

Congress of the United States

Washington, DC 20515

September 4, 2001

The Honorable David M. Walker
Comptroller General of the United States
General Accounting Office
441 G Street, NW
Washington, D.C. 20548

Dear Mr. Walker:

We are writing to request that GAO study the issue of the security of the vaccine supply. As you know, last year there was a delay in the delivery of much of the flu vaccine supply. This raised concern that the vaccine would be unavailable to high-risk individuals and caused a marked increase in the price some consumers had to pay for the flu vaccine. The Centers for Disease Control and Prevention (CDC) is predicting delays again this year.

Some areas of the country are also experiencing shortages of the tetanus vaccine, and there has been concern that there could be shortages of the DTaP vaccine, which is part of the routine childhood immunization schedule. The tetanus shortage was precipitated by the withdrawal of Wyeth-Lederle from the tetanus vaccine market, leaving only two manufacturers of the vaccine licensed in the United States.

For many of the vaccines recommended for both children and adults there is only one manufacturer licensed in the United States. For example, Wyeth is the sole manufacturer of Prevnar, the newly licensed and recommended vaccine against a variety of pneumococcal diseases. Aventis is the sole manufacturer for U.S. licensed meningococcal vaccine for adults. Merck is the only manufacturer of the MMR vaccine which prevents against measles, mumps, and rubella.

The fact that so many vaccines are manufactured by single manufacturers raises questions about the security of the vaccine supply. This situation is compounded by the fact that in recent years, some manufacturers have left the vaccine market, diminishing competition.

In your report, we would like you to examine the security of the vaccine supply for vaccines recommended by CDC for adults and children and what steps the federal government can take to assure the long term stability of vaccine supplies. Specifically, we are interested in answers to the following questions:

1. How real is the danger of vaccine shortages?

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2. What are the possible complications resulting from vaccine shortages?
3. Which federal agencies are involved in maintaining the vaccine supply? What are their roles and responsibilities?
4. Is the current regulatory process appropriate to ensure that vaccines used in the United States are both safe and in adequate supply?
5. In the case of a shortage, either because of an emergency such as a fire at a manufacturing plant or a natural disaster or because a company decides to withdraw from the vaccine market, does the government have adequate systems in place to ensure supply?
6. What changes in the current system should be made to ensure that there are adequate supplies of vaccines in the United States?
7. What are the market forces that have led vaccine manufacturers to cease production of currently recommended vaccines?
8. What are the barriers to new companies entering the vaccine market?
9. Are there incentives that the federal government should establish to encourage vaccine manufacturers to enter or stay in the market?
10. What are the bases for the current vaccine pricing structures? Do these pricing structures inhibit manufacturers from participating in the vaccine market?
11. Are there measures that the federal government takes to ensure the supply of other products necessary for public health that would be applicable to vaccines?

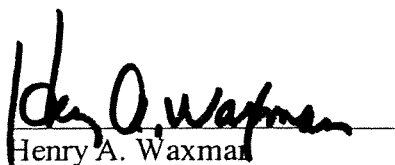
We are also interested in answers to the following questions relating to international vaccine development:

1. Are there vaccines licensed in developed countries outside the United States that are not licensed in the United States that could be licensed in the United States? If so, why are those vaccines not licensed in the United States?
2. What are the effects of international vaccine development efforts on the vaccine market in the United States?

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Please contact Sarah Despres at (202) 225-5420 to discuss the timeline and plans for conducting this study.

Sincerely,



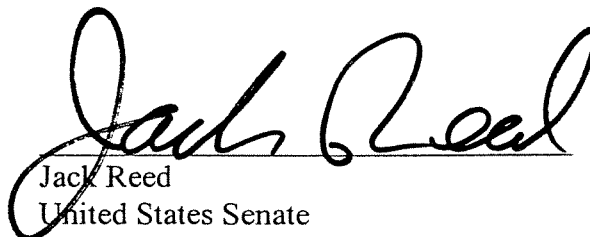
Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



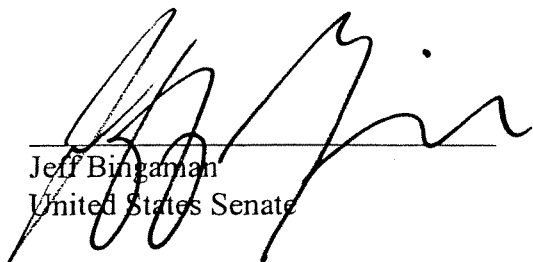
Edward M. Kennedy
Chairman
Committee on Health, Education,
Labor, and Pensions



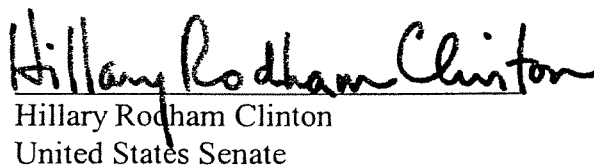
Gary A. Condit
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Jack Reed
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United States Senate



Richard J. Durbin
United States Senate

cc: Senator Bill Frist