of the bill maintain that this existing stock pile of CFC epinephrine inhalers should not go to waste and that this amount in storage would not negatively impact the environment. They cite an FDA statement in 2008 which expressed that removing the inhalers would reduce emissions by only a fraction of 1 percent of total global CFC emissions. Also, supporters point out that these inhalers help those with asthma who live long distances from medical service providers self-administer this medication.

<u>Committee Action</u>: Representative Michael Burgess (R-TX) introduced H.R. 6190 on July 25, 2012. On July 19, 2012, the House Energy and Commerce Subcommittee on Energy and Power marked up the bill and reported it out by voice vote. On August 1, 2012, the full House Energy and Commerce Committee reported the bill out favorably by voice vote.

Administration Position: No Statement of Administration Policy is available.

<u>Cost to Taxpayers:</u> The August 22, 2012 Congressional Budget Office (CBO) <u>cost estimate</u> for the bill estimates that there would be no significant impact on the federal budget.

Does the Bill Expand the Size and Scope of the Federal Government?: The bill provides an exemption to the current ban on sale or distribution of a banned medical substance for a limited time period until August 1, 2013.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: No.

<u>Does the Bill Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?</u>: The Committee report states that the bill contains no <u>earmarks</u>.

² The Dissenting Views included in the Committee report reference a similar product to be entering the market. It is a hand-held, battery-operated atomizer that uses vials of a variant of epinephrine called Asthmanefrin (as of a July 19, 2012 Subcommittee Markup of similar legislation).

Constitutional Authority: The Constitutional Authority Statement accompanying the bill upon introduction states, "Congress has the power to enact this legislation pursuant to the following: The attached legislation falls within Congress' authority to regulate interstate commerce as found in Article I, Section 8, clause 3 of the U.S. Constitution, which provides the authority for the Congress to 'To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.' The epinephrine Administration (FDA), and the propellant at issue is regulated by the Environmental Protection Agency. The product further falls within the subject matter of an international treaty known as the Montreal Protocol on Substances that Deplete the Ozone Layer, of which the U.S. is a signatory."

RSC Staff Contact: Joe Murray, <u>Joe.Murray@mail.house.gov</u>, (202) 226-0678.

H.R. 6371 – Streamlining Claims Processing for Federal Contractor Employees Act (Walberg, R-MI)

<u>Order of Business</u>: The bill is scheduled to be considered on Tuesday, November 13, 2012, under a motion to suspend the rules requiring two thirds majority vote for passage.

<u>Summary</u>: <u>H.R. 6371</u> amends Title 40 to transfer certain functions from the GAO to the Department of Labor relating to the processing of claims for the payment of workers who were not paid appropriate wages under Section 3144 of Title 40.

Additional Background: Section 3144 of Title 40:

Sec. 3144. Authority of Comptroller General to pay wages and list contractors violating contracts

- (a) Payment of Wages.
 - o (1) In general.- The Comptroller General shall pay directly to laborers and mechanics from any accrued payments withheld under the terms of a contract any wages found to be due laborers and mechanics under this subchapter.
 - (2) Right of action.- If the accrued payments withheld under the terms of the contract are insufficient to reimburse all the laborers and mechanics who have not been paid the wages required under this subchapter, the laborers and mechanics have the same right to bring a civil action and intervene against the contractor and the contractor's sureties as is conferred by law on persons furnishing labor or materials. In those proceedings it is not a defense that the laborers and mechanics accepted or agreed to accept less than the required rate of wages or voluntarily made refunds.
- (b) List of Contractors Violating Contracts.-
 - (1) In general.- The Comptroller General shall distribute to all departments of the Federal Government a list of the names of persons whom the Comptroller

General has found to have disregarded their obligations to employees and subcontractors.

(2) Restriction on awarding contracts.- No contract shall be awarded to persons appearing on the list or to any firm, corporation, partnership, or association in which the persons have an interest until three years have elapsed from the date of publication of the list.

<u>Committee Action</u>: Representative Tim Walberg (R-MI) introduced this legislation on September 11, 2012 and it was referred to the House Committee on Education and the Workforce.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: No.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

<u>Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?</u>: No.

Does the Bill Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: No.

<u>Constitutional Authority</u>: The Constitutional Authority Statement accompanying the bill states, "Congress has the power to enact this legislation pursuant to the following: Article I, section 8 of the Constitution of the United States."

RSC Staff Contact: Derek S. Khanna, Derek.Khanna@mail.house.gov, (202) 226-0718.

S. 1956 – European Union Emissions Trading Scheme Prohibition Act of 2011 (Sen. Thune R-SD)

<u>Order of Business</u>: The legislation is scheduled to be considered under suspension of the rules on Tuesday, November 13, 2012. The bill will require two-thirds majority vote for passage, and provides forty minutes of debate equally divided and controlled by the chair and ranking minority member of the Committee on Transportation and Infrastructure.

<u>Summary</u>: S.1956 will prohibit operators of U.S. civil aircraft from participating in the European Union's emissions trading scheme if the department determines the prohibition to be in the public interest. The legislation requires the Secretary of Transportation to prohibit an operator of a civil aircraft of the United States from participating in any emissions trading scheme unilaterally established by the European Union. S. 1956 also requires the Secretary of Transportation, the Administrator of the Federal Aviation Administration, and other appropriate officials of the United States Government to use

their authority to conduct international negotiations and take other actions necessary to ensure that operators of civil aircraft of the United States are held harmless from any emissions trading scheme unilaterally established by the European Union. The legislation restricts these departments from obligating or otherwise spending any amounts in the Airport and Airway Trust Fund or otherwise made available to the department or other federal agency to pay any tax or penalty imposed on U.S. aircraft operators through the EU emissions plan. The legislation requires the Secretary of Transportation, the Administrator of the Federal Aviation Administration, and other appropriate officials of the United States Government:

- should, as appropriate, use their authority to conduct international negotiations, including using their authority to conduct international negotiations to pursue a worldwide approach to address aircraft emissions, including the environmental impact of aircraft emissions; and
- shall, as appropriate and except as provided, take other actions under existing authorities that are in the public interest necessary to hold operators of civil aircraft of the United States harmless from the emissions trading scheme.

Background: Starting in 2012, the Emissions Trading Scheme will cover emissions from air carriers that operate flights within, to, and from European Union member states. According to the committee report posted for H.R. 2594, "the European Union's Emissions Trading Scheme (EU ETS) began in 2005 with the capping of emissions of carbon dioxide (CO2) from more than 10,000 stationary sources within the EU (covered sectors include: power plants; petroleum refining; iron and steel production; coke ovens; pulp and paper; and cement, glass, lime, brick, and ceramics production). Under the ETS, the EU auctions a specified number of emissions allowances for each multi-year period, and distributes a certain number of allowances for free. A covered emitter is required to submit to regulatory authorities one allowance for each ton of CO2 emitted during the period. There is an active market for allowance trading, in which the emitter may sell unneeded allowances to others or purchase whatever additional allowances it requires."

<u>Committee Action</u>: S. 1956 was introduced by Sen. John Thune (R-SD) on 12/7/2011. On 8/2/2012 the legislation was reported by the Commerce, Science, and Transportation by Senator Rockefeller with an amendment in the nature of a substitute. On 9/22/2011 the legislation passed Senate with an amendment by Unanimous Consent.

Administration Position: A Statement of Administration Policy has not been released.

<u>Cost to Taxpayers</u>: According to the Congressional Budget Office (CBO) report, enacting S. 1956 would have no significant impact on the federal budget; the bill would not affect direct spending or revenues.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: According to CBO, "S. 1956 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). S. 1956 would impose a private-sector mandate, as defined in UMRA, if U.S. air carriers would be prohibited from participating in the ETS. The cost of the mandate would depend on how the prohibition is administered by the Department of Transportation. Because information about how the prohibition would be implemented is not available, CBO has no basis for estimating the cost, if any, to U.S. air carriers."

<u>Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax</u> Benefits/Limited Tariff Benefits?: Yes

Constitutional Authority: No statement on constitutional authority was available.

RSC Staff Contact: Ja'Ron Smith, ja'ron.smith@mail.house.gov, (202) 226-2076.

H.R. 6586 – To Extend the Application of Certain Space Launch Liability Provisions Through 2014 (Palazzo, R-MS)

<u>Order of Business</u>: The bill is scheduled to be considered on Tuesday, November 13, 2012, under a motion to suspend the rules requiring two thirds majority vote for passage.

<u>Summary</u>: <u>H.R. 6586</u> extends current liability protection provisions for two more years. This would extend the current authority of the government, through the Office of Commercial Space Transportation at the federal Aviation Administration (FAA) to indemnify launch service providers for losses between \$500 million at \$2.7 billion (from December 31, 2012 to December 31, 2014).

This liability protection is a backstop to private companies for third party liability. If a private company has an accident and third parties are injured, the federal government could be a backstop to their liability up to \$2.7 billion, subject to new Congressional authorization under an expedited procedure.

<u>Committee Action</u>: The legislation was introduced on November 9, 2012 and referred to the House Committee on Science, Space and Technology.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: Not available.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

<u>Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?</u>: No.

Does the Bill Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: No.

<u>Constitutional Authority</u>: Congress has the power to enact this legislation pursuant to the following: "Article I, Section 8, Clause 3 and Article I, Section 8, Clause 18."

RSC Staff Contact: Derek S. Khanna, Derek.Khanna@mail.house.gov, (202) 226-0718.