



**REP. HENRY A. WAXMAN**  
**RANKING MINORITY MEMBER**  
**COMMITTEE ON GOVERNMENT REFORM**  
**U.S. HOUSE OF REPRESENTATIVES**  
**OCTOBER 21, 2004**

## **Fact Sheet**

---

# **Flu Vaccine Crisis: Administration Spending**

---

Since the fall of 2001, the Administration has disregarded a series of recommendations to shore up our nation's fragile vaccine supply from experts at the Institute of Medicine, Government Accountability Office, and National Vaccine Advisory Committee. These experts had advised the administration to establish a National Vaccine Authority, expand financial incentives for vaccines, streamline FDA approval for vaccines, and develop a plan to ensure that high-risk individuals are vaccinated during a shortage. In each case, the Administration failed to take the recommended action.

Despite these failures, the Administration has maintained that it has done everything possible to ensure adequate supplies of flu vaccine. According to HHS Secretary Tommy Thompson, "We have been planning for an event such as this literally since we walked through the doors of HHS back in 2001."<sup>1</sup> In particular, Administration officials have cited increased funding of flu-related activities as proof of its preparedness.

In fact, a close examination of Administration spending reveals:

- (1) the Administration has proposed cuts in public health preparedness for the flu and other outbreaks;
- (2) the Administration has rejected the recommendations of experts for increased funding in key areas;
- (3) the Administration is claiming credit for funding increases that were mandated by legislation enacted during the Clinton Administration; and
- (4) in the few areas with real funding increases, these increases have been insufficient or are in doubt.

## **Reduced Funding for Public Health Preparedness for the Flu and Other Outbreaks**

The President's fiscal year 2005 budget proposes cutting \$262 million (3.6%) from the budget for the Centers for Disease Control and Prevention, including \$105 million from state and local public health preparedness. If enacted, these cuts would undermine the ability of cities, counties, and states to protect their citizens from flu and other outbreaks of infectious disease. At a February 2004 hearing of the Government Reform Committee, Dr. Shelley Hearne of the

nonpartisan Trust for America's Health testified that the Administration's budget "places our public health defenses at serious risk."<sup>2</sup> 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."<sup>3</sup>

## **Failure to Implement the Recommendations of Experts for Increased Funding in Key Areas**

Health experts have recommended that the Administration invest in coordinating the federal efforts to strengthen the vaccine supply,<sup>4</sup> expediting approval of applications from vaccine manufacturers,<sup>5</sup> and expanding the market for flu vaccine in the United States.<sup>6</sup> These recommendations were made by the Institute of Medicine and the Government Accountability Office, as well as other experts. None of them have been implemented by the Bush Administration.

Gaps in the Administration's budget have drawn bipartisan criticism in Congress. Republican Chairman Tom Davis and Democrat Henry A. Waxman of the Government Reform Committee wrote to the Appropriations Committee earlier this year that the President's budget "does not provide any increase in funding for pandemic flu preparedness at CDC and state and local health departments, despite the need for improved planning."<sup>7</sup>

## **Claiming Credit for Legislation Passed During the Clinton Administration**

The Administration claims credit for a major increase in CDC funding for the flu vaccine. In fact, much of CDC's recent flu funding was required under legislation that passed in 1993 and was signed into law by President Clinton. This legislation, which established the Vaccines for Children Program, requires that the federal government pay for the purchase of recommended childhood vaccines for children served by Medicaid and public health clinics. When an independent advisory committee added the flu vaccine to the list of recommended childhood vaccines, the Vaccines for Children Program triggered the requirement that the federal government buy the vaccine.

At a hearing before the Appropriations Committee, Administration officials said it would cost an extra \$13 million under a separate program (the section 317 program) to ensure that all children — not just those covered by the Vaccines for Children Program — would be able to get the flu vaccine. But the Administration did not propose this increase, ensuring that even without the current shortage, infants at risk would have gone without vaccine.<sup>8</sup>

## **Insufficient Funding Increases**

In the few areas where the Administration has increased funding for the flu vaccine, these funding increases have been inadequate:

- **Medicare Reimbursement.** The Administration has increased funding for Medicare reimbursement of flu vaccination, which was set under the Medicare Modernization Act at 95% of the wholesale price. According to the American Medical Association and a coalition of medical groups, however, at this level, “many practices may not even be recovering their costs.”<sup>9</sup>
- **FDA Spending.** The Administration claims it has increased FDA spending related to “research and licensing” by \$1.1 million. This is a miniscule amount in an FDA budget of \$1.8 billion and it has not resulted in increased inspection or enforcement efforts. To the contrary, FDA appears to have inspected the troubled Chiron plant at the minimum rate of once every two years. Even after Chiron announced a major contamination problem in August, FDA did not send a team of inspectors until nearly six weeks later — after British regulators had shut down the plant.
- **Stockpile.** The Administration claims credit for investing \$161 million in a strategic stockpile of influenza vaccine and medications. In fact, this stockpile is insufficient. There are only 4.5 million stockpiled doses of flu vaccine. This is less than one-tenth of the current shortfall of flu vaccine. In addition, GAO has found that the Administration has failed to ensure that states can distribute medications in the stockpile quickly and effectively.<sup>10</sup>
- **NIH Research.** The Administration deserves credit for increasing research funding on the next generation of flu vaccines. However, the stability of this commitment is uncertain. Last year, the Administration shifted \$145 million out of infectious disease research funding to meet a congressional requirement to procure an experimental anthrax vaccine. Dr. Anthony Fauci, who leads infectious disease research at NIH, described the requirement that NIH participate in this kind of applied research contract as unprecedented in the 116-year history of NIH. He said, “We are not happy about it.”<sup>11</sup>

## **Inadequate Planning**

The Administration is taking credit for having released a draft flu pandemic plan this summer. However, in September 2004, just one week before the current crisis, the Government Accountability Office testified that the Administration’s draft provided insufficient guidance to state and local health officials on how to handle a vaccine shortage.<sup>12</sup> Moreover, despite a federal law requiring them to do so each year and despite requests from Congress, the Administration has failed to update — even once — a comprehensive vaccine plan covering priorities in testing, licensing, production, procurement, and distribution of vaccines.<sup>13</sup>

---

## ENDNOTES

<sup>1</sup> *News Conference with Secretary of Health and Human Services Tommy Thompson*, Federal News Service (Oct. 19, 2004).

<sup>2</sup> Dr. Shelley Hearne, Testimony before the Committee on Government Reform (Feb. 12, 2004).

<sup>3</sup> Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb. 12, 2004).

<sup>4</sup> IOM, *Statement from the IOM Council on Vaccine Development* (Nov. 5, 2001).

<sup>5</sup> GAO, *Childhood Vaccines: Ensuring Adequate Supply Poses Continuing Challenges* (Sept. 2002).

<sup>6</sup> IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003).

<sup>7</sup> Letter from Chairman Tom Davis and Ranking Minority Member Henry A. Waxman to Appropriations Committee Chairman Ralph Regula and Ranking Minority Member David R. Obey (May 4, 2004).

<sup>8</sup> Federal funds through the 317 program supplement Vaccines for Children Program expenditures. The Administration declined to ask for any additional 317 funds at the time that the influenza vaccine was recommended for children. CDC Director Dr. Julie Gerberding estimated that adding \$13 million to the 317 program could ensure that states could provide vaccine to uncovered children. But the administration did not ask for these extra funds. Hearings before a Subcommittee of the Committee on Appropriations, *Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2005: Part 3 — Department of Health and Human Services, Public Health Service*, 98 (2004). In February 2004, Virginia Health Commissioner Robert B. Stroube testified, “Additional funding is needed to cover the pediatric influenza vaccine recommendations.” Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb. 12, 2004).

<sup>9</sup> *Id.*

<sup>10</sup> GAO, *HHS Bioterrorism Preparedness Programs: States Reported Progress but Fell Short of Programs Goals for 2004* (Feb. 10, 2004).

<sup>11</sup> *Bush: Get Anthrax Vaccine*, Newsday (July 28, 2003).

<sup>12</sup> GAO, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks* (Sept. 28, 2004).

<sup>13</sup> 42 U.S.C. § 300aa-3. For congressional correspondence, see e.g., Letter from Rep. Henry A. Waxman to Secretary of Health and Human Services Tommy G. Thompson (May 1, 2003).