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OCTOBER 14, 2005

Fact Sheet

The Administration's Preparation for Avian Flu

On October 4, 2005, President Bush spoke at length about the dangers of an influenza pandemic. He stated: "The people of the country ought to rest assured that we're doing everything we can."

In fact, the Administration's record has been characterized by neglect and poor management. An influenza pandemic, which experts fear could develop from a highly contagious avian flu circulating in Asia, could kill millions of people and cause widespread economic disruption. Yet over the last five years, the Administration has:

- **Ignored at least six major expert reports and statements related to an influenza pandemic.** Experts recommended major new investments in public health, incentives for vaccine manufacturers, and expanded federal purchase of vaccine to ensure access.
- **Proposed substantial cuts in funding for public health preparedness.** In fiscal year 2005, the President proposed cutting \$105 million from state and local public health departments. In fiscal year 2006, the President proposed \$130 million in cuts. The Administration's failure to purchase available quantities of the antiviral drug Tamiflu has left the United States waiting in line behind other nations.
- **Failed to finalize a national response plan for an influenza pandemic.** Since November 2000, the Government Accountability Office has issued six separate reports criticizing the Administration's failure to develop a national response plan. GAO repeatedly found that the persistent failure to complete a response plan significantly undermined our nation's readiness for a pandemic.
- **Failed to endorse or propose pandemic-flu legislation.** Several important legislative proposals related to an influenza pandemic have been proposed in the House and the Senate. The Administration and the Republican leadership in Congress have neither supported any of these proposals nor put forward their own legislation.

The few positive steps taken by the Administration over the last five years have been limited. They include modest investments in research for the next generation of influenza vaccines and the testing and purchasing of a modest number of doses of avian flu vaccine. As a result, the United States lags behind other developed nations in preparing for an influenza pandemic.

Ignoring Expert Recommendations

Over the last five years, a series of expert bodies have made recommendations that would have bolstered the nation's fragile vaccine supply and improved the nation's readiness for an outbreak of avian flu or other influenza pandemic. These recommendations have been routinely ignored by Administration officials. In fact, it was not until October 7, 2005, that President Bush met with vaccine manufacturers to ask what could be done to increase their capacity to provide influenza vaccine for a pandemic.¹

November 2001: Institute of Medicine Statement on the Need for a National Vaccine Authority

In November 2001, the Council of the Institute of Medicine, which is the institution's governing body, 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.² 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, nor did they enhance the existing office that oversees vaccine policy.

October 2002: National Vaccine Advisory Committee Report on the Need for Incentives for Vaccine Manufacturers

In October 2002, the National Vaccine Advisory Committee of 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 did not create this multi-disciplinary group to assess incentives for the vaccine supply.

¹ *Bush, Executives Consider Strategies to Ramp Up Vaccine Production*, Washington Post (Oct. 8, 2005).

² 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).

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

March 2003: Institute of Medicine Report on the Need for Investment in Antiviral Stockpiles and Public Health Infrastructure

April 2003: GAO Report on Gaps in Public Health Preparedness

In March 2003, the Institute of Medicine made a series of urgent recommendations in a report entitled *Microbial Threats to Health*. To prepare for an influenza pandemic or other global outbreak of infectious disease, the Institute of Medicine called for, among other measures, major investments in significant stockpiles of antiviral drugs and public health infrastructure.⁴ These recommendations were echoed in a report released by the General Accounting Office in April 2003. GAO found major gaps in public health and hospital preparedness at state and local levels.⁵

The Administration did not pursue significant stockpiles of antiviral drugs and failed to propose a significant new investment in public health preparedness.

August 2003: Institute of Medicine Report on the Need for Market Incentives for Vaccines

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 Institute 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.”⁶

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

December 2004: National Vaccine Advisory Committee Report on the Need to Bolster Annual Influenza Vaccination

In December 2004, the National Vaccine Advisory Committee of HHS released a report entitled *Strengthening the Nation's Influenza Vaccination System*. The report focused on ways to improve influenza vaccination to save lives during annual flu seasons and “foster preparedness for an influenza pandemic.” The Committee recommended a series of steps to reduce barriers to vaccination, including new initiatives to vaccinate patients in emergency departments and to expand vaccination programs for adults.⁷

⁴ Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, and Response* (Mar. 18, 2003) (online at <http://www.iom.edu/report.asp?id=5381>).

⁵ General Accounting Office, *Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 2003).

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

⁷ Charles M. Holmes et al. *Strengthening the Nation's Influenza Vaccination System: A National Vaccine Advisory Committee Assessment*, *American Journal of Preventive Medicine*, 221-226 (Oct. 2005) (online at <http://www.hhs.gov/nvpo/nvac/NationsInfluenzaVaxSysAJPMOct05.pdf>).

The Administration did not implement the recommended initiatives, such as the initiative to vaccinate patients in emergency departments or expand vaccination programs for adults.

Cutting Funds for Public Health

Asked earlier this month about preparations for an influenza pandemic, HHS Secretary Michael Leavitt has stated “any suggestion the president hasn’t been fully engaged on this pre-Katrina would be wrong.”⁸ Contrary to Secretary Leavitt’s assertion, the budgets submitted by the White House to Congress have included major cuts in public health preparedness, undermining the nation’s defenses against a flu pandemic.

Fiscal Year 2005 Budget

In February 2004, President Bush submitted a budget to Congress that proposed cutting \$113 million from the Centers for Disease Control and Prevention in fiscal year 2005, including \$105 million from state and local public health preparedness.⁹

At a February 2004 hearing of the Government Reform Committee, Dr. Robert B. Stroube, Virginia’s State Health Commissioner, testified: “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.”¹⁰

The President’s budget for pandemic flu also drew bipartisan opposition. Republican Chair Tom Davis and Democratic Ranking Member Henry Waxman of the Government Reform Committee wrote in May 2004 that the 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.”¹¹

In the final appropriations legislation, Congress restored the Administration’s proposed cuts to state and local public health preparedness, but did not provide for any increase.

⁸ *The Race Against Avian Flu*, Newsweek (Oct. 17, 2005).

⁹ CDC, *FY 2005 CDC Budget Request — Detail of Increases/Decreases* (Feb. 2, 2004).

¹⁰ Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb.12, 2004).

¹¹ 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).

Fiscal Year 2006 Budget

In February 2005, the President proposed cutting the budget of the Centers for Disease Control and Prevention by \$531 million in fiscal year 2006, including \$130 million in cuts for state and local public health preparedness.¹²

According to Patrick M. Libbey, the executive director of the National Association of City and County Health Officials, the budget proposal would severely impair public health preparedness. He stated: "Local health departments make sure that life-saving vaccines or equipment actually reach the victims It's outrageous that the proposed budget reduces funding for local health departments to fight bioterrorism and would force them to scale back their efforts."¹³

The House-passed version of the 2006 appropriations for HHS restored only \$52 million of the \$130 million in the Administration's proposed cuts. The appropriations legislation is still pending in the Senate.

Tamiflu Purchases

The failure to propose adequate budgets for public health preparedness has impacted the ability of the United States to purchase the key antiviral drug Tamiflu, which is the only drug believed to be effective against avian flu. The supply of Tamiflu currently held by HHS can treat just 2% of the U.S. population, compared to stockpiles in other nations that can treat 20% to 40% of the population. According to one recent report, "had the administration placed a large order just a few months ago, Roche, Tamiflu's maker, could have delivered much of the supply by next year."¹⁴ Instead, the United States now has to wait at least two years to bolster its stockpile.

Delaying a Response Plan

In a series of reports since November 2000, the Government Accountability Office has called on the Department of Health and Human Services to finalize a national response plan to an influenza pandemic. As of October 12, 2005, such a plan had yet to be finalized.

November 2000 GAO Report

In November 2000, GAO reported that federal efforts to develop a pandemic influenza plan were being hindered because "key federal decisions have not been made." These decisions included determining "the proportion of vaccines and antiviral drugs to be purchased, distributed, and administered by the public and private sectors" and "priorities for which population groups

¹² CDC, *FY2006 CDC Functional Table Reflecting New Budget Structure* (Feb. 11, 2005).

¹³ National Association of City and County Health Officials, *Restore Bioterrorism Funds, Local Health Officials Appeal* (Mar. 31, 2005).

¹⁴ *After Delay, U.S. Faces Line for Flu Drug*, New York Times (Oct. 7, 2005).

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should receive vaccines and antiviral drugs first when supplies are limited.” GAO found that the lack of a plan “could contribute to public confusion and weaken the effectiveness of the public health response” to an influenza pandemic. GAO recommends that “HHS...complete the national response plan.”

May 2001 GAO Report

In May 2001, GAO reported on fundamental weaknesses in the U.S. vaccine supply system. GAO found that “HHS has not completed a national pandemic response plan that would, among other things, address how to deal with shortages of vaccine.”¹⁵

April 2003 GAO Report

In April 2003, GAO found that the absence of a national response plan is impeding public health preparedness at the state and local levels. GAO stated: “In our 2000 report on the influenza pandemic, we recommended that HHS ... complete the national response plan. To date, only limited progress has been made.”¹⁶

February 2004 GAO Report

In February 2004, GAO reiterated that “federal plans for the purchase, distribution, and administration of vaccines and drugs in response to an influenza pandemic still have not been finalized, complicating the efforts of states to develop their state plans and heightening concern about our nation’s ability to respond effectively to an influenza pandemic.”¹⁷

September 2004 GAO Report

In September 2004, GAO reviewed a HHS draft pandemic influenza plan, which had been released in August 2004, and found that it “leaves some important decisions about the purchase, distribution, and administration of vaccines unresolved.” In addition, GAO found that “the draft plan does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic.” The result, according to GAO, is that “states are left to make their own decisions, potentially compromising the timing and adequacy of a response to an influenza pandemic.”¹⁸

¹⁵ GAO, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for high Risk People* (May 2001).

¹⁶ GAO, *Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 2003).

¹⁷ GAO, *Public health Preparedness: Response Capacity Improving, but Much Remains to be Accomplished* (Feb. 2004).

¹⁸ GAO, *Federal Challenges in Responding to Influenza Pandemics* (Sept. 2004).

June 2005 GAO Report

In June 2005, GAO reviewed preparedness efforts for an influenza pandemic and found the absence of a final preparedness plan to be a key barrier to progress. The agency stated: “key questions about the federal role in purchasing and distributing vaccines during a pandemic remain, and clear guidance on potential priority groups is lacking in HHS’s current draft of its pandemic preparedness plan.” GAO again concluded that “until key federal decisions are made, public health officials at all levels may find it difficult to plan for an influenza pandemic, and the timeliness and adequacy of response efforts may be compromised.”¹⁹

The Consequences of Delay

The pervasive delays in the preparation of the national response plan have had significant consequences. In September 2004, just one week prior to last year’s shortage of flu vaccine, GAO testified 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.”²⁰ As GAO anticipated, the Administration’s response to the flu vaccine shortage was marred by confusion, long lines, and poor access to vaccine for many high-risk individuals.

Failing to Support Pandemic-Flu-Related Legislation

In addition to failing to implement expert recommendations, reducing public health budgets, and delaying the national response plan, the Administration has failed to support recent legislation to close gaps in the nation’s preparedness for an influenza pandemic.

The Flu Protection Act

On February 15, 2005, Representative Rahm Emanuel and Senator Evan Bayh introduced the Flu Protection Act of 2005.²¹ The bill would create an outreach and education campaign; encourage early orders of flu vaccine; and institute efforts to increase production of, and access to, flu vaccine. The Administration has not endorsed this legislation.

Attacking Viral Influenza Across Nations Act

On April 28, 2005, Representative Nita Lowey and Senator Barack Obama introduced the Attacking Viral Influenza Across Nations Act of 2005.²² The legislation would amend the Public Health Service Act to increase planning, preparedness, training and coordination of state activities addressing pandemic flu. The bill would also require stockpiling of vaccines and

¹⁹ GAO, *Influenza Pandemic: Challenges in Preparedness and Response* (June 2005).

²⁰ GAO, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks* (Sept. 2004).

²¹ S.375 and H.R.813.

²² S.969 and H.R.3369.

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antiviral medicines, and would it would direct the Secretary of Health and Human Services to take steps to address pandemic flu in other countries. The Administration has not endorsed this legislation.

Vaccine Access and Supply Act

On July 29, 2005, Representative Henry Waxman and Senator Edward Kennedy introduced the Vaccine Access and Supply Act.²³ The bill would guarantee the market for the influenza vaccine and promote a stable vaccine supply. It has been endorsed by the American Public Health Association, the Association of State and Territorial Health Officials, and the National Association of City and County Health Officials. But the Administration has not supported the legislation.

Other Measures

Over the last five years, the Administration has made some positive steps to address the threat of an influenza pandemic. For example, the Administration has made modest investments in research for the next generation of influenza vaccines, improved reimbursement for influenza vaccination in Medicare, provided funding to promote year-round production of eggs for vaccine development, and provided support for global surveillance of influenza. Recently, NIH has tested and HHS has contracted for a modest number of doses of avian flu vaccine.

These steps, however, are small compared to the gaping holes in our nation's preparedness. Recently, a report from the *Trust for America's Health* found that the United Kingdom and Canada are significantly ahead of the United States in preparing for an influenza pandemic. In part because of the lack of preparations, the report estimated that even a mid-level pandemic could kill over 500,000 Americans.²⁴

²³ S.1527 and H.R.3502.

²⁴ Trust for America's Health, *A Killer Flu?* (June 2005).