

GAO

Report to the Committee on Oversight  
and Government Reform, House of  
Representatives

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October 2007

# INFLUENZA VACCINE

## Issues Related to Production, Distribution, and Public Health Messages





Highlights of [GAO-08-27](#), a report to the Committee on Oversight and Government Reform, House of Representatives

## Why GAO Did This Study

Annual vaccination is the main method for preventing seasonal influenza, which typically occurs in the United States from late fall to early spring. Manufacturers produce vaccine through a lengthy and complex process.

Manufacturers and medical supply distributors then ship vaccine to providers such as physicians. Each year, the Department of Health and Human Services's (HHS) Centers for Disease Control and Prevention (CDC) recommends who should be targeted for vaccination, including those at higher risk for influenza-related complications or medical care—for example, adults aged 50 years and older, young children, and some individuals with chronic medical conditions. CDC bases its recommendations on those made by the agency's Advisory Committee on Immunization Practices (ACIP).

GAO examined: (1) factors that affect the quantity of vaccine produced and when it reaches providers, (2) issues related to making vaccine available to high-risk and other target groups, and (3) public health messages produced and disseminated by CDC and others to promote vaccination.

GAO reviewed relevant documents and interviewed officials from CDC, other public health entities, manufacturers, and medical supply distributors, and examined data on vaccine doses produced and shipped.

To view the full product, including the scope and methodology, click on [GAO-08-27](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crosse@gao.gov](mailto:crosse@gao.gov).

# INFLUENZA VACCINE

## Issues Related to Production, Distribution, and Public Health Messages

### What GAO Found

Several factors affect the quantity of vaccine produced for a given influenza season and when it reaches providers who administer the vaccine. One factor is the difficulty of manufacturing a new vaccine each year, which includes adherence to a relatively inflexible and sequential process, challenges of growing new virus strains, and maintaining safety and quality control practices to produce a sterile vaccine. Other factors include limitations in the production capacity of manufacturers and demand for vaccine throughout the influenza season. In addition, the distribution route the vaccine takes from the manufacturer to the provider can also affect how much time elapses before the vaccine reaches individual providers.

Issues related to making vaccine available to high-risk and other target groups recommended by CDC and ACIP include the locations in which these individuals receive vaccinations, how vaccine is distributed to providers, and the timing of vaccine distribution to different types of providers. According to data from CDC, individuals in high-risk and other target groups have received influenza vaccinations at various locations where different types of providers administer the vaccine, including physicians' offices, workplaces, clinics, or other settings. Certain types of providers, such as physicians, reported that they received their vaccine orders after other types of providers, such as mass immunizers that provide vaccinations at retail stores. Available data for the 2006–07 influenza season indicated, however, that most types of providers received vaccine in similar time frames. CDC officials acknowledged that individual providers' experiences at the local level could vary. In an effort to help state and local health officials manage the availability of vaccine for high-risk or other target groups, CDC and state health officials have undertaken several efforts, including the creation of monitoring tools and the implementation of a state-specific vaccine distribution program.

CDC and others have produced and disseminated public health messages—such as press releases and public service announcements—designed to promote seasonal influenza vaccination. These include messages designed to maintain public demand for vaccination later in the influenza season and to encourage preferential vaccination of certain groups during times of vaccine shortage or delay. CDC has taken steps to assess its influenza-related public health messages before disseminating them to the public and has conducted limited data collection afterwards. Although no comprehensive evaluations have been conducted to assess the impact of influenza-related messages after dissemination, CDC and other officials GAO interviewed identified key elements, such as clear and consistent messages, that they believe are important to producing effective public health messages. However, there are impediments to effectively implementing these elements, such as the need to modify messages during the season as circumstances change.

We provided a draft of this report to HHS for comment. The department provided technical comments, which we incorporated as appropriate.

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## **Abbreviations**

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
HHS	Department of Health and Human Services

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United States Government Accountability Office  
Washington, DC 20548

October 31, 2007

The Honorable Henry A. Waxman  
Chairman  
The Honorable Tom Davis  
Ranking Member  
Committee on Oversight and Government Reform  
House of Representatives

On average each year in the United States, seasonal influenza—which is caused by influenza viruses—is associated with more than 200,000 hospitalizations and 36,000 deaths. Particular groups of individuals are at increased risk for influenza-related complications or at higher risk for medical care—including those aged 50 years and older, pregnant women, young children, and individuals with chronic medical conditions. The primary method for preventing influenza in these groups, and in the general population, is annual vaccination with influenza vaccine.<sup>1</sup> The influenza season in the United States generally occurs from late fall to early spring, with infections typically peaking in January or February. October through November is considered to be the best time for influenza vaccination; in most years, however, vaccination in December or later can still be beneficial. Because circulating influenza virus strains change, a new vaccine is created each year based on the three influenza virus strains that the Department of Health and Human Services's (HHS) Food and Drug Administration (FDA) determines to be likely to cause serious illness in the United States that year.<sup>2</sup> The vaccine is produced through a lengthy and complex process that involves growing the influenza virus strains in millions of chicken eggs.

HHS's Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) make recommendations on which groups should be targeted for annual influenza vaccination in the

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<sup>1</sup>Influenza vaccination is performed by a diverse group of providers, including state and local health departments, other medical facilities, and mass immunizers—visiting nurse agencies or for-profit companies that contract with and conduct influenza vaccination clinics at workplaces, retail stores, long-term care facilities, and other locations.

<sup>2</sup>FDA's determination of strains to be included in the seasonal influenza vaccine is based on a review of surveillance data, the availability of appropriate materials, and consultation with an FDA advisory committee.

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United States. Individuals in this target population for the 2007–08 influenza season include those in high-risk groups<sup>3</sup>—such as adults aged 50 years and older, children aged 6 to 59 months, pregnant women, and persons aged 6 months and older with certain chronic medical conditions—and individuals in other target groups, such as health care workers and others in close contact with those at high risk. CDC officials have raised concerns that, should shortages or delays in distribution of vaccine occur, vaccine would not be available for individuals in high-risk or other target groups during the time when demand for vaccination among these groups has traditionally been highest. In addition, these officials raised concerns, when vaccine has been more plentiful, that not all individuals in the target population for whom annual vaccination is recommended have been seeking or receiving vaccination. For example, only about half of those in groups at higher-risk for influenza-related complications and only about one-fifth of those in other target groups received influenza vaccination, according to CDC estimates.<sup>4</sup>

We previously reported on manufacturing difficulties experienced during the 2000–01 influenza season that illustrated the challenges in producing a new influenza vaccine each year on a timely basis. We reported on the delays in shipment and resulting initial vaccine shortage experienced for that season, and we also reported on the vaccine shortage experienced for the 2004–05 influenza season.<sup>5</sup> You observed that, despite changes since the 2000–01 season, concerns about the reliability of influenza vaccine supply and distribution persist. This report discusses (1) factors that affect the quantity of seasonal influenza vaccine produced and when vaccine reaches providers who administer vaccine, (2) issues related to making

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<sup>3</sup>Throughout this report, we use the term *high-risk* to refer to those groups of individuals ACIP has identified for the 2007–08 influenza season as being at increased risk for influenza-related complications or at higher risk for medical care—that is, for influenza-associated clinic, emergency department, or hospital visits. See Centers for Disease Control and Prevention, “Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007,” *Morbidity and Mortality Weekly Report*, vol. 56 (June 29, 2007): 1-53.

<sup>4</sup>See Centers for Disease Control and Prevention, “Estimates of Influenza Vaccination Target Population Sizes in 2006 and Recent Vaccine Uptake Levels,” <http://www.cdc.gov/flu/professionals/vaccination/pdf/targetpopchart.pdf> (downloaded April 2, 2007).

<sup>5</sup>See GAO, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People*, GAO-01-624 (Washington, D.C.: May 15, 2001); GAO, *Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation*, GAO-05-984 (Washington, D.C.: Sept. 30, 2005); and see Related GAO Products at the end of this report.

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vaccine available for high-risk and other target groups, and (3) public health messages produced and disseminated by CDC and others to promote seasonal influenza vaccination.

To address these objectives, we reviewed relevant documents and interviewed officials from CDC and FDA; national associations representing state and local health officials,<sup>6</sup> public health officials, medical supply distributors,<sup>7</sup> physicians, and long-term care providers; and all five manufacturers of seasonal influenza vaccine for the U.S. market for the 2007–08 influenza season as of August 31, 2007.<sup>8</sup> We also selected judgmental samples of (1) medical supply distributors; (2) mass immunizers—organizations that conduct influenza vaccination clinics at workplaces, retail stores, long-term care facilities, and other locations; and (3) state health departments.<sup>9</sup> For each organization in our samples, we reviewed relevant documents and interviewed officials.

To determine the quantity of seasonal influenza vaccine produced and when vaccine reaches providers who administer vaccine, we examined data from CDC regarding the number of influenza vaccine doses produced and distributed each month for the 2000–01 influenza season through the 2006–07 influenza season. We also reviewed data from CDC on the

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<sup>6</sup>We also spoke with state and local health officials who are members of national associations representing state and local health officials.

<sup>7</sup>Medical supply distributors purchase vaccine from manufacturers and resell it to customers such as physicians, hospitals, state and local health departments, other distributors, and others seeking vaccine in order to administer vaccinations.

<sup>8</sup>For the 2007–08 influenza season, five vaccines were licensed by FDA for the U.S. market as of August 31, 2007: (1) Fluarix, manufactured by a part of GlaxoSmithKline plc, GlaxoSmithKline Biologicals, (2) FluLaval, manufactured by a subsidiary of GlaxoSmithKline plc, ID Biomedical Corporation of Quebec, (3) FluMist, manufactured by MedImmune Vaccines, Inc., (4) Fluvirin, manufactured by Novartis Vaccines and Diagnostics Limited, and (5) Fluzone, manufactured by sanofi pasteur. The policy of sanofi pasteur is to spell its name without capital letters. We interviewed officials and obtained information from GlaxoSmithKline Biologicals regarding both Fluarix and FluLaval; and interviewed officials and obtained information from MedImmune Vaccines, Inc., Novartis Vaccines and Diagnostics Limited, and sanofi pasteur regarding FluMist, Fluvirin, and Fluzone, respectively. On September 28, 2007, FDA approved an additional influenza vaccine, Afluria, manufactured by CSL Limited, for the U.S. market for the 2007–08 season.

<sup>9</sup>We selected these samples to reflect a mix of distributors, mass immunizers, and states; however, our samples were not statistically representative and cannot be generalized. Our judgmental samples included six medical supply distributors that plan to distribute influenza vaccine for the 2007–08 season, four mass immunizers, and six state health departments. For additional information on our scope and methodology, see app. I.



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cumulative percentage of doses manufacturers and medical supply distributors reported shipping each month to different types of providers for the 2006–07 influenza season. To identify the locations in which high-risk groups receive their vaccinations, we reviewed data from CDC’s Behavioral Risk Factor Surveillance System,<sup>10</sup> a poll contracted by CDC, and other surveys CDC administered on immunization practices. To identify efforts undertaken by CDC and state health officials to help state and local officials manage availability of vaccine for high-risk and other target groups, we reviewed data from and documentation of the Internet-based distribution database that CDC created—the Flu Vaccine Finder, a component of CDC’s Secure Data Network<sup>11</sup>—and interviewed health department officials from our sample of states. We assessed the reliability of these data and determined they were sufficiently reliable for our purposes.

To examine public health messages that CDC and others have produced and disseminated to promote seasonal influenza vaccination, we reviewed influenza vaccination communication plans produced by CDC and research and surveys conducted by CDC. We conducted our work in accordance with generally accepted government auditing standards from May through October 2007.

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## Results in Brief

Several factors—including challenges in manufacturing a new vaccine each year, limitations in the production capacity of manufacturers, and fluctuating demand for vaccine by providers and patients—affect the quantity of vaccine produced for a given influenza season and when it reaches providers who administer the vaccine. Manufacturing challenges inherent to the production of seasonal influenza vaccine include the necessity of adhering to a relatively inflexible and sequential process involving multiple players including the World Health Organization, CDC, FDA, and manufacturers; difficulties growing new virus strains; and problems associated with maintaining safety and quality control practices to produce a sterile vaccine. Each of these manufacturing challenges has

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<sup>10</sup>The Behavioral Risk Factor Surveillance System is a state-based system of health surveys that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury.

<sup>11</sup>The Secure Data Network is an ongoing project sponsored by CDC to allow CDC field staff, researchers, and public health partners to securely exchange confidential, proprietary, or sensitive data over the Internet.

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the potential to affect all manufacturers; however, in any given year, the degree to which these challenges affect the quantity of vaccine that an individual manufacturer produces or when that manufacturer's vaccine is shipped to providers may vary significantly. Overall production capacity—that is, the maximum amount of vaccine that manufacturers can produce, package, and ship at any given time—may also limit the quantity of vaccine produced and can delay when vaccine is available to providers. Another limiting factor is demand for vaccine throughout the influenza season. Because demand for vaccine is highest in October and November and then tapers off in December and later, manufacturers may decide to stop production if they do not believe there is sufficient demand later in the season, thereby limiting the quantity produced for that influenza season and how late in the season it is available. For individual providers who administer influenza vaccinations, the distribution route the vaccine takes from the manufacturer to the providers can also affect how much time elapses before the vaccine reaches them.

Issues related to making vaccine available to high-risk and other target groups include the locations in which these individuals receive vaccinations, how vaccine is distributed to providers, and the timing of vaccine distribution to different types of providers. According to data from CDC, individuals in high-risk and other target groups have received influenza vaccinations at various locations where different types of providers, including physicians, hospitals, pharmacies, state and local health departments, and mass immunizers, administer vaccine. All manufacturers we spoke with and more than half of the medical supply distributors we interviewed reported that, for the 2007–08 influenza season, they plan to continue or begin distributing vaccine to all types of providers in multiple shipments—that is, they plan to fill a portion of each customer's order as vaccine becomes available—so that all customers may have at least some vaccine available for high-risk or other target groups. Other medical supply distributors reported shipping vaccine using a variety of other distribution practices, such as filling vaccine orders in the order in which they were received. As a result of these distribution practices, it is possible that some providers receive vaccine and offer vaccinations to anyone who wants it before other providers have received enough vaccine to vaccinate their patients in high-risk or other target groups. In recent years, certain types of providers, such as physicians and state and local health departments, reported they received their vaccine orders later than other types of providers, such as mass immunizers that provide vaccinations at retail stores. National data collected by CDC for the 2006–07 influenza season indicated that, in aggregate, most types of providers, including private providers such as physicians, received vaccine

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in similar time frames. However, the data also indicated that state and local health departments received a smaller percentage of the doses distributed in the early fall than later in the season. CDC officials acknowledged that individual providers' experiences at the local level could vary. In an effort to help state and local health officials manage the availability of vaccine for high-risk and other target groups, CDC and state health officials have undertaken several efforts, including the creation of monitoring tools and the implementation of a state-specific vaccine distribution program.

CDC and others have produced and disseminated public health messages designed to promote seasonal influenza vaccination and CDC has taken some steps to assess its messages. Efforts to communicate public health messages undertaken by CDC and others—including state and local health departments and provider associations—include production and dissemination of press releases, educational materials, and public service announcements designed to promote vaccination, as well as messages aimed at maintaining public demand later in the season and encouraging preferential vaccination of certain groups during times of vaccine shortage or delay. CDC has taken steps to assess its influenza-related public health messages before disseminating them to the public and has collected some data afterwards. Although no comprehensive evaluations have been conducted, CDC and other officials we interviewed identified elements, such as clear and consistent messages, that are important to effective public health messages promoting influenza vaccination. However, there are impediments to effectively implementing these elements, such as the need to modify messages during the season as circumstances change.

We provided a draft of this report to HHS for comment. The department provided technical comments, which we incorporated as appropriate.

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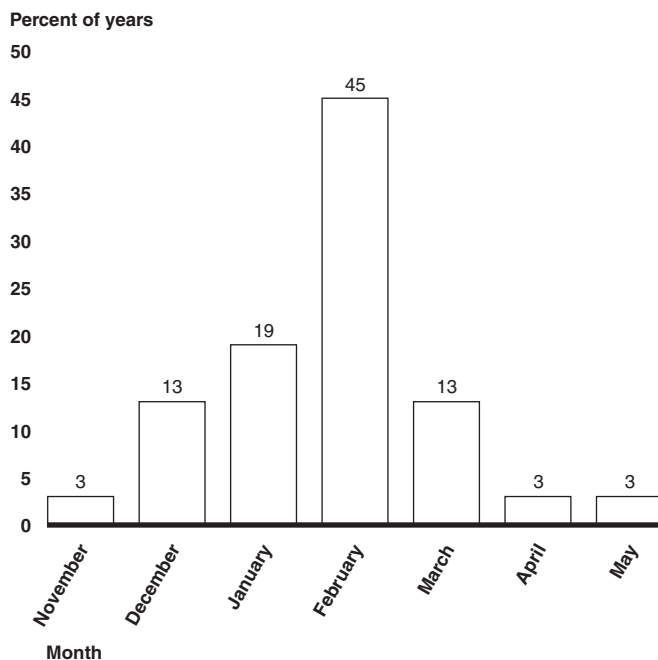
## Background

Influenza is characterized by cough, fever, headache, and other symptoms and is more severe than some viral respiratory infections, such as the common cold. Most people who contract seasonal influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. On average each year in the United States more than 36,000 individuals die and more than 200,000 are hospitalized from influenza and related complications.

Vaccination, administered annually to provide protection against particular influenza virus strains expected to be prevalent that year, is the primary method for preventing seasonal influenza and its more severe

complications. After vaccination, the body takes about 2 weeks to produce the antibodies that protect against infection. Traditionally CDC has recommended vaccination begin around October each year. However, because influenza seasons most often peak in January or February, in most years vaccination in December or later can still be beneficial. As shown in figure 1, the influenza season peaked in January or February in nearly two-thirds of the past 30 seasons.

**Figure 1: Month of Peak Influenza Activity, 1976 through 2006**



Source: CDC, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007," *Morbidity and Mortality Weekly Report*, vol. 56 (2007): 5.

Notes: The peak month of activity was defined as the month with the greatest percentage of respiratory specimens testing positive for influenza virus. Percentages do not add to 100 percent due to rounding.

Two types of vaccine are recommended for protection against seasonal influenza in the United States: (1) an inactivated virus vaccine injected into muscle or (2) a live attenuated vaccine administered as a nasal spray.<sup>12</sup> The injectable vaccine—which represents the vast majority of influenza vaccine administered—can be used to immunize healthy individuals aged

<sup>12</sup>A live attenuated vaccine contains attenuated, or weakened, influenza viruses.

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6 months and older and those at increased risk of complications or more likely to require medical care, including high-risk individuals.<sup>13</sup> The live attenuated vaccine, in contrast, is approved for use only among healthy individuals aged 2 through 49 years who are not pregnant.<sup>14</sup> This live attenuated vaccine represented less than 3 percent of the vaccine doses produced for sale in the United States for the 2006–07 influenza season.

Because of fluctuations in the most prevalent virus strains of seasonal influenza, a new influenza vaccine is produced each year. Seasonal influenza vaccine is produced by manufacturers each year in a lengthy and complex process that involves a sequential set of steps (see fig. 2):<sup>15</sup>

1. **Virus Strain Selection:** In late winter each year, FDA determines the three influenza virus strains assessed to be most likely to cause serious illness in the United States the following influenza season.<sup>16</sup> One or two of the three strains selected for inclusion in the vaccine are usually new compared to the prior season. For example, for the 2000–01 influenza season and all but one of the subsequent seasons, FDA has changed at least one strain selected for the vaccine—that is, at least one selected strain has differed from the strains included in the previous season’s vaccine. For one season, the 2003–04 season, FDA selected the same three influenza virus strains for the vaccine that were included in the prior season’s vaccine.

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<sup>13</sup>Manufacturers may produce different formulations of the vaccine, and formulations are indicated for certain age groups. For example, for the 2006–07 influenza season, only one manufacturer made formulations of its injectable vaccine that were approved for use in children aged 6 months through 3 years of age. For that age group, the manufacturer made formulations in multidose vials that contain a preservative, as well as in preservative-free single-use prefilled syringes.

<sup>14</sup>On September 19, 2007, FDA expanded the group approved for use of the live attenuated vaccine FluMist from healthy individuals aged 5 through 49 years to those aged 2 through 49 years.

<sup>15</sup>These steps describe the manufacturing process for the inactivated injectable vaccine, which represented over 97 percent of vaccine doses produced for sale in the United States for the 2006–07 influenza season. Live attenuated vaccine administered as a nasal spray is produced in a similar process that follows a similar timeline.

<sup>16</sup>FDA conducts this strain selection process in consultation with its Vaccines and Related Biological Products Advisory Committee. Surveillance information from the World Health Organization and CDC is evaluated, as is the availability of materials suitable for commercial production of vaccine.

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2. **Production and Purification:** Manufacturers and FDA obtain samples of each of the three selected virus strains from one of the World Health Organization Collaborating Centres.<sup>17</sup> The manufacturers then inject the virus samples of each selected strain into separate batches of fertilized eggs to amplify the amount of virus. The viruses grown at this stage are called seed viruses and are tested by FDA. After manufacturers develop an appropriate seed virus for each of the three virus strains, these seed viruses are injected into millions of fertile chicken eggs and allowed to replicate.<sup>18</sup> Producing these fertile eggs is more difficult than producing eggs grown for human consumption and FDA requires that the fertile eggs meet particular sanitation and other requirements. Each virus strain is grown separately inside the eggs over the course of several days, after which it is harvested, inactivated, and purified.<sup>19</sup>
  3. **Testing, Filling, and Packaging:** Using biological materials provided by FDA, manufacturers and FDA test the virus strains produced by the manufacturers to determine the purity and yield of the virus and to ensure that the potency of the virus is sufficient for immunization. The three virus strains are then combined to create the vaccine for that season. Once the vaccine is created, manufacturers fill vaccine doses into vials and syringes. Labels are applied denoting the vaccine lot number and expiration date. FDA may conduct additional testing before officially releasing each lot for distribution; according to FDA, the agency typically releases a lot within 3 weeks, provided the lot has satisfied FDA standards.<sup>20</sup>
  4. **Shipping to Customers:** Manufacturers ship released vaccine to customers, which can include medical supply distributors, physicians,

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<sup>17</sup>The four World Health Organization Collaborating Centres are located in Australia, Japan, the United Kingdom, and the United States. CDC is the Collaborating Centre in the United States.

<sup>18</sup>Manufacturers report that they usually begin production of one virus strain that they anticipate FDA will select for the following influenza season's vaccine—for example, a strain that was included in the prior season's vaccine—in January, prior to FDA's strain selection and distribution of that influenza season's strains.

<sup>19</sup>In contrast, the live attenuated vaccine administered as a nasal spray is not inactivated.

<sup>20</sup>Influenza vaccine is subject to official lot release by FDA. Manufacturers submit samples of each lot of vaccine, along with summaries of the history of manufacture and the results of all the tests performed, to FDA, which may then perform additional tests before officially releasing the lot for distribution. The manufacturer may not distribute the vaccine lot until FDA releases it.

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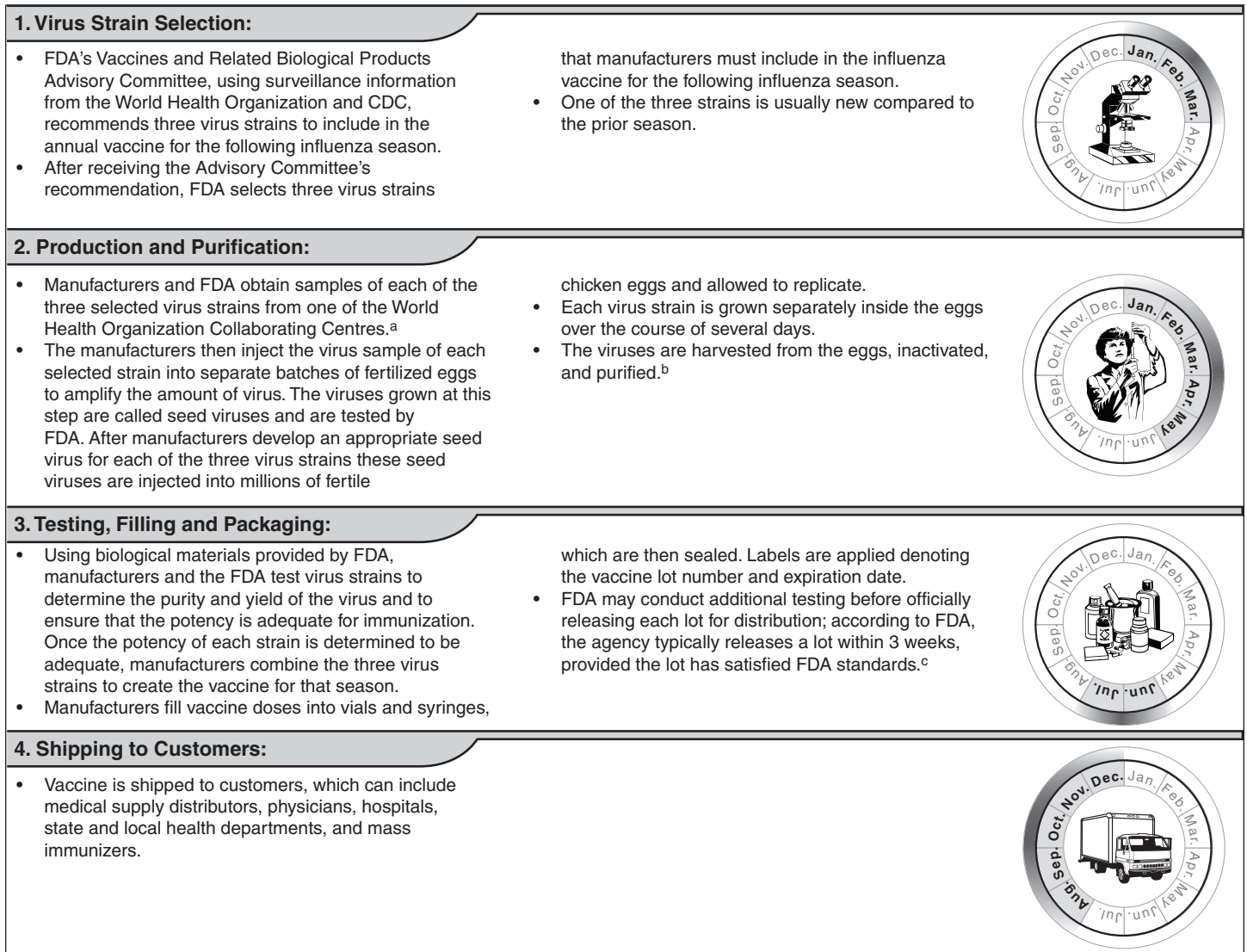
hospitals, state and local health departments, and mass immunizers.<sup>21</sup>  
The vaccine must be kept refrigerated within a prescribed temperature range.<sup>22</sup>

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<sup>21</sup>Some customers may also be members of group purchasing organizations—entities that help health care providers realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors.

<sup>22</sup>For the 2007–08 season, the live attenuated vaccine administered as a nasal spray also requires refrigeration within a prescribed temperature range.

**Figure 2: Seasonal Influenza Vaccine Production Cycle**



Source: GAO. Art Explosion.

Notes: These steps describe the manufacturing process for the inactivated injectable vaccine, which represented over 97 percent of vaccine doses produced for sale in the United States for the 2006–07 influenza season. Live attenuated vaccine administered as a nasal spray is produced in a similar process that follows a similar timeline.

The months associated with these steps are approximate and may vary from influenza season to influenza season.

<sup>a</sup>The four World Health Organization Collaborating Centres are located in Australia, Japan, the United Kingdom, and the United States. CDC is the Collaborating Centre in the United States.



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<sup>b</sup>In contrast, the live attenuated vaccine administered as a nasal spray is not inactivated.

<sup>c</sup>Influenza vaccine is subject to official lot release by FDA. Manufacturers submit samples of each lot of vaccine, along with summaries of the history of manufacture and the results of all the tests performed, to FDA, which may then perform additional tests before officially releasing the lot for distribution. The manufacturer may not distribute the vaccine lot until FDA releases it.

Vaccine production generally takes 6 or more months after virus strains have been selected, according to vaccine manufacturers, and vaccines for certain influenza virus strains have been difficult to mass-produce. Manufacturers are currently pursuing new production technologies, which may allow for more robust and reliable influenza vaccine production and may speed up the production process. For example,

- One such production technology involves growing the influenza virus in cells rather than chicken eggs.<sup>23</sup> While eggs must be ordered up to 1 year in advance for egg-based production, cells used in cell-based production are more readily available, allowing for faster start up of vaccine manufacturing—the required amount of cells can be produced from frozen cells in a few days to weeks. In addition, cell-based production may present fewer contamination problems than egg-based production.
- Another technology under development makes seed viruses using genetic techniques rather than through the current trial-and-error process in which the virus strains are grown and sampled for the desired characteristics. This technology may allow for more reliable production of seed viruses—an essential step in the vaccine production process.
- Technology resulting in the development of a universal vaccine that would be effective against multiple virus strains would eliminate the need for current processes required to reformulate seasonal influenza vaccine each year. As a result, vaccine could be produced and available at any time of

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<sup>23</sup>While cell-based production methods are new for influenza vaccines, they have been used for other vaccines such as chickenpox, hepatitis A, polio, and shingles. HHS has awarded more than \$1 billion in contracts to develop cell-based technologies for influenza vaccines.

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the year. However, despite recent increases in funding,<sup>24</sup> a completely universal influenza vaccine may be years away.<sup>25</sup>

Manufacturers aim to make influenza vaccine available before the fall vaccination period when demand for vaccination has traditionally been the highest. At the end of the influenza season unused doses expire and cannot be used in subsequent years.<sup>26</sup> For example, more than 18 million doses left over from the 2006–07 influenza season expired in 2007. Accordingly, manufacturers seek to match their vaccine production to expected demand for the vaccine so that no doses remain unsold at the end of the influenza season.

Manufacturers sell vaccine directly to providers who administer vaccine, including physicians, hospitals, pharmacies, federal agencies, state and local health departments, and mass immunizers. In addition, manufacturers sell vaccine to medical supply distributors, who in turn sell it to providers and other customers such as other medical supply distributors. Providers administer vaccinations in a variety of locations, including physicians' offices, public health clinics, nursing homes, and nonmedical locations such as workplaces and retail stores. Millions of individuals receive influenza vaccinations through mass immunization campaigns in these nonmedical settings, where organizations such as visiting nurse agencies under contract administer the vaccine.<sup>27</sup>

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<sup>24</sup>For example, Dynavax Technologies Corporation was recently awarded a \$3.25 million grant from the National Institutes of Health to continue development of a universal influenza vaccine.

<sup>25</sup>In April 2007, the World Health Organization's Strategic Advisory Group of Experts on Immunization concluded that it was realistic to expect that vaccines offering protection against multiple influenza strains could be developed; however, no specific time frame was given. In May 2007, the World Health Organization reported that a universal vaccine might not be available in the next 5 to 10 years.

<sup>26</sup>According to FDA, the expiration dating period for inactivated virus vaccine is set so that influenza vaccine for one influenza season cannot be confused with vaccine for subsequent seasons.

<sup>27</sup>According to a Gallup poll conducted for CDC in 2005, adults received influenza vaccination in the following locations: physicians' offices (39 percent), workplaces (17 percent), other clinics or health centers (10 percent), stores or pharmacies (10 percent), health departments (8 percent), hospitals (6 percent), senior or recreational centers (4 percent), other locations (4 percent), and schools (2 percent).

The number of manufacturers of seasonal influenza vaccine for the U.S. market and the number of doses produced and distributed have changed over the past seven seasons (see table 1).<sup>28</sup> For the 2007–08 influenza season, six U.S.-licensed manufacturers are expected to produce an estimated 132 million doses of seasonal influenza vaccine.

**Table 1: Number of U.S.-Licensed Manufacturers of Seasonal Influenza Vaccine and Number of Doses Produced and Distributed, 2000–01 through 2006–07 Influenza Seasons**

Influenza season	Number of licensed manufacturers	Total number of doses produced (in millions)	Total number of doses distributed (in millions)
2000–01	3	78	70
2001–02	3	88	78
2002–03	3	95	83
2003–04	3	87	83
2004–05	3 <sup>a</sup>	61	57
2005–06	4	92	82
2006–07	5 <sup>b</sup>	121	103

Source: CDC and FDA.

Notes: Table includes the number of doses produced by manufacturers and distributed to customers such as medical supply distributors, physicians, or other types of providers.

<sup>a</sup>Of the three manufacturers of seasonal influenza vaccine for the 2004–05 influenza season, two produced and distributed vaccine and one ceased production and did not distribute any vaccine for the U.S. market after its license was suspended by the United Kingdom in October 2005. In addition to these three manufacturers, two foreign manufacturers' vaccines were purchased by HHS and made available in the United States under an investigational new drug protocol; however, none of these doses were distributed.

<sup>b</sup>The manufacturers of vaccine licensed for the 2006–07 season and their vaccines were: GlaxoSmithKline Biologicals, a part of GlaxoSmithKline plc (Fluarix), ID Biomedical Corporation of Quebec, a subsidiary of GlaxoSmithKline plc (FluLaval), MedImmune Vaccines, Inc. (FluMist), Novartis Vaccines and Diagnostics Limited (Fluvirin), and sanofi pasteur (Fluzone). The policy of sanofi pasteur is to spell its name without capital letters.

Since influenza vaccine production and distribution are largely private-sector activities, HHS and other federal entities have limited authority to

<sup>28</sup>See app. II for a list of U.S.-licensed manufacturers of seasonal influenza vaccine from the 2000–01 season through the 2007–08 influenza season.

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control influenza vaccine production and distribution.<sup>29</sup> CDC administers a number of programs to help make vaccines, including influenza vaccine, affordable for low-income and other populations. For example, under CDC's Vaccines for Children program, vaccines are provided free of charge for certain children 18 years of age or younger, including those who are Medicaid-eligible, uninsured, or those without insurance coverage for vaccinations. CDC also reserves stockpiles of certain vaccines for use in the event of a vaccine shortage or disease outbreak.

For each influenza season, ACIP, after consulting with CDC, makes recommendations on who should be targeted for vaccination and, in some years, has modified its annual recommendations after issuing them in order to address vaccine shortage, such as during the 2004–05 season.<sup>30</sup> For the 2007–08 season, ACIP recommends vaccination for two categories of individuals: (1) high-risk individuals—that is, those persons at increased risk for medical complications or more likely to require medical care, such as children aged 6 to 59 months, pregnant women, persons aged 50 years or older, and persons with certain chronic conditions; and (2) close contacts of those at high risk—that is, persons who live with or care for persons at high risk, such as family members and health care workers. According to ACIP, approximately 73 percent of the U.S. population is included in one or more of these target groups. However, not everyone in these recommended target groups receives a vaccination each year—only an estimated one-third of them received vaccination, according to CDC estimates.<sup>31</sup> For the 2007–08 season, in addition to recommending that providers vaccinate individuals in high-risk and other target groups, ACIP

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<sup>29</sup>With specified exceptions, the Federal Food, Drug, and Cosmetic Act prohibits the resale of prescription drugs, including influenza vaccine, after their purchase by health care entities such as public or private hospitals. This prohibition does not apply to resale for emergency medical reasons. In addition, because the term “entity” does not include wholesale distributors, this prohibition does not apply to resale by wholesale distributors. See 21 U.S.C. §353(c)(3).

<sup>30</sup>See app. III for additional information on ACIP recommendations for prevention and control of influenza and on the priority groups—comprised of subsets of the high-risk and other target groups—that ACIP recommended receive priority for available vaccine during seasons with vaccine delays or shortage.

<sup>31</sup>See app. III for information on the estimated population in each target group. The vaccination rates among the different high-risk and other target groups vary. For example, about 65 percent of adults aged 65 years and older and about 42 percent of health care workers less than 65 years of age received vaccination, according to CDC estimates. See Centers for Disease Control and Prevention, “Estimates of Influenza Vaccination Target Population Sizes in 2006 and Recent Vaccine Uptake Levels.”

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recommends that all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others should be vaccinated.

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## Manufacturing Challenges, Limitations in Production Capacity, and Fluctuating Demand for Vaccine May Limit the Quantity of Vaccine Produced or Delay When Vaccine Reaches Providers

Several factors may affect the quantity of vaccine produced for a given season and when it reaches providers who administer the vaccine. These factors include: challenges in manufacturing a new vaccine each year; limitations in the production capacity of manufacturers; and demand for vaccine by providers and patients that fluctuates throughout the season. For an individual provider, additional factors, including the route the vaccine takes from the manufacturer to the provider, can affect how much and when a particular provider receives vaccine.

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## Manufacturing Challenges May Limit the Quantity of Seasonal Influenza Vaccine Produced or Delay When Vaccine Reaches Providers

Manufacturing challenges inherent to the production of a new seasonal influenza vaccine each year include the necessity of adhering to a relatively inflexible and sequential process involving multiple players, difficulties growing new virus strains, and problems associated with maintaining safety and quality-control practices to produce a sterile vaccine. Each of these challenges has the potential to affect all manufacturers; however, in any given year the degree that these challenges affect the number of doses that an individual manufacturer produces or when that manufacturer's vaccine becomes available may vary significantly.

- **Adherence to a sequential set of steps involving multiple players.** Influenza vaccine is produced by manufacturers through a relatively inflexible process involving a sequential set of critical steps that are undertaken by multiple players including the World Health Organization, CDC, FDA, and manufacturers. Certain steps in the process must be completed before other steps can start and the timing and outcome of these steps can affect both the quantity of vaccine produced and when the vaccine reaches providers. For example, FDA typically does not have sufficient information until late each winter to identify the influenza virus

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strains likely to be prevalent during the upcoming season. As a result, FDA selects the three virus strains that will make up the vaccine for the upcoming season usually between late February and early March; once these selections are made, the manufacturers, using samples of each selected virus strain, develop seed viruses that are suitable for subsequent vaccine production. Manufacturers reported that the timeline for FDA's strain selection and the subsequent distribution of samples of strains to develop seed viruses does not allow them enough time to produce all three virus strains in time for the fall vaccination period. As a result, manufacturers consult with CDC and FDA, assess preliminary data, and complete their own analyses as to what FDA's choice of virus strains for the upcoming season might be. Manufacturers usually begin producing one of the influenza virus strains that they believe will be included in the vaccine in January in advance of FDA's strain selection.<sup>32</sup>

- **Difficulties growing a new virus strain.** Manufacturers have experienced delays in producing and distributing vaccine for several recent influenza seasons because of challenges inherent to growing influenza virus strains. For example, for the 2000–01 influenza season, difficulties experienced by two manufacturers growing a new virus strain contributed to an overall delay of about 6 to 8 weeks in distributing vaccine to most customers and an initial shortage of vaccine supply.<sup>33</sup> For the 2006–07 influenza season, several manufacturers reported problems growing one of the two new virus strains that, for one major manufacturer, resulted in a delay of about 3 weeks in vaccine production. Since this manufacturer was the only producer of vaccine licensed for children aged 6 through 47 months, the delay in its production may have affected some providers' ability to have vaccine available for this population.
- **Problems associated with maintaining safety and quality-control practices.** Problems associated with maintaining safety and quality-control practices to produce a sterile vaccine can limit the quantity of seasonal influenza vaccine produced and when it reaches providers. In 2002, one manufacturer that had produced seasonal influenza vaccine for more than two decades exited the U.S. market after it was fined by FDA for failing to correct manufacturing deficiencies. In 2004, another

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<sup>32</sup>If a manufacturer were to begin production of a virus strain in January that did not end up being one of the strains selected by FDA for the vaccine—a situation that manufacturers report has yet to occur—it is possible that the manufacturer would not have enough time to grow a different virus strain in time to distribute the vaccine for fall vaccination.

<sup>33</sup>[GAO-01-624](#).

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manufacturer announced that because of potential contamination discovered when a small quantity of its vaccine failed sterility tests, it would not release any vaccine for the U.S. market. This manufacturer had been expected to produce approximately half of the estimated doses of influenza vaccine for the 2004–05 season.<sup>34</sup> More recently, in May 2007, FDA issued a warning letter to a different manufacturer because of deviations from good manufacturing practices, including some which could potentially lead to sterility problems.<sup>35</sup> In September 2007, the manufacturer reported that it had resolved the observances contained in the warning letter.<sup>36</sup>

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### Production Capacity May Limit the Quantity of Seasonal Influenza Vaccine Produced and May Delay When Vaccine Reaches Providers

Overall production capacity—that is, the maximum amount of vaccine that manufacturers can produce, package, and ship at any given time—may limit the quantity of seasonal influenza vaccine produced and may delay when vaccine reaches providers. Manufacturers reported that, even in years with fewer manufacturing challenges, they are limited in the number of doses that they can produce and fill at a given time, and, therefore, not all doses of influenza vaccine are available by the beginning of each influenza season. Instead, manufacturers distribute vaccine as it becomes available beginning in late summer or in the fall and generally continuing into the winter, with the proportion of vaccine distributed each month varying from year to year (see fig. 3). Because vaccine is produced in batches over the course of several months, only a portion of the full year’s production is available each month to vaccinate individuals against influenza.

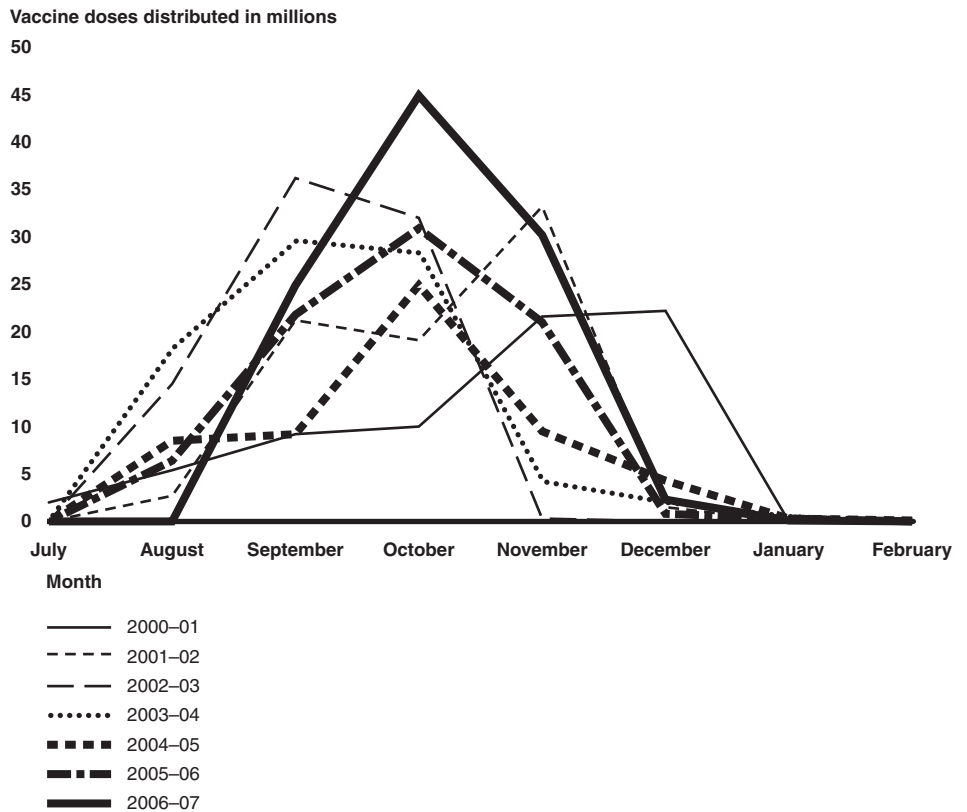
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<sup>34</sup> [GAO-05-984](#).

<sup>35</sup> Good manufacturing practices include requirements applicable to the entire manufacturing process to help ensure that biological products, such as vaccines, are safe, pure, and potent.

<sup>36</sup> The manufacturer had previously reported that it expected to address the problem without affecting the quantity of vaccine produced.

**Figure 3: Distribution of Influenza Vaccine Doses in Millions by Month, 2000–01 through 2006–07 Influenza Seasons**



Source: CDC.

More doses of influenza vaccine could be produced for each influenza season if either the current manufacturers increased their production capacity or if more manufacturers entered the U.S. market. All of the manufacturers of seasonal influenza vaccine for the U.S. market that we interviewed reported plans to increase production capacity for future seasons. In addition, on September 28, 2007, a sixth manufacturer, which has reported that it will eventually have the capacity to produce as many as 20 million doses of seasonal influenza vaccine for the U.S. market, received FDA approval for the 2007–08 season.<sup>37</sup>

<sup>37</sup>In October 2007, this manufacturer reported that it will make approximately 2 million doses immediately available to the U.S. market for the 2007-08 season.



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## Demand for Influenza Vaccine Affects the Quantity of Seasonal Influenza Vaccine Produced

Since demand for influenza vaccine typically peaks in October and November and then tapers off, manufacturers may decide to limit or stop production if they do not believe there is sufficient demand to sell all of the doses they have the capacity to produce—thereby limiting the quantity produced for that season and how late in the season it is available. For example, one manufacturer reported that it has capacity to produce more doses of influenza vaccine than its planned production for the 2007–08 season, but reported that production of the additional doses would be contingent in part on demand for doses later in the season. Even in seasons when there were vaccine shortages during the traditional fall vaccination period, some doses remained unsold at the end of the season. For example, even though there was an initial shortage of influenza vaccine for the 2000–01 season, after additional doses became available later in the season, approximately seven million doses of influenza vaccine went unsold.

In past seasons when demand for influenza vaccine has occurred later in the season, supply has not always been available to meet it. For example, during the 2003–04 influenza season, there was late-season demand for seasonal influenza vaccine after reports of influenza-related deaths among children. However, there was not enough influenza vaccine available at the time to meet demand and individuals that wanted vaccine were not able to obtain it. To prevent this scenario from occurring again in subsequent seasons, beginning for the 2004–05 season, CDC began contracting with manufacturers to produce a small quantity of influenza vaccine to be available later in the season to ensure that some vaccine would be available in the event of a late-season outbreak of influenza and related demand for vaccine.

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## Distribution Routes May Affect When Seasonal Influenza Vaccine Reaches Individual Providers

In addition to the timing of the production and shipment of vaccine from the manufacturer, the distribution route that the vaccine takes from the manufacturer to a provider can also affect how much time elapses before the vaccine reaches individual providers who have ordered it. If, for example, a provider's order is routed through a medical supply distributor, it may take longer for vaccine to reach that provider than it would if a provider's order was routed directly from the manufacturer—a route with no stops to reach the provider. For the 2007–08 season, manufacturers of two of the five influenza vaccines licensed for the U.S. market as of August 31, 2007, reported plans to distribute the majority of their vaccine through medical supply distributors. The manufacturers of the three other vaccines told us they planned to distribute some vaccine through medical supply distributors. According to the Health Industry Distributors

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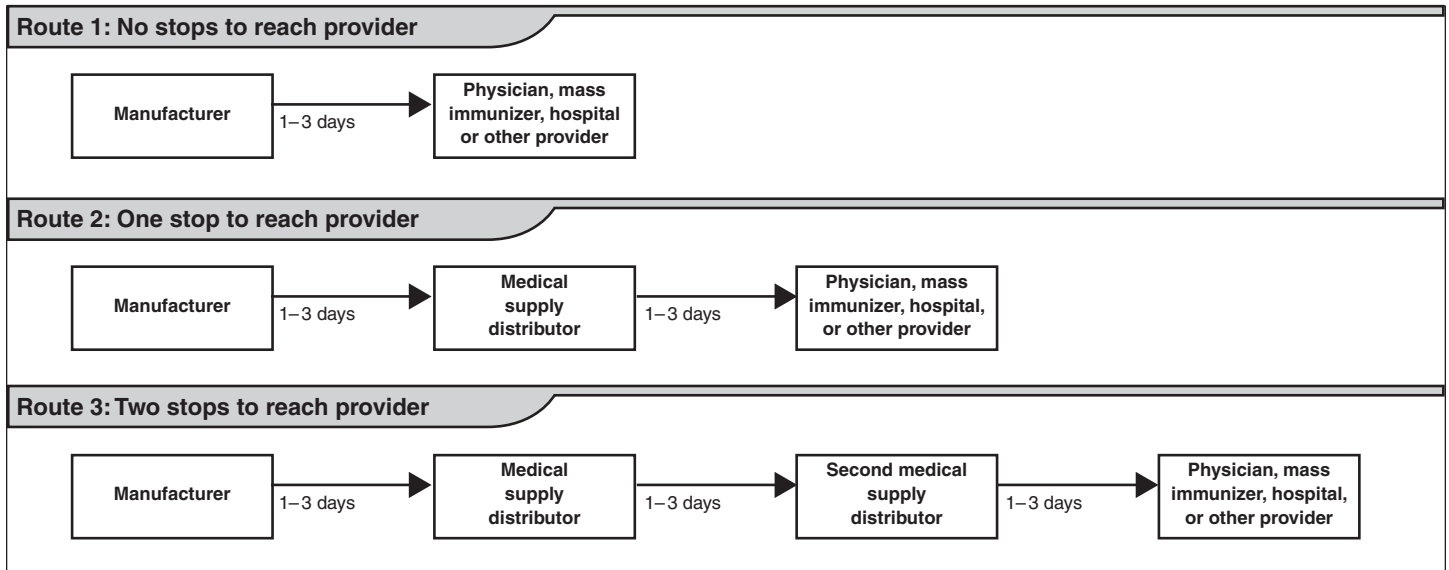
Association, the distribution route for about half of the vaccine sold for the 2006–07 influenza season was through medical supply distributors, 8 of every 10 of those doses went to a physician’s office or a clinic, and medical supply distributors shipped vaccine to providers in 1 to 3 days after the distributors received the vaccine from the manufacturers. The association also estimated that the route for about half of the vaccine sold for the 2006–07 influenza season was shipped directly from the manufacturer to the provider.<sup>38</sup> As shown in figure 4, if it takes from 1 to 3 days for manufacturers to distribute vaccine to their customers once it is ready for shipment, the route a provider’s order takes—that is, whether it is routed directly from the manufacturer to the provider, which can take as little as 1 day,<sup>39</sup> or whether it is routed through multiple medical supply distributors or a central location for distribution as is the case for some state health departments—affects the time that elapses from the date the manufacturer ships the vaccine until an individual provider receives it.

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<sup>38</sup>Health Industry Distributors Association, “2006-07 Influenza Vaccine Production & Distribution Market Brief,” (Alexandria, Va.: Health Industry Distributors Association, 2007) [http://www.hida.org/attachment.asp?attachment\\_id=10509](http://www.hida.org/attachment.asp?attachment_id=10509) (downloaded Oct. 3, 2007).

<sup>39</sup>An official from the American Medical Association participating in the National Influenza Vaccine Summit estimated it takes from 1 to 3 days for a manufacturer to distribute vaccine to customers.

**Figure 4: Potential Impact of Different Distribution Routes of Vaccine Orders from Manufacturer to Provider**



Source: GAO.

## Issues Related to Vaccine Distribution May Affect Vaccine Availability for High-Risk and Other Target Groups

Issues related to making vaccine available for high-risk and other target groups include the locations where these groups are vaccinated, how vaccine is distributed to the providers who administer vaccinations, and the timing of vaccine distribution to different types of providers. According to data from CDC, individuals in high-risk and other target groups have received influenza vaccinations at various locations where different types of providers administer vaccine. Manufacturers and medical supply distributors we interviewed reported that, for the 2007–08 influenza season, they plan to distribute vaccine using a variety of distribution practices including shipping vaccine as it becomes available through multiple shipments and filling vaccine orders in the order in which they were received. In recent years, certain types of providers, such as physicians and state and local health departments, reported that they received their vaccine orders later than other types of providers, such as mass immunizers. National data collected by CDC for the 2006–07 influenza season indicated that in aggregate most types of providers, including private providers such as physicians, received vaccine in similar time frames. However, the data also indicated that state and local health departments received a smaller percentage of the doses distributed in the early fall than later in the season. CDC officials acknowledged that

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individual providers' experiences at the local level could vary. In an effort to help state and local health officials manage the availability of vaccine for high-risk or other target groups, CDC and state health officials have undertaken several efforts, including the creation of monitoring tools and the implementation of a state-specific vaccine distribution program.

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**High-Risk and Other Target Groups Receive Vaccinations at Various Locations Where Different Types of Providers Administer Vaccine**

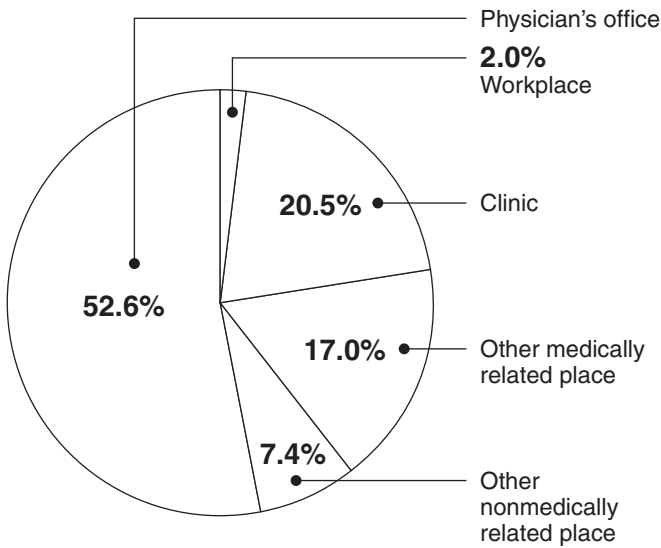
Individuals in high-risk and other target groups receive influenza vaccinations at various locations where different types of providers, such as physicians, hospitals, pharmacies, and state and local health departments, administer vaccine. For example, CDC data from 2004 show that more than half of one population group considered at high-risk for complications in 2004—adults aged 65 years and older—and about a third of one target group recommended for vaccination in 2004—adults aged 50 through 64 years—received influenza vaccination at physicians' offices. A smaller proportion of adults in these groups received influenza vaccination at other locations, including workplaces and clinics (see fig. 5).<sup>40</sup>

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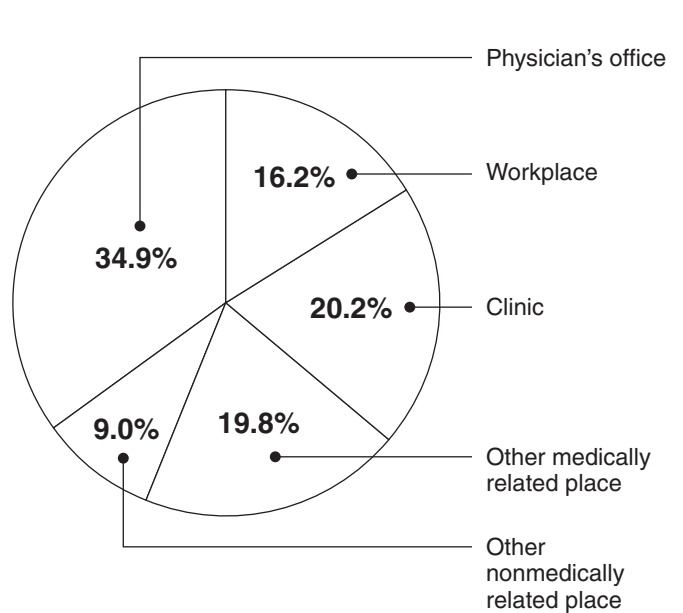
<sup>40</sup>For the 2007–08 influenza season, ACIP considers both of these population groups as part of the high-risk groups.

**Figure 5: Locations Where Adults Aged 65 Years and Older and Aged 50 through 64 Years Reported Receiving Most Recent Influenza Vaccination, 2004**

Adults aged 65 years and older



Adults aged 50 through 64 years

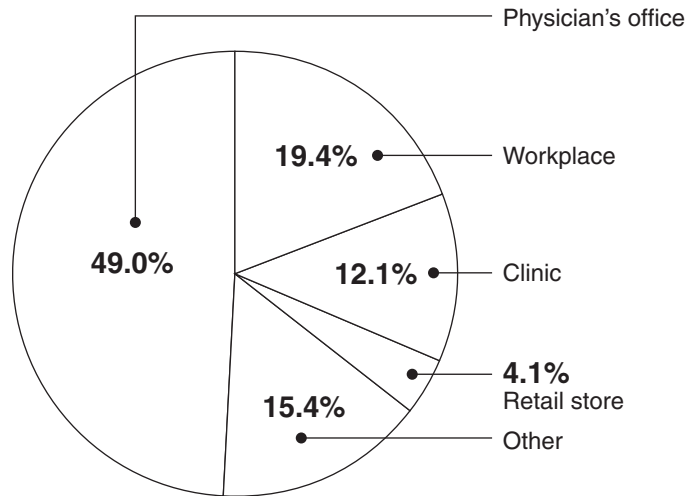


Source: CDC's National Adult Immunization Survey Module, 2004.

Notes: Percentages do not add to 100 percent because of rounding. For data on high-risk adults aged 65 years and older, the category "Other medically related place" includes hospitals (7.2 percent), pharmacies (6.1 percent), and other medically related places (3.7 percent); the category "Workplace" also includes home visits. For data on adults aged 50 through 64 years, the category "Other medically related place" includes hospitals (9.2 percent), hospital vans or mobile units (2.0 percent), pharmacies (4.7 percent), and other medically related places (3.9 percent); the category "Other nonmedically related places" includes other nonmedically related places (8.7 percent) and home visits (0.3 percent).

CDC data from 2002 indicated that about half of individuals included in another target group recommended for vaccination—adults aged 18 to 64 years with certain chronic conditions—also received vaccinations at physicians' offices, and the remaining individuals in this target group reported receiving vaccination at other locations such as workplaces (see fig. 6).

**Figure 6: Locations Where High-Risk Adults with Certain Chronic Conditions Reported Receiving Most Recent Influenza Vaccination, 2002**



Source: CDC's Behavioral Risk Factor Surveillance System, 2002.

Note: Data are for high-risk adults aged 18 through 64 years with chronic conditions of diabetes or asthma or both. The category "Other" includes hospitals (5.1 percent), health departments (4.6 percent), other places (4.6 percent), and community centers (1.1 percent).

## Manufacturers and Medical Supply Distributors Ship Vaccine Using a Variety of Distribution Practices

All manufacturers we interviewed and four of six medical supply distributors we spoke with reported that for the 2007–08 influenza season they will continue or begin distributing vaccine as it becomes available using multiple shipments. This distribution practice allows for all types of providers to have some vaccine available for their high-risk patients when vaccine is initially distributed. CDC encouraged distributing vaccine in multiple shipments—a practice referred to as multiphased shipments—for the 2005–06 influenza season, stating that this distribution strategy enables all types of providers to administer vaccine initially to those persons at high risk, even when supplies are limited.<sup>41</sup>

In addition to the practice of multiphased shipments, one manufacturer and two medical supply distributors took steps to collect information from their customers on the number of doses in an order that are intended for

<sup>41</sup>CDC recommended this strategy because of uncertainty in the production of vaccine for that season. See CDC, "Influenza Vaccine Prebooking and Distribution Strategies for the 2005–06 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 54, no. 12 (2005): 307–308.

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certain priority groups, such as high-risk individuals, so that the manufacturer and medical supply distributors could, if necessary, distribute vaccine to customers serving those groups on a priority basis. However, officials from medical supply distributors and CDC reported differing perspectives on the utility of this information for prioritizing distribution to those serving individuals in certain priority groups, including high-risk groups. For example, two of the six medical supply distributors we interviewed reported that they routinely collect information from their customers on the number of doses ordered that are intended for high-risk individuals and may use this information to determine distribution of the vaccine. One reported that its distribution practice is to give priority to those individual providers that are serving more high-risk individuals; the other medical supply distributor reported that it intends to use the information to prioritize orders only in the event of a vaccine shortage.<sup>42</sup> CDC officials, however, reported that collecting such information from customers on their patients in priority groups was not useful for prioritizing distribution to those serving individuals in these groups. For the 2005–06 influenza season, CDC encouraged manufacturers and medical supply distributors to collect information from their customers on the number of doses being ordered for priority groups, but according to CDC officials, the manufacturer that produced most of the vaccine that season reported such information had limited utility for prioritizing orders; these officials reported that the manufacturer found that the vast majority of its customers reported that nearly all of the doses they ordered were for individuals in priority groups. As a result, CDC officials said they no longer recommend collecting such information.<sup>43</sup>

Other medical supply distributors reported using other distribution practices. For example, one medical supply distributor stated that it fills vaccine orders in the order in which it received the orders. Also, for the 2007–08 season, two of the six medical supply distributors we interviewed

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<sup>42</sup>The other four medical supply distributors we interviewed did not report that they plan to collect information from their customers on the number of doses ordered that are intended for high-risk or other target groups.

<sup>43</sup>CDC recommended obtaining information on doses ordered for high-risk individuals for the 2005–06 season, following the significant and unexpected shortage of vaccine during the 2004–05 season. When that shortage occurred, CDC recommended vaccine distribution be prioritized to certain groups. CDC was only able to successfully facilitate the directed distribution and redistribution of vaccine so that the vaccine would be made available to those priority groups through extensive collaboration and information sharing between multiple parties including the major manufacturer of vaccine that season, and state and local health officials. For more information, see [GAO-05-984](#).

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reported guaranteeing delivery of all vaccine ordered by a specific date to customers. As a result of these distribution practices, it is possible that some providers receive vaccine and offer vaccinations to anyone who wants them before other providers have received enough vaccine to vaccinate their patients in high-risk or other target groups.

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### CDC Data Indicate State and Local Health Departments Generally Received a Smaller Amount of Vaccine Than Other Providers in Early Fall

In recent years, certain types of providers, such as physicians and state and local health departments, reported they received their vaccine orders after other types of providers, such as mass immunizers that provide vaccinations at retail stores. For example, representatives from one national association representing physicians and one national association representing state and local public health officials told us that in past seasons many physicians did not receive their vaccine orders until November or later but other types of providers—particularly those providing vaccinations in mass immunization clinics at retail stores—had vaccine earlier in the fall. As a result, association officials stated that these other types of providers were able to vaccinate anyone who wanted a vaccination before physician practices had received a sufficient number of doses for their patients.

According to CDC, a large percentage of high-risk individuals receive their annual vaccination at physicians' offices. Some officials from national associations representing physicians asserted that physicians should receive priority in vaccine distribution. According to a national association representing physicians and officials from a state health department, physicians have reported that if they do not have vaccine when patients seek it, those patients may not return for vaccination when the physician has vaccine. According to a national association representing pediatricians, establishing a reliable place for vaccination is especially crucial for children, given the ACIP recommendation for the 2007–08 influenza season that children aged 6 months through 8 years receive two shots 30 days apart in their first year of vaccination. In addition, according to this association, having unused doses can be a financial burden to these physicians, as they are responsible for paying for any vaccine orders they place and receive, regardless of whether they administer the vaccine or not. While CDC data indicated that most physicians CDC surveyed intend to continue administering influenza vaccine as a service to their patients, association officials reported that this financial burden may serve as an incentive for some individual physicians to discontinue purchasing and administering the vaccine in the future.



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State and local health officials and national associations representing them also reported that they believe state and local health departments generally have received their vaccine orders later in the season, and in some instances, after other types of providers. State and local health departments are responsible for distributing the influenza vaccine to those providers who vaccinate high-risk populations through the Vaccines for Children program, for example. Therefore, officials we spoke with asserted that state and local health departments should receive vaccine in the same time frames as other types of providers.

According to CDC officials, with more than 200 million individuals in high-risk and other target groups who should be vaccinated between late fall and early spring each influenza season, all types of providers have an important role to play in providing vaccinations. Therefore, having multiple opportunities for vaccination available to individuals in high-risk and other target groups is especially important as ACIP considers continued expansion of its recommendations on which groups should be targeted for vaccination for each influenza season. For example, mass immunization clinics at retail stores play an important role in increasing influenza vaccination rates because they may provide access to the vaccine for a population that does not regularly see a physician or would not otherwise receive the vaccine, according to officials from CDC, a national association representing physicians, and state and local health departments.

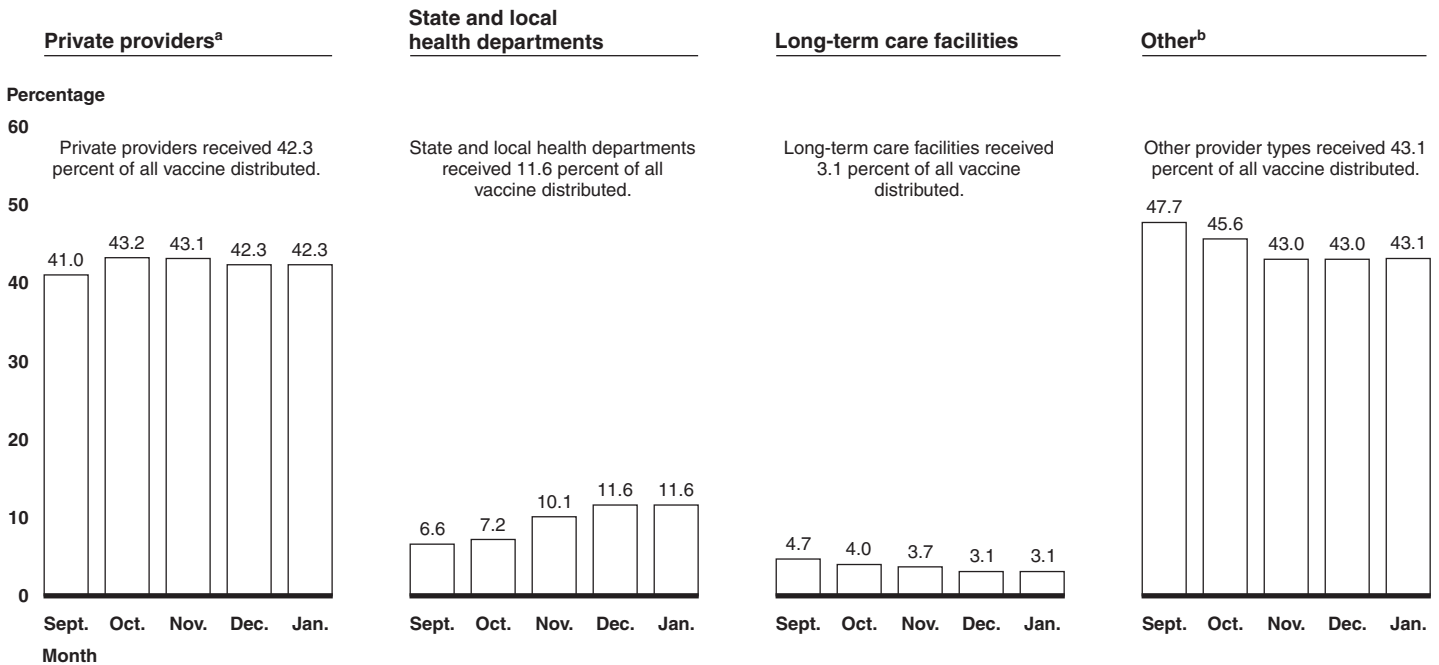
Despite reports from physicians and other types of providers indicating otherwise, national data for the 2006–07 influenza season indicate that most types of providers, including private providers such as physicians, received vaccine in a similar proportion over the months the vaccine was distributed (see app. IV and fig. 7).<sup>44</sup> Specifically, CDC analyzed national data on the percentage of the total vaccine doses distributed as of each month—these data show that private providers, including physicians, received about 42 percent of the cumulative number of doses distributed as of each month, as well as about 42 percent of the total number of doses distributed for the 2006–07 season. However, the national data support the testimonies from state and local health officials that they received a

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<sup>44</sup>According to CDC, data identifying distribution of vaccine to mass immunizers were not available within a single provider category; rather, because these types of providers are classified differently by different manufacturers and medical supply distributors, doses received by them are included within a number of provider type categories.

smaller percentage of doses in the early fall than later in the influenza season.

**Figure 7: Percentage of Cumulative Number of Vaccine Doses Distributed, by Provider Type and Month, 2006–07 Influenza Season**



Source: CDC.

Notes: Because a different number of additional doses were distributed each month, it is possible for one type of provider to receive a higher percentage of all doses distributed as of the end of one month than the percentage of cumulative doses the provider received as of the end of the following month. According to CDC, data identifying distribution of vaccine to mass immunizers were not available within a single provider category; rather, because these types of providers are classified differently by different manufacturers and medical supply distributors, doses received by them are included within a number of provider type categories.

<sup>a</sup>The category “Private providers” includes physicians, as well as outpatient clinics and facilities, health maintenance organizations, and surgery centers.

<sup>b</sup>The category “Other” includes vaccine doses distributed to medical supply distributors (15.6 percent), hospitals (9.9 percent), the federal government (5.1 percent), pharmacies (3.5 percent), other private provider types (2.9 percent), corporations (2.5 percent), the military (2.2 percent), correctional facilities (0.0 percent), and other public provider types (1.4 percent). These percentages indicate the total percentage of all vaccine doses distributed to the provider type during the 2006–07 influenza season. The decrease in the percentage of the cumulative number of doses distributed to provider types in the “Other” category from September to October reflects the higher percentage of doses medical supply distributors received in September, which then decreased later in the season. See app. IV for complete data on the percentage of the cumulative number of vaccine doses distributed by month to all types of providers during the 2006–07 influenza season.

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CDC officials acknowledged that the aggregated, national data on vaccine distribution to private providers such as physicians do not reflect physicians' testimonies and that individual providers' experiences at the local level may vary significantly. In addition, several factors, such as size of order, with whom an order is placed, and the distribution route, may influence the perception that other types of providers received their vaccine orders before physicians. For example, the policy of some manufacturers and medical supply distributors to distribute the vaccine in multiphased shipments sometimes results in only a small number of vaccine doses being allocated to an individual provider per shipment. As a result, providers, including physicians, may choose to ask the medical supply distributors to delay shipment until a greater number of doses are available to fill the providers' order so, for example, a physician's office could hold a vaccination clinic. Manufacturers may also choose to fill a percentage of larger orders first and delay shipping smaller orders until later—a practice, according to one manufacturer, that is often easier to do because of the logistics of shipping. In addition, officials from one national association representing physicians reported that it is likely that the route through which smaller physicians' offices receive vaccine may entail an additional layer of distribution, such as multiple medical supply distributors, thus extending the time for the vaccine to reach an individual provider. In contrast, many mass immunizers that hold clinics in retail stores may receive vaccine more quickly than physicians if the mass immunizers place, and subsequently receive, large vaccine orders directly from the manufacturer or a national medical supply distributor.

Officials from CDC and state health departments had little explanation as to why state and local health departments received more of their vaccine orders late in the season. One official from a state health department stated that her department received its vaccine order for the 2006–07 season late because the manufacturer with whom the department ordered experienced production problems. However, officials from CDC and two state health departments we spoke with were unable to speculate as to the reason for this distribution pattern, and CDC officials reported that the agency is researching why this occurred.

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### CDC and State Health Officials Have Undertaken Efforts to Help Monitor the Availability of Vaccine

In order to help state and local health officials manage the availability of vaccine for high-risk or other target groups, CDC and state health officials have undertaken several efforts. These efforts include the creation of monitoring tools and the implementation of a state-specific vaccine distribution program.

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When faced with a shortage of vaccine for the 2004–05 season, CDC created a tool, the Flu Vaccine Finder, “to provide information to enhance visibility of influenza vaccine distribution for state and local health officials and to assist in their management of influenza vaccine availability issues and challenges.”<sup>45</sup> This tool, which has been modified for subsequent seasons, continues to be used by CDC and state health officials. For the 2006–07 season, CDC collected information to be included in the Flu Vaccine Finder on a weekly basis throughout the influenza season from all manufacturers and seven major medical supply distributors on all vaccine distributed. Specifically, the information collected included a product identifier,<sup>46</sup> state and zip code to which the vaccine was distributed, number of doses distributed, and type of provider to whom the vaccine was distributed. For the 2005–06 and 2006–07 influenza seasons, the Flu Vaccine Finder also included a listing of doses that had been already ordered from a subset of manufacturers and medical supply distributors.

CDC officials reported that the agency has used the Flu Vaccine Finder data to conduct a limited amount of routine analyses. Specifically, the agency routinely conducts two analyses using the data: total distribution of vaccine by month and total distribution of vaccine by provider type. In addition, according to CDC, data from the Flu Vaccine Finder have been used by some state officials to find out information on the number of vaccine doses distributed to a state or locality by provider type and vaccine availability by zip code. State health officials have also used the data to monitor the number of doses of vaccine distributed to certain types of providers, such as hospitals and local health departments, and to locate providers following vaccine-related adverse events. For example, CDC officials stated that one state health department used the Flu Vaccine Finder data coupled with the state’s data on the number of long-term care beds to determine if the state’s long-term care facilities had received

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<sup>45</sup>Jeanne M. Santoli, “Influenza Vaccine Distribution Data and Use of Data During the 2006–07 Season” (PowerPoint presentation at the 2007 National Influenza Vaccine Summit, Atlanta, Georgia, April 2007). For more information on the flu vaccine distribution information collected by CDC and made available to states through the Flu Vaccine Finder, see app. V.

<sup>46</sup>The Flu Vaccine Finder includes the National Drug Code number, a universal product identifier for human drugs which identifies the labeler, product, and trade package size. For example, for the influenza vaccine, the National Drug Code number identifies the manufacturer of the vaccine, the type of vaccine (preservative-free or preservative-containing), and the presentation of the vaccine (.25 milliliters, .5 milliliters, etc., and single dose syringes or multidose vials).

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enough vaccine to vaccinate their population. However, according to CDC, 40 of the 56 states and urban areas that are eligible to use the Flu Vaccine Finder have requested access to it for the 2007–08 influenza season, suggesting that not all state officials have found this to be a useful tool or are aware of this resource. To encourage use of the Flu Vaccine Finder, CDC officials reported that they are designing a Flu Vaccine Finder guidance document to share with users of the Flu Vaccine Finder, outlining some of the analyses states have performed using Flu Vaccine Finder data to help monitor vaccine distribution within states.

State health officials suggested changes to the Flu Vaccine Finder, which they reported would make the Flu Vaccine Finder a more useful tool for monitoring vaccine distribution. Their suggestions included adding data on the specific providers receiving the vaccine, county-level data, data identifying all types of providers, and making the data more timely:

- **Data on specific providers receiving the vaccine.** The 2006–07 version of the Flu Vaccine Finder included data on the zip code to which a manufacturer or medical supply distributor delivered a vaccine shipment; however, according to state and local health officials we spoke with, the Flu Vaccine Finder did not indicate the name or address of the particular provider that received the vaccine. State health officials reported that the provider who administered the vaccine may be in a different zip code from the location of where the vaccine was originally shipped. Officials also stated that knowing which specific providers have vaccine and where the vaccine was administered is helpful for determining which populations have access to the vaccine and which areas or providers are in need.
- **Addition of county-level data.** According to CDC, state health officials stated that to make the Flu Vaccine Finder more useful to them, data on the number of doses distributed by county, rather than by zip code, would be helpful because some state health officials reported that public health activities are organized at the county level. One state official reported having to create its own zip code-to-county crosswalk in order to complete county-level data analysis—an imperfect process since some zip codes may cross county lines.
- **Data identifying all types of providers.** The Flu Vaccine Finder does not have a provider type category for mass immunizers; rather, because these providers are classified differently by different manufacturers and medical supply distributors, doses received by them are included within a number of provider type categories, according to CDC. As a result, an official from one state health department reported being unable to tell how many vaccine doses have been shipped to mass immunizers, giving them

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an incomplete picture as to how the available vaccine was distributed in their state.

- **More timely data.** CDC officials stated that the Flu Vaccine Finder data are generally a week old when they become available to users because of the time necessary for CDC to collect the data from manufacturers and medical supply distributors and upload these data into the system. State health officials reported that having real-time data would be helpful to effectively determine which types of providers are in need of vaccine at a given point in time.

Some state health officials reported that they have utilized other mechanisms, such as surveying individual providers in their jurisdictions, to determine which providers have received a sufficient vaccine supply to vaccinate their high-risk and other target groups and which providers are in need. For example, one state, Minnesota, created its own database to monitor vaccine distribution in the state during the 2004–05 season. State health officials surveyed the individual providers in each of the state’s public health jurisdictions on their vaccine supply, and then entered the information into a database. This database then provided information for state officials to determine the need for and availability of vaccine across the state. Health officials from other states have reported administering informal surveys of individual providers on their vaccine supply during times of shortage. State health officials reported using the information on vaccine supply to facilitate voluntary redistribution—that is, providers with excess vaccine supply were identified by health officials and asked to give their left over doses to providers who needed it most, such as occurred during the 2004–05 influenza season. According to a representative from a national association representing state and territorial health officials, these informal surveys were very time and resource intensive, however.

One state, Rhode Island, created its own vaccine distribution program to manage the availability and distribution of vaccine in the state. Specifically, Rhode Island is implementing a program for the 2007–08 season in which the state health department will manage the purchasing and distribution of vaccine among the state’s providers for vaccination of adults. Specifically, the state health department plans to purchase and distribute about 250,000 influenza vaccine doses among participating

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providers free of charge to vaccinate adults who have health insurance or are working for or insured through a Rhode Island company.<sup>47</sup>

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## CDC and Others Have Produced Public Health Messages, and CDC Has Taken Some Steps to Assess Its Messages

CDC and others have produced a variety of public health messages designed to promote influenza vaccination, including messages to encourage preferential vaccination of certain high-risk and other target groups during times of vaccine delay or shortage. CDC has also taken some steps to assess its messages. For example, CDC has tested its messages prior to dissemination and collected some data to give the agency a sense of the impact its messages may be having on the public after dissemination. However, CDC and others have not conducted comprehensive evaluations on the impact of messages after dissemination. Although no comprehensive evaluations have been conducted, CDC and other officials we interviewed identified key elements, such as clear and consistent messages, that they believe are important to producing effective public health messages. However, there are impediments to effectively implementing these elements.

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## CDC and Others Have Produced and Disseminated Influenza-Related Public Health Messages

CDC has produced and disseminated public health messages designed to promote seasonal influenza vaccination. These messages provide information to the public and others—including providers and other public health entities—about influenza and aim to motivate individuals, particularly those in high-risk and other target groups, to receive influenza vaccination. CDC uses diverse means to convey its messages to the public, such as press releases, information posted on CDC's Web site, print materials, and media campaigns. CDC has also created messages designed to reach specific populations, such as materials printed in Spanish or public service announcements disseminated via Spanish-language radio.

Other public health entities also produce and disseminate their own messages to promote seasonal influenza vaccination. For example:

- Some state and local public health departments produce and disseminate print material, Web site information, and press releases, and inform the public through media and other means about the importance of vaccination.

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<sup>47</sup>Rhode Island's uninsured residents are eligible to receive influenza vaccinations through other programs administered by the state.

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- Provider associations, such as the American Medical Association and the American Academy of Pediatrics, produce and disseminate policy statements and other guidelines that adhere to ACIP recommendations for influenza vaccination, according to representatives of these associations we interviewed.
  - The American Lung Association, in collaboration with one major vaccine manufacturer, runs a Web-based educational initiative to encourage vaccination.
  - CDC and others participate in an influenza season press kickoff event held early each fall. This event, hosted by the National Foundation for Infectious Diseases,<sup>48</sup> has involved senior HHS officials from CDC and the Centers for Medicare & Medicaid Services<sup>49</sup> and has involved the participation of provider associations, such as the American Medical Association and the American Academy of Pediatrics.

For the 2006–07 influenza season, CDC and other partners—including the Association of State and Territorial Health Officials, National Association of County and City Health Officials, and Association of Immunization Managers—implemented a National Influenza Vaccination Week during the last week of November in 2006 to promote influenza vaccination. Throughout the week, CDC and other partnering organizations disseminated print materials and television and radio public service announcements encouraging late-season vaccination. CDC also contacted providers of influenza vaccine to encourage them to continue vaccination into December and beyond by recommending vaccinations to their patients and scheduling additional vaccination clinics and longer hours at these clinics. CDC officials reported that the agency plans to make National Influenza Vaccination Week an annual event.

During times of vaccine shortage or delay, CDC has produced and disseminated modified public health messages to encourage prioritization

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<sup>48</sup>The National Foundation for Infectious Diseases is a nonprofit organization whose mission includes educating the public and health care professionals about infectious diseases, such as influenza.

<sup>49</sup>The Centers for Medicare & Medicaid Services administers Medicare, the government-sponsored insurance program for persons aged 65 years and older and other qualified persons. The Medicare program pays for influenza vaccinations for Medicare beneficiaries and the Centers for Medicare & Medicaid Services partners with CDC to promote influenza vaccination among Medicare beneficiaries.



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of available vaccine to allow those groups identified by ACIP—including some but not all of ACIP’s initial target population of high-risk individuals—to be preferentially vaccinated before others. For example, during the vaccine shortage of the 2004–05 season, CDC held frequent press conferences beginning in October 2004 asking individuals who did not belong to one of these groups identified by ACIP to step aside and defer vaccination so that those in ACIP-identified priority groups would have vaccine available to them.<sup>50</sup>

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### CDC Has Taken Some Steps to Assess Its Public Health Messages

CDC has taken steps to assess its influenza-related public health messages before disseminating them to the public through focus groups and other activities, and has collected some data to give the agency a sense of the impact its messages may be having on the public after dissemination. For example, CDC has monitored media coverage of its messages and—in response to a recommendation we made in 2001—collected data to assess the public’s recall of the content and source of the messages disseminated for the 2000–01 season. CDC and others have not, however, conducted comprehensive evaluations to assess the impact of influenza-related messages after they are disseminated to the public.

CDC officials involved in communicating the agency’s influenza-related public health messages told us the agency tests its messages before they are disseminated to the public using focus groups and other similar methods. For example, CDC conducts in-depth interviews with providers, and leads focus group discussions with target audiences, such as African-American seniors, Hispanics, and seniors with chronic conditions. CDC officials reported that the goal of these efforts is to help determine if the agency’s influenza-related public health messages are easily understood by these audiences. These officials told us the feedback they receive is used to revise the messages as necessary before disseminating them to the public.

CDC officials we interviewed also reported that the agency has collected some data to provide a sense of the impact its messages may be having on the public. For example, due to the influence that media reports can have on public demand for vaccination, CDC officials reported that the agency monitors media sources—such as newspapers, press releases, and wire

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<sup>50</sup>See [GAO-05-984](#) and app. III for revisions to groups recommended for vaccination by ACIP during the 2004–05 influenza season vaccine shortage.

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services—during the influenza season to assess the volume and content of influenza-related stories in the news. CDC has also monitored the number of calls to the agency’s information hotline following influenza-related public health campaigns. The agency also collected limited information related to its public health messages in response to our recommendation that CDC assess the relative success of its past outreach and education efforts to help the agency prepare for potential delays or shortages of vaccine in subsequent seasons.<sup>51</sup> Specifically, CDC conducted a mail survey in June 2001 that, in part, assessed the public’s recall of the content and source of the influenza-related public health messages disseminated that year.<sup>52</sup> Based on the survey results, CDC officials concluded that the importance of continuing to vaccinate persons in December or later should be emphasized more strongly in the future, especially when vaccine is not available earlier in the season.

CDC has not conducted comprehensive evaluations to assess the impact of the influenza-related messages it uses on promoting vaccination after these messages are disseminated to the public. CDC officials reported that the agency does not conduct formal impact analyses of its influenza-related public health messages after these messages are disseminated—such as analyses to determine what messages successfully influence changes in behavior. These officials, who are responsible for producing and disseminating influenza-related messages, commented that it would be difficult to discern the impact of public health messages disseminated by CDC and others because these messages are just one factor among many that can influence vaccination. Given the complexity of such an evaluation, these officials noted that CDC resources available for influenza-related communications do not support formal impact analyses. One of these officials estimated that, to complete a post-dissemination evaluation of CDC’s influenza-related messages, it would cost five times CDC’s total budgeted amount for seasonal influenza-related public health communications. For fiscal year 2007, this budgeted amount was an estimated \$1.5 million.<sup>53</sup> In addition to CDC officials, officials we interviewed representing state and local health departments, national

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<sup>51</sup>See [GAO-01-624](#).

<sup>52</sup>CDC conducted a mail survey in June 2001 of 3,719 individuals that assessed vaccination coverage levels, timing of vaccination, place of vaccination, reasons for not being vaccinated, and messages heard about vaccination.

<sup>53</sup>This \$1.5 million for fiscal year 2007 included additional funding for National Influenza Vaccination Week.

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associations representing physicians, and a public health association reported that they had not conducted, nor were they aware of, studies examining the impact of the influenza-related public health messages they or others produced.

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### Elements Important for Producing Effective Public Health Messages Face Impediments to Implementation

Although no comprehensive evaluations have been conducted to assess the impact of influenza-related public health messages on vaccination, CDC and other officials identified elements they believe, based on their experience, are important to producing public health messages regarding seasonal influenza vaccination that will have an impact on promoting vaccination. These elements included clear and consistent messages, messages encouraging late-season vaccination, and the importance of recommendations from health care providers in creating public demand for vaccination. However, there are impediments to effectively implementing these elements.

- **Clear and consistent messages.** Officials we interviewed from CDC and state and local health departments stressed the importance of consistent influenza-related messages disseminated to the public. For example, officials from CDC and state health departments stressed the importance of consistency in messages coming from different public health entities. Similarly, we reported in 2005 on the importance of clear and consistent messages in averting public confusion regarding who should be vaccinated and when they should receive the vaccine.<sup>54</sup> For example, we reported that during the 2004–05 influenza season, health officials in California told us, at one time, local radio stations in the state were running two public service announcements—one from CDC advising those aged 65 years and older to be vaccinated, and one from the California Department of Health Services advising those aged 50 years and older to be vaccinated. These officials emphasized that these mixed messages created confusion. In addition to consistency in messages coming from different public health entities, officials we interviewed from CDC, as well as national associations representing physicians, stressed the importance of consistency in messages sent by any one public health entity because inconsistency during an influenza season and between seasons may also create confusion. For example, some individuals in target groups who heeded CDC’s messages to step aside during the 2004–05 season still thought it was not appropriate for them to get vaccinated after CDC stopped disseminating these messages later in the season. CDC has

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<sup>54</sup>[GAO-05-984](#).

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recognized the importance of clarity and consistency in influenza-related public health messages in its communications plans for the 2007-08 influenza season. A CDC official involved in communicating the agency's messages acknowledged past inconsistencies in messages disseminated by different public health entities but noted that many public health entities look to CDC to take the lead with public health messages and the result, overall, was a high level of consistency in the messages disseminated from different entities. This official also stated, however, that it is difficult to maintain a consistent message during or between influenza seasons, because messages need to adapt to the dynamic and complex situations that comprise influenza seasons. For example, messages need to be modified to account for changes in ACIP recommendations, which could result in the public hearing differing messages before and after these ACIP revisions are made.

- **Messages encouraging late-season vaccination.** CDC and other health officials we interviewed reported that public demand for influenza vaccination typically wanes after November. According to these and other officials, they believe interest wanes in part because the public has been conditioned by prior messages from CDC and other public health entities to believe that they must receive vaccination before late November for it to be effective. CDC and other officials representing state health departments we interviewed, as well as national associations representing physicians, reported that it is important that public health messages effectively encourage late-season vaccination so that as many people as possible can be protected against influenza and related complications. These efforts are also important to help minimize surplus vaccine left over at the end of influenza season. The experience by some states during the 2006 National Influenza Vaccination Week, however, illustrates the difficulties encountered when trying to coordinate promotion of late-season vaccination with vaccine availability. Specifically, officials from three of the six states we interviewed reported the timing of the National Influenza Vaccination Week—which was held from November 27 to December 3, 2006—was problematic for their state because it occurred before an adequate vaccine supply was available. For example, officials from the Minnesota Department of Health told us that they were unable to participate in National Influenza Vaccination Week because local health departments in the state had not yet received vaccine by that week. An official from the Texas Department of State Health Services told us the department received approximately half of its vaccine in the 2 weeks immediately preceding National Influenza Vaccination Week—probably too late for many providers in the state to participate in the initiative, this official said. An official from the Washington State Department of Health

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told us the department did not receive the bulk of its vaccine until during that week.

- **Recommendations from health care providers influence demand.** CDC officials we interviewed reported that the agency has consistently found that a recommendation from a physician or other health care provider is the most important factor in an individual's decision to get vaccinated. Officials representing state health departments and national associations representing physicians also acknowledged the importance of providers' recommendations. CDC officials reported that the agency has made efforts to encourage providers to recommend vaccination to their patients, including providing patient education tools that physicians can use when discussing vaccination with their patients. However, despite these efforts, available data suggest that getting providers to recommend vaccination for their patients has been difficult. For example, a January 2007 phone survey of adults conducted for CDC by an independent research organization found that less than 40 percent of respondents reported that their physician or other health care worker discussed getting an influenza shot with them.

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## Agency Comments

We provided a draft of this report to HHS for comment. The department provided technical comments, which we incorporated as appropriate.

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As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Health and Human Services and other interested parties. We will also provide copies to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>. We will also make copies available to others upon request.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made contributions to this report are listed in appendix VI.



Marcia Crosse  
Director, Health Care

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# Appendix I: Scope and Methodology

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In conducting this study, we reviewed relevant documents and interviewed officials from the Department of Health and Human Services's (HHS) Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) and manufacturers of all five seasonal influenza vaccines licensed for the U.S. market for the 2007–08 season as of August 31, 2007.<sup>1</sup> We also reviewed relevant documents and spoke with officials from the American Public Health Association, the National Foundation for Infectious Diseases, and three national associations representing state and local public health officials: the Association of Immunization Managers, Association of State and Territorial Health Officials, and National Association of County and City Health Officials.<sup>2</sup> We reviewed relevant documents and spoke with officials from the Health Industry Distributors Association, a national association representing medical supply distributors, as well from national associations representing physicians and long-term care providers, including the American Medical Association, American Academy of Pediatrics, the National Center for Assisted Living, and the American Health Care Association. We also reviewed documents related to the 2007 National Influenza Vaccine Summit.<sup>3</sup>

We also selected judgmental samples of (1) medical supply distributors; (2) mass immunizers—organizations that conduct mass immunization

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<sup>1</sup>For the 2007–08 influenza season, five vaccines were licensed by FDA for the U.S. market as of August 31, 2007: (1) Fluarix, manufactured by a part of GlaxoSmithKline plc, GlaxoSmithKline Biologicals, (2) FluLaval, manufactured by a subsidiary of GlaxoSmithKline plc, ID Biomedical Corporation of Quebec, (3) FluMist, manufactured by MedImmune Vaccines, Inc., (4) Fluvirin, manufactured by Novartis Vaccines and Diagnostics Limited, and (5) Fluzone, manufactured by sanofi pasteur. The policy of sanofi pasteur is to spell its name without capital letters. We interviewed officials and obtained information from GlaxoSmithKline Biologicals regarding both Fluarix and FluLaval; and interviewed officials and obtained information from MedImmune Vaccines, Inc., Novartis Vaccines and Diagnostics, Limited, and sanofi pasteur regarding FluMist, Fluvirin, and Fluzone, respectively. These five manufacturers also produced seasonal influenza vaccine for the U.S. market for the 2006–07 influenza season. On September 28, 2007, FDA approved an additional influenza vaccine, Afluria, manufactured by CSL Limited, for the U.S. market for the 2007–08 season.

<sup>2</sup>We also spoke with members of the Association of Immunization Managers and the National Association of County and City Health Officials who are state and local health officials.

<sup>3</sup>The National Influenza Vaccine Summit participants include stakeholders interested in influenza prevention such as CDC, the American Medical Association, manufacturers, medical supply distributors, and others such as state health departments. The summit meets annually to address important issues in influenza immunization.

clinics at workplaces, retail stores, long-term care facilities, and other locations; and (3) state health departments. For each organization in our samples, we reviewed relevant documents and interviewed officials. We selected the samples to reflect a mix of medical supply distributors, mass immunizers, and states; however, our samples were not statistically representative and cannot be generalized to all medical supply distributors, mass immunizers, or states.

For our judgmental sample of medical supply distributors, we selected six medical supply distributors that plan to distribute influenza vaccine for the 2007–08 season.<sup>4</sup> These six distributors represented a mix of organizations that distributed seasonal influenza vaccine to different markets (i.e., physician offices, hospitals, long-term care facilities); distributed different types of influenza vaccine products; and varied in whether they guaranteed delivery of the vaccine by a specific date, provided data to CDC for its Flu Vaccine Finder, and participated in the Flu Vaccine Business Practices Initiative.<sup>5</sup> In addition, we interviewed one medical supply distributor who distributed the influenza vaccine in prior seasons, but has decided not to for the 2007–08 influenza season.

For our judgmental sample of mass immunizers, we selected four mass immunizers who represented a mix of organizations that vaccinated individuals in different regions of the country; provided seasonal influenza vaccine in a variety of delivery locations (i.e., places of work, retail stores, other nonmedical settings); and were based on different business models (for-profit and nonprofit). We also interviewed representatives from entities that contract with mass immunizers to provide vaccinations including one retail store, one long-term care and assisted living facility, and one workplace.

For our judgmental sample of state health departments, we selected six states that represented a mix of states from different regions of the country; with different population sizes; with varied influenza vaccination

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<sup>4</sup>The Health Industry Distributors Association estimated that 25 medical supply distributors distribute vaccine in the United States in 2007.

<sup>5</sup>Members of the Flu Vaccine Business Practices Initiative have voluntarily committed themselves to adhering to a set of “responsible business practices” including compliance with all of CDC’s guidelines and initiatives, purchasing vaccine only from manufacturers or manufacturer-authorized medical supply distributors, and adhering to manufacturer vaccine storage and handling guidelines. This initiative is sponsored by the Health Industry Distributors Association.

success,<sup>6</sup> and that varied in whether they used CDC's Flu Vaccine Finder and have proposed innovative approaches for distributing influenza vaccine.<sup>7</sup>

To determine the quantity of seasonal influenza vaccine produced and when vaccine reaches providers who administer vaccine, we examined data from CDC regarding the number of influenza vaccine doses produced and distributed each month for the 2000–01 influenza season through the 2006–07 influenza season. We also reviewed data from CDC on the cumulative percentage of doses manufacturers and medical supply distributors shipped each month to different types of providers for the 2006–07 influenza season. To identify the locations in which high-risk groups receive their vaccinations, we reviewed data from CDC's Behavioral Risk Factor Surveillance System—a state-based system of health surveys that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury. We also reviewed data from a Gallup poll conducted on behalf of CDC, as well as CDC's National Adult Immunization Survey. In addition, to identify efforts undertaken by CDC and state health officials to help state and local officials manage availability of vaccine for high-risk and other target groups, we reviewed data from and documentation of the Flu Vaccine Finder, the Internet-based distribution database that CDC created to assist state and local health officials in their management of influenza vaccine availability issues, and interviewed health department officials from our sample of states. We assessed the reliability of these data by interviewing officials from CDC, manufacturers, and medical supply distributors knowledgeable about the data and by reviewing documents related to the data. On the basis of our assessment, we determined the data were sufficiently reliable for our purposes.

To identify actions CDC and others have taken to communicate public health messages that promote seasonal influenza vaccination, we also reviewed influenza vaccination communication plans produced by CDC and research and surveys conducted by CDC.

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<sup>6</sup>To determine vaccination rates, we used immunization rates for adults aged 65 years and older for 2005 from CDC's Behavioral Risk Factor Surveillance System.

<sup>7</sup>The six states we selected were Colorado, Maryland, Minnesota, Rhode Island, Texas, and Washington.



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We conducted our work in accordance with generally accepted government auditing standards from May through October 2007.

# Appendix II: Manufacturers of Seasonal Influenza Vaccine for the U.S. Market, 2000–01 through 2007–08 Influenza Seasons

The manufacturers of seasonal influenza vaccine for the U.S. market have changed between the 2000–01 influenza season, when there were three manufacturers, and the 2007–08 influenza season, for which there were six licensed manufacturers as of September 28, 2007 (see table 2).

**Table 2: Manufacturers of Seasonal Influenza Vaccine for the U.S. Market, 2000–01 through 2007–08 Influenza Seasons**

Manufacturer	Influenza season							
	2000–01	2001–02	2002–03	2003–04	2004–05 <sup>a</sup>	2005–06	2006–07	2007–08
sanofi pasteur (Aventis Pasteur Inc.) <sup>b</sup>	●	●	●	●	●	●	●	●
Wyeth Laboratories, Inc.	●	●	●					
Novartis Vaccines and Diagnostics Limited (Chiron Vaccines Limited; PowderJect Pharmaceuticals plc; Medeva Pharma Limited; Evans Vaccines Limited) <sup>c</sup>	●	●	●	●	● <sup>d</sup>	●	●	●
MedImmune Vaccines, Inc. <sup>e</sup>				● <sup>f</sup>	●	●	●	●
GlaxoSmithKline Biologicals					● <sup>g</sup>	●	● <sup>h</sup>	● <sup>h</sup>
ID Biomedical Corporation of Quebec							● <sup>h</sup>	● <sup>h</sup>
CSL Limited								●

Source: CDC and FDA.

Notes: Table shows manufacturers of seasonal influenza vaccine licensed for the U.S. market for the 2007–08 season as of September 28, 2007.

<sup>a</sup>For the 2004–05 season, in addition to the three manufacturers, two foreign manufacturers' vaccines were made available by FDA under an investigational new drug protocol. Although HHS purchased about 1.5 million doses of this vaccine, no doses were distributed that season.

<sup>b</sup>Aventis Pasteur Inc., became sanofi pasteur in January 2005.

<sup>c</sup>In 2006, Novartis Vaccines and Diagnostics Limited acquired Chiron Vaccines Limited. In 2003, Chiron Vaccines Limited acquired PowderJect Pharmaceuticals plc. In 2001, PowderJect acquired Medeva Pharma Limited; Medeva had previously acquired Evans Vaccines Limited.

<sup>d</sup>Chiron's license was suspended by the United Kingdom in October 2004 because of contamination at its manufacturing facility there and Chiron ceased production of the vaccine for the U.S. market for the 2004–05 season.

<sup>e</sup>MedImmune Vaccines, Inc. manufactures live attenuated vaccine administered as a nasal spray, sold under the trade name FluMist. All other manufacturers produce inactivated virus vaccine administered as an injection.

<sup>f</sup>Wyeth Laboratories, Inc. distributed MedImmune's FluMist vaccine during the 2003–04 season.

<sup>g</sup>GlaxoSmithKline Biologicals's vaccine was not licensed for the United States for the 2004–05 season, but the manufacturer's vaccine was made available for that season by FDA under an investigational new drug protocol. Although HHS purchased about 1.2 million doses of GlaxoSmithKline's vaccine, no doses were distributed that season.

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**Appendix II: Manufacturers of Seasonal  
Influenza Vaccine for the U.S. Market, 2000–  
01 through 2007–08 Influenza Seasons**

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<sup>1</sup>ID Biomedical Corporation of Quebec, the licensed manufacturer of one influenza vaccine (FluLaval), is a subsidiary of GlaxoSmithKline plc. GlaxoSmithKline Biologicals, also part of GlaxoSmithKline plc, is the licensed manufacturer of another influenza vaccine, Fluarix.

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# Appendix III: Advisory Committee on Immunization Practices (ACIP) Recommendations

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In spring or summer each year, ACIP, after consulting with CDC, makes recommendations on which population groups should be targeted for annual influenza vaccination. Since publishing its recommendations for the 2000–01 season, ACIP has changed its recommendations on who should be targeted for vaccination, primarily expanding the groups it has recommended (see table 3).<sup>1</sup> ACIP has also modified its recommendations to address a vaccine shortage or delay; for two seasons, ACIP published revised recommendations that narrowed the groups that should receive priority for available vaccine (see tables 4 and 5). For the 2006–07 season, approximately 73 percent of the U.S. population—an estimated 218 million individuals—were included in ACIP’s target groups (see table 6).

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<sup>1</sup>In addition, for the 2000–01 through 2007–08 seasons, ACIP has advised that, in addition to the high-risk and other target groups for whom providers are recommended to provide vaccinations, all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others, should be vaccinated, depending on vaccine availability.

**Appendix III: Advisory Committee on  
Immunization Practices (ACIP)  
Recommendations**

**Table 3: ACIP Influenza Vaccination Recommendations, 2000–01 through 2007–08 Influenza Seasons**

Target group	Influenza season							
	2000–01 <sup>a</sup>	2001–02	2002–03	2003–04	2004–05 <sup>b</sup>	2005–06	2006–07 <sup>c</sup>	2007–08 <sup>c</sup>
<b>Persons at increased risk for influenza-related complications<sup>d</sup></b>								
Children aged 6 to 23 months <sup>e</sup>			encouraged	encouraged	✓	✓	✓	✓
All women who will be pregnant during the influenza season					✓	✓	✓	✓
Pregnant women in second or third trimester during the influenza season	✓	✓	✓	✓	✓	✓	✓	✓
Adults aged 65 years and older	✓	✓	✓	✓	✓	✓	✓	✓
Residents of nursing homes and other chronic-care facilities	✓	✓	✓	✓	✓	✓	✓	✓
Persons aged 6 months and older with certain chronic medical conditions	✓	✓	✓	✓	✓	✓	✓	✓
<b>Persons with elevated prevalence of chronic medical conditions, or with increased risk for influenza-associated clinic, emergency department, or hospital visits<sup>d</sup></b>								
Adults aged 50 through 64 years <sup>f</sup>	✓	✓	✓	✓	✓	✓	✓	✓
Healthy children aged 24 to 59 months <sup>f</sup>							✓	✓
<b>Persons who can transmit influenza to those at high risk<sup>d</sup></b>								
Household contacts of persons at high risk, including those of children less than 6 months of age	✓	✓	✓	✓	✓	✓	✓	✓
Health care workers	✓	✓	✓	✓	✓	✓	✓	✓

Source: GAO analysis of CDC's *Morbidity and Mortality Weekly Reports*, 2000 through 2007.

Notes: A check mark (✓) indicates vaccination was recommended for that group for that season.

<sup>a</sup>The check marks in this column represent those target groups ACIP recommended for vaccination for the 2000–01 influenza season prior to ACIP issuing revised recommendations in October 2000.

<sup>b</sup>The check marks in this column represent those target groups ACIP recommended for vaccination for the 2004–05 influenza season prior to ACIP issuing revised recommendations in October 2004.

<sup>c</sup>For the 2006–07 through 2007–08 seasons, ACIP also recommended that healthy children aged 6 months through 8 years who had not been previously vaccinated receive two doses of vaccine.

**Appendix III: Advisory Committee on Immunization Practices (ACIP) Recommendations**

<sup>d</sup>ACIP generally refers to persons at increased risk for influenza-related complications as the “high-risk” groups within the target population and the other persons in the target population for annual vaccination as the “other target groups.” For the 2007–08 influenza season, ACIP also considers as part of the “high-risk” groups those persons at higher risk for influenza-associated clinic, emergency department, or hospital visits—including adults aged 50 through 64 years and children aged 24 to 59 months.

<sup>e</sup>For the 2002–03 and 2003–04 seasons, ACIP encouraged vaccination of healthy children aged 6 to 23 months when feasible because they are at increased risk for influenza-related hospitalization. For the 2007–08 season, ACIP recommended vaccination of children aged 6 to 23 months because they are at increased risk for influenza-related hospitalization.

<sup>f</sup>For the 2000–01 through 2005–06 seasons, adults aged 50 through 64 years were recommended for vaccination because of an elevated prevalence of chronic medical conditions in this age group. For the 2006–07 and 2007–08 seasons, adults aged 50 through 64 years and healthy children aged 24 to 59 months were recommended for vaccination because of a higher risk for medical care—that is an increased risk of influenza-associated clinic, emergency department, or hospital visits.

**Table 4: Target Groups ACIP Recommended for Influenza Vaccination for the 2000–01 Influenza Season, before and after October 2000**

Target groups	April 2000 <sup>a</sup>	October 2000 <sup>b</sup>
Pregnant women in second or third trimester during the influenza season	✓	✓
Adults aged 65 years and older	✓	✓
Residents of nursing homes and other chronic-care facilities	✓	✓
Persons aged 6 months through 64 years with certain chronic medical conditions	✓	✓
Health care workers	✓	✓
Household contacts of persons at high-risk	✓	✓
Adults aged 50 through 64 years	✓	

Source: CDC, “Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP),” *Morbidity and Mortality Weekly Report*, vol. 49, no. RR-3 (2000) and CDC, “Updated Recommendations From the Advisory Committee on Immunization Practices in Response to Delays in Supply of Influenza Vaccine for the 2000-01 Season,” *Morbidity and Mortality Weekly Report*, vol. 49, no. 39 (2000): 888-892.

Note: Check marks (✓) denote priority groups recommended by ACIP, at the time shown, for vaccination.

<sup>a</sup>ACIP advised that in addition to the groups for which vaccination is recommended, all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others, should be vaccinated, depending on vaccine availability.

<sup>b</sup>The revised recommendations, published after a delay in influenza vaccine availability, also stated that special efforts should be made in December and later to vaccinate adults aged 50 through 64 years.

**Appendix III: Advisory Committee on  
Immunization Practices (ACIP)  
Recommendations**

**Table 5: Target Groups ACIP Recommended for Influenza Vaccination for the 2004–05 Influenza Season, before and after October 2004**

<b>Target groups</b>	<b>May 2004<sup>a</sup></b>	<b>October 2004<sup>b</sup></b>
Children aged 6 to 23 months	✓	✓
All women who will be pregnant during the influenza season	✓	✓
Adults aged 65 years and older	✓	✓
Residents of nursing homes and other chronic-care facilities	✓	✓
Persons aged 6 months and older with certain chronic medical conditions	✓	✓
Health care workers	✓	✓
Persons aged 2 to 64 years who are household contacts of persons at high-risk <sup>c</sup>	✓	
Persons aged 2 to 64 years who are household contacts of children younger than 6 months <sup>c</sup>	✓	✓
Adults aged 50 through 64 years who are not household contacts of high-risk individuals	✓	

Source: CDC, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 53, no. RR-6 (2004) and CDC, "Interim Influenza Vaccination Recommendations, 2004-05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 39 (2004): 923-924.

Note: Check marks (✓) denote priority groups recommended by ACIP, at the time shown, for vaccination.

<sup>a</sup>ACIP advised that in addition to the groups for which vaccination is recommended, all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others, should be vaccinated, depending on vaccine availability.

<sup>b</sup>These revised recommendations were published in response to a shortage of influenza vaccine.

<sup>c</sup>These groups belonged to a single category in ACIP's May 2004 recommendations.

**Appendix III: Advisory Committee on  
Immunization Practices (ACIP)  
Recommendations**

**Table 6: Estimates of ACIP Target Group Populations Sizes, 2006**

<b>Target group</b>	<b>Population in millions</b>	<b>Percent of total U.S. population</b>
<b>Persons at increased risk for influenza-related complications</b>		
Children aged 6 to 23 months	6.0	2.0%
All women who will be pregnant during the influenza season	4.0	1.3
Adults aged 65 years and older	37.2	12.5
Persons aged 24 months through 64 years with certain chronic medical conditions	44.0	14.8
<b>Subtotal</b>	<b>91.2</b>	<b>30.6</b>
<b>Persons with elevated prevalence of chronic medical conditions, or with increased risk for influenza-associated clinic, emergency department, or hospital visits</b>		
Adults aged 50 through 64 years	18.0	6.0
Children aged 24 to 59 months	7.1	2.4
<b>Subtotal</b>	<b>25.1</b>	<b>8.4</b>
<b>Persons who can transmit influenza to those at high risk</b>		
Household contacts of persons at high risk or children aged 24 through 59 months	94.8	31.8
Health care workers	7.0	2.4
<b>Subtotal</b>	<b>101.8</b>	<b>34.1</b>
<b>Total target population</b>	<b>218.1</b>	<b>73.1%</b>

Source: CDC analysis of United States Census Bureau data.

Note: Population sizes are based on United States Interim population projections by age, sex, race, and Hispanic origin: 2000 to 2050 (Population Projections Branch, United States Census Bureau, released May 11, 2004). Percentages are based on a total population estimate of about 298 million.



# Appendix IV: Cumulative Percentage of Vaccine Distributed by Provider Type during 2006–07 Influenza Season

For the 2006–07 influenza season, manufacturers distributed 103 million doses of vaccine to customers such as physicians, state and local health departments, or other types of providers who administer vaccinations. Manufacturers distributed vaccine as it became available, with the proportion of vaccine distributed each month varying. Table 7 shows the cumulative percentage of vaccine distributed to different types of providers throughout the 2006–07 influenza season, according to CDC.

**Table 7: Percentage of Cumulative Number of Doses Distributed by Month and Provider Type, 2006-07 Influenza Season**

Provider type	September	October	November	December	January
Corporations	2.2%	2.5%	2.6%	2.5%	2.5%
Correctional facilities	0.0	0.0	0.0	0.0	0.0
Distributors	24.9	16.2	18.3	15.7	15.6
Federal government	1.1	3.9	3.3	5.0	5.1
Hospitals	9.2	12.9	10.4	9.9	9.9
Long-term care facilities	4.7	4.0	3.7	3.1	3.1
Military	0.6	1.0	0.8	2.2	2.2
Other private provider types	3.4	2.9	2.7	2.8	2.9
Other public provider types	1.3	1.1	1.1	1.4	1.4
Pharmacies	5.0	5.1	3.8	3.5	3.5
Private providers <sup>a</sup>	41.0	43.2	43.1	42.3	42.3
State and local health departments	6.6	7.2	10.1	11.6	11.6

Source: CDC.

Notes: Percentages do not add to 100 percent because of rounding. Table indicates the cumulative number of doses distributed to provider types as of September 29, 2006; October 20, 2006; November 10, 2006; December 22, 2006; and January 12, 2007. According to CDC, there was minimal change in percentage of doses distributed to provider types after January 12, 2007, and therefore CDC did not conduct analyses of the percentage of doses distributed beyond this date. Data identifying distribution of vaccine to mass immunizers were not available within a single provider category, according to CDC; rather, because these types of providers are classified differently by different manufacturers and medical supply distributors, doses received by them are included within a number of provider type categories.

<sup>a</sup>The category “Private providers” includes physicians, as well as outpatient clinics and facilities, health maintenance organizations, and surgery centers.

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# Appendix V: CDC's Flu Vaccine Finder

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An effort by CDC to provide state and some local health officials with information to help them monitor where vaccine is distributed is the Flu Vaccine Finder component of the Secure Data Network.<sup>1</sup> Initially created to address a severe vaccine shortage that occurred in the 2004–05 influenza season, the Flu Vaccine Finder “provides information to enhance the visibility of influenza vaccine distribution for state and local health officials to assist in their management of influenza vaccine availability issues and challenges.”

Fifty-six states, cities, and urban areas that are CDC immunization grantees—all 50 states and 6 cities and urban areas—are eligible to use the Flu Vaccine Finder, but to access it, grantees must request and receive access from CDC.<sup>2</sup> CDC officials reported that for the 2007–08 influenza season, once CDC approval is received, each grantee is allowed to identify five individuals within their organization to be users of the Flu Vaccine Finder; these users have access to data for their state or jurisdiction.

Since its inception, the Flu Vaccine Finder has evolved, specifically in the number and type of contributors of data and the type of information available:

- **2004–05 influenza season.** After one of the two major vaccine manufacturers exited the market for that influenza season in October 2004 because of contamination at its manufacturing facility, a severe vaccine shortage occurred. In response, CDC developed the Flu Vaccine Finder as part of its plan to help state and local health officials direct available vaccine to certain high-risk groups. The Flu Vaccine Finder was first available to users in November 2004 and included data from the remaining major influenza vaccine manufacturer. In addition to providing information on where that manufacturer had shipped vaccine, users could also order vaccine through the Flu Vaccine Finder.<sup>3</sup>

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<sup>1</sup>CDC's Secure Data Network is an ongoing project sponsored by CDC to allow field staff, researchers, and public health partners to securely exchange confidential, proprietary, or sensitive data over the Internet.

<sup>2</sup>Immunization grantees are recipients of grants from CDC's National Center for Immunization and Respiratory Diseases (formerly the National Immunization Program) that support effective immunization systems and high rates of coverage through scientific assistance for evaluation, delivery, communications, and partnership development.

<sup>3</sup>For more information about CDC's two-part plan to help state and local officials direct vaccine to high-risk groups during the vaccine shortage in the 2004–05 season as well as the inception of the Flu Vaccine Finder, see [GAO-05-984](#).

- **2005–06 influenza season.** According to CDC officials, the Flu Vaccine Finder was expanded to include data from two manufacturers and seven major medical supply distributors for the 2005–06 season, and information on the number of doses that had been already ordered by users was also available. However, CDC discontinued the Flu Vaccine Finder's feature for ordering influenza vaccine that had been available during the 2004–05 influenza season. For this season, the Flu Vaccine Finder was available to users beginning in December 2005.
- **2006–07 influenza season.** Before the start of the 2006–07 season, CDC officials met with manufacturers and major medical supply distributors to receive feedback on the Flu Vaccine Finder and instruct them on the type of data CDC would be requesting from them and the process for submitting this information to CDC during the season. For this season, the Flu Vaccine Finder included data from seven major medical supply distributors, along with all U.S.-licensed manufacturers. Data, including a onetime listing of doses ordered in advance from those manufacturers and medical supply distributors who submitted the information, were available to users from September 2006 until the end of January 2007.
- **2007–08 influenza season.** CDC officials reported that the Flu Vaccine Finder will include data from at least the manufacturers of five licensed vaccines and six major medical supply distributors for this season. CDC officials also reported that they expect data will be available to users from September 2007 until the end of January 2008.

For the 2007–08 season, CDC officials stated that they requested that manufacturers and medical supply distributors submit information weekly to CDC for the Flu Vaccine Finder on the vaccine doses they distributed for the season so far.<sup>4</sup> The requested weekly information includes:

- National Drug Code number of vaccine distributed,<sup>5</sup>

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<sup>4</sup>According to CDC officials, CDC requested that manufacturers do not provide data on doses shipped to medical supply distributors participating in the Flu Vaccine Finder in order to avoid a duplication of information from that being submitted by the six major medical supply distributors.

<sup>5</sup>The National Drug Code number is a universal product identifier for human drugs which identifies the labeler, product, and trade package size. For example, for the influenza vaccine, the National Drug Code number identifies the manufacturer of the vaccine, the type of vaccine (preservative-free or preservative-containing), and the presentation of the vaccine (.25 milliliters, .5 milliliters, etc., and single dose syringes or multidose vials).

- state where influenza vaccine is distributed,
- zip code where influenza vaccine is distributed,
- number of doses distributed,
- date the vaccine doses were shipped, and
- type of provider where vaccine is distributed.

Manufacturers and medical supply distributors do not classify in a uniform way the types of providers to whom vaccine is distributed. Therefore, for use in the Flu Vaccine Finder, CDC recodes data submitted by manufacturers and medical supply distributors on the type of provider into one of the following categories:<sup>6</sup>

- corporation/occupational health,
- correctional facility,
- distributors,
- federal government,
- hospitals/emergency departments/dialysis centers,
- long-term care,
- military,
- other private provider,
- other public provider,
- pharmacy,
- private providers, and

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<sup>6</sup>According to CDC, data identifying distribution of vaccine to mass immunizers were not available within a single provider category; rather, because these types of providers are classified differently by different manufacturers and medical supply distributors, doses received by them are included within a number of provider type categories.

- state/local health department.

CDC officials reported that it typically takes about a week for the information submitted by manufacturers and medical supply distributors to be made available by CDC in the Flu Vaccine Finder. Users are able to view Flu Vaccine Finder data for their state or jurisdiction online as well as download data into a spreadsheet format which allows them to then perform their own analyses. The spreadsheet contains variables for which manufacturers and medical supply distributors submitted data. According to CDC officials, CDC does not conduct data reliability tests of the data in the Flu Vaccine Finder because the data represent a “census” of influenza vaccine distribution data and another data source does not exist for reliability testing. In addition, CDC officials reported that about 15 percent of doses distributed during the 2006–07 season and captured by the Flu Vaccine Finder were shipped from manufacturers or medical supply distributors to other medical supply distributors for resale. CDC officials reported that the Flu Vaccine Finder does not capture to which types of providers the medical supply distributors then resell these doses.

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# Appendix VI: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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# Related GAO Products

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*Influenza Pandemic: Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage.* [GAO-06-221T](#). Washington, D.C.: November 4, 2005.

*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.

*Influenza Pandemic: Plan Needed for Federal and State Response.* [GAO-01-4](#). Washington, D.C.: October 27, 2000.

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