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## **Influenza Vaccine Shortages and Implications**

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# Influenza Vaccine Shortages and Implications

## Summary

On October 5, 2004, Chiron, a California-based biotechnology company, notified U.S. health officials that British regulatory authorities had suspended production of influenza (“flu”) vaccine in its plant in Liverpool, England, due to vaccine safety concerns. The plant was slated to provide between 46 million and 48 million doses of flu vaccine for the U.S. market for the imminent 2004-2005 flu season, almost half the expected nationwide supply.

The announcement of Chiron’s suspension prompted the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) to re-define the groups most at risk, to be given priority for the available vaccine doses. CDC activated its Emergency Operations Center to coordinate nationwide tracking of available vaccine doses, high-priority individuals who might need them, and infections signaling the beginning of the winter flu season. The Food and Drug Administration (FDA) sent a team to the Liverpool plant to determine if any of the affected Chiron vaccine lots could be salvaged (they later determined that they could not) and sought to identify additional sources of vaccine from other manufacturers, domestically and abroad. States launched plans to locate and re-distribute or ration doses of vaccine, and responded to widespread reports of price-gouging. The response of local, state and federal agencies was limited because most of the U.S. flu vaccine market is in private hands.

Some members of Congress introduced legislation in response to the shortage, or pointed to legislative proposals introduced earlier in the 108<sup>th</sup> Congress in response to flu vaccine supply problems during the 2003-2004 season. Two hearings on influenza vaccine were held immediately prior to announcement of the shortage, indicating Congress’s ongoing interest in this issue. An additional hearing was scheduled and held after the shortage was announced. Congress also passed (in P.L. 108-357, the American Jobs Creation Act of 2004) a provision adding flu vaccine to the National Vaccine Injury Compensation Program (VICP).

The flu vaccine shortage illustrates two serious challenges that the federal government faces in responding to public health threats. Law and tradition place much of the control of the current situation either with the states, or with the private sector, and the threshold over which the federal government would wrest control from either appears high. Free market forces operate, and the public health system responds in a decentralized fashion. As a consequence, federal efforts may seem disorganized, and the federal government may appear unresponsive.

As communities across the country saw long lines of sick and elderly citizens waiting in vain for flu vaccine, policymakers asked why the national system to provide this potentially life-saving product was so unreliable, and what could be done about it. Some have expressed concern that this situation bodes ill for national preparedness for an influenza pandemic or a large-scale bioterrorism event. This report will describe the current system of flu vaccine production and delivery, the causes of supply problems, and options for improvement. It will be updated as circumstances warrant.

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# Influenza Vaccine Shortages and Implications

## Introduction

The Centers for Disease Control and Prevention (CDC) estimates that influenza (“flu”), a viral respiratory illness, causes 36,000 deaths and 200,000 hospitalizations in the United States each year. For many years, vaccination has been urged for those at highest risk of serious illness from flu, such as older persons and those with chronic illnesses. Peculiarities of flu vaccine production, especially its finite shelf life (it is good only for the one season for which it is produced), have led to supply and demand imbalances in recent years. Overall demand for flu vaccine has grown over the past decade. But CDC reports that there have been vaccine surpluses each of the past five winters, and unused vaccine has been discarded. (See **Table 1.**) Within a season, maldistribution of vaccine may lead to shortages at particular times and places, despite an overall surplus. Gauging demand from year to year in what is mostly a private-sector market is a matter of both art and science, an exercise fraught with difficulty.

On October 5, 2004, Chiron, a California-based biotechnology company, notified U.S. health officials that British regulatory authorities had suspended production of influenza (“flu”) vaccine in its plant in Liverpool, England, due to vaccine safety concerns. The plant was slated to provide between 46 million and 48 million doses of injectable flu vaccine (Fluvirin®) for the U.S. market for the imminent 2004-2005 flu season, almost half the planned nationwide supply of 100 million doses. Aventis-Pasteur (Aventis), a French-based company with a plant in Swiftwater, Pennsylvania, was slated to produce 52 million doses of its injectable flu vaccine (Fluzone®).

Since the Chiron suspension was announced, Aventis has announced that its production for this season is on target, and can be augmented somewhat to a total of 58 million doses by continuing production through January 2005. An additional manufacturer, MedImmune, based in Maryland, produces a flu vaccine made of live virus for intra-nasal administration (FluMist,™ also referred to as live attenuated influenza vaccine, or LAIV). MedImmune was slated to produce 2 million doses for the current season after the product was poorly received in the 2003-2004 season. The company has announced that it can ramp up production somewhat, but because LAIV is a live virus product it is not licensed for use in the most vulnerable groups now prioritized by CDC. The Defense Department is trying to obtain doses of LAIV for its healthy recruits slated for overseas deployment, in order to assure force protection without consuming the limited civilian supply of injectable vaccine.

The announcement of Chiron's suspension prompted CDC and its Advisory Committee on Immunization Practices (ACIP) to re-define the groups most at risk (enumerated in **Table 2**), to be given priority for the available vaccine doses. CDC also activated its Emergency Operations Center to coordinate nationwide tracking of available vaccine doses, high-priority individuals who might need them, and infections signaling the beginning of the winter flu season. Officials from HHS and CDC repeat in public statements that vaccine doses from Aventis will continue to roll off the production lines for several months, and urge those at risk not to stand in long lines because they believe that there will not be future opportunities to be vaccinated.

In addition, CDC has developed clinician recommendations for the use of *antiviral drugs*. These are drugs that can be given before infection occurs as a preventative, or during illness to minimize serious complications. The Department of Health and Human Services (HHS) estimates that 40 million doses of antiviral drugs will be available, including 7 million doses purchased by HHS to treat low-income individuals, and the remainder within the private sector.

The Food and Drug Administration (FDA) sent a team to the Liverpool plant to determine if any of the affected Chiron vaccine lots could be salvaged (and later announced that they could not), and sought to identify additional sources of vaccine from other manufacturers, domestically and abroad. Both British and U.S. regulatory agencies are required to assure the safety and efficacy of the Chiron product, for export and import respectively. If available vaccine were located in other countries, the products would not be currently licensed in the United States and would require approval by the FDA as Investigational New Drugs to be used here. The House Committee on Government Reform began an investigation of the FDA to determine whether it knew or should have known of the impending production failure, as its British counterpart did, since FDA is required to assure the safety and efficacy of this product for importation.

States have responded to the shortage by launching plans to locate and re-distribute or ration doses of vaccine, and by pursuing widespread reports of price-gouging. Some localities have held lotteries to apportion limited vaccine to those in priority groups.

Also following announcement of the Chiron suspension, the Securities and Exchange Commission (SEC) and the Justice Department launched inquiries into whether the company knew of the imminent failure of its annual production before its public announcement. In addition, several class-action stakeholder lawsuits were filed against Chiron on the premise that the company had not fulfilled its disclosure obligations.

As communities across the country saw long lines of sick and elderly citizens waiting in vain for flu vaccine, policymakers asked why the national system to provide this potentially life-saving product was so unreliable, and what could be done about it. Some have expressed concern that this situation bodes ill for national preparedness for an influenza pandemic or a large-scale bioterrorism event. This report will describe the current system of flu vaccine production and delivery, the causes of supply problems, and options for improvement.

## Scientific and Technical Issues

### Annual Strain Selection and Vaccine Production

In general, vaccines, which are regulated as *biologics* by the FDA Center for Biologics Evaluation and Research (CBER), are more tricky to produce than are drugs. Manufacturers must successfully grow the particular virus or other organism of interest while avoiding the growth of other organisms that might contaminate the final product. Several peculiarities of the influenza virus itself and its production process make flu vaccine production especially complicated. There are numerous points at which the process could fail, and has failed in recent years.

The influenza virus changes over time. From year to year, the dominant strains of virus in circulation change, which is why we may get sick every year from flu, in contrast with having lifelong immunity to more stable viruses such as measles. Each year in late winter, the FDA, with input from the National Vaccine Advisory Committee and using surveillance information from the World Health Organization (WHO) and CDC, reviews virus strains in global circulation and selects three that are most likely to cause serious illness in the United States during the subsequent winter season (i.e., one year hence). The chosen strains are incorporated into that next winter's *trivalent* flu vaccine, which typically contains at least one new strain each year. Strain selection may be based on both the dominance and severity of strains in circulation, but may be limited by certain obstacles. For example, an especially virulent strain called *Fujian* was an obvious choice for the 2003-2004 flu vaccine, but it could not be successfully grown in eggs in time to include it in last year's vaccine. This problem was eventually surmounted, and based on its continuing circulation, the Fujian strain was included in the 2004-2005 flu vaccine.

To make large amounts of virus for vaccine production, the virus must be grown in fertilized eggs. Large numbers of fertilized eggs are required each year to support vaccine production. They must be specially produced, assuring the health of the laying hens, appropriate sanitation, care in transport, incubation, and other actions as required by the FDA to assure vaccine safety and efficacy. This endeavor is far more complicated than the production of unfertilized eggs for food. Reliance on eggs and is a rate-limiting step in flu vaccine production, requiring many weeks for growing the virus and extracting it from the eggs, and introducing contamination risks.

Each year the current flu vaccine production system is a race against the clock. Strains must be selected by February in order that they can be grown, purified, processed and made into vaccine. Under optimal conditions vaccine is made in batches from August through November, barely making it to market ahead of the annual influenza epidemic. Breakdowns in the process, especially one occurring in the fall as with the Chiron vaccine, can subvert the entire production volume. It is difficult, if not impossible, to start over within a given season, so as with the Chiron situation, a large-scale process failure can lead to complete loss of the entire season's vaccine production from that supplier.

## Opportunities to Streamline Vaccine Production

The flu vaccine production process can be optimized in a number of ways. A promising option is replacement of the cumbersome egg-growth step with *cell culture* methods, in which the virus is grown in tubes or vats of certain mammalian cells. With this technique growth is faster, more controlled, takes up less space, and introduces fewer contamination problems than using eggs. Cell culture techniques could make the annual flu vaccine production cycle less prone to failures and more amenable to re-starting production within a season if problems do arise. In other words, cell culture techniques can provide *surge capacity* within existing infrastructure. This technique is not currently FDA-approved for use in flu vaccine production, but is in early stages of clinical trials, funded by the National Institutes of Health (NIH). Potential problems must be evaluated, such as the risk of cell components and genes getting into the vaccine or the virus. Also, for existing flu vaccine manufacturers to use this method they would have to renovate existing facilities or construct new ones, and would have to develop consistency in meeting Good Manufacturing Practices and other standards if they are to reliably produce vaccine each year.

Flu vaccine production can also be optimized by using *reverse genetics* to purify the selected strains. Currently, obtaining strains with the right characteristics for vaccine production is a trial-and-error process; strains are grown together in batches and sampled in a search for those with the desired properties. With reverse genetics, the desired parts of the viral genome are cloned and combined to create strains of virus with the right combinations of traits to stimulate immunity, and to grow well in eggs. Reverse genetics is not currently an FDA-approved technique for vaccine production, but NIH-funded clinical trials are currently underway using the technique to produce vaccine for the strain of avian influenza (“bird flu”) now circulating in Asia, in the event that it becomes a serious human pathogen. The safety and efficacy of flu vaccine produced using this technique remains to be evaluated. In addition, there are unresolved intellectual property issues, as well as consumer acceptance concerns (especially in Europe), because the vaccine virus produced is a genetically modified organism.

Another opportunity to optimize annual flu vaccine production rests with steady enhancement of global influenza surveillance, which could improve the speed and accuracy of strain selection.

Ultimately, the influenza virus holds two trump cards for which science does not offer solutions on the near horizon. First, there is a limited ability to predict how the virus will modify itself into each year’s dominant circulating strains. Once these strains emerge, there is a race against time to produce vaccine while the strains are actually causing illness somewhere on the planet. Second, the regular *shifts* of the viral genome (and the more cataclysmic *drifts* that define a pandemic) are inherent in its RNA, and the resulting evasion of the human immune response is inherent in our DNA. This relationship has existed for eons, and no near-term scientific breakthrough is likely to change it. Those seeking to prevent influenza infection are stuck with the prospect of annual flu vaccines for the foreseeable future.



## Legal and Policy Issues

### Overview

The flu vaccine shortage announced on October 5, 2004, unfolded within a complex interaction of government and private sector actions, leading many to question whether the federal government's authority is adequate to prevent these types of crises. States and the federal government have different roles and authorities with respect to this event. In general, public health authority rests with the states as an exercise of their police powers. As a result, states have taken the lead in restricting vaccine distribution to high-risk individuals and in prosecuting price-gouging. The federal government, through the *Commerce Clause* in the Constitution, is responsible for assuring the safety and efficacy of vaccines in commerce in the United States, but this authority does not extend to controlling the distribution or administration of the product. In a public health emergency, the Public Health Service Act grants the Secretary of HHS broad authority to take such actions as necessary to control infectious disease. Traditionally, the federal government has supported states in exercising their public health authorities rather than subsuming them. HHS Secretary Tommy G. Thompson has said that he does not intend to declare the flu vaccine shortage a public health emergency.<sup>1</sup>

Flu vaccination is a medical procedure, and many people voluntarily choose to be vaccinated in settings that are primarily non-governmental, such as a physician's office, a workplace, or a local grocery store. While federal, state and local governments do not control these activities directly, they play an important role in studying the use and impacts of flu vaccination, making recommendations and providing guidance on the use of flu vaccine, and educating providers and the public about their findings and recommendations. Examples of relevant public health research on flu vaccination include studying the effectiveness of vaccine in preventing illness in different risk groups, and studying the economic impacts of flu vaccine such as reduced absenteeism in the workplace. Government-supported education efforts include educational materials for providers outlining the use of different types of flu vaccines in specific populations, and flyers and public service announcements encouraging vaccination.

Federal policies and recommendations also drive private-sector flu vaccine demand. This is discussed further in an upcoming section on "Determining Annual Flu Vaccine Production."

### Federal Responsibility for Vaccines

The National Vaccine Program Office in HHS serves to coordinate vaccine-related activities in several agencies, and is the hub for federal pandemic influenza preparedness activities. The FDA is responsible for assuring the safety and efficacy of vaccines, according to 21 C.F.R. § 601. The NIH conducts intramural vaccine

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<sup>1</sup> U.S. Department of Health and Human Services, "Flu Vaccines and Antivirals," transcript of news conference, Oct. 19, 2004.

research and development and funds research in universities. The Health Resources and Services Administration (HRSA) administers the National Vaccine Injury Compensation Program (VICP), which provides compensation for injuries judged to have been caused by certain listed vaccines. The CDC houses the National Immunization Program, which coordinates research projects, state grant programs (including funding for purchase of vaccines), and other immunization activities and supports the Advisory Committee on Immunization Practices (ACIP). CDC also administers the Vaccines for Children (VFC) program, authorized in Medicaid law to provide immunizations for children who are uninsured, Medicaid recipients, Native Americans, and Alaska Natives at their doctors' offices and federally qualified health centers.

Vaccine responsibilities lie outside of HHS as well. The Department of Defense (DOD) maintains research and development programs for vaccines against both naturally occurring infectious diseases and bioweapons agents. DOD administers routine and deployment-related vaccines to military personnel and some civilian employees and contractors. As a primary healthcare provider, DOD also administers vaccines to its retirees and to current personnel and their families. The Department of Veterans Affairs administers vaccines to veterans within its healthcare system.

State and local governments carry out relevant activities within their public health role, such as conducting vaccine clinics, maintaining immunization registries, and establishing immunization requirements for school attendance. (These requirements apply to vaccine-preventable childhood diseases such as measles and whooping cough, but not influenza at this time.) In response to the current flu vaccine shortage, many states have taken action to prohibit administration of vaccine to non-priority individuals and to track available vaccine, among other activities.

## Determining Annual Flu Vaccine Production

In the winter of 2003-2004 Americans received 83 million doses of flu vaccine; 87 million were produced. According to the CDC, doses of unused flu vaccine have been discarded in each of the last five years. (See **Table 1.**) Vaccine manufacturers bear the loss from surpluses, and they attempt to carefully gauge demand each year to avoid these losses. Demand has grown in the past ten years, though, as a result of growing ranks of high-risk groups such as the elderly, increasing use of vaccine by other high-risk groups, and growing interest from low-risk groups, such as employers seeking to decrease absenteeism by offering the vaccine to workers at no cost.

**Table 1. Surplus Flu Vaccine, 1999-2003**  
(doses in millions)

	1999-2000	2000-2001	2001-2002	2002-2003	2003-2004
Doses produced	77.2	77.9	87.7	95.0	86.9
Doses used	76.8	70.4	77.7	83.0	83.1
Surplus	0.4	7.5	10.0	12.0	3.8 <sup>a</sup>

**Source:** Communication from CDC, Oct. 20, 2004.

**Note:** Target production for the 2004-2005 season was approximately 100 million doses.

a. Most of this surplus was live attenuated (intra-nasal) influenza vaccine.

Flu vaccine demand is also driven by federal policies and recommendations. In the spring of 2004, for the upcoming flu season, the ACIP added healthy young children aged 6 to 23 months to the list of groups that should receive the vaccine. To encourage beneficiaries to be vaccinated, Medicare began covering the full cost of flu vaccine and administration in 1993. The *Healthy People 2010* project, a public-private national goal-setting agenda for health, set a goal of 90% for influenza vaccine coverage for certain high-risk groups. Recently there has been greater emphasis on the prevention of influenza in institutionalized populations. In 2000 CDC published guidance encouraging *standing orders* programs to increase flu vaccination coverage in long-term care facilities and other settings. These programs give nurses “standing orders” to administer annual flu vaccines to residents without a physician’s explicit authorization. In 2002, the Centers for Medicare and Medicaid Services (CMS) removed the physician signature requirement for flu vaccine for Medicare and Medicaid participating hospitals, long-term care facilities, and home health agencies. The ACIP also recommends that healthcare workers receive flu vaccine, following studies showing that vaccination of workers reduces mortality in elderly residents in long-term care facilities.

Based on historical demand and on the new pediatric recommendation from the ACIP, the two manufacturers licensed for the 2004-2005 season, Aventis and Chiron, planned to make 100 million doses, about evenly split between them. The failure of all annual production by Chiron cut the supply in half.

## Flu Vaccine Distribution

The path of flu vaccine from assembly line to injection is complex and largely outside of government control. Manufacturers sell the product to distributors, or may also sell it directly to pharmacy chains, health maintenance organizations, hospitals, state health departments, and others. Vaccine may be transferred through multiple distributors along the way.

The CDC, as a purchaser, would have access to distribution information for the product it has purchased even if the product does not physically pass through CDC’s direct control. But almost 90% of the product is circulated outside of government control, and has not been tracked. The Government Accountability Office (GAO) has noted the lack of a means to redirect flu vaccine during a shortage, a system that would depend on centralized tracking.<sup>2</sup> In the face of the current shortage, HHS Secretary Thompson announced that CDC had set up a secure website for state health officials to use to identify available vaccine in their jurisdictions. Aventis and many of its downstream distributors were providing information for the site, information which the Secretary stressed was proprietary and which state health officials must protect as such. This is the first time such a system has been used to track flu vaccine. A further complexity: when the shortage was announced the FDA waived its prohibition against the transfer of vaccine among hospitals and other healthcare entities, to facilitate their own reallocation efforts. These downstream reallocations,

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<sup>2</sup> Government Accountability Office, GAO-04-1100T, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks*, testimony, September 28, 2004.

while clearly helpful under the circumstances, may not be captured in the new CDC tracking system.

## Re-Prioritizing Groups in Response to the Shortage

In the afternoon of October 5, 2004, the day Chiron advised U.S. officials of its failed production for 2004-2005, CDC and its Advisory Committee on Immunization Practices (ACIP) issued interim vaccine recommendations, designating “priority groups” for vaccine coverage following the shortage. The groups previously recommended to receive vaccine and the narrowed recommendations announced after the shortage, are listed in **Table 2**. CDC has subsequently estimated that the pre-shortage target population of roughly 185 million people (about 2/3 of the population) would be reduced to about 98 million priority recipients. Based on historical vaccine usage by these groups (which ranges from 12.4% for pregnant women to 66.2% for those over age 64), CDC estimated that only about 43 million doses would be needed to vaccinate those in priority groups.<sup>3</sup> CDC acknowledges that some vaccine was administered to non-priority groups before the shortage was announced, and that despite best efforts, reallocation of remaining vaccine to priority groups will be imperfect.

It is worth noting that the expansion of federal recommendations over time, and the growing recognition of the health benefits of flu vaccination even in healthy individuals, drives demand and serves as a market incentive to increase supply. In the face of a severe shortage, public and private actions to encourage flu vaccination in lower-risk groups have had to be abandoned for the 2004-2005 flu season.

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<sup>3</sup> Centers for Disease Control and Prevention, *Interim Estimates of Populations Targeted for Influenza Vaccination*, fact sheet, Oct. 11, 2004.

**Table 2. Federal Recommendations for Flu Vaccine, Before and After the Vaccine Shortage**

<b>Group</b>	<b>Pre-shortage recommendation</b>	<b>Post-shortage recommendation</b>
Children	All children aged 6-23 months, or older than 23 months with other risk factor	All children aged 6-23 months, or older than 23 months with other risk factor
Children and adolescents on aspirin therapy	All such persons	All such persons
Pregnant women	All women who will be pregnant during the flu season	All women who will be pregnant during the flu season
Adults and children aged 2-64 years with certain chronic conditions, including cardiovascular or respiratory conditions such as asthma	All such persons	All such persons
Persons institutionalized in chronic care facilities	All residents of such facilities	All residents of such facilities
Persons aged 50-64 years	All such persons	Only those with other risk factors
Persons aged 65 or older	All such persons	All such persons
Persons who can transmit influenza to those at high risk	All healthcare personnel in all inpatient, outpatient and home-care settings, and household contacts of high-risk persons	Healthcare workers involved in direct patient care and out-of-home caregivers and household contacts of children younger than six months

**Sources:** Pre-shortage recommendations: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR Recommendations and Reports, May 28, 2004.

Post-shortage recommendations: Interim Influenza Vaccination Recommendations, 2004-05 Influenza Season: Guidance from CDC, in coordination with the ACIP, Oct. 5, 2004.

## Vaccine Rationing

While the federal government has broad authority to take actions necessary to control infectious diseases in an emergency, traditionally the exercise of public health authority in this respect has rested with states. As a consequence, when the flu vaccine shortage was announced and CDC recommended that vaccine be prioritized to certain groups, several states, counties and the District of Columbia issued orders requiring healthcare providers to comply, and established fines for the administration of scarce vaccine to non-priority individuals. Some of the states declared the situation a public health emergency, while others used narrower authorities to support their orders. A current listing of state actions is maintained by the Association of State and Territorial Health Officials (ASTHO) at [<http://www.astho.org>.]

CDC is facilitating states' efforts by gathering information about existing supplies and unmet needs during the current shortage, though it lacks authority to compel manufacturers, distributors, states or others to provide this information. While CDC reports good voluntary cooperation with this effort, the GAO has repeatedly noted the absence of a coordinated national system to assure that those most in need receive flu vaccine when supplies are limited.<sup>4</sup> HHS Secretary Tommy G. Thompson has said that he does not intend to declare the flu vaccine shortage a public health emergency, and the federal government will not exercise authority to control vaccine distribution or administration.<sup>5</sup>

CDC's plan to identify vaccine doses in distribution and coordinate a three-part information exchange — unmet need, available vaccine, and circulating flu virus — has not been done before and may serve as a useful exercise in preparedness for any number of public health emergencies. Since it is a new effort, its utility in the face of the current vaccine shortage has yet to be demonstrated.

## Price Gouging

Media reports of price gouging were widespread following the announcement of the vaccine shortage, with reports that distributors were seeking more than ten times the original price. At least two states, Florida and Kansas, have responded with lawsuits. The National Association of Attorneys General notes that at least half of the states have statutes prohibiting price-gouging, though there are a variety of definitions and triggering events, not all of which would apply to this situation. However, the Association also notes that most if not all states could bring action under broader, more flexible authorities that prohibit “unfair and deceptive acts and practices.”<sup>6</sup>

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<sup>4</sup> Government Accountability Office, GAO-04-1100T, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks*, testimony, September 28, 2004.

<sup>5</sup> U.S. Department of Health and Human Services, “Flu Vaccines and Antivirals,” transcript of news conference, Oct. 19, 2004.

<sup>6</sup> Personal communication, Dennis Cuevas, National Association of Attorneys General, Oct. 18, 2004.

On October 14, 2004, HHS issued a press release urging states to aggressively prosecute flu vaccine price-gouging.<sup>7</sup> State action would require not only the requisite authority, but also the decision to act and the resources to do so. Some in Congress, concerned that states may not always be able to respond effectively, have asked about relevant federal authorities. Neither CDC nor FDA has authority to act in this matter, though CDC (which activated its Emergency Operations Center when the shortage was announced) is gathering reports of price-gouging and referring them to state attorneys general. On October 22, 2004, HHS announced that it had filed (along with the Department of Justice) a friend of the court brief in support of Florida's price-gouging lawsuit against a distributor.<sup>8</sup> HHS reported that the brief lays out the public health threat posed by price gouging, namely that price gouging leads to allocation of scarce flu vaccine based on who has the most money and not on who has the most need, that it risks the health of Medicare and Medicaid eligible patients, who are vulnerable and most in need of the vaccine, and that it may also lead to violations of the Federal Food, Drug, and Cosmetic Act such as tampering with, and counterfeiting of, flu vaccine.

On October 15, 2004, the House Committee on Government Reform called on the Federal Trade Commission (FTC) to launch a nationwide investigation of flu vaccine price-gouging, and to report on enforcement actions it is taking or plans to take.<sup>9</sup> It is not clear under what specific authority the FTC would act, as there is no federal price gouging statute. However, as noted above for states, the Commission could possibly bring an action under its general authority to prohibit unfair or deceptive acts or practices under the Federal Trade Commission Act.

## Economic Issues

### Overview

Vaccines for the U.S. market are made by private, for-profit firms, and most of the supply is privately controlled. For the 2004-2005 season, CDC purchased 11.4 million doses of flu vaccine, or about 11% of total production. (See **Table 3** for a breakdown of CDC purchases.) The public purchase price ranged from \$6.80 to \$10.00 per dose, depending on the formulation, which is generally lower than private sector prices.

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<sup>7</sup> Department of Health and Human Services, "HHS Secretary Urges States to Aggressively Prosecute Flu Vaccine Price Gouging" press release, Oct. 14, 2004.

<sup>8</sup> Department of Health and Human Services, "HHS Files Brief in Support of Florida Price Gouging Lawsuit," press release, Oct. 22, 2004.

<sup>9</sup> House Committee on Government Reform, "Davis and Waxman Ask FTC to Launch Inquiry on Flu Vaccine Price Gouging," press release, Oct. 15, 2004.

**Table 3. CDC Purchases of Flu Vaccine for 2004-2005**

Program	Doses from supplier (thousands)		Total
	Aventis	Chiron	
Vaccines for Children (VFC)	4,752	255	5,007
Section 317 (purchases for states)	900	377	1,277
Purchases to stockpile	2,500	2,000	4,500
Purchases using state funds	461	179	640
<b>Total</b>	<b>8,613</b>	<b>2,811</b>	<b>11,424</b>

**Source:** Communication from CDC on Oct. 10, 2004.

**Note:** Table reflects purchasing contracts prior to announcement of shortage.

Manufacturers point to a number of disincentives that deter them from the flu vaccine market, such as poor profitability, risk of a production failure, and injury liability.<sup>10</sup> Policymakers point to a number of problems in assuring adequate supply, including too few manufacturers, low vaccination rates among groups who are advised to be vaccinated, unpredictable timing and severity of annual flu seasons, and reluctance of manufacturers to overshoot demand estimates. The current flu vaccine shortage resulted from failure of production by a company that held almost 50% of the market share, because there were only two companies producing injectable flu vaccine for the U.S. market in 2004. During the 2001-2002 season, when there were three manufacturers supplying the U.S. market, one sustained significant losses from unused surplus vaccine, which led to its decision to drop out of the market

Many have noted that expanded public purchases of vaccine would have helped this situation only if such purchases had increased overall production by shifting some of the risk of over-production from the manufacturer to the government. Then, if a product were to fail, the other supplier would have produced relatively more and a shortage would not have been as severe. Long term, many feel that it is essential to have more manufacturers involved, so the consequences of a failure of one would have less impact on supply. But absent a substantial increase in demand, diversification would likely cut into the market for existing manufacturers, potentially reducing their incentives for remaining engaged.

A number of these issues have been discussed in the context of Project BioShield, a program to promote research and development of countermeasures for bioterrorism. In some ways Project BioShield is an imperfect model for flu vaccine shortages, because BioShield is designed to create production incentives for products that lack a commercial market. Nonetheless, there are enough similar issues at play

<sup>10</sup> Christine Gorman, "The Flu Snafu: A Vaccine Shortfall Grows Into a Political Headache," *Time*, Nov. 1, 2004.



that flu vaccine supply may be added to the agenda in ongoing discussions of the BioShield program. For example, the Project BioShield Act of 2004, P.L. 108-276, contains a provision which allows the Secretary of HHS to temporarily authorize the emergency use of non-licensed drugs and vaccines. Some in Congress have called on the Secretary of HHS to exercise this new authority, by locating available flu vaccine in other countries and making it available to Americans as quickly as possible. As Congress considers follow-on legislation to address remaining concerns (S. 666, the Biological, Chemical, and Radiological Weapons Countermeasures Research Act), additional issues such as ways to expand vaccine production capacity may also be relevant for flu vaccine. (For more information, see CRS Report RS21507, *Project BioShield*, by Frank Gottron, and CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron and Eric Fischer.)

The next section will explore several disincentives to flu vaccine manufacture, and several proposals for removing these barriers or otherwise stabilizing the annual flu vaccine market.

## **Economic Risk**

It is often suggested that making flu vaccine is not a good business proposition. The product is not highly profitable. Furthermore, production of vaccines is technically difficult, and lot failures resulting from sterility breaks or other causes are not uncommon. Flu vaccine is especially tricky because of the time constraints inherent in using eggs, and because vaccine does not have a shelf life beyond the year it is produced. It is difficult to start from scratch if a problem crops up mid-way in production. If annual demand is overestimated, unused vaccine is discarded at a loss to the manufacturer.

Manufacturers have an obligation to investors to make sound business decisions, and to adhere to standards of transparency in their business conduct. Following Chiron's announcement of its failed flu vaccine production for 2004-2005, the company became the subject of Securities and Exchange Commission (SEC) and Justice Department inquiries, reportedly to determine whether Chiron knew of the imminent failure of its product before its public announcement.<sup>11</sup> Several class-action shareholder lawsuits were filed on the premise that the company had not fulfilled its disclosure obligations.<sup>12</sup> The company has since announced that it is committed to producing flu vaccine for the 2005-2006 season, but that it cannot assure that its Liverpool plant can meet regulatory standards by February 2005, when production would have to begin in earnest.<sup>13</sup> These seemingly conflicting statements reflect the challenges the company faces in meeting multiple obligations. Its shareholders likely expect accurate projections of future performance. The U.S.

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<sup>11</sup> Paul Elias, "Grand Jury Investigating Chiron's Flu Vaccine Failure," *Associated Press*, Oct. 13, 2004.

<sup>12</sup> Bernadette Tansey, "Chiron Shows a Profit: Battered Flu Vaccine Company Circling the Wagons," *San Francisco Chronicle*, Oct. 21, 2004.

<sup>13</sup> *Ibid.*

federal government, in order to assist Chiron and other flu vaccine manufacturers in setting production targets for the 2005-2006 season, will have to know fairly soon if Chiron will be a supplier.

## **Injury Liability**

An Aventis executive, when asked about the impact of injury liability on flu vaccine producers, commented that it is a burden, that it is absorbed as a cost of doing business, and that his company is committed to remaining in the flu vaccine business.<sup>14</sup>

Vaccine manufacturers have two potential avenues for protection against injury liability claims. They can purchase insurance to cover the costs of defending against or paying out claims, and incorporate costs into the price of vaccine. Also, certain vaccines are covered under the National Vaccine Injury Compensation Program (VICP). Congress added flu vaccine to the VICP list in October 2004, in the American Jobs Creation Act of 2004 (P.L.108-357), which was signed by the President on October 22, 2004. Under VICP, an excise tax applied to vaccine sales pays for a public compensation fund. Congress enacted the program in 1986 as a no-fault alternative to the tort system for resolving claims resulting from adverse reactions to mandated childhood vaccines. Individuals of any age alleging injury from any covered vaccine must seek compensation through the program first, though they may decline a proposed award and then seek a remedy in court. The program is administered by the Office of Special Programs in the Health Resources and Services Administration (HRSA). (See [<http://www.hrsa.gov/osp/vicp/INDEX.HTM>]). HRSA says that the program has been successful in providing compensation to those injured by vaccine-associated adverse events, in reducing liability for vaccine manufacturers and healthcare workers who administer vaccines, and in achieving vaccine market stabilization.

## **Proposals to Stabilize the Flu Vaccine Market**

Some in Congress and others have proposed a number of incentives to vaccine manufacturers to encourage entry into the market and to guarantee demand for vaccine, which would in turn promote diversity of manufacturers and increase annual supply.

**Government Buy-Back of Surplus.** Under this proposal the federal government would purchase vaccine that remained unused at the end of a season. This would work, in theory, by encouraging manufacturers to produce more than they believed they could sell, thereby providing a cushion if annual supply were to fall short for any reason. However, if manufacturing problems or other supply disruptions did not occur, wastage of unused doses would become a government expense rather than a private one.

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<sup>14</sup> U.S. Department of Health and Human Services, "Flu Vaccines and Antivirals," transcript of news conference, Oct. 19, 2004.

**Government Purchase for Stockpiling.** Under this proposal, the federal government would purchase doses of vaccine at the beginning of the season, to serve as a cushion if needed. However, because of its one-season shelf life, flu vaccine is not an attractive candidate for stockpiling. Products such as smallpox vaccine have a long shelf life, and stockpile purchases can be considered one-time expenditures for which a high cost is acceptable. CDC purchased 4.5 million doses of flu vaccine to stockpile for the 2004-2005 season, at a cost of \$40 million. Two and a half million of these doses were produced by Aventis and can be used to ameliorate the current shortage, but this is a small amount in the face of a shortfall of 46 million doses. A federal flu vaccine purchase of sufficient magnitude to cushion a two-supplier market in the event that one failed would be costly, considering that in each of the past five years there have been surpluses of flu vaccine, and that this current year's shortage may be the exception. But by expanding annual demand, stockpile purchasing could encourage additional manufacturers to enter the market.

**Incentives for Construction of New Facilities.** Since the shortage was announced, several vaccine manufacturers have expressed interest in entering the flu vaccine market. For new manufacturers to be licensed in the United States, they must apply years in advance for FDA approval, and pay for plant construction or renovation, clinical trials and other regulatory obligations before any profit can be realized. Given the high capital cost for entry into this market, some have proposed offering tax credits or other incentives to offset these costs and encourage new manufacturers to join the U.S. flu vaccine market.

## Implications for Pandemic Preparedness

Influenza circulates around the globe every year, changing slightly each year so that healthy adults have partial immunity to new strains. The virus, its genome in constant flux, typically makes healthy people sick, but not too sick, each year. Now and then, usually several times in a century, the virus changes enough that there is no partial immunity. This event, called an influenza *pandemic*, results in severe illness and death, even in healthy people. The CDC estimates that in the United States, while an annual flu season results in 36,000 deaths, on average, a pandemic could cause more than 200,000. The extent and severity of illness, and the disabling impact on healthy young people, could cause serious disruptions in services and social order.

Some have expressed concern that the current flu vaccine shortage presages problems for a national response to an influenza pandemic. The current situation is in some ways a relevant drill for pandemic preparedness, but in other ways is different. In the face of the current flu vaccine shortage, many are concerned with the logistics of finding available vaccine and vaccinating high-risk individuals. Others are concerned about fairness in the way that companies and federal, state and local agencies are handling the situation. There is little circulating flu virus at this time, but as the season progresses there may be additional concerns about the availability of antiviral drugs, about whether people who are ill should be compelled to stay home, and similar issues.

Many of these concerns about limited resources and equity in their allocation will be writ large during a flu pandemic. Potentially, a vaccine could not be produced until a pandemic virus strain is actually circulating. For this and other reasons, severe vaccine shortages are expected during an influenza pandemic. The WHO and HHS each have published plans for influenza pandemic preparedness.<sup>15</sup> Both stress the role of basic infection control practices and have expanded guidance for handling large numbers of victims, such as expanding capacity for isolation and enacting plans to keep people at home.

The WHO says that with current technology, worldwide production capacity for influenza vaccine would cover only 5% of the world's population. Countries are advised to consider how they would apportion this scarce resource. WHO notes that because healthy individuals may become severely ill, or may even die from infection with a pandemic flu strain, consideration should be given to maintaining essential services by prioritizing vaccine delivery to critical service providers such as healthcare, public health and public safety workers. Americans are accustomed to deferring to those who are most vulnerable in situations where risk of death is low, as they have been asked to do for the current flu vaccine shortage, but a pandemic may require a different message.

Some in Congress have expressed concern that a portion of the U.S. flu vaccine supply is produced in a foreign facility. The concern is that during a flu pandemic or other emergency, foreign governments may seize vaccines and production facilities within their borders. The International Federation of Pharmaceutical Manufacturers Associations reports that in 2003, more than 95% of the world's flu vaccine was produced in nine countries: Australia, Canada, France, Germany, Italy, Japan, Netherlands, the United Kingdom and the United States. The global flu vaccine market is a confusing patchwork of companies and subsidiaries which may be based in one country, be producing vaccine in another, and be marketing in multiple other countries. Aventis and Chiron are the only companies currently licensed to produce injectable flu vaccine for the U.S. market. While others have expressed interest since the U.S. flu vaccine shortage was announced, it could take many years for them to have plants inspected, conduct clinical trials, and meet other FDA regulatory requirements before they could have a licensed product available in the U.S. market. This timeline would apply whether the manufacturer or plant were domestic or foreign.

While both the WHO and HHS plans also stress the use of antiviral drugs, these are likely to be in very short supply as well. A similar problem may arise with access to healthcare facilities and providers. A flu pandemic could result in mass casualty situations, and while these may be isolated in time and place, they may force what is referred to as *degradation of care*, the circumstance in which a standard of care is lowered in the face of overwhelming resource constraints in order to maximize

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<sup>15</sup> World Health Organization, "Influenza Pandemic Preparedness Plan: The Role of WHO and Guidelines for National or Regional Planning," Geneva, Switzerland, April 1999, and U.S. Department of Health and Human Services, "Pandemic Influenza Preparedness and Response Plan," Aug. 26, 2004.

overall survival. Providers are concerned about the ramifications on social order and liability, and have sought federal guidance on this matter.

CDC's plan to coordinate information about flu vaccine availability, pockets of unmet need, and circulating influenza virus, using geographic information systems (GIS), gathering information from states and private entities, and relaying it back, is a useful preparedness exercise for any number of natural or intentional public health emergencies, including pandemic influenza. In addition, efforts to bolster bioterrorism preparedness have yielded bonuses for pandemic preparedness, such as the development of techniques to streamline vaccine development. Generally, advancements in the development of vaccines for pandemic influenza will benefit annual flu vaccine development as well.

Despite advances in technology, serious questions remain about the exercise of federal authority during an influenza pandemic. Many of these questions are also being raised in the face of the current flu vaccine shortage. Should the federal government have, or exercise, authority to identify and control doses of scarce flu vaccine? Should the federal government have, or exercise, authority to control administration of vaccine by healthcare providers? Is the current model, which leverages state authorities with federal assistance, adequate for the current shortage, or for pandemic influenza or other public health emergencies? Given that the federal government has overarching emergency authorities but has not used them, will federal officials know how to conduct themselves if such authorities were invoked in an emergency? The current flu vaccine shortage presents a small study of these important questions.

## Conclusion

It is intuitively appealing to think that federal officials, when faced with a public health emergency, could take charge of information and assets, and assure that remedies and burdens were equitably and efficiently distributed. Actually, the current shortage of flu vaccine illustrates two serious challenges that the federal government faces in a public health emergency. Law and tradition place much of the control of the current situation either with the states, or with the private sector, and the threshold over which the federal government would wrest control from either appears high. The federal government does not dictate the practice of medicine or compel companies to do business. As a result, in situations like this one, free market forces operate, the public health system responds in a decentralized fashion, efforts may seem disorganized, and the federal government may appear unresponsive.

Since the terror attacks of 2001, some barriers have been overcome without substantial changes in the legal landscape. An example is state preparedness planning with uniform guidance, so that states aim for the same targets in planning for mass drug distribution, or in overhauling their emergency public health authorities. Decentralization of public health authority to states is less of a problem if all of them can respond capably and in a consistent fashion. Another example is the government use of proprietary information, such as drug store sales, to conduct surveillance for unusual health events. The current flu vaccine shortage is yet another exercise in the coordination of these partners in response to a national

challenge, another opportunity to explore creative solutions, and another chance for lessons learned.

## **Congressional Actions in the 108<sup>th</sup> Congress**

### **Legislation**

Selected legislative proposals aimed at addressing flu vaccine production or shortages are listed. A number of bills were introduced before this year's shortage was announced, some in response to flu vaccine problems during the 2003-2004 season. Several proposals would subject flu vaccine to an excise tax, in order to add it to the Vaccine Injury Compensation Program table. A version of this provision was passed in H.R. 4520 / S. 1637, which was signed by the President on October 22, 2004. Other proposals in authorizing legislation listed below have not been considered in either chamber as of this writing.

#### **H.R. 3758 (Emanuel)**

To amend the Public Health Service Act to provide for an influenza vaccine awareness campaign, ensure a sufficient influenza vaccine supply, and prepare for an influenza pandemic or epidemic, to amend the Internal Revenue Code of 1986 to encourage vaccine production capacity, and for other purposes.

Introduced February 3, 2004.

#### **H.R. 4520 / S. 1637 (Thomas, Grassley)**

The American Jobs Creation Act of 2004, includes a provision to add any trivalent vaccine against influenza as a taxable vaccine for purposes of the excise tax on certain vaccines.

Became P.L. 108-357 on October 22, 2004.

#### **H.R. 5243 (DeFazio)**

To amend the Public Health Service Act to provide for emergency distributions of influenza vaccine.

Introduced October 7, 2004.

#### **S. 15 (Gregg)**

Project BioShield Act of 2004, to amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures. Introduced March 11, 2003.

Became P.L. 108-276 on July 21, 2004.

#### **S. 666 (Lieberman)**

The Biological, Chemical, and Radiological Weapons Countermeasures Research Act, to provide incentives to increase research by private sector entities to develop

antivirals, antibiotics, vaccines and other products to prevent and treat illnesses associated with a biological, chemical, or radiological weapons attack.

Introduced March 19, 2003.

**S. 754 (Frist)**

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines (including flu vaccine) and improving and clarifying the vaccine injury compensation program.

Introduced April 1, 2003.

**S. 1817 (Santorum)**

To amend the Internal Revenue Code of 1986 to include influenza vaccines in the Vaccine Injury Compensation Program.

Introduced November 4, 2003.

**S. 1896 (Grassley)**

To add to the definition of taxable vaccines any vaccine against hepatitis A and any trivalent vaccine against influenza.

Introduced November 19, 2003.

**S. 2038 (Bayh)**

To amend the Public Health Service Act to provide for an influenza vaccine awareness campaign, ensure a sufficient influenza vaccine supply, and prepare for an influenza pandemic or epidemic, to amend the Internal Revenue Code of 1986 to encourage vaccine production capacity, and for other purposes.

Introduced January 28, 2004.

**S. 2959 (Dayton)**

To amend the Public Health Service Act to ensure an adequate supply and distribution of influenza vaccine.

Introduced October 8, 2004.

**S. 2968 (Reed)**

To amend the Public Health Service Act to address the shortage of influenza vaccine, and for other purposes.

Introduced October 8, 2004.

**H.R. 2660 / S. 1356 (Regula / Specter)**

Making appropriations for Labor, Health and Human Services, Education and Related Agencies for FY2004, includes funding for influenza vaccine stockpile purchase.

Became Public Law No. 108-199 on January 23, 2004.

**H.R. 5006 / S. 2810 (Regula / Specter)**

Making appropriations for Labor, Health and Human Services, Education and Related Agencies for FY2005. House bill has passed, Senate bill has been reported.

House and Senate bills specify funding for flu vaccine purchase.

## Hearings

House Committee on Government Reform, hearing on *The Nation's Flu Shot Shortage*, October 8, 2004.

Senate Committees on the Judiciary and Health, Education, Labor and Pensions, joint hearing on *BioShield Legislation*, October 6, 2004.

House Appropriations Committee, Subcommittee on Labor, Health and Human Services and Education, hearing on *Influenza Vaccine*, October 5, 2004.

Senate Special Aging Committee, hearing on *Influenza and the Elderly*, September 28, 2004.

House Committee on Government Reform, Subcommittee on Human Rights and Wellness, hearing on *Mercury and Autism*, September 8, 2004.

House Appropriations Committee, Subcommittee on Labor, Health and Human Services and Education, hearing on *Global Diseases Programs Appropriations*, April 28, 2004.

House Committee on Government Reform, hearing on *Health System Preparedness to Handle Health Threats*, focused on the current influenza season, February 12, 2004.

## Investigations

The House Committee on Government Reform is conducting an investigation into FDA's role in the shutdown of the Chiron plant. The Committee Chairman and Ranking Member sent a letter to the FDA Acting Commissioner, requesting information, on October 13, 2004, available at [<http://reform.house.gov/UploadedFiles/101304fdaletterrelease.pdf>].

## Information Resources

### CRS Products

CRS Report RL31793, *Vaccine Policy Issues for the 108th Congress*, by Susan Thaul.

CRS Report RS21507, *Project BioShield*, by Frank Gottron.

CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron and Eric Fischer.

CRS Report RS21747, *Avian Influenza: Multiple Strains Cause Different Effects Worldwide*, by Jim Monke.



CRS Report RL31333, *Federal and State Isolation and Quarantine Authority*, by Angie A. Welborn (discusses state and federal authority for public health emergencies).

CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Bioterrorism*, by Holly Harvey and Sarah Lister.

## **Government Accountability Office (GAO) Products**

GAO-04-1100T, *Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks*, testimony, September 28, 2004.

GAO-04-458T, *Public Health Preparedness: Response Capacity Improving, but Much Remains to Be Accomplished*, testimony, February 12, 2004.

GAO-02-987, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges*, report, September 13, 2002.

GAO-01-786T, *Flu Vaccine: Steps Are Needed to Better Prepare for Possible Future Shortages*, testimony, May 30, 2001.

GAO-01-624, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People*, report, May 15, 2001.

## **Health and Human Services (HHS) Resources**

HHS National Vaccine Program Office Home Page: general information on vaccines, and the Draft Pandemic Influenza Preparedness and Response Plan. [<http://www.hhs.gov/nvpo/>].

## **Centers for Disease Control and Prevention (CDC) Resources**

CDC Influenza Home Page: information for health professionals and the general public, including guidelines related to the current vaccine shortage, [<http://www.cdc.gov/flu/>].

CDC, Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR Recommendations and Reports, May 28, 2004, recommendations prior to announcement of the vaccine shortage for 2004-2005.

CDC National Immunization Program Home Page: information about CDC-funded vaccine purchases and related information, [<http://www.cdc.gov/nip/>].

CDC Public Health Law Program Home Page: information on state authorities and actions taken to assure priority distribution of flu vaccine, [<http://www.phppo.cdc.gov/od/phlp/Influenza.asp>].

## **Food and Drug Administration (FDA) Resources**

FDA Center for Biologics Evaluation and Research, Influenza Virus Vaccine 2004-2005 Home Page: information about Chiron, Aventis, and MedImmune vaccine production, [<http://www.fda.gov/cber/flu/flu2004.htm>].

## **Health Resources and Services Administration (HRSA) Resources**

HRSA National Vaccine Injury Compensation Program (VICP) Home Page, [<http://www.hrsa.gov/osp/vicp/INDEX.HTM>].

## **National Institutes of Health (NIH) Resources**

NIH National Institute of Allergy and Infectious Diseases influenza Home Page: [<http://www.niaid.nih.gov/dmid/influenza/>].

## **World Health Organization (WHO) Resources**

WHO Influenza Home Page at [<http://www.who.int/csr/disease/influenza/en/>].

## **Other Key Resources**

National Vaccine Advisory Committee: "Strengthening the Supply of Routinely Recommended Vaccines in the United States: Recommendations from the National Vaccine Advisory Committee," *JAMA* 290(23), December 17, 2003, pp. 3122-3128.