



REP. HENRY A. WAXMAN
RANKING MINORITY MEMBER
COMMITTEE ON GOVERNMENT REFORM
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Fact Sheet

The Flu Vaccine Crisis

On October 5, 2004, British regulators shut down the Liverpool manufacturing facility of the Chiron Corporation, which was supposed to provide the United States with half of this year's supply of flu shots. The result is a vaccine shortage that has left at least 30 million seniors, infants, and others at high risk without access to the vaccine.

The Bush Administration Should Have Prevented the Flu Vaccine Shortage

The Bush Administration failed to respond to a series of warnings and recommendations urging action to prevent this crisis. The Administration:

- disregarded the Institute of Medicine's advice in 2001 to establish a National Vaccine Authority that would coordinate a response to the vaccine supply crisis;¹
- rejected the Government Accountability Office's recommendation in 2002 to fast track FDA approval for vaccines;²
- took no action on a recommendation from the National Vaccine Advisory Committee in 2002 to improve financial incentives for vaccine manufacturers;³ and
- ignored an Institute of Medicine report in 2003 calling for major changes in vaccine financing to improve supply.⁴

Contrary to expert advice, President Bush proposed a \$105 cut in state and local public health preparedness funding. Dr. Robert B Stroube, Virginia's State Health Commissioner, testified that the "Administration's proposed cuts could jeopardize our ability to respond to a terrorist event, outbreak of an infectious disease or other public health threats or emergencies . . . such a cut will jeopardize our ability to protect the public we serve."⁵

The Bush Administration Missed Warning Signs at the Vaccine Plant

FDA's job is to ensure the supply of safe and effective drugs for the American people. Under the Bush Administration, it appears that the agency missed several important warning signs of problems at the Chiron facility:

- A June 2003 inspection by FDA found “systemic quality-control issues” that “led inspectors to conclude that Chiron wouldn’t necessarily be able to discover problems, identify the root cause and take steps to prevent similar issues from arising again.”⁶ But FDA did not inspect this facility again until after the crisis hit.
- On August 25, 2004, Chiron announced that several million doses of vaccine were contaminated. While British regulators conducted a full inspection and shut the facility down, FDA was relying on weekly conference calls with the company for information.

In addition, FDA is now withholding documents about its oversight of the Chiron facility from Congress.⁷

The Bush Administration Failed to Plan for a Shortage

The national scramble for vaccine in response to today’s shortage is a direct result of the Administration’s failure to plan. From May 2001 to September 2004, the Government Accountability Office repeatedly warned that there was no plan in place to ensure that those at highest risk of death from influenza would be vaccinated in the event of a shortage. Just one week before the crisis hit, GAO testified, “In our follow-up work, we found no indication that the situation would be different if there was a shortage today.”⁸

The Vaccine Crisis Is Not Due to Liability Concerns

During the presidential debate on October 13, 2004, President Bush blamed liability concerns for the vaccine shortage facing the nation. In fact, nonpartisan experts including the Institute of Medicine, the Government Accountability Office, and the head of infectious disease research at NIH have not found liability to be a major factor in vaccine supply problems.⁹

Liability issues have little impact on vaccine availability because manufacturers of vaccine are already shielded from liability under the Vaccine Injury Compensation Program, which was established by Congress in 1986. Under this program, a no-fault compensation program gives vaccine manufacturers broad liability protection, while at the same time assuring adequate compensation for those injured by vaccines. Congress recently passed legislation to add the flu vaccine to this program.

The President’s campaign has criticized Senator Kerry for opposing H.R. 5, a product liability bill. This legislation exempts claims covered by the Vaccine Injury Compensation Program and thus has no bearing on the flu vaccine crisis.

More information on the flu vaccine crisis can be found at <http://democrats.reform.house.gov/investigations.asp?Issue=Flu+Vaccine+Crisis>.

ENDNOTES

¹ IOM, *Statement from the IOM Council on Vaccine Development* (Nov. 5, 2001).

² GAO, *Childhood Vaccines: Ensuring Adequate Supply Poses Continuing Challenges* (Sept. 2002).

³ National Vaccine Advisory Committee, *Strengthening the Supply of Routinely Recommended Vaccines in the United States* (Jan. 2003).

⁴ IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003).

⁵ Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb. 12, 2004).

⁶ *U.S. Uncovered Problems at Chiron Plant in 2003: 'Quality Control Issues' Were Similar to Concerns*, Wall Street Journal (Oct. 11, 2004).

⁷ Letter from Rep. Henry A. Waxman to Rep. Tom Davis (Oct. 22, 2004).

⁸ GAO, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks* (Sept. 28, 2004).

⁹ See IOM, *supra* note 4; GAO, *supra* notes 2 and 8; and *Flu Vaccine Shortage Sways 2004 Campaign*, Associated Press (Oct. 21, 2004).