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Issue Brief

Protecting the Nation's Health: Ensuring a Stable Supply of Influenza Vaccine

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ABSTRACT: The looming threat of an influenza pandemic concerns government officials worldwide as they attempt to address shortages and flaws in the vaccination system. Currently, only two vaccine manufacturers are licensed for U.S. production. This fact, combined with the complexity of production, has resulted in a supply that can be easily interrupted. Policymakers are considering various options to spur research and development, stabilize the supply of vaccines, and improve their prioritization and distribution.

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Policy Context

Recent flu vaccine production problems have underscored the uncertainty of an adequate and stable vaccine supply. For the 2004–2005 flu season, the U.S. supply is about 65 million doses, compared with the 100 million expected, due to the suspension of production at one of the two vaccine manufacturers licensed by the Food and Drug Administration. Mismatches between supply and demand for vaccines in both directions have become common occurrences in recent years. The social and economic consequences of yearly influenza epidemics are significant. About 36,000 Americans die each year from influenza, and approximately 200,000 are hospitalized. The annual direct costs of medical care are estimated at $1 billion to $3 billion. When compounded with the indirect costs to business of declines in worker productivity (both from employee absenteeism due to illness and for caring for family members), costs for the 2004–2005 season are expected to total $20 billion.[1]

Challenges facing public health officials and vaccine manufacturers are symptomatic of more general problems regarding vaccine supply, which has resulted in shortages of major childhood vaccines in recent years. In

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2002, eight of the 11 recommended children's vaccines experienced shortages. Further, the looming threat of an influenza pandemic, akin to the 1918 Spanish Flu which killed up to 50 million people worldwide and 600,000 Americans, concerns government officials worldwide, as they attempt to prepare a response to such an outbreak while addressing current shortages and flaws in the system.

Influenza Vaccine Production and State of the Industry

Production of flu vaccine involves a complicated series of interconnected processes, including individuals and organizations from both the public and private sectors, domestic and international. In 2004, manufacturing difficulties at the Chiron Corporation plant in Liverpool, England, cut the U.S. supply in half—a loss of approximately 50 million doses.[2]

Vaccines are biologicals, and thus, unlike drugs, rely on biological systems. Current flu vaccine manufacturing technology relies on growing the virus strains in eggs, so-called egg-based production. This process requires long lead times and introduces variability and uncertainty into the process not present in the predictable chemical reactions used to produce drugs. For example, some viruses grow better than others—in the 2000–2001 season, difficulty growing one of the three strains led to a delay in the delivery of influenza vaccine. Contamination (as occurred in the 2004–2005 season at the Chiron plant) can render batches of vaccine unusable.

Because the prevalent strains of flu change each year, a new vaccine, containing a selection of three strains, must be produced each year.[3] The Vaccine and Related Biological Products Advisory Committee (an expert advisory committee to the FDA) reviews the global influenza surveillance data to make recommendations on the three influenza virus strains to be included in the vaccine year. Subsequently, public sector laboratories (e.g., FDA and CDC) provide these seed strains to all influenza vaccine manufacturers who then use their proprietary processes to produced the vaccines that are distributed in late summer and early fall.

The production process has remained essentially unchanged during the past 40 years. Hundreds of thousands of eggs are needed per day during the vaccine production cycle. These eggs are eight-day fertilized eggs and therefore chickens need to be lined up to produce the eggs for "just in time" delivery. If a strain not included in the vaccine emerges during the flu season, current technologies make rapid production and surge capacity next to impossible to achieve. Figure 1 details the annual production process.

The vaccine industry as a whole represents less than 2 percent of all pharmaceutical sales. Over the past 30 years, the number of vaccine manufacturers licensed for the U.S. market has declined from 30 to five. Today, only four companies make all 11 recommended children's vaccines. When vaccines are supplied by one manufacturer, or at most a few, the likelihood for disruption of the supply increases.

The consolidation of the entire vaccine market may be related to the relatively low profit margins on vaccines compared with other pharmaceuticals, though newer vaccines appear to be more profitable for manufacturers than older products.[6] Other factors thought to have made the overall vaccine market less attractive to private industry include concerns about regulatory requirements, liability,[7] as well as the large government presence in the purchase of the majority of childhood vaccines. The federal contract price is often less than half the private market price of the vaccine.

While the government plays a large role in the purchase of most childhood vaccines, the flu vaccine market is predominantly private: private purchases make up between 85–90 percent of the market, with government purchase accounting for between 10–15 percent. The public purchase price for the 2004–2005 season ranged from $6.80 to $10 per dose,[8] while private sector prices were generally higher. The government contract price

Figure 1. Outline of the Annual Process of Development, Manufacturing, and Distribution of Influenza Vaccine[4]

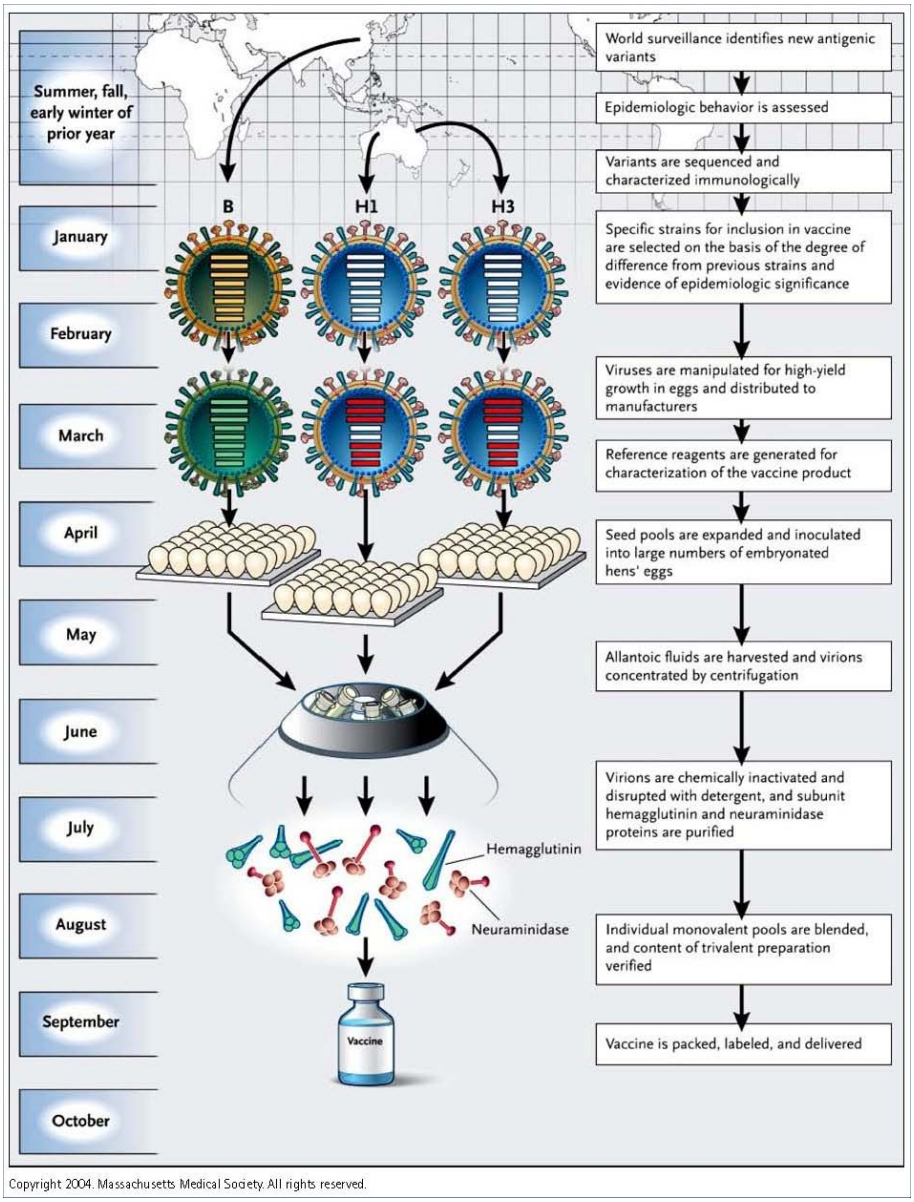

Table 1. Producers of Selected Vaccines for the U.S. Market, 2003[5]

	Number of Vaccine Producers
Haemophilus influenzae type b	3
Influenza	2
Hepatitis A	2
Hepatitis B	2
DTaP (Diphtheria and tetanus toxoids, and acellular pertussis)	2
MMR (Measles, mumps, and rubella)	1
Tetanus toxoid	1
Tetanus-diphtheria	1
Inactivated poliovirus	1
Varicella	1
Pneumococcal conjugate	1
Meningococcal	1
Pneumococcal polysaccharide	1

for influenza vaccine is among the lowest of all vaccines purchased by the government.[9]

Government reimbursement for administration of flu vaccine has increased in recent years. As of January 1, 2005, the average reimbursement to providers who deliver flu vaccine to a Medicare patient will be $19, up from $11.71 in 2001.[10] Despite increases in reimbursement, providers who administer flu vaccines may lose money: a recent study found that providers lose between $2.16 to $34.56 per dose because of varying administrative costs and Medicare reimbursement for influenza administration. Some have suggested that third-party payers should provide higher compensation to offset such losses.[11]

While about a dozen manufacturers of flu vaccine operate worldwide, only two are licensed for U.S. production of inactivated injected vaccine: France's Sanofi-Aventis and California-based Chiron Corporation.[12] This fact, and the complexity of production as discussed previously, has resulted in a supply that can be easily interrupted. Most recently, after the 2002–2003 flu season, Wyeth, citing losses of over $50 million, millions of unused doses, and the looming costs of updating its production facility to meet FDA standards,[13] exited the market.[14]

Several factors can result in a mismatch between supply and demand. Production glitches such as contamination (2004–2005 season) and difficulties growing the virus (2000–2001 season) have led to short-term shortages. Surges in demand caused by public interest or concern over access, an early and severe flu season (2003–2004 and 2004–2005 seasons) and expanded recommendations for vaccination can all increase demand. The first major innovation in flu vaccine, MedImmune's live intranasal vaccine launched in the 2003–2004 season, experienced low demand.[15]

The past several years have seen disruptions in supply, though in each case, excess vaccine went unused and the costs were absorbed by manufacturers.

Paradoxically, the flu vaccine market seems to be growing. In 2004, the Centers for Disease Control and Prevention's Advisory Committee for Immunization Practices (ACIP)[18] recommended universal flu vaccine for all children 6–23 months old and the vaccine is likely to be recommended for all Americans in coming years. Whether or not the pull of a growing market will be enough to entice manufacturers to enter the market is unclear. It can take up to five years and cost hundreds of millions of dollars to build a manufacturing facility and have it inspected and approved.[19] At the same time, the move toward non-egg-based technologies[20] may deter firms with these technologies from making necessary capacity investments.[21]

Several firms in the U.S. and abroad are experimenting with alternative production technologies in an effort to decrease the lead time and reduce dependence on egg-based production. Moving to cell-based culture (i.e., in human, monkey, or dog cells) could be especially helpful in the case of a pandemic, when fast production and surge capacity would be essential.[22] The use of reverse genetics, which would allow for more consistent isolation of the desired vaccine strains, has also been pursued as a way to improve the creation of seed strains each year.

Table 2. Surplus Flu Vaccine, 1999–2003[16]

	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[17]

Note: Numbers in millions.

The Role of Government: Efforts to Stabilize Vaccine Supply, Encourage Innovation, and Prepare for Pandemic Influenza

The government, at the federal, state, and local levels, is intimately involved in many aspects of the flu vaccine supply, including regulation, immunization promotion, disease surveillance, research on new production technologies and optimal use of existing doses, purchasing and distribution, public policy, and pandemic preparedness.[23]

Regulation

The FDA's Center for Biologics Evaluation and Research (CBER) is responsible for approving vaccines. As part of its work, the FDA inspects manufacturing facilities and licenses manufacturers. CBER also works closely with the CDC and international officials to determine the strains to be included in each year's vaccine.

New approaches to vaccine development will require close collaboration with the FDA. Acting FDA Commissioner Lester Crawford has remarked on the FDA's support of new production methods. Testifying before the Senate Special Committee on Aging, Crawford highlighted funding requests to shift vaccine development to cell-based culture and to provide for year-round availability of eggs for the egg-based vaccine. Further, Crawford discussed the FDA's efforts under the Current Good Manufacturing Practices Initiative, in which the Agency is working with industry to encourage new technologies to improve the manufacturing process.[24]

Ensuring vaccine safety is tasked to the FDA. Prior to market approval, the FDA reviews all data submitted as part of a firm's application (Biological License Application, or BLA). Once licensed, manufacturers are required to submit samples of each lot of vaccine produced. Further, in collaboration with CDC, the FDA collects data on adverse events through the Vaccine Adverse Event Reporting System (VAERS).

Immunization Promotion and Disease Surveillance

The Advisory Committee on Immunization Practices (ACIP) issues recommendations on the annual vaccination schedule. In October 2004, the CDC, in coordination with its ACIP, revised guidelines on priority populations that should receive limited supplies of vaccine, and then later, in December, relaxed the recommendations to include adults aged 50-64 and close contacts of persons in high-risk groups.[25] With the most recent shortage, the CDC, in collaboration with the sole manufacturer, Aventis, and the Association of State and Territorial Health Officials, developed a distribution plan to allocate available vaccines to high-risk patients.

The CDC is responsible for disease surveillance and therefore tracks influenza cases throughout the season across the country.[26] The Influenza Branch of the CDC, in collaboration with hundreds of centers, health departments, and epidemiologists across the globe, determines when and where influenza is circulating, detects the types of circulating strains and changes in strains, tracks influenza-related illnesses, and measures the impact influenza has on deaths in the U.S. The CDC is part of the World Health Organizations Global Influenza Surveillance Network, which tracks the emergence of flu strains in an effort to ensure the timely recognition of pandemic strains and appropriate international responses.

Research and Development

The federal government plays an active role in research related to influenza through the National Institutes of Health (NIH), the CDC, and the National Vaccine Program Office (NVPO), among others. Recently, the NIH funded research to determine the efficacy of a partial dose of influenza vaccine. Researchers found that intradermal administration resulted in the same or better immunogenicity as the standard vaccine and route of administration.[27] Further, the NIH is concerned

with basic R&D of new antivirals and cell-culture technologies.

The National Vaccine Program Office has been tasked with accelerating the development of FDA-licensed cell-culture vaccines produced in the United States. Cell-based vaccines, by shortening the timeline of vaccine production and enhancing ability to expand production capacity, would augment the supply in the event of an influenza pandemic.

Purchasing, Distribution, and the National Stockpile
In contrast to childhood vaccines, where public purchase dominates the market, most flu vaccines are purchased directly from the manufacturer or through private distributors by state governments, large employers and health plans, and private physicians. Vaccine brokers may act as middlemen between the manufacturers and end-purchasers.

There is no formal distribution network for influenza vaccine, a fact that was made clear in the most recent shortage. Because of the large private purchase market, government officials have little control over the ultimate distribution of vaccine. Recommendations made by the ACIP have no enforceability[28] and discretion over vaccine use is the purview of individual physicians and the policies of health plans, managed care organizations, and insurers.[29] A recent survey found that during the fall of 2004, 37 percent of seniors and 54 percent of adults with chronic conditions who attempted to get the flu vaccine were unsuccessful. Further, 51 percent of seniors and 63 percent of chronically ill adults did not try to get the vaccine.[30]

Purchases for the national vaccine stockpile are funded through the Vaccines for Children (VFC) program. Congress allocated $40 million to this end for both FY2004 and FY2005. The stockpile is to be used in the event of a shortage, in which case VFC-eligible children are given priority, though doses may be allocated to state and local health departments.[31]

Public Policy and Stabilization of the Yearly Supply
The federal government has considered a variety of options to stabilize the supply and encourage manufacturers to remain in the market, including stockpiling and addressing liability concerns.

One reason cited for the decline in number of vaccine manufacturers in general is that of liability, which may discourage investment in vaccines. Influenza was recently added to the list of vaccines covered under the Vaccine Injury Compensation Program, which applies to all child vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children.[32]

Other options under consideration by the government include a guaranteed purchase of vaccine each year, as well as government buybacks of excess vaccine at the end of each season.

Pandemic Preparedness
Government officials, while trying to address current supply issues, are increasingly focusing on preparation for an influenza pandemic—the emergence of a completely novel and virulent strain. The Department of Health and Human Services has awarded several grants for the production of pilot lots of pandemic influenza vaccine as well as commercial scale lot production of 2 million doses of the vaccine, and for stocking chicken eggs to produce flu vaccine year-round.

In August 2004, HHS released a draft plan for the nation's response should a pandemic occur.[33] The Government Accountability Office notes that the draft plan "leaves decisions about the purchase, distribution, and administration of vaccines open for public comment and for the states to decide individually . . . [and] does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic."[34]

Legislative Action

In the wake of the recent influenza supply disruptions, Congress included $100 million for R&D in

new technologies for flu vaccine production in the Consolidated Appropriations Act, 2005 (Public Law No. 108-447).

Congress also held a number of hearings[35] to address vaccine supply concerns during the 108th Congress. Issues raised at the hearings covered:

- Problems leading to current shortage
- Priority policies for available vaccines to ensure that high-risk individuals receive vaccines in case of shortage
- Vaccine distribution
- Tracking and surveillance of influenza activity as well as delivery of vaccine at the local level (vaccine tracking system)
- Stabilizing the future vaccine supply
- Policies to encourage manufacturers to increase supply and to enter the flu market as well as the vaccine market in general
- The role of the FDA in regulating vaccine manufacturers and inspection of plants (including foreign inspection systems)
- The role of the pricing of vaccines in affecting vaccine supply
- Price-gouging of influenza vaccine
- Role of liability concerns in the vaccine market
- Pandemic preparation

In general, the bills introduced in the 108th Congress dealing with vaccine supply issues focused on reforming vaccine distribution and providing incentives to manufacturers. For example, one bill would allow the Department of Health and Human Services to seize vaccine supplies in the event of an emergency, and would also allow HHS to assess compliance with distribution guidelines. Those bills addressing incentives faced by manufacturers would provide tax credits to those firms investing in vaccine capacity. None of these bills received action.

Conclusion

The fragility of the influenza vaccine supply has been of increasing concern. Policymakers, concerned about the annual impact of influenza and looking ahead to the potential impact of an influenza pandemic, have considered various options to spur research and development, stabilize the supply, and improve prioritization and distribution of vaccines.

Notes

[1] Kris Maher. "Flu Season Threatens Productivity," *Wall Street Journal*, page A2, October 18, 2004. Estimate of $20 billion from David Cutler, relying on estimates of days lost per worker, median hourly wage, and number of workers, personal communication.

[2] For coverage of the suspension of production at Chiron, please see: Jeanne Whalen, Pui-Wing Tam, and Sarah Lueck. "Vulnerable System. Behind the Flu Vaccine Shortage: Struggle to Police Drugs Globally," *Wall Street Journal*, page A1, November 5, 2004; Andrew Pollack. "U.S. Will Miss Half Its Supply of Flu Vaccine," *New York Times*, October 6, 2004.

[3] John Treanor. (2004) "Weathering the Influenza Vaccine Crisis," *The New England Journal of Medicine*, Vol. 351, No. 20, pp. 2037–2040, for a detailed description of the process.

[4] John Treanor. (2004) "Weathering the Influenza Vaccine Crisis," *New England Journal of Medicine*, Vol. 351, No. 20, p. 2039.

[5] From Institute of Medicine. (2004) *Financing Vaccines for the 21st Century*, p. 127, Table 5-5.

[6] Prevnar, the pneumococcal conjugate vaccine developed by Wyeth, may top sales of $1 billion this year. See Andrew Pollack. "Vaccines Are Good Business for Drug Makers," *New York Times*, October 29, 2004.

[7] Some vaccines, including all children's vaccines administered through the Vaccines for Children Program, are covered under the Vaccine Injury Compensation Program (VICP). Influenza was added to the VICP in October 2004. Individuals who are injured by vaccines must first go through the VICP. If they reject the VICP proposed award, they can then file suit in court.

[8] Sarah H. Lister. *Influenza Vaccine Shortages and Implications*, CRS Report for Congress, Congressional Research Service, October 29, 2004, p. CRS-11.

[9] See Appendix A for the CDC Vaccine Price List. http://www.cdc.gov/nip/vfc/cdc_vac_price_list.pdf.

[10] The reimbursement formula used by CMS includes 90 percent of the list price of the vaccine, no shipping and handling, and an administration fee. Unlike all other interventions, the administrative fee for adult vaccination does not include physician work credits. The administrative fee varies depending on where the vaccination is delivered. For example, Medicare-enrolled practices get smaller administrative fees than those not enrolled in Medicare. Source: Margaret Coleman, CDC, National Immunization Program, personal communication.

[11] M. Coleman et al. 2005. "Estimating Medical Practice Expenses from Administering Adult Influenza Vaccinations," *Vaccine*, Vol. 23, No. 7, 4 January 2005, pp. 915–923.

[12] FluMist, the live aerosol vaccine, is licensed for use in the United States.

[13] The FDA's Current Good Manufacturing Practices (CGMP) have been cited by Wyeth's Peter Paradiso as a reason for Wyeth's exit from influenza market. (Testimony before the Senate Committee on Aging, November 16, 2004.)

[14] David Brown. "How U.S. Got Down to Two Makers of Flu Vaccine," *Washington Post*, October 17, 2004, p. A01.

[15] One reason advanced for why FluMist has seen low demand, despite reports of shortages in the 2003–2004 season, is that the vaccine is recommended for individuals ages 5–49 years, and thus is not indicated for the more vulnerable populations, young children and the elderly, for whom the vaccine is recommended. In addition, FluMist has been priced higher than the traditional injected vaccine, and this may have led to low demand.

[16] From Sarah H. Lister. *Influenza Vaccine Shortages and Implications*, CRS Report for Congress, Congressional Research Service, October 29, 2004, p. CRS-6.

[17] Most of the 3.8 million surplus doses were FluMist.

[18] The ACIP is a panel of experts selected by the Secretary of HHS to provide advice on the most effective means to prevent vaccine-preventable diseases. The ACIP develops written recommendations for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. See http://www.cdc.gov/nip/ACIP/default.htm.

[19] Scott Gottlieb. "Vaccine Makers Get a Shot in the Arm," *Forbes*, October 11, 2004.

[20] Flu vaccine has been manufactured in chicken eggs for the past 40 years. Non-egg-based technologies in development include growing the virus in mammalian cells. Such cell-based technologies offer the potential benefits of reduced lead time, improved effectiveness, and the fact that individuals with egg allergies would be able to use them.

[21] David Brown. "How U.S. Got Down to Two Makers of Flu Vaccine," *Washington Post*, October 17, 2004, p. A01.

[22] Karen Hopkin. "Egg Beaters: Flu Vaccine Makers Look Beyond the Chicken Egg," *Scientific American*, February 23, 2004.

[23] See Appendix B for a list of government roles.

[24] Current Good Manufacturing Practices are regulations promulgated by the FDA and which require that manufacturers, processors, and packagers of drugs, medical devices, some food and blood provide safe, pure and effective products. For information on the CGMP Initiative, see Statement of Lester M. Crawford, D.V.M., Ph.D. Acting Commissioner of Food and Drugs on FDA's Ongoing Efforts to Ensure the Safety, Effectiveness, and Availability of Influenza and Other Vaccines before Special Committee on Aging United States Senate November 16, 2004. http://www.fda.gov/ola/2004/vaccines1116.html.

[25] Centers for Disease Control and Prevention (CDC). (2004). Interim Influenza Vaccination Recommendations—2004–05 Influenza Season. October 5, 2004; Centers for Disease Control and Prevention (CDC). (2004). CDC's Advisory Committee on Immunization Practices Expands

Priority Groups for Inactivated Influenza Vaccination. December 17, 2004.

[26] The CDC posts surveillance reports at http://www.cdc.gov/flu/weekly/fluactivity.htm.

[27] Richard T. Kenney et al. (2004) "Dose Sparing with Intradermal Injection of Influenza Vaccine," *New England Journal of Medicine*, Vol. 351, No. 2, November 25, 2004.

[28] In the most recent flu vaccine shortage, some states, including the District of Columbia, established fines for providers who did not follow guidelines on administration of vaccine to priority individuals. Further information can be found at http://www.astho.org. From Sarah H. Lister. *Influenza Vaccine Shortages and Implications*, CRS Report for Congress, Congressional Research Service, October 29, 2004, p. CRS-10.

[29] General Accounting Office Report to Congressional Requesters. "Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People," GAO-01-624, May 2001.

[30] Robert J. Blendon et al. "Experiences Obtaining Influenza Vaccination Among Persons in Priority Groups During a Vaccine Shortage—United States, October–November 2004," *Morbidity and Mortality Weekly Report*, Vol. 53, No. 49, pp. 1153–55, December 17, 2004.

[31] Centers for Disease Control and Prevention. Influenza Vaccine Bulletin #2: Flu Season 2004–2005 May 20, 2004.

[32] The Vaccine Injury Compensation Program was established by the National Childhood Vaccine Injury Act of 1986 (P.L.99-660) and was intended to address falling vaccination rates, the exit of vaccine manufacturers, and vaccine shortages in the early 1980s, which were blamed on the rise in litigation against manufacturers. The VICP is a no-fault system for resolving vaccine injury claims and covers all vaccines recommended by the CDC for routine administration to children. For details on the VICP, see http://www.hrsa.gov/osp/vicp/INDEX.HTM.

[33] Department of Health and Human Services. Pandemic Influenza Response and Preparedness Plan. August 2004. http://www.hhs.gov/nvpo/pandemicplan/index.html.

[34] General Accounting Office. (2004). "Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks," Testimony before the Special Committee on Aging, U.S. Senate, Statement of Janet Heinrich, Director, Health Care-Public Health Issues, September 28, 2004.

[35] Committee testimony and proceedings can be found at: http://energycommerce.house.gov/108/Hearings/11182004hearing1404/hearing.htm; http://reform.house.gov/GovReform/Hearings/EventSingle.aspx?EventID=1412; and http://reform.house.gov/GovReform/Hearings/EventSingle.aspx?EventID=1468.

Appendix A.

Vaccines for Children Program (VFC)

CDC Vaccine Price List

Prices last reviewed/updated: December 1, 2004

Vaccine	Brandname/ Tradename	Packaging	CDC Cost/ Dose	Private Sector Cost/ Dose	Contract End Date	Manufacturer
DTaP/	Tripedia® DAPTACEL®	10 pack - 1 dose vials 10 pack - 1 dose vials	$11.75 $12.75	$21.40 $22.04	3/31/05	Aventis Pasteur
DTaP/	Infanrix®	10 pack - 1 dose vials 5 pack - 1 dose T-L syringes. No Needle	$13.75 $13.75	$20.96	3/31/05	GlaxoSmithKline
DTaP-Hep B-IPV*	Pediarix®	10 pack - 1 dose vials 5 pack - 1 dose T-L syringes. No Needle	$35.48 $35.48	$70.72 $70.72	3/31/05	GlaxoSmithKline
DTaP-Hib #	TriHIBit®	5 pack - 1 dose vials	$23.40	$41.72	3/31/05	Aventis Pasteur
e-IPV•	IPOL®	10 dose vials	$10.14	$21.80	3/31/05	Aventis Pasteur
Hepatitis B-Hib^	COMVAX®	10 pack - 1 dose vials	$22.83	$43.56	3/31/05	Merck
Hepatitis A Pediatric•	VAQTA®	10 pack - 1 dose vials	$11.90	$29.62	3/31/05	Merck
Hepatitis A Pediatric•	Havrix®	1 dose vials 10 pack - 1 dose vials 5 pack - 1 dose T-L syringes. No Needle 25 pack - 1 dose T-L syringes. No Needle	$12.25 $12.25 $12.25 $12.25	$26.66	3/31/05	GlaxoSmithKline
Hepatitis A Adult•	VAQTA®	1 dose vials 10 pack - 1 dose vials	$18.75 $18.75	$62.76 $59.24	6/30/05	Merck
Hepatitis A Adult•	Havrix®	1 dose vials 1 dose T-L syringes. No Needle 5 pack - 1 dose T-L syringes, No Needle	$18.50 $18.50 $18.50	$52.40	6/30/05	GlaxoSmithKline
Hepatitis A-Hepatitis B Adult^	Twinrix®	1 dose vials 10 pack - 1 dose vials 5 pack - 1 dose T-L syringes, No Needle	$36.91 $36.91 $36.91	$77.41	6/30/05	GlaxoSmithKline
Hepatitis A-Hepatitis B 18 only^	Twinrix®	1 dose vials 10 pack - 1 dose vials 5 pack - 1 dose T-L syringes, No Needle	$36.91 $36.91 $36.91	$77.41 $77.41 $77.41	3/31/05	GlaxoSmithKline
Hepatitis B• Pediatric/Adolescent	ENGERIX B®	1 dose vials 10 pack - 1 dose vials 5 pack - 1 dose T-L syringes, No Needle 25 pack - 1 dose T-L syringes, No Needle	$9.50 $9.50 $9.50 $9.50	$21.37	3/31/05	GlaxoSmithKline
Hepatitis B• Pediatric/Adolescent	RECOMBIVAX HB®	10 pack - 1 dose vials	$9.00	$23.20	3/31/05	Merck
Hepatitis B 2 dose• ¤Adolescent (11-15)	RECOMBIVAX HB®	10 pack - 1 dose vials	$24.25	$59.09	3/31/05	Merck
Hepatitis B-Adult•	RECOMBIVAX HB®	1 dose vials 10 pack - 1 dose vials	$24.50 $24.50	$58.95 $58.34	6/30/05	Merck

Appendix A.

Vaccines for Children Program (VFC)

CDC Vaccine Price List

continued

Vaccine	Brandname/ Tradename	Packaging	CDC Cost/ Dose	Private Sector Cost/ Dose	Contract End Date	Manufacturer
Hepatitis B-Adult•	ENGERIX-B®	1 dose vials 5 pack - 1 dose T-L syringes, No Needle 25 pack - 1 dose T-L syringes, No Needle	$24.25 $24.25 $24.25	$48.65	6/30/05	GlaxoSmithKline
Hib•	PedvaxHIB®	10 pack - 1 dose vials	$9.95	$22.77	3/31/05	Merck
Hib•	ActHIB®	5 pack - 1 dose vials	$7.65	$21.78	3/31/05	Aventis Pasteur
Influenza¤	Fluzone®	10 dose vials	$6.80	$8.50	4/30/05	Aventis Pasteur
Influenza	Fluzone® Pediatric dose Preservative-free	10 pack - 1 dose syringes	$10.00	$12.00	4/30/05	Aventis Pasteur
Influenza¤	Fluvirin®	10 dose vials	$7.54	$8.50	4/30/05	Chiron Corp.
Influenza (Live, Intranasal)	FluMist™	Pack of 10 Single-dose Sprayers	$13.49	$22.50	3/31/05	MedImmune Vaccines, Inc.
MMR/	MMRII®	10 pack - 1 dose vials	$16.25	$38.05	3/31/05	Merck
Pneumococcal 7-valent• (Pediatric)	Prevnar®	5 pack - 1 dose vials	$51.58	$61.65	3/31/05	Wyeth/Lederle
Pneumococcal Polysaccharide (23 Valent)	Pneumovax®	10 pack of 5 dose vials	$13.65	$21.99	6/30/05	Merck
Tetanus & Diphtheria Toxoids ¤ ^	Tetanus & Diphtheria Toxoids Adsorbed for Adults	15 dose vials	$9.75	$11.99	6/30/05	Massachusetts Biologic Labs (Henry Schein Inc.)
Tetanus & Diphtheria Toxoids^	DECAVAC™	10 pack – 1 dose syringes No Needle	$15.90	$17.50	3/31/05	Aventis Pasteur
Varicella•	Varivax®	10 pack - 1 dose vials	$48.00	$62.78	3/31/05	Merck

/ Vaccine cost includes $2.25 dose Federal Excise Tax
Vaccine cost includes $3.00 per dose Federal Excise Tax
^ Vaccine cost includes $1.50 per dose Federal Excise Tax
* Vaccine cost includes $3.75 per dose Federal Excise Tax
• Vaccine cost includes $0.75 per dose Federal Excise Tax
¤ Vaccines which contain Thimerosal as a preservative

Appendix B. Government Agencies Involved in Immunization

Health and Human Services (HHS)

National Vaccine Program Office (NVPO)

Coordinates vaccine-related activities in several HHS agencies; responsible for federal influenza pandemic preparedness. http://www.hhs.gov/nvpo

National Vaccine Advisory Committee (NVAC).

NVAC advises the director of the NVPO on ways to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to achieve optimal prevention of adverse reactions to vaccines. http://www.hhs.gov/nvpo/nvac/

Centers for Disease Control and Prevention (CDC)

National Immunization Program (NIP)

Provides leadership for the planning, coordination, and conduct of immunization activities nationwide. http://www.cdc.gov/nip/default.htm

Advisory Committee on Immunization Practices (ACIP)

Develops written recommendations for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. http://www.cdc.gov/nip/ACIP/default.htm

Vaccines for Children Program (VFC)

Purchases vaccines for uninsured children, Medicaid recipients, Native Americans and Alaska natives, as well as the national stockpile. http://www.cdc.gov/nip/vfc/Default.htm

Immunization Grant Program (317 grant program)

The 317 grant program works to ensure that children, adolescents, and adults receive appropriate immunizations by partnering with health providers in the public and private sectors. Through this program, established in 1963, the CDC provides federal grants to state, local, and territorial public health agencies for program operations and vaccine purchases. http://www.cdc.gov/programs/immun04.htm

Food and Drug Administration (FDA)

Center for Biologics Evaluation and Research (CBER)

Responsible for ensuring the safety and efficacy of vaccines, including inspecting manufacturing plants and granting licenses. http://www.fda.gov/cber/

Vaccines and Related Biological Products Advisory Committee (VRPBAC).

VRPBAC reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products that are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs. http://www.fda.gov/cber/advisory/vrbp/vrbpmain.htm

Appendix B. Government Agencies Involved in Immunization* (continued)

National Institutes of Health (NIH)
Supports both intramural (at NIH) and extramural research. http://www.nih.gov

Centers for Medicare and Medicaid Services (CMS)
CMS reimburses providers for a variety of vaccinations, including influenza. http://www.medicare.gov

Health Resources and Services Administration (HRSA)

Vaccine Injury Compensation Program (VICP)
Provides compensation for injuries caused by vaccination. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. The VICP covers all vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. http://www.hrsa.gov/osp/vicp/INDEX.HTM

Advisory Commission on Childhood Vaccines (ACCV)
The Advisory Commission on Childhood Vaccines advises and makes recommendations to the Secretary on matters related to VICP responsibilities. http://www.hrsa.gov/osp/vicp/accv.htm

Department of Defense (DOD)

Conducts research and development of vaccines, administers vaccines to personnel, retirees and their families and veterans (through the Veterans Health Administration). http://www.vaccines.army.mil/

State and Local Governments

Responsible for establishing and enforcing school vaccination requirements, ensuring administration to high-priority individuals, and tracking immunization.

* Sources: Sarah A. Lister. (2004). Influenza Vaccine Shortages and Implications. Congressional Research Service, RL32655; Institute of Medicine. (2004). Financing Vaccines for the 21st Century; Web sites as referenced above. This list is not exhaustive.

Other issue briefs produced for The Commonwealth Fund/John F. Kennedy School of Government 2005 Bipartisan Congressional Health Policy Conference

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