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Fact Sheet

Flu Vaccine Crisis: The Administration's Response to Recommendations and Warnings

Over the last three and a half years, the Bush Administration has ignored a series of flu vaccine warnings and recommendations from the Government Accountability Office, the Institute of Medicine, and others. These experts 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. But in each case, the Administration failed to take the recommended action. In fact, the most recent budget submitted by President Bush proposed cutting funding for public health preparedness.

Failure to Address Vaccine Supply Problems

From 2001 to the present, the Bush Administration has ignored a series of warnings about the fragility of the flu vaccine supply and recommendations for response.

National Vaccine Authority. In November 2001, the Council of the Institute of Medicine issued an extraordinary statement urging the creation of a National Vaccine Authority to coordinate a high-level response to a growing crisis in the supply of important vaccines, including the flu vaccine.¹ The Council of the Institute of Medicine is the organization's governing body. At the time, the Council included Dr. Anthony Fauci, head of the National Institute on Allergy and Infectious Diseases at NIH, Dr. Gail Wilensky, who had led the Health Care Financing Administration under President George H.W. Bush, and Dr. Kenneth Shine, the head of the Institute of Medicine.

The Administration did not create a National Vaccine Authority.

Fast Track Vaccine Approval. In September 2002, the Government Accountability Office (GAO) found that delays in FDA approval were creating a barrier to entry to the vaccine market. GAO recommended that FDA "consider revising FDA policies for fast track and priority review approval of vaccines currently under development to allow their use, even in periods of non-shortage, in cases where FDA determines that applying them would help address the unmet need of a stable and sufficient vaccine supply."²

The Administration did not implement this recommendation.

Manufacturer Incentives. In October 2002, the National Vaccine Advisory Committee to the Department of Health and Human Services released a major report on vaccine supply. The Committee recommended the creation of a “multi-disciplinary group to evaluate the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines.”³

The Administration never created this multi-disciplinary group.

Market Incentives. In August 2003, the Institute of Medicine identified inadequate reimbursement and gaps in insurance coverage of vaccination as key factors in reducing pharmaceutical company interest in vaccine production. The IOM found that “federal and state governments currently lack a coherent policy” to address this problem, creating “uncertainty among both producers and purchasers, which in turn reduces incentives for future vaccine development.”⁴

The Administration did not develop any major new initiatives to guarantee an acceptable market for the flu vaccine or other vaccines.

Adult Vaccine Availability. In February 2004, the CDC’s director of immunization services made a presentation to the National Vaccine Advisory Committee on the influenza vaccine. Dr. Lance E. Rodewald stated that there was “no authority to finance vaccines” for adults. He also highlighted that there was “no clear lead” in the public health community to assure vaccination of high-risk adults and “minimal” control of vaccines.⁵

The Administration failed to address the concerns of Dr. Rodewald.

Public Health Preparedness. The Bush Administration has aggravated vaccine supply problems by seeking cuts in funding to support public health preparedness. The President’s fiscal year 2005 budget proposes reducing funding for state public health preparedness by \$105 million. 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 proposed \$105 million dollar cut for state public health preparedness “places our public health defenses at serious risk.”⁶ 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.”⁷

Failure to Plan for a Flu Vaccine Shortage

The recommendations described above address how to prevent vaccine shortages. A distinct but related issue is how to respond to shortage if it occurs. In this area too, the Administration disregarded numerous warnings from experts. Specifically, the Administration failed to respond to a series of reports by the Government Accountability Office finding that (1) a flu vaccine shortage could turn into a public health crisis and that (2) the Administration lacked plans to

ensure that individuals at high risk of hospitalization and death from influenza would be vaccinated first.

GAO's May 2001 Report. In the fall of 2000, a delay in producing flu vaccine resulted in a shortage for two months. In response, GAO issued a report in May 2001 entitled "Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People."⁸ GAO found that during the 2000 shortage:

- While CDC issued recommendations about which individuals should receive priority for vaccination, it was difficult for these recommendations to be implemented.
- Many doctor's offices did not have any vaccine, even for the highest-risk patients.
- Mass vaccination campaigns at grocery stores and other locations generated confusion and controversy.

The GAO report concluded: "There is no mechanism currently in place to distribute flu vaccine to high-risk individuals before others."⁹ After recommending that CDC develop such a mechanism, GAO warned: "The circumstances that led to the delay and early shortage of flu vaccine during the 2000–01 flu season could repeat themselves in the future."¹⁰

These findings were reiterated in May 2001 testimony to Congress. GAO stated: "Manufacturing difficulties could occur in the future and again illustrate the fragility of current methods to produce a new vaccine every year. Compounding the problem is that when the supply of vaccine is short, there is no system to ensure that high-risk people have priority for receiving flu shots."¹¹

GAO's April 2003 Report. Two years later, GAO again addressed problems in planning for the distribution of flu vaccine during a shortage. Specifically, GAO described the absence of plans for reaching those individuals at highest risk of hospitalization and death during a flu pandemic. Such plans could also be used during a vaccine shortage.

GAO reported: "Although state officials acknowledge the need for flexibility in planning because many aspects of a pandemic cannot be known in advance, the absence of more detail leaves them uncertain about how to plan for the use of limited supplies of vaccine and drugs."¹² In testimony before Congress, GAO elaborated: "CDC . . . has not made the final decisions on plan provisions necessary to mitigate the effects of potential shortages of vaccines and antiviral drugs. Until such decisions are made, the timeliness and adequacy of response efforts may be compromised."¹³

GAO's September 2004 Assessment. On September 28, 2004, just one week before the United States lost half of its supply of flu vaccine, GAO reported on the progress that the Administration had made in preparing for a vaccine shortage. GAO found that three years after its first warnings, the Administration was still not prepared to respond to a flu vaccine shortage. In congressional testimony, GAO stated:

Our work has also found that there is no mechanism in place to ensure distribution of flu vaccine to high-risk individuals before others when the vaccine is in short supply. . . . In our follow-up work, we found no indication that the situation would be different if there was a shortage today.¹⁴

The Current Flu Vaccine Crisis. As GAO warned, the Administration does not have an effective plan for responding to the current shortage of the flu vaccine. This shortage was triggered when British officials found contamination problems at the Chiron facility in England, causing the United States to lose half of its supply of flu vaccine.

As GAO predicted, the Administration has been unable to implement a coordinated strategy to ensure that manufacturers supply physician's offices and public health clinics that serve those at highest risk. Instead, the Administration has been forced to rely on a series of recommendations that are increasingly difficult to implement. Some of these have been contradictory. For example, CDC Director Dr. Julie Gerberding recently recommended that "people not wait in long lines, but rather try to call ahead for an appointment for the vaccine or to contact their provider for recommendations."¹⁵ However, many health care providers have no vaccine, even for those at highest risk, and are instructing their patients to go wait in line.

The result has been a growing public health crisis. Thousands of elderly, frail, and infirm Americans have been forced into a scramble for vaccine. In California, a 79-year-old woman collapsed and died after waiting for more than four hours for a flu shot.¹⁶

ENDNOTES

¹ The Council noted, "the availability of influenza vaccines has been delayed over the past several years and in 2000, one company stopped production." 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. Lance E. Rodewald, *Public Sector Roles in Adult and Childhood Influenza Vaccination* (Feb. 3, 2004).

⁶ Dr. Shelley Hearne, Testimony before the Committee on Government Reform (Feb. 12, 2004).

⁷ Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb. 12, 2004).

⁸ U.S. Government Accounting Office, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People* (May 2001).

⁹ *Id.* at 11.

¹⁰ *Id.* at 22.

¹¹ U.S. Government Accounting Office, *Flu Vaccine: Steps are Needed to Better Prepare for Possible Future Shortages* (May 2001).

¹² GAO, *Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 9, 2003).

¹³ GAO, *Improvements to Public Health Capacity Are Needed for Responding to Bioterrorism and Emerging Infectious Diseases* (May 7, 2003).

¹⁴ GAO, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks* (Sept. 28, 2004) (emphasis added).

¹⁵ Dr. Julie Gerberding, *News Teleconference Regarding Flu Vaccination*, FDCH Political Transcripts (Oct. 15, 2004).

¹⁶ *Flu Shot Re-Supply is 6–8 Weeks Away*, Los Angeles Times (Oct. 16, 2004).