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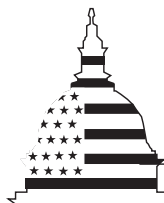
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Reform, House of Representatives

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INFLUENZA PANDEMIC

Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage

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Highlights of [GAO-06-221T](#), a statement for the record for the Committee on Government Reform, House of Representatives

Why GAO Did This Study

Concern has been rising about the nation's preparedness to respond to vaccine shortages that could occur in future annual influenza seasons or during an influenza pandemic—a global influenza outbreak. Although the timing or extent of a future influenza pandemic cannot be predicted, studies suggest that its effect in the United States could be severe, and shortages of vaccine could occur. For the 2004–05 annual influenza season, the nation lost about half its expected influenza vaccine supply when one of two major manufacturers announced in October 2004 that it would not release any vaccine. GAO examined federal, state, and local actions taken in response to the shortage, including lessons learned. The nation's experience during the unexpected 2004–05 vaccine shortfall offers insights into some of the challenges that government entities will face in a pandemic.

GAO was asked to provide a statement on lessons learned from the 2004–05 vaccine shortage and their relevance to planning and preparing for similar situations in the future, including an influenza pandemic. This statement is based on a GAO report, *Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation* (GAO-05-984), and on previous GAO reports and testimonies about influenza vaccine supply and pandemic preparedness.

www.gao.gov/cgi-bin/getrpt?GAO-06-221T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

INFLUENZA PANDEMIC

Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage

What GAO Found

A number of lessons emerged from federal, state, and local responses to the 2004–05 influenza vaccine shortage that carry implications for handling future vaccine shortages in either an annual influenza season or an influenza pandemic.

- First, limited contingency planning slows response. At the start of the 2004–05 influenza season, when the supply shortfall became apparent, the nation lacked a contingency plan specifically to address severe shortages. The absence of such a plan led to delays and uncertainties on the part of state and local public health entities on how best to ensure access to vaccine by individuals at high risk of severe influenza-related complications.
- Second, streamlined mechanisms to expedite vaccine availability are key to an effective response. During the 2004–05 shortage, for example, federal purchases of vaccine licensed for use in other countries but not the United States were not completed in time to meet peak demand. Some states' experience also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another.
- Third, effective response requires clear and consistent communication. Consistency among federal, state, and local communications is critical for averting confusion. State and local health officials also emphasized the value of updated information when responding to changing circumstances, using diverse media to reach diverse audiences, and educating providers and the public about prevention alternatives.

Over the past 5 years, GAO has urged the Department of Health and Human Services (HHS) to complete its plan to prepare for and respond to an influenza pandemic. GAO has reported on the importance of planning to address critical issues such as how vaccine will be purchased and distributed; how population groups will be given priority for vaccination; and how federal resources should be deployed before the nation faces a pandemic. On November 2, 2005, HHS released its pandemic influenza plan. GAO did not have the opportunity to review the plan before issuing this statement to determine the extent to which the plan addresses these critical issues.

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to provide information on our recent review of the 2004–05 influenza vaccine shortage, with lessons to consider as the nation improves its ability to respond to an influenza pandemic (a global influenza outbreak resulting from a major genetic change in the influenza virus).¹ Concern about the nation’s preparedness to respond to an influenza pandemic has been growing for some time, in part because of the increase in the number of identified human cases of avian influenza in Asia.² Studies suggest that a pandemic’s effects in the United States could be severe, and shortages of vaccine could occur. The nation’s experience responding to the shortage of annual influenza vaccine for the 2004–05 influenza season—in which the nation faced an unexpected loss of nearly half its projected vaccine supply—offers insight into the some of the challenges that federal, state, and local entities will face if a pandemic occurs.

My statement includes findings from our recent report on last winter’s influenza vaccine shortage and discusses lessons learned from that experience that could help prepare the nation to respond to future vaccine shortages in either an annual influenza season or an influenza pandemic.³ My statement also draws from several GAO reports and testimonies on influenza vaccine supply, pandemic planning, and emergency preparedness for emerging infectious diseases that we have issued since October 2000.⁴ This body of work includes interviews with officials in the Department of Health and Human Services (HHS), such as officials from

¹An influenza pandemic is defined by the emergence of a novel influenza virus, to which much or all of the population is susceptible, that is readily transmitted person to person and causes outbreaks in multiple countries. Among the most notorious 20th-century outbreaks was the “Spanish influenza” of 1918, which is estimated to have killed 500,000 or more people in the United States and 40–50 million people worldwide.

²Since December 2003, 122 confirmed avian influenza cases in humans have been reported to the World Health Organization (WHO); these cases have occurred in four countries, and about half the victims died. See World Health Organization, “Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO,” http://www.who.int/csr/disease/avian_influenza/country/cases_table_2005_11_01/en/index.html, downloaded Nov.1, 2005. Avian influenza has also been confirmed in birds in Europe.

³GAO, *Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation*, GAO-05-984 (Washington, D.C.: Sept. 30, 2005).

⁴See “Related GAO Products” at the end of this testimony.

the Centers for Disease Control and Prevention (CDC) and the National Vaccine Program Office. For the report on the 2004–05 influenza vaccine shortage, we conducted site visits at a sample of states and localities.⁵ We also interviewed officials from public health departments and a major influenza vaccine manufacturer; national organizations, including the Association of State and Territorial Health Officials and the Association of Immunization Managers; organizations that conduct mass immunization clinics; and a large purchaser of influenza vaccine. We conducted all of our work in accordance with generally accepted government auditing standards.

In summary, a number of lessons emerged from federal, state, and local responses to the 2004–05 influenza vaccine shortage that carry implications for handling future vaccine shortages in either an annual influenza season or an influenza pandemic. First, limited contingency planning slows response. At the start of the 2004–05 influenza season, when the nation unexpectedly lost roughly half its projected influenza vaccine supply, the nation lacked a contingency plan specifically for a severe vaccine shortage. The absence of such a plan led to delays and uncertainties on the part of state and local public health entities on how best to ensure access to vaccine by individuals at high risk of severe influenza-related complications. Since 2000, we have encouraged the development of a plan to address critical issues that could arise in an influenza pandemic. Second, streamlined mechanisms to expedite vaccine availability are key to an effective response. During the 2004–05 shortage, for example, federal purchases of vaccine licensed for use in other countries but not the United States were not completed in time to meet peak demand. Some states' experience also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another. Third, effective response requires clear and consistent communication. Consistency among federal, state, and local communications is critical for averting confusion. State and local health officials also emphasized the value of updated information when responding to changing circumstances, using diverse media to reach diverse audiences, and educating providers and the public about prevention alternatives.

⁵The states were California, Florida, Maine, Minnesota, and Washington, and the localities were San Diego and San Francisco, California; Miami-Dade County, Florida; Portland, Maine; Stearns County, Minnesota; and Seattle–King County, Washington. We selected these states and localities on the basis of geography, population size, and state vaccination success rates.

Background

Influenza is more severe than some viral respiratory infections, such as the common cold. During an annual influenza season, most people who contract influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. People aged 65 years and older, people of any age with chronic medical conditions, children younger than 2 years, and pregnant women are generally more likely than others to develop severe complications from influenza. In an average year in the United States, more than 36,000 individuals die and more than 200,000 are hospitalized from influenza and related complications.

Pandemic influenza differs from annual influenza in several ways. According to the World Health Organization, pandemic influenza spreads to all parts of the world very quickly, usually in less than a year, and can sicken more than a quarter of the global population, including young, healthy individuals. Although health experts cannot predict with certainty which strain of influenza virus will be involved in the next pandemic, they warn that the avian influenza virus identified in the human cases in Asia, known as H5N1, could lead to a pandemic if it acquires the genetic ability, so far absent, to spread quickly from person to person.

Vaccination is the primary method for preventing influenza and its complications. Produced in a complex process that involves growing viruses in millions of fertilized chicken eggs, influenza vaccine is administered each year to protect against particular influenza strains expected to be prevalent that year. Experience has shown that vaccine production generally takes 6 or more months after a virus strain has been identified; vaccines for certain influenza strains have been difficult to mass-produce. After vaccination for the annual influenza season, it takes about 2 weeks for the body to produce the antibodies that protect against infection. According to CDC recommendations, the optimal time for annual vaccination is October through November. Because the annual influenza season typically does not peak until January or February, however, in most years vaccination in December or later can still be beneficial.

At present, two vaccine types are recommended for protection against influenza in the United States: an inactivated virus vaccine injected into muscle and a live virus vaccine administered as a nasal spray. The injectable vaccine—which represents the large majority of influenza vaccine administered in this country—can be used to immunize both healthy individuals and individuals at highest risk for severe complications, including those with chronic illness and those aged 65

years and older. The nasal spray vaccine, in contrast, is currently approved for use only among healthy individuals aged 5 to 49 years who are not pregnant. For the 2003–04 influenza season, two manufacturers—one with production facilities in the United States (sanofi pasteur⁶) and one with production facilities in the United Kingdom (Chiron)—produced about 83 million doses of injectable vaccine, which represented about 96 percent of the U.S. vaccine supply. A third U.S. manufacturer (MedImmune) produced the nasal spray vaccine.⁷ For the 2004–05 influenza season, CDC and its Advisory Committee on Immunization Practices (ACIP) initially recommended vaccination for about 188 million people in designated priority groups, including roughly 85 million people at high risk for severe complications.⁸ On October 5, 2004, however, Chiron announced that it could not provide its expected production of 46–48 million doses—about half the expected U.S. influenza vaccine supply.

Although vaccination is the primary strategy for protecting individuals who are at greatest risk of severe complications and death from influenza, antiviral drugs can also help to treat infection. If taken within 2 days of a person’s becoming ill, these drugs can ease symptoms and reduce contagion. In the event of a pandemic, such drugs could lower the number of deaths until a pandemic influenza vaccine became available. Four antiviral drugs have been approved by the Food and Drug Administration (FDA) for treatment of influenza: amantadine, rimantadine, oseltamivir, and zanamivir.⁹

HHS has primary responsibility for coordinating the nation’s response to public health emergencies. Within HHS, CDC is one of the agencies that

⁶The company spells its name without capital letters.

⁷Another injectable influenza vaccine for adults, produced by GlaxoSmithKline Biologicals, based in Belgium, was approved and licensed by FDA on August 31, 2005, for the U.S. market. The company expects to produce about 8 million doses for the 2005–06 influenza season.

⁸Not everyone in target populations receives a vaccination each year. For example, CDC reported that in 2003 an estimated 66 percent of people aged 65 years and older received an influenza vaccination. See Centers for Disease Control and Prevention, “Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP),” *Morbidity and Mortality Weekly Report*, vol. 54, no. RR-8 (2004), 1–40.

⁹According to CDC, the H5N1 avian influenza virus is resistant to amantadine and rimantadine, commonly used for influenza; oseltamivir and zanamivir would probably work to treat influenza caused by the H5N1 virus, but additional studies are still needed to prove their effectiveness.

protect the nation's health and safety. CDC's activities include efforts to prevent and control diseases and to respond to public health emergencies. CDC and ACIP recommend which population groups should be targeted for vaccination each year and, when vaccine supply allows, recommend that any person who wishes to decrease his or her risk of influenza be vaccinated.¹⁰ In addition, the National Vaccine Program Office is responsible for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities; the office also issued a draft national pandemic influenza preparedness plan in August 2004.¹¹

Preparing for and responding to an influenza pandemic differ in several respects from preparing for and responding to an annual influenza season. For example, past influenza pandemics have affected healthy young adults who are not typically at high risk for severe influenza-related complications, so the groups given priority for early vaccination may differ from those given priority in an annual influenza season. In addition, according to CDC, a vaccine probably would not be available in the early stages of a pandemic. Shortages of vaccine would therefore be likely during a pandemic, potentially creating a situation more challenging than a shortage of vaccine for an annual influenza season.

Limited Contingency Planning Slows Response

One lesson learned from the 2004–05 season that is relevant to a future vaccine shortage in either an annual influenza season or a pandemic is the importance of planning before a shortage occurs. At the time the influenza vaccine shortage became apparent, the nation lacked a contingency plan specifically designed to respond to a severe vaccine shortage. The absence of such a plan led to delays and uncertainty on the part of many state and local entities on how best to ensure access to vaccine during the shortage by individuals at high risk of severe complications and others in priority groups. Faced with the unanticipated shortfall, CDC redefined the priority

¹⁰In addition, FDA plays a role in preparing for annual influenza seasons and a potential pandemic in approving and regulating use of vaccines and drugs, including antiviral medications. FDA also develops influenza reference strains and reagents and makes them available to manufacturers for vaccine development and evaluation.

¹¹Department of Health and Human Services, National Vaccine Program Office, *Draft Pandemic Influenza Preparedness and Response Plan* (Washington, D.C.: August 2004).

groups it had recommended for vaccination¹² and asked sanofi pasteur, the remaining manufacturer of injectable vaccine, to suspend distribution until the agency completed its assessment of the shortage's extent and developed a plan to distribute the manufacturer's remaining vaccine to providers serving individuals in the priority groups. Developing and implementing this distribution plan took time and led to delays in response and some confusion at state and local levels.

Our work showed that several areas of planning are particularly important for enhancing preparedness before a similar situation occurs in the future, including defining the responsibilities of federal, state, and local officials; using emergency preparedness plans and emergency health directives; and facilitating the distribution and administration of vaccine.

- Clearly defining responsibilities of federal, state, and local officials can minimize confusion. During the 2004–05 vaccine shortage, even though CDC worked with states and localities to coordinate roles and responsibilities, problems occurred. For example, CDC worked with national professional associations to survey long-term-care providers throughout the country to determine if seniors had adequate access to vaccine. Maine and other states, however, also surveyed their long-term-care providers to make the same determination. This duplication of effort expended additional resources, burdened some long-term-care providers in the states, and created confusion.¹³
- Emergency preparedness plans help coordinate local response. State and local health officials in several locations we visited reported that using existing emergency plans or incident command centers (the organizational systems set up specifically to handle the response to emergency situations) helped coordinate effective local responses to the vaccine shortage. For example, public health officials from Seattle–King County said that using the county's incident command system played a vital role in coordinating an effective and timely local response and in communicating a clear message to the public and providers. In addition, according to

¹²These revised recommendations decreased the number of people in groups recommended for vaccination by about half, from about 188 million to about 98 million. See Centers for Disease Control and Prevention, "Interim Influenza Vaccination Recommendations, 2004–05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 39 (2004), 923–924.

¹³After the 2004–05 influenza season, CDC reviewed its response to the vaccine shortage and took a number of steps, including issuing interim guidelines in August 2005 to assist in responding to possible future shortages.

public health officials, emergency public health directives helped ensure access to vaccine by supporting providers in enforcing the CDC recommendations and in helping to prevent price gouging in certain states.

- Partnerships between the public and private sectors can facilitate distribution and administration of vaccine. In San Diego County, California, for example, local health officials worked with a coalition of partners in public health, private businesses, and nonprofit groups throughout the county. Other mechanisms facilitated administering the limited supply of influenza vaccine to those in high-risk or other priority groups. In Stearns County, Minnesota, for example, public health officials worked with private providers to implement a system of vaccination by appointment. Rather than standing in long lines for vaccination, individuals with appointments went to a clinic during a given time slot.

Although an influenza pandemic may differ in some ways from an annual influenza season, experience during the 2004–05 shortage illustrated the importance of having contingency plans in place ahead of time to prevent delays when timing is critical. Some health officials indicated that, as a result of the experience with the influenza vaccine shortage, they were revising state and local preparedness plans or modifying command center protocols to prepare for future emergencies. For example, experiences during the 2004–05 influenza season led Maine state officials to recognize the need to speed completion of their pandemic influenza preparedness plan.

Over the past 5 years, we have reported on the importance of planning to address critical issues such as how vaccine will be purchased and distributed; how population groups will be given priority for vaccination; and how federal resources should be deployed before the nation faces a pandemic. We have also urged HHS to complete its pandemic preparedness and response plan, which the department released in draft form in August 2004. This draft plan described options for vaccine purchase and distribution and provided planning guidance to state and local health departments. As we testified earlier, however, the draft plan lacked clear guidance on potential priority groups for vaccination in a pandemic, and key questions remained about the federal role in purchasing and distributing vaccine.¹⁴ The experience in 2004–05 also highlighted the importance of finalizing such planning details. On

¹⁴See GAO, *Influenza Pandemic: Challenges in Preparedness and Response*, [GAO-05-863T](#) (Washington, D.C.: June 30, 2005).

November 2, 2005, HHS released its pandemic influenza plan. We did not, however, have an opportunity to review the plan before issuing this statement to determine whether the plan addresses these critical issues.

Streamlined Mechanisms for Expediting Vaccine Availability Are Key to Effective Response

A second lesson from the experience of the 2004–05 vaccine shortage that is relevant to future vaccine shortages in either an annual influenza season or a pandemic is the importance of streamlined mechanisms to make vaccine available in an expedited manner. For example, HHS began efforts to purchase foreign vaccine that was licensed for use in other countries but not the United States shortly after learning in October 2004 that Chiron would not supply any vaccine. The purchase, however, took several months to complete, and so vaccine was not available to meet the fall 2004 demand; by the end of the season, this vaccine had not been used. In addition, recipients of this foreign vaccine could have been required to sign a consent form and follow up with a health care worker after vaccination—steps that, according to health officials we interviewed in several states, would be too cumbersome to administer.

Some states' experience during the 2004–05 vaccine shortage also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another; the lack of mechanisms to do so delayed redistribution to some states. During the 2004–05 shortage, some state health officials reported problems with their ability to purchase vaccine, both in paying for vaccine and in administering the transfer process. Minnesota, for example, tried to sell its available vaccine to other states seeking additional vaccine for their priority populations. According to federal and state health officials, however, certain states lacked the funding or flexibility under state law to purchase the vaccine when Minnesota offered it. As we have previously testified, establishing the funding sources, authority, or processes for quick public-sector purchases may be needed as part of pandemic preparedness.¹⁵

Recognizing the need for mechanisms to make vaccine available in a timely manner in the event of a pandemic, HHS has taken some action to address the fragility of the current influenza vaccine market. In its budget request for fiscal year 2006, CDC requested \$30 million to enter into guaranteed-purchase contracts with vaccine manufacturers to help ensure vaccine supply. According to the agency, maintaining an abundant supply

¹⁵ [GAO-05-863T](#).

of annual influenza vaccine is critically important for improving the nation's preparedness for an influenza pandemic. HHS is also taking steps toward developing a supply of vaccine to protect against avian influenza strains that could be involved in a pandemic.¹⁶

Effective Response Requires Clear and Consistent Communication

Experience during the 2004–05 shortage also illustrated the critical role communication plays when demand for vaccine exceeds supply and information about future vaccine availability is uncertain, as could happen in a future annual influenza season or a pandemic. During the 2004–05 shortage, CDC communicated regularly through a variety of media as the situation evolved. State and local officials, however, identified several communication lessons for future seasons or if an influenza pandemic occurred:

- Consistency among federal, state, and local communications is critical for averting confusion. State health officials reported several cases where inconsistent messages created confusion. Health officials in California, for example, reported that local radio stations in the state were running two public service announcements simultaneously—one from CDC advising those aged 65 years and older to be vaccinated, and one from the state advising those aged 50 years and older to be vaccinated.
- Disseminating clear, updated information is especially important when responding to changing circumstances. Beginning in October 2004, CDC asked individuals who were not in a high-risk group or another priority group to forgo or defer vaccination; this message, however, did not include instructions to check back with their providers later in the season, when more vaccine had become available. According to CDC, an estimated 17.5 million individuals specifically deferred vaccination to save

¹⁶In addition, HHS has also taken steps to stockpile antiviral drugs, which could be beneficial in the event of a pandemic, before a vaccine specific for the responsible virus strain is available or during a period of limited vaccine supply. By December 2004, HHS had purchased and stockpiled enough of two antiviral medications (rimantadine and oseltamivir) to treat more than 7 million people, and the department recently announced intentions to buy enough antiviral drugs to treat 20 million people. Like vaccine, however, antiviral drugs take several months to produce from raw materials, and HHS's National Vaccine Program Office has reported that in a pandemic, the manufacturing capacity and supply of antiviral drugs are likely to be less than global demand.

vaccine for those in priority groups;¹⁷ local health officials said that many did not return when vaccine became available.

- Using diverse media helps reach diverse audiences. During the 2004–05 influenza season, public health officials emphasized the value of a variety of communication methods—such as telephone hotlines, Web sites, and bilingual radio advertisements—to reach as many individuals as possible and to increase the effectiveness of local efforts to raise vaccination rates. In Seattle–King County, Washington, for example, health department officials reported that a telephone hotline was important because some seniors did not have Internet access. Public health officials in Miami-Dade County, Florida, said that bilingual radio advertisements promoting influenza vaccine for those in priority groups helped increase the effectiveness of local efforts to raise vaccination rates.
- Education can alert providers and the public to prevention alternatives. In the 2004–05 shortage, some of the nasal spray vaccine for healthy individuals went unused, in part because of fears that the vaccine was too new and untested or that the live virus in the nasal spray could be transmitted to others.¹⁸ Further, public health officials we interviewed said that education about all available forms of prevention, including the use of antiviral medications and good hygiene practices, can help reduce the spread of influenza.

Concluding Observations

Experience during the 2004–05 influenza vaccine shortage highlights the need to prepare the nation for handling future shortages in either an annual influenza season or an influenza pandemic. In particular, that season’s shortage emphasized the vital need for early planning, mechanisms to make vaccine available, and effective communication to ensure available vaccine is targeted to those who need it most. As our work over the past 5 years has noted, it is important for federal, state, and local governments to develop and communicate plans regarding critical issues—such as how vaccine will be purchased and distributed, which

¹⁷See Centers for Disease Control and Prevention, “Estimated Influenza Vaccination Coverage among Adults and Children—United States, September 1, 2004–January 31, 2005,” *Morbidity and Mortality Weekly Report*, vol. 54, no. 12 (2005), 304–307.

¹⁸The nasal spray vaccine was recommended for individuals aged 5–49 years who were not pregnant, including some individuals, such as health care workers in this age group and household contacts of children younger than 6 months, in the priority groups defined by CDC.

population groups are likely to have priority for vaccination, and what communication strategies are most effective—before we face another shortage of annual influenza vaccine or, worse, an influenza pandemic.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov. Kim Yamane, Assistant Director; George Bogart; Ellen W. Chu; Nicholas Larson; Jennifer Major; and Terry Saiki made key contributions to this statement.

Related GAO Products

Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation. [GAO-05-984](#). Washington, D.C.: September 30, 2005.

Influenza Pandemic: Challenges in Preparedness and Response. [GAO-05-863T](#). Washington, D.C.: June 30, 2005.

Influenza Pandemic: Challenges Remain in Preparedness. [GAO-05-760T](#). Washington, D.C.: May 26, 2005.

Flu Vaccine: Recent Supply Shortages Underscore Ongoing Challenges. [GAO-05-177T](#). Washington, D.C.: November 18, 2004.

Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks. [GAO-04-1100T](#). Washington, D.C.: September 28, 2004.

Public Health Preparedness: Response Capacity Improving, but Much Remains to Be Accomplished. [GAO-04-458T](#). Washington, D.C.: February 12, 2004.

Flu Vaccine: Steps Are Needed to Better Prepare for Possible Future Shortages. [GAO-01-786T](#). Washington, D.C.: May 30, 2001.

Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People. [GAO-01-624](#). Washington, D.C.: May 15, 2001.

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