



BUDGET COMMITTEE



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Judd Gregg, Chairman

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For Immediate Release

December 5, 2005

Senate Budget Committee Chairman Gregg and Senator Burr: SEC Should Allow Revenue Recognition for Pandemic Flu Vaccine Placed in Emergency Stockpiles

Policy Will Promote a Robust Stockpile Program; Protect Public Health and National Security

WASHINGTON, DC – Senate Budget Committee Chairman Judd Gregg and Senator Richard Burr today called on the Securities and Exchange Commission (SEC) to permit manufacturers to recognize revenue for lifesaving pandemic flu vaccines and bio-defense medical countermeasures when they are placed in government stockpiles.

Current SEC guidelines prevent manufacturers from counting this revenue until the product is drawn from the stockpile, which hopefully never will be necessary in the case of pandemic flu vaccines and bio-defense medical countermeasures.

“We are concerned that SEC revenue recognition guidelines could serve as a disincentive to the establishment and maintenance of stockpiles for bio-defense countermeasures, pandemic flu vaccines and products, medical products, and adult and childhood vaccines,” said Chairman Gregg in a Dec. 5th letter to SEC Chairman Christopher Cox.

“Therefore, we request that the SEC permit immediate revenue recognition for medical products that are purchased by the federal government and are held under contract in vendor-managed stockpiles,” Chairman Gregg said. “Such a policy will promote a robust stockpile program and help ensure completion of future stockpile requests by permitting manufacturers to realize revenues for fulfilled stockpile orders.”

Chairman Gregg and Senate Majority Leader Bill Frist earlier this year introduced the *Protecting America in the War on Terror Act* (S. 3), and Chairman Gregg introduced the *Bioterror and Pandemic Preparedness Protection Act* (S. 1437) in July. Provisions from both of those bills were included in the *Biodefense and Pandemic Vaccine and Drug Development Act* (S. 1873), which was passed by the HELP Committee on Oct. 18th.

(Letter is attached.)

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December 5, 2005

The Honorable Christopher Cox
Chairman
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Dear Chairman Cox:

We are concerned that Security and Exchange Commission (SEC) revenue recognition guidelines could serve as a disincentive to the establishment and maintenance of stockpiles for biodefense countermeasures, pandemic flu vaccines and products, medical products and adult and childhood vaccines (hereinafter medical products). Therefore, we request that the SEC permit immediate revenue recognition for medical products that are purchased by the Federal Government and are held under contract in vendor managed stockpiles.

As you know, medical product manufacturers have historically recognized stockpile revenue when products are initially sold to the Department of Health and Human Services (HHS), delivered into the stockpile and held exclusively for use by the Federal Government. However, recent interpretations of SEC Guidelines on Revenue Recognition in Financial Statements (SAB 101) have required the deferral of revenue recognition until the product is ultimately drawn down from the stockpile. Requiring deferral of revenue for medical products in the stockpile that will only be used in a vaccine shortage or a national emergency that – we hope will never occur – places an unreasonable business limitation on medical product manufacturers. The situation is exacerbated for products that may not expire or ever be used; and thus, may never be drawn down from the stockpile.

Our staffs have had numerous discussions with HHS and SEC staff over the past several months. Agency officials appear to recognize that this barrier to revenue recognition should not be a disincentive to participate in the Federal stockpile program.

For these reasons, we request that the SEC reexamine the unique circumstances surrounding the substance of the transaction contemplated by a product contracted for a government stockpile and held and maintained in the interests of public health and national security.

An alternative method of accounting would allow immediate revenue recognition for medical products pursuant to a Federal Government contract involving the stockpiling, holding, storing, rotating, or other management of an inventory of vaccines, countermeasures, or medical products – except for any revenue required to be credited back due to returned payments or product. Such a policy will promote a robust stockpile program and help ensure completion

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of future stockpile requests by permitting manufacturers to realize revenues for fulfilled stockpile orders.

We look forward to working with you to reduce regulatory barriers to vaccine, biodefense countermeasure and medical product stockpiling to help protect the public health and national security. If your staff has any questions about this request or requires additional information, please have them contact Peggy Binzer of Senator Gregg's staff at (202) 224-0566.

Sincerely,



Judd Gregg
U.S. Senator



Richard Burr
U.S. Senator