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April 18, 2005

The Honorable Tom Davis
Chairman
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman,

I request that the Committee on Government Reform hold an oversight hearing to examine the federal government's failure to establish an adequate stockpile of pediatric vaccines.

Five years ago, there were shortages of five routinely recommended vaccines covering eight serious diseases of childhood. In response to this crisis, the Bush Administration pledged in 2002 to create a 6-month stockpile of each vaccine "as soon as feasible."[1] The Administration then budgeted over $700 million for this task.[2]

Three years later, however, little progress has been made. As reported in yesterday's *Washington Post*, there are adequate amounts of only two pediatric vaccines in the stockpile.[3] The stockpile does not contain any doses of the critical vaccine that protects against diphtheria, whooping cough, and tetanus.

A key problem appears to be an accounting rule of the Securities and Exchange Commission. This rule prevents companies from classifying payment for stockpiled vaccine as "revenue" on their balance sheets. Without "revenue recognition," several major vaccine manufacturers are refusing to provide vaccine to the stockpile.

This situation presents a real threat to public health. Without an adequate stockpile, even a minor disruption in vaccine supply can lead to shortages that place the health of millions of U.S. children at risk.

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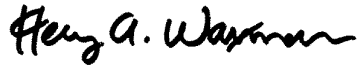
[1] General Accounting Office, *Vaccine Supply: Ensuring an Adequate Supply Poses Continuing Challenges* (Sept. 2002).
[2] U.S. Department of Health and Human Services, *FY 2004 Budget in Brief, 26* (2003).
[3] *Pediatric Vaccine Stockpile at Risk*, Washington Post (Apr. 17, 2005).

I urge you to call a Committee hearing to examine this situation. Bipartisan interest and a public hearing would create pressure on the leaders of the involved federal agencies and vaccine manufacturers to discuss and resolve the problem. Such a hearing would be a logical extension of our Committee's recent work on vaccine supply and public health preparedness.

I recommend that the Committee call as witnesses Secretary of Health and Human Services Mike Leavitt, Chairman of the Securities and Exchange Commission William H. Donaldson, and the Chief Executive Officers of all companies that make vaccines for the stockpile. These include Merck & Co. Inc., Sanofi-Aventis, Wyeth, and GlaxoSmithKline.

I look forward to your reply.

Sincerely,



Henry A. Waxman
Ranking Minority Member