

CRS Report for Congress

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Vaccine Policy Issues

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Summary

This report's focus is on vaccination, one of the most cost-effective methods available to prevent infectious diseases. Whether a vaccine's target is naturally occurring or present because of hostile intent, the issues policy makers must deal with include vaccine development, production, availability, safety, effectiveness, and access. Vaccines are biologics: their basic components begin as living material. They introduce bacteria or dead or weakened viruses into a person or animal to stimulate an immune reaction that the body will remember if assaulted by the same pathogen in the future.

There is no central federal authority for vaccine policy. In the Department of Health and Human Services (HHS), the National Vaccine Program Office (NVPO) coordinates vaccine-related activities, and the Food and Drug Administration (FDA) is responsible for the regulation of vaccines and other biologics. Also involved in vaccine activities are other components of HHS (e.g., the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), the Departments of Defense, Veterans Affairs, and Homeland Security, and the U.S. Agency for International Development.

Concerned about bioterrorist attacks in the United States, the 107th Congress passed several vaccine-related measures and the 108th Congress continued with legislative and oversight activities regarding the development and purchase of vaccines against possible bioterrorist attacks and dealing with the sudden shortage of influenza vaccine at the outset of the 2004-2005 flu season.

Obstacles to vaccine availability — such as production costs, concern for liability expenses, weak markets, and difficulties in predicting need — often have economic roots. As mechanisms to enhance availability, Congress may consider financial incentives, public-private partnerships, improved coordination, and alternatives to safety and effectiveness documentation.

A pillar of U.S. policy on drugs and vaccines is the protection of the individuals who use them. FDA does not license a product for sale in the United States until it is satisfied that the vaccine is safe and effective. Scientists, clinicians, Members of Congress, and the public must make decisions of vaccine safety despite uncertainties and varying perceptions of risk. To ameliorate the difficulties, Congress could address post-licensure adverse-event surveillance, education and risk communication, studies in pharmacoepidemiology and pharmacoeconomics, and improving available mechanisms to compensate individuals injured by vaccinations.

Successful development and production of safe and effective vaccines does not ensure that everyone who needs a vaccine gets it. Congress may take up the coordination of government childhood immunization programs and financing levels and strategies for vaccine-related care. Noting concern for health needs of developing countries, some Members seek to increase access to existing vaccines and to spur development of affordable vaccines for global health threats. This report will be updated as warranted.

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Vaccine Policy Issues

Vaccines are almost staple topics in daily U.S. media. Television news viewers have known about a flu vaccine shortage and that heated differences of opinion highlight discussions of possible risks involved in both routine childhood immunizations and vaccinations that the U.S. military requires of its personnel. Some may even have heard that scientists recently announced some success with a malaria vaccine.

This report's focus is on vaccination, one of the most cost-effective methods available to prevent infectious diseases. Whether a vaccine's target is naturally occurring or present because of hostile intent, the issues to address include vaccine development, production, availability, safety, effectiveness, and access.

Background

What Is A Vaccine?

Vaccines are *biologics* — their basic components begin as living material — that introduce “weakened or killed disease-causing bacteria, viruses, their components”¹ (such as proteins, recombinant proteins, or polysaccharides) or toxoids into a person or animal to stimulate an immune reaction that the body will remember if exposed to the same pathogen in the future. Most vaccines are given by injection.

Although many people use the words *vaccination*, *immunization*, and *inoculation* interchangeably, the terms are not technically synonymous. *Vaccination* is “the physical act of administering any vaccine ...” and *immunization* is a “more inclusive term denoting the process of inducing or providing immunity artificially by administering an immunobiologic.”² *Inoculation* also involves introducing a microorganism but not necessarily intentionally; the term *vaccination* was coined to mean intentional inoculation with the vaccinia virus that causes cowpox to provoke an immune response to protect against the smallpox virus.

¹Food and Drug Administration (FDA), “Vaccines Provide Effective Protection and FDA Makes Sure They are Safe,” *Just the Facts*, FDA Publication No. FS 02-6, Feb. 2002, at [<http://www.fda.gov/opacom/factsheets/justthefacts/19vaccine.html>], visited Nov. 22, 2004.

²Centers for Disease Control and Prevention, General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices, *Morbidity and Mortality Weekly Report (MMWR)*, 1994;43 (No. RR-1).

The U.S. Food and Drug Administration (FDA) licenses 46 vaccines, covering 20 diseases, now available for public use in the United States.³ Dozens more are in active development; research teams worldwide are working to develop vaccines against tuberculosis, malaria, HIV/AIDS, Alzheimer's disease, some cancers, and other diseases of which most Americans have never heard. The National Immunization Program, part of the U.S. Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP), issues recommended immunization schedules for children, adolescents, and adults in the United States.⁴

Procedures for the Approval and Regulation of Biologics

FDA procedures to approve a biologic for marketing in the United States follow the same basic format as the procedures for new drug approvals.⁵ Animal testing is extensive, including the safety assessment of the viruses grown in animal or human cells. After satisfactory animal safety testing, clinical trials in humans begin.

Phase I clinical trials, which include a small number of human volunteers, test for safety. The sponsor continues with Phase II and Phase III trials to gather evidence of the biologic's effectiveness in larger groups of individuals, while continuing to monitor safety data. If the product remains feasible, the sponsor, based on data collected in the clinical trials, submits two license applications to FDA: a product license for the vaccine and an establishment license for the manufacturing plant.

FDA scientists review the clinical data, along with the proposed labeling and manufacturing protocols; inspect the manufacturing facility to assess whether it can produce a consistent product; and performs test on the vaccine and its components. Advisory committees, made up of experts from outside of FDA, also review the data, are available for consultation, and make recommendations to FDA regarding approval.

Because contamination is a greater threat with vaccines than with drugs because they are made from living organizations, FDA maintains an active presence even after a vaccine is approved. It requires extensive testing of vaccines and all

³A smallpox vaccine is available only through DOD or CDC programs. Vaccines Licensed for Immunization and Distributed in the U.S., information last updated Sept. 21, 2004, at [<http://www.fda.gov/cber/vaccine/licvacc.htm>], visited Oct. 16, 2004.

⁴For 2004, ACIP recommendations, which vary by age and medical conditions of potential recipients, include vaccines for diphtheria, *Haemophilus influenzae* type b, hepatitis A, hepatitis B, influenza, measles, meningococcal disease, mumps, pertussis, pneumococcal disease, polio, rubella, tetanus, and varicella (chicken pox) ([<http://www.cdc.gov/nip>], visited Oct. 25, 2004).

⁵The FDA website provides links related to the FDA approval process for biologics; for example: Isadora B. Stehlin, How FDA Works to Ensure Vaccine Safety, *FDA Consumer*, Dec. 1995, at [http://www.fda.gov/fdac/features/095_vacc.html]; and Michelle Meadows, Understanding Vaccine Safety: Immunization Remains Our Best Defense Against Deadly Disease, *FDA Consumer*, July - Aug. 2001, at [http://www.fda.gov/fdac/features/2001/401_vacc.html].

ingredients (e.g., diluents, preservatives, or adjuvants) for characteristics including identity, purity, and potency. FDA continues to assess the production process, too, including samples of each lot and data regarding purity and potency.

Finally, because even large clinical trials can identify only common potential adverse effects, FDA maintains postmarketing surveillance programs and sometimes works with a manufacturer in Phase IV studies of long term safety and effectiveness.

Stakeholders

Many groups have a stake in vaccine-related issues, including the government entities responsible for research and development, licensing, post-licensing surveillance of adverse reactions, provision of health care, protection of the population, interstate and international trade, intellectual property protections, and homeland security.

There is no central authority for vaccine policy within the federal government. In the Department of Health and Human Services (HHS), the National Vaccine Program Office (NVPO) coordinates vaccine-related activities and the FDA is responsible for the regulation of human vaccines and other biologics.⁶ The National Institutes of Health (NIH) conducts intramural vaccine research and development and funds research in universities, for example. CDC, charged with protecting the health and safety of the population, houses the National Immunization Program (NIP) and its ACIP, which work to coordinate nationwide activities, including the Vaccines for Children (VFC) program and the state immunization grants program.⁷ CDC also

⁶In the United States, FDA — mostly within its Center for Biologics Evaluation and Research (CBER) — bears the responsibility for vaccine regulation, primarily under the authorities granted the Secretary of HHS in the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. To receive a license from FDA to market a vaccine, the sponsor (often the manufacturer) must demonstrate to the satisfaction of FDA that the product is safe and effective for human use. Data to support those claims come, primarily, from clinical trials. Once a product is approved, the sponsor must comply with detailed Good Manufacturing Practices (GMPs) and regulations concerning the surveillance of adverse reactions among individuals receiving the vaccine. FDA policies regarding vaccine approval are similar to FDA policies for prescription drugs. See CRS reports focusing on drugs: CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV; CRS Report RL30913, *Pharmaceutical Research and Development: A Description and Analysis of the Process*, by Richard E. Rowberg; and CRS Report RS20033, *Food and Drug Administration: Selected Funding and Policy Issues*, by Donna U. Vogt.

⁷Following a congressional directive in P.L. 99-660, in 1986 HHS established a National Vaccine Program within the Public Health Service's Office of the Assistant Secretary for Health to coordinate vaccine research, development, safety and efficacy testing, and production and procurement across federal agencies. Transferred organizationally in 1994 to CDC and then back to HHS, the National Vaccine Program Office manages the Inter-Agency Vaccine Group and the National Vaccine Advisory Committee, and works toward achieving the National Vaccine Plan [published in 1994], which involves "pursuing the prevention of infectious diseases through immunizations" (<http://www.hhs.gov/nvpo>],
(continued...)

maintains the Strategic National Stockpile (SNS), which includes some vaccines against bioterror agents. The National Vaccine Injury Compensation Program (VICP), which is jointly administered by the Health Resources and Services Administration (HRSA), where it is located, and the U.S. Court of Federal Claims and the U.S. Department of Justice, “provides compensation for injuries judged to have been caused by certain vaccines.”⁸ Also administered from HRSA is the Smallpox Vaccine Injury Compensation Program, set up in 2003.⁹

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. DOD administers routine and deployment-related vaccines to military personnel and some civilian employees and contractors. As a primary health care provider, DOD also administers vaccines as necessary to its retirees and current personnel and their families. The Department of Veterans Affairs administers vaccines to U.S. veterans who seek care in its facilities. The U.S. Agency for International Development (USAID) supports routine immunization programs in developing countries and works to reduce the impact of vaccine-preventable disease worldwide. State and local governments conduct vaccine activities within their public health role, such as conducting vaccine clinics, maintaining immunization registries, and establishing immunization requirements for school attendance. Veterinary biologics are regulated by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, under authority of the Virus, Serum and Toxin Act. These products must meet similar standards of safety, efficacy, purity and potency as do human products.

Interested parties outside government include individuals and private entities, both for-profit and not-for-profit, such as current and potential vaccine recipients and their families, employers offering health care benefits, insurers, traditional vaccine manufacturers, biotechnology firms, trade associations such as the Pharmaceutical Research and Manufacturers of America, academic biomedical researchers, economists, trial lawyers, health care professionals and institutions, and patient and disease-specific advocacy groups.

Laws Approved by the 107th Congress

Concerned about bioterrorist attacks in the United States, the 107th Congress approved several bills that included vaccine-related issues:

The USA PATRIOT Act (P.L. 107-56) includes a sense-of-Congress statement expressing the need to provide funding for bioterrorism preparedness and response (Section 1013); the National Defense Authorization Act for Fiscal Year 2002 (P.L.

⁷(...continued)
visited Nov. 10, 2004).

⁸The National Vaccine Injury Compensation Program home page is at [<http://www.hrsa.gov/osp/vicp>], visited Nov. 4, 2004.

⁹The Smallpox Vaccine Injury Compensation Program home page is at [<http://www.hrsa.gov/smallpoxinjury>], visited Nov. 4, 2004.

107-107) directs the Secretary of Defense to accelerate research, development, and production of items such as vaccines for defense against biological agents used as weapons, and includes authorization to build a government-owned contractor-operated vaccine production facility (Section 1044). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) directs the HHS Secretary to undertake specific activities with regard to national stockpiles of drugs and vaccines and the accelerated approval of high-priority countermeasures (Sections 121-126).

The Homeland Security Act (HSA) of 2002 (P.L. 107-296) protects manufacturers and health care workers who administer the smallpox vaccine from tort liability and restricts that liability assumed by the United States to negligence of those parties (Section 304). Other sections of the HSA of 2002 that related to vaccines have since been repealed.^{10,11}

Legislative Activity in the 108th Congress

The 108th Congress passed some vaccine-related legislation. The Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20) created a mechanism to compensate individuals who, in response to a Secretarial request for smallpox vaccine preparedness, are injured by the vaccinia virus used in smallpox vaccines. Vaccinees and their contacts are eligible for medical care expense reimbursement, lost income benefit, and death benefits, administered through the HHS Health Resources and Services Administration.¹² Other enacted laws that include references to vaccine coverage or funding are the Consolidated Appropriations Resolution, 2003 (108-7); the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (P.L. 108-25); the National Defense Authorization Act for Fiscal Year 2004 (P.L. 108-136); the Medicare Prescription Drug, Improvement, and

¹⁰These CRS reports, most produced to support discussion of homeland security, address vaccine-related issues: CRS Report RL31960, *Smallpox Vaccine Injury Compensation*, by Susan Thaul; CRS Report RL31864, *High-Threat Biological Agents: Characteristics, Effects, and Policy Implications*, by Dana A. Shea; CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Angie A. Welborn; CRS Report RL31694, *Smallpox Vaccine Stockpile and Vaccination Policy*, by Judith Johnson; CRS Report RL31649, *Homeland Security Act of 2002: Tort Liability Provisions*, by Henry Cohen; CRS Report RL31354, *Possible Impacts of Major Counter Terrorism Security Actions on Research, Development, and Higher Education*, by Genevieve J. Knezo; and CRS Report RL31263, *Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law*, by C. Stephen Redhead, Donna U. Vogt, and Mary E. Tiemann.

¹¹H.J.Res. 2 (P.L. 108-7, Division L, Section 102) repealed Sections 1714-1716 of the HSA of 2002, which would have covered adverse effects attributed to thimerosal, a mercury-containing vaccine preservative, within the National Vaccine Injury Compensation Program. The Project BioShield Act of 2004 (P.L. 108-276, Section 3) returned the Strategic National Stockpile (of drugs and vaccines) to the Dept. of Health and Human Services, undoing Sections 502 and 503 of the HSA of 2002, which had transferred management responsibility to the Dept. of Homeland Security.

¹²For more detail, see CRS Report RL31960, by Thaul.

Modernization Act (P.L. 108-173); and the Consolidated Appropriations Resolution, 2004 (P.L. 108-199).

Dozens of bills relating to vaccine research, purchase, and coverage were introduced in the 108th Congress. The Improved Vaccine Affordability and Availability Act (S. 754), introduced by Senate Majority Leader Frist, received the most attention, but scheduled markups of the bill were postponed several times in spring 2003. The bill would “amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program....” In fall 2004, in response to the sudden shortage of influenza vaccine, additional bills were introduced and several hearings were held.¹³

Continuing Legislative Issues

In its final three sections, this report organizes the range of legislative issues pertaining to vaccines that Members of Congress may consider into three groups:

- availability,
- safety and effectiveness, and
- access.

Cost — of research, development, production, regulation and oversight, for example — underlies each of these concerns.

Availability

Thirty-seven American companies made vaccines in 1967; in October 2004, there were nine.¹⁴ Why? Reasons given are mostly economic. The road to a shot in the arm can take decades of research and development and, according to industry estimates, about \$800 million per licensed vaccine,¹⁵ requiring great financial reserves to sustain a company through the research and development and clinical trial process. Once a vaccine is licensed, its continued production remains complex, as the 2004-2005 flu vaccine shortage in the United States illustrates.

¹³CRS Report RL32655, *Influenza Vaccine Shortage and Implications*, by Sarah A. Lister and Erin D. Williams, includes a comprehensive listing of legislation.

¹⁴Rino Rappuoli, Henry I. Miller, Stanley Falkow, The Intangible Value of Vaccination, *Science*, v. 297, Aug. 9, 2002, p. 937; and FDA, Vaccines Licensed for Immunization and Distributed in the US, information updated Sept. 2004, at [<http://www.fda.gov/cber/vaccine/licvacc.htm>].

¹⁵Pharmaceutical Research and Manufacturers of America (PhRMA), PhRMA Industry Profile 2002. Researchers at the Tufts Center for the Study of Drug Development added in the cost of post-approval studies and revised the estimate to \$897 million (News Release, May 13, 2003, at [<http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>], visited Nov. 23, 2004).

Problems

Production Costs. Because vaccines are biologics, even routine manufacture involves care, expertise, and expense much beyond that required for pharmaceuticals. To produce a drug, the manufacturer essentially repeats a chemical formula. Vaccines require dedicated production facilities that include physical and chemical barriers to protect workers from pathogen exposure and finely regulated temperature and ventilation to keep the biologics viable while stored. Also, because the product is injected, the purity standard has to be much higher than for a pill. Although FDA inspects both drug- and vaccine-production facilities, it inspects every lot of vaccine produced and only a sample of drug production lots.¹⁶

For example, manufacturers ceased production of licensed vaccines against plague because of manufacturing difficulties, and against adenovirus infection because of contract cost issues. To restart production, these or other manufacturers must submit new license applications to FDA, conform to current good manufacturing practice standards, and demonstrate the safety and effectiveness of the new vaccines — all before they can make the vaccine available to the public.

Production Failures. In October 2004, when the U.S. manufacturer Chiron announced that the British drug regulatory authorities had shut its Liverpool plant, the United States was instantly plunged into a flu vaccine shortage. Chiron was slated to supply approximately half of the vaccine for U.S. use in the 2004-2005 flu season. The British agency — and then with FDA concurrence — found some bacterial contamination and manufacturing practices that could not assure the safety of the rest of the vaccine production.¹⁷

Liability. Why go to the trouble for a product that does not promise the sales volume common to pharmaceuticals — particularly when manufacturers may be liable if vaccines cause injury? The huge claims for compensation that followed the swine flu immunization program in the mid-1970s have made the vaccine industry wary. Manufacturer executives recall, for example, discussions of unindemnified liability in their decisions to decline plans to produce anthrax or Lyme disease vaccines.

Market. For some diseases, scientists know how to produce protective vaccines but manufacturers have chosen not to pursue the time-consuming and expensive steps necessary to obtain FDA approval. For some, there is insufficient market size in the United States to warrant the effort. An example is the tick-borne encephalitis vaccine that DOD administered to troops in Bosnia during the 1990s. Although licensed in Europe where the disease-carrying ticks are more widespread, the vaccine is not FDA-licensed. To get FDA approval requires U.S. clinical trials

¹⁶FDA, Vaccine Frequently Asked Questions (FAQs), Center for Biologics Evaluation and Research, at [<http://www.fda.gov/cber/faq/vacfaq.htm>], visited Nov. 10, 2004.

¹⁷See CRS Report RL32655, *Influenza Vaccine Shortage and Implications*, by Sarah A. Lister, for an extended discussion of the issues.

for safety. Neither the interested manufacturer nor DOD has been willing to bear the expense of those trials.¹⁸

Malaria, tuberculosis, and HIV/AIDS kill 7 million and sicken 400 million worldwide each year.¹⁹ Yet, aside from HIV, manufacturers have little incentive to develop vaccines because U.S. incidence is low, involving mostly travelers or immigrants and their contacts, and preventive and treatment medications are readily available. In countries where vaccines could make a big difference, few resources are available to support development or purchase. Interestingly, private benefactors have been stepping in to support public-good-focused research. The Bill and Melinda Gates Foundation, for example, gave \$150 million to the Malaria Vaccine Initiative, which announced in October 2004 initial findings that a malaria vaccine it is developing with industry was somewhat effective in young children.²⁰

Planning. Finally, difficulties with planning can render even licensed vaccines temporarily unavailable. In 2002, such problems created shortages of licensed vaccines for eight of the 11 vaccine-preventable childhood diseases.^{21,22,23}

Aside from production set-backs, influenza vaccine poses a perennial challenge involving choice of vaccine components and amount to manufacture. Each year, public health authorities and manufacturers analyze worldwide surveillance information to determine which flu virus strains are likely to put humans at risk in the coming year. Sometimes, the viral strain that most threatens the U.S. public is

¹⁸U.S. Army Medical Materiel Development Activity Information Paper, Tick-Borne Encephalitis Virus Vaccine, dated Sept. 30, 2004, at [<http://www.usamma.army.mil/info335.pdf>], visited Oct. 25, 2004.

¹⁹Joint United Nations Programme on HIV/AIDS, Global summary of the AIDS epidemic, Dec. 2004, at [http://www.unaids.org/wad2004/EPI_1204_pdf_en/Chapter0-1_intro_en.pdf]; World Health Organization (WHO), Tuberculosis, fact sheet no. 104, revised March 2004, at [<http://www.who.int/mediacentre/factsheets/fs104/en/print.html>]; and WHO, What is Malaria, Roll Back Malaria information sheet, at [http://www.rbm.who.int/cmc_upload/0/000/015/372/RBMInfosheet_1.htm], all visited Nov. 23, 2004.

²⁰Pedro L. Alonso, Jahit Sacarlal, John J. Aponte, Amanda Leach, et al., Efficacy of the RTS,S/AS02A vaccine against *Plasmodium falciparum* infection and disease in young African children: randomised controlled trial, *The Lancet*, v. 364, issue 9443, pp. 1411-1420, Oct. 16, 2004.

²¹Robin J. Strongin, U.S. Childhood Vaccine Availability: Legal, Regulatory, and Economic Complexities, National Health Policy Forum Issue Brief, no. 785, Nov. 15, 2002, at [<http://www.nhpf.org/pubs/pubs.htm#2002>].

²²Questions and Answers on 2002 Vaccine Shortages, National Immunization Program, at [http://www.cdc.gov/nip/news/shortages/faqs_shortages_3-7-02.htm#s1], and Current Vaccine Delays and Shortages, NIP, at [<http://www.cdc.gov/nip/news/shortages/default.htm#Which>], both visited Nov. 23, 2004.

²³As of Oct. 2004, the NIP reports a shortage of only influenza vaccine among all CDC-recommended vaccines for children and adolescents. Current Vaccine Delays and Shortages, NIP, at [<http://www.cdc.gov/nip/news/shortages/default.htm#Which>], visited Oct. 25, 2004.

not among those chosen for that year's vaccine, the situation in 2003 when vaccine developers could not formulate a *Fujian* component in time for the season's distribution.²⁴

Because influenza changes slightly each year, healthy adults have partial immunity to new strains; each year, the virus typically makes healthy people sick, but not too sick. Several times a century, however, the virus changes enough that there is no partial immunity. This situation can lead to rapid worldwide spread of the virus, called an influenza pandemic, with severe illness and death, even in healthy people, and possible serious disruptions in services and social order. Some have expressed concern that the problems evident in the national response to the 2004-2005 flu vaccine shortage serve as a relevant drill — and warning — for pandemic preparedness.²⁵

Also a topic of international surveillance and planning is avian influenza (“bird flu”) — an influenza strain affecting poultry in Asia — in anticipation of its possible joining with a viral strain that infects humans. Rather than a unique circumstance, this international investigation is part of the intensive, ongoing process of animal and human (clinical and laboratory) surveillance, testing, and action that is public health practice. For example, CDC laboratories collaborate with the World Health Organization in testing and describing avian viruses to help in developing a potential vaccine.²⁶

Possible Legislative Solutions

Congress may consider at least four kinds of measures to enhance vaccine availability: financial incentives, public-private partnerships, improved coordination, and alternatives to safety and effectiveness documentation.

Financial Incentives. Most people in the United States now view protections against bioterrorism or biowarfare agents, such as vaccines, as in the public interest. Many also so categorize all vaccines, whether intended against naturally occurring or bioterror-related infectious diseases. The bottom line in persuading companies to produce vaccines is largely one of opportunity cost: whether they can afford to put aside other potentially lucrative projects to do so.

Over the years, Members of Congress have proposed changes to the Internal Revenue Code involving tax credits for certain vaccine research and distribution activities to effectively lower the cost to manufacturers. Another way to provide a financial incentive is to assure that a primary purchaser is available to generate demand for the vaccine. When the government is the primary purchaser, such as for

²⁴See CRS Report RL32655, by Lister; and Questions and Answers: The 2003-2004 Flu Season, CDC, at [<http://www.cdc.gov/flu/about/qa/0304season.htm>], visited Nov. 22, 2004.

²⁵See CRS Report RL32655, by Lister.

²⁶CDC, Avian Influenza, at [<http://www.cdc.gov/flu/avian/>] and World Health Organization, Avian influenza, at [http://www.who.int/csr/disease/avian_influenza/en/], both visited Nov. 22, 2004.

anthrax or smallpox vaccines, it can develop contracts with manufacturers that address volume, liability protection, and long-term plans, for example, that make production practical.

In his 2003 State of the Union speech, President George W. Bush proposed a federal initiative, Project BioShield, to encourage private industry to develop medical countermeasures to bioterrorism threats. The Project BioShield Act of 2004 was signed into law in July 2004 (P.L. 108-276).²⁷

Liability. Because some manufacturers have named liability concerns among reasons to forgo vaccine production, legislative proposals have addressed indemnification, liability insurance, and injury compensation plans. Protection of potential manufacturers, seen as a necessary incentive to participation, was included in the Homeland Security Act of 2002 and the Smallpox Emergency Personnel Protection Act of 2003. The American Jobs Creation Act of 2004²⁸ added the influenza vaccine to those that the National Vaccine Injury Compensation Program covers.

Partnerships. Some Members of Congress have expressed interest in industry consortia or public-private partnerships to accelerate vaccine research and development and manufacture. This may involve considering issues of intellectual property protection among collaborators and anti-trust law accommodations to allow private manufacturers to make joint decisions. Such partnerships have been recommended as ways to spread financial risk, thus making vaccines available for diseases that are prevalent among small or impoverished groups.

Improved Coordination. Better coordination among federal regulators, private manufacturers, government scientists, and purchasers could avoid many supply shortages, such as occurred with childhood vaccines in 2002. Coordination could also shorten the time between initial research and product licensure. Policy analysts look for mechanisms to streamline FDA administrative — but not human safety and effectiveness assurance — procedures. Some, including the Institute of Medicine (IOM), have suggested establishing a National Vaccine Authority.²⁹ Two other IOM committees, in DOD-sponsored reports addressing naturally occurring infectious diseases³⁰ and biowarfare agents,³¹ recommended better coordination

²⁷For a fuller discussion of the legislative activity, 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.

²⁸P.L.108-357, signed by the President on Oct. 22, 2004.

²⁹Council of the Institute of Medicine, Statement on Vaccine Development, Nov. 5, 2001, at [<http://www.iom.edu/report.asp?id=5487>], visited Nov. 23, 2004.

³⁰IOM, *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military*, Stanley M. Lemon, Susan Thaul, Salem Fisseha, Heather C. O'Maonaigh, editors, Washington, D.C., National Academies Press, 2002.

³¹IOM, *Giving Full Measure to Countermeasures: Addressing the DOD Program to Develop* (continued...)

within the DOD vaccine acquisition programs and between DOD and other entities, particularly HHS. These groups anticipate that a coordinated decision and budget authority could present a coherent front to private manufacturers and within government. After the 2002 reports, DOD assigned vaccine acquisition responsibilities to a higher administrative level³² and interagency agreements and working groups have been formed. Cutting down on frustrations arising from getting different answers or timetables from different offices could make vaccine work more appealing to those in research and development and manufacture.

While almost any change in research and development, production, monitoring, and sales would involve FDA, some questions focus on FDA itself. These include the extent to which its budget limits the scope and timeliness of its activities. Some analysts suggest that FDA standards are too high to be reasonably feasible.

Sometimes all the necessary pieces of potential solutions exist, but without an organizing force. For years, various representatives of HHS, DOD, and private manufacturers had met over contracts to develop and produce vaccines to protect, for example, against smallpox and anthrax. The September and October 2001 attacks on the U.S. population quickly dissolved the sticking points. Political will — and its ability to get all the right people and their checkbooks in the room at the same time — fueled action to acquire smallpox vaccine, both doses of previously made and licensed product and contracts to develop new products. In the years since then, HHS has announced contracts to develop new vaccines against smallpox, plague, and tularemia;³³ and, with Project BioShield funding, a second-generation anthrax vaccine will be stored in the Strategic National Stockpile.³⁴

Ensuring Safety and Effectiveness May Delay Availability. It takes a long time from the start of clinical trials to FDA licensure.³⁵ Many observers

³¹(...continued)

Medical Countermeasures Against Biological Warfare Agents, Lois M. Joellenbeck, Jane S. Durch, and Leslie Z. Benet, editors, Washington, D.C., National Academies Press, 2004.

³²First Joint Program Executive Office for Chemical and Biological Defense Formed, U.S. DOD News Release [http://www.defenselink.mil/news/Apr2003/b04252003_bt277-03.html] dated April 25, 2003, visited Nov. 23, 2004; and DOD briefing (by COL David Danley and others) to CRS staff, Apr. 30, 2003.

³³HHS, HHS Awards \$232 Million in Biodefense Contracts for Vaccine Development, *News Release*, Oct. 7, 2004, at [<http://www.hhs.gov/news/press/2004pres/20041007a.html>].

³⁴HHS, HHS Continues to Strengthen Umbrella of Protection from Bioterrorism, *News Release*, Sept. 10, 2004, at [<http://www.hhs.gov/news/press/2004pres/20040910.html>].

³⁵PhRMA cites research estimating 10 to 15 years from idea to FDA approval (J.A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, *Journal of Health Economics*, v. 22, pp. 151–185, 2003, cited in *Pharmaceutical Industry Profile 2004*, Washington, D.C., PhRMA, 2004, at [<http://www.phrma.org/publications/publications/2004-03-31.937.pdf>]). FDA performance standards call for review of a new drug or biologics application within 10 months of submission (6 months for priority review), goals it met over 95% of the time in 2002 (FDA, FY 2003 Performance Report to Congress, at

consider much of that time as necessary to ensure that vaccines produced and sold are safe and effective. FDA has formal mechanisms to expedite the review process: fast-track drug development, priority review, and accelerated approval. Its “Animal Rule” and provisions under the Project BioShield Act of 2004 also support shorter time from idea to approved public use.³⁶ The Congress could assess the extent to which the laws that direct HHS and DOD to facilitate or accelerate research and development and approval of bioterrorism countermeasures as well as needed vaccines for serious conditions³⁷ are succeeding and consider legislative ways to help those processes along.

Fast-Track Mechanism. The Food and Drug Administration Modernization Act of 1997 (FDAMA, P.L. 105-115) described a “Fast Track” mechanism whereby the manufacturer and FDA discuss development plans and strategies before the formal submission of a Biologics License Application (BLA, for a vaccine application, for example) or a New Drug Application (NDA, for a drug). The early interaction can help clarify goals and work through obstacles that would delay approval decisions if they became evident only at BLA submission.³⁸

Accelerated Approval. For the treatment of a serious or life-threatening illness, FDA regulations allow “accelerated approval” of a biologic product that provides a “meaningful therapeutic benefit ... over existing treatments.” The approval is based on clinical trials that, rather than using standard outcome measures such as survival or illness, use “a surrogate endpoint that is reasonably likely ... to predict clinical benefit.” FDA usually requires postmarketing studies of biologics approved this way.³⁹

Animal Rule. Scientists use clinical trials and field trials to test a vaccine’s effectiveness. Clinical trials designed to test vaccines for most infectious diseases usually involve random assignment of individuals to groups — members of one group are given the new vaccine and members of the other (the control group) are

³⁵(...continued)

[<http://www.fda.gov/oc/pdufa/report2003/orgnpas2003.html>]).

³⁶Cynthia L. Kelley, Senior Advisor for Counterterrorism Medical Countermeasures, FDA Center for Biologics Evaluation and Research, “Fast-Tracking Biodefense Vaccines and Therapeutics: An Urgent Challenge We Must Meet,” presentation prepared for the Third Annual Research, Technologies and Applications in Biodefense, Washington, D.C., Aug. 18, 2004, at [<http://www.fda.gov/cber/summaries/biodef081804ck.pdf>]; and William E. Egan, Acting Director, FDA Office of Vaccines Research and Review, “Routes to Expedite Vaccine Approvals,” presentation prepared for the World Vaccine Congress, Lyon, France, Oct. 2004, at [<http://www.fda.gov/cber/summaries/worldvacc101104we.pdf>].

³⁷The FDA Modernization Act of 1997 (FDAMA, P.L. 105-115); the National Defense Authorization Act for Fiscal Year 2002 (P.L. 107-107); and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188).

³⁸FDA, Guidance for Industry, Fast Track Drug Development Programs — Designation, Development, and Application Review, at [<http://www.fda.gov/cber/gdlns/fsttrk.pdf>], visited Nov. 9, 2004.

³⁹21 CFR 601 subpart E, Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses.

given a placebo or an existing licensed vaccine — to assess whether the investigational vaccine would effectively prevent disease. When the disease under study has no known treatment and has severe outcomes (including death), it is unethical to challenge human research subjects, because if the vaccine is not effective, the subjects are irreparably harmed. Field trials, in which scientists observe naturally occurring disease among vaccinated and unvaccinated groups, are not feasible for diseases that occur sporadically or would occur only in the context of bioterror or biowarfare action. For these reasons, researchers and regulators may sometimes need alternative models for demonstrating vaccine effectiveness.

In 2002, FDA published its long-debated final Animal Efficacy Rule. The regulations apply only “when adequate and well-controlled clinical studies in humans cannot be ethically conducted and field efficacy studies are not feasible.” They allow submission of data from animal studies of effectiveness as evidence to support licensure applications of new drug and biological products that target “serious or life-threatening conditions” in humans.⁴⁰ It could apply, for example, to inhalational anthrax, for which there is no surrogate of immunity and no natural endemic disease. Although no vaccine has yet been approved under this rule, FDA used the rule for the first time in February 2003 to approve a drug.⁴¹ Congress may follow the implementation of this rule and discuss alternative actions in its oversight of safety, effectiveness, and availability goals.

Priority Review. Unlike Fast Track, Accelerated Approval, or Animal Rule activities, the Priority Review process begins only when a manufacturer officially submits a BLA (or an NDA). Priority Review, therefore, does not alter the steps taken in a drug’s development or testing for safety and effectiveness. It does, however, for products believed to address unmet needs, shorten the anticipated amount of time until approval decision from 10 months to 6 months.⁴²

Medical Countermeasures to Bioterrorism Attack. Although FDA, NIH, and DOD had been working on vaccines against potential bioterrorism or biowarfare agents, the events of September and October 2001 infused the efforts with resources and political capital. Product development was supported with increased interaction among and within government agencies and with manufacturers, and consideration of fast track, accelerated approval, and animal efficacy mechanisms to bring products to review. The Project BioShield Act of 2004 allows the HHS Secretary (with directions regarding potential risk and benefit and required recordkeeping) to authorize the emergency-use of products that do not have FDA approval in the event of potential serious or life-threatening effects of a biological agent for which there

⁴⁰21 CFR, Parts 314 and 601; FDA, New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible, Final rule, *Federal Register*, vol. 67, no. 105, pp. 37988-37998, May 31, 2002, at [<http://www.gpoaccess.gov/fr/advanced.html>], visited Nov. 23, 2004.

⁴¹FDA Approves Pyridostigmine Bromide as a Pretreatment Against Nerve Gas. *FDA News*, Feb. 5, 2003, at [<http://www.fda.gov/bbs/topics/NEWS/2003/NEW00870.html>], visited Nov. 23, 2004.

⁴²FDA, Oncology Tools: Fast Track, Priority Review and Accelerated Approval, CDER, at [<http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm>], visited Nov. 8, 2004.

is no approved product. Other provisions of the Act address spending authority for medical countermeasure (such as vaccines) development and purchase.

Safety and Effectiveness

A pillar of U.S. policy on drugs and vaccines is the protection of the individuals who use them. Vaccines cannot be marketed within the United States without a license from FDA; and FDA does not license a product until it is satisfied that the vaccine is safe and effective and that the manufacturing process can produce it. Congress may be called upon again to discuss issues of both safety and effectiveness. This could mean assessing how safe is *safe*. It will also mean defining effectiveness: absolute or simply better than nothing or better than the available alternative? It can also mean assessing effectiveness in terms of value-for-cost.

Safety is assessed by the nature and frequency of adverse reactions attributable to vaccine use. A vaccine need not be side-effect free for FDA licensure; the licensed smallpox vaccine carries an estimate, based on data from its routine use 30 years ago, of one or two deaths per million recipients. Similarly, effectiveness does not mean that a vaccine must protect permanently or completely. Researchers attempt to assess *efficacy*, generally, with expensive and lengthy clinical trials that compare infection or illness rates in two groups, both exposed to the disease-causing agent, but with only one provided with the hypothesized vaccine protection. *Effectiveness* describes how the product works in a real-world situation. For drugs, effectiveness is often lower than efficacy because of interactions with other medications or health conditions of the patient, sufficient dose or duration of use not prescribed by the physician or followed by the patient, or use for a off-label condition that had not been tested. Because vaccines are administered by the clinician, some of these conditions are not relevant. Effectiveness may, however, still be diminished by the health of the vaccinee and whether circumstances permit all shots in a required series to be given according to schedule.

FDA and CDC monitor safety, in part, with their Vaccine Adverse Event Report System (VAERS), which assembles reports from parents, clinicians, and manufacturers of problems that may be related to vaccination. Another FDA program, MedWatch, informs the public with clinical information about safety issues involving vaccines and other medical products. These so-called *passive* surveillance systems rely on consumers and physicians to both recognize adverse events as possibly vaccine-related and to follow through with reporting their concern to FDA. Such reports are valuable aids to researchers looking for potential risks. The picture painted by the data, however, is incomplete.⁴³

⁴³The FDA webpage that gives an overview of VAERS describes strengths and limitations of the reporting system ([<http://www.fda.gov/cber/vaers/what.htm>]).

Problems

Side-Effects. Some scientists, parents, and consumer advocates raise concerns that U.S. vaccine policy, with its recommended 20 shots to infants by age two,⁴⁴ endangers the children it aims to protect. They cite hypotheses that the vaccines or preservatives or packaging might cause autism and other neurodevelopmental disorders. One focus has been on thimerosal, a mercury-containing preservative used in some vaccines. In this case, even though the science is not definitive,⁴⁵ manufacturers have chosen to reformulate many vaccines so thimerosal is not used.

An example of the government's interagency system to protect vaccine recipients involves the rotavirus vaccine that the CDC Advisory Committee on Immunization Practices had added to the list of recommended infant vaccinations in 1998. During the year of mass use, VAERS flagged reports of bowel obstruction soon after rotavirus vaccination; CDC recommended suspending those vaccinations until it could study the apparent association. In October 1999, after scientific review of the data, the ACIP withdrew its earlier recommendation that the rotavirus vaccine be given to infants.⁴⁶

Insufficient Knowledge and Inadequate Risk Communication. Often, decisions of vaccine safety revolve around perceptions of risk, methodologic limits of risk assessment, and communication of what is known about risks. Scientists, clinicians, Members of Congress, and public policy analysts continue to face choices on risk — hypothetical and real — that do not offer clear alternatives. These involve uncertainties, both scientific and political, and, therefore, will reflect personal and communal values. Smallpox vaccination policy, for example, must weigh risks and benefits whose balance may differ when considered from the perspective of the nation or the perspective of the individual.

Knowledge, therefore, is not an issue only for public policy. Some parents refuse pertussis (whooping cough) and measles vaccines for their children out of concern about vaccine safety. In some of these cases, and in polio vaccine refusals

⁴⁴CDC, Parents Guide to Childhood Immunization, NIP, at [<http://www.cdc.gov/nip/publications/Parents-Guide/pg-app1-sched.pdf>], visited Oct. 25, 2004.

⁴⁵The Immunization Safety Review Committee of the Institute of Medicine reported in 2001 that it “was unable to conclude, however, from the existing evidence whether thimerosal does or does not cause neurodevelopmental disorders” (IOM, *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*, Kathleen Stratton, Alicia Gable, Marie C. McCormick, editors, Washington, D.C., National Academies Press, 2001). Three years later, having reviewed additional scientific studies, the IOM authoring committee concluded that the evidence “favors rejection” of the idea that either the measles-mumps-rubella vaccine or thimerosal-containing vaccines cause autism (IOM, *Immunization Safety Review: Vaccines and Autism*, Washington, D.C., National Academies Press, 2004).

⁴⁶ACIP's rotavirus vaccine fact sheet is at [<http://www.cdc.gov/nip/publications/fs/Rotavirus.htm>], visited Nov. 15, 2003.

(reportedly based on misinformation about side effects) in developing countries seeking to eliminate disease,⁴⁷ avoidable and potentially horrible diseases still occur.

How can anyone decide whether getting immunized is worth the risk? Implementation of government decisions concerning anthrax vaccination was hindered by concern about similar questions of uncertainty. Some members of the U.S. armed forces balked at mandatory anthrax vaccination, raising questions of safety. In October 2004, DOD stopped its anthrax vaccination program following a U.S. District Court for the District of Columbia injunction. The Court based its action on its finding that FDA had not solicited public comment on its finding that the vaccine was safe and effective for protection against inhalational anthrax.⁴⁸

Assessment of Competing Products. Comparisons of effectiveness among all available products and between a new product and others already on the market are possible. One could compare multiple single vaccines with various combined (polyvalent) products, or currently licensed smallpox vaccine with both the diluted form being tested and products now in the development pipeline. Industry and university researchers have worked on some analyses of safety, effectiveness, and cost. Is there enough detail and rigor in these comparative studies? How can legislators assess the merits of the debate over side effects — and a proper remedy for injury? Or ensure sound research about competing products? Or that the public is better informed?

Production of Generic Biologics. Vaccines have not been prime candidates for generic production in part because of the technologic difficulties in measuring whether two products are equivalent. In fact, the Hatch-Waxman Act (The Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417) amendments to the FDCA that deal with Abbreviated New Drug Applications were not matched with a provision for abbreviated applications for biologics licenses under the Public Health Service Act. Now, manufacturers and the public are looking to newer biotechnology procedures as a possible route to lower medical costs.⁴⁹

Possible Legislative Solutions

Improving Post-Licensure Adverse-Event Surveillance. Congressional approval of the National Childhood Vaccine Injury Act of 1986 (P.L. 99-660) set into

⁴⁷CDC, Progress Toward Global Eradication of Poliomyelitis, Jan. 2003-April 2004, *Morbidity and Mortality Weekly*, vol. 53, no. 24, June 25, 2004, pp. 532-535, at [<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5324a5.htm>]; and Amy Waldman, Distrust Reopens the Door for Polio in India, *The New York Times*, Jan. 19, 2003.

⁴⁸AVIP, Anthrax Vaccine Immunization Program Pause, Oct. 27, 2004, at [<http://www.anthrax.osd.mil/resource/policies/policies.asp>], visited Dec. 13, 2004.

⁴⁹Lester M. Crawford, Acting Commissioner of Food and Drugs, HHS, “The Law of Biologic Medicine,” statement before the Committee on the Judiciary, U.S. Senate, June 23, 2004, at [<http://www.fda.gov/ola/2004/fob0623.html>]; and Arman H. Nadershahi and Joseph M. Reisman, Generic Biotech Products: Provisions in Patent Drug Development Law, *BioProcess International*, Oct. 2003, pp. 26-31, at [<http://www.knobbe.com/Pages/art10.htm>], visited Nov. 2, 2004.

motion the VAERS activities in FDA and CDC for monitoring vaccine adverse events. Congress may choose to strengthen surveillance programs such as VAERS, address data coordination, and communicate surveillance analyses in ways that build trust among concerned parents and patient advocacy groups.

When it comes to smallpox, Congress has acknowledged the need for the consistent documentation of vaccine administration and side effects along with coordination of the many related federal, state, and local activities.⁵⁰ As the smallpox immunization program proceeds, Congress may want to review the completeness of the surveillance program and the usefulness of its output.

Education and Risk Communication. Websites for HHS offices, including CDC, the National Immunization Program, the Advisory Committee on Immunization Practices, and the National Vaccine Program Office, and others have hundreds of links to consumer-oriented health information, addressing reasons to immunize, common misconceptions, safety, and even “evaluating immunization information on the Internet.”⁵¹ CDC and state health departments also try to ensure that all health care providers are handing out the federally requested Vaccine Information Statements each time a vaccine is administered.⁵²

Despite such Internet efforts and others, government education programs are not reaching all who should be immunized or who have reservations. Congress might consider additional approaches to public communication of risk and medical choices.

Studies in Pharmacoepidemiology and Pharmacoeconomics. Some legislators, in considering cost, would broaden the analysis to include value-for-cost, arguing that if the government is going to consider paying for drugs, it may as well pay for the most effective ones. Researchers are adapting the study design and statistical methods of epidemiology and economics, along with those fields’ traditional way of framing research questions, to questions regarding drugs and vaccines.

Because declarations of comparative effectiveness could affect manufacturers’ market share and individuals’ access to drugs and vaccines, the success of that activity could depend, in part, on all stakeholders’ trusting in the unbiased and expert credentials of the entity analyzing and presenting the comparisons. Some have suggested that the government, a public-private group, or a “quasi-governmental” institution perform this function.⁵³ Others may feel such analysis is too fraught with uncertainty for government decisions and is best left to individual physicians.

⁵⁰For example, in P.L. 107-188, Title XXVIII, Section 2801.

⁵¹The National Immunization Program website [<http://www.cdc.gov/nip>] has a link to the National Network for Immunization Information, Parents: Evaluating Information on the Web, at [<http://www.immunizationinfo.org/parents/evaluatingWeb.cfm>], visited Nov. 23, 2004.

⁵²CDC, Vaccine Information Statements, at [<http://www.cdc.gov/nip/publications/vis/>].

⁵³Gail R. Wilensky, How to Curb Spending on Drugs, *The Washington Post*, editorial, Feb. 15, 2004.

In its Medicare legislation, the 108th Congress directed the HHS Agency for Healthcare Research and Quality (AHRQ) to “conduct and support research” dealing with “the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs)....”⁵⁴ How to fund these activities — and to what extent — remains a topic of debate.

Compensation. For those times when safety efforts have been unsuccessful, earlier Congresses have addressed compensation. Since its creation by Congress in 1986, the National Vaccine Injury Compensation Program (VICP)⁵⁵ has made many awards, primarily to families of children, following injuries deemed to have been associated with ACIP-recommended vaccinations. For several years, sentiment has been growing in Congress that modifications to the program are needed to make it more fair and efficient. Senator Bill Frist proposed changes to VICP in his Improved Vaccine Affordability and Availability Act (S. 754, introduced April 1, 2003); committee mark-up of the bill has been postponed indefinitely.⁵⁶

As the nation began to vaccinate certain military personnel and civilian health care workers against smallpox, some Members of Congress discussed proposals that would create non-tort mechanisms for smallpox vaccine injury compensation. On April 30, 2003, President Bush signed the Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20), which the House and Senate had adapted from the Administration’s proposal. It includes provisions to pay for smallpox vaccine injury-related medical care, lost employment income under specified circumstances, and death benefits. HRSA published the required injury table in August 2003⁵⁷ and the administrative guidelines for the Smallpox Vaccine Injury Program in December 2003.⁵⁸ Because the perceived urgency for smallpox vaccination diminished coincidentally with the compensation program’s passage, it remains theoretical to what extent the program would have succeeded in recruiting volunteers.

Access

Successful development and production of a safe and effective vaccine does not ensure that everyone who needs a vaccine gets it. People have to (1) know about it and believe it will benefit them; (2) live near a health care provider willing to administer it; and (3) be able to afford the cost of vaccination and follow-up care, if necessary.

⁵⁴Section 1013, P.L. 108-173.

⁵⁵The National Vaccine Injury Compensation Program fact sheet is at [http://www.hrsa.gov/osp/vicp/fact_sheet.htm], visited Nov. 15, 2004.

⁵⁶Mary Agnes Carey, Parties Seek Bicameral Compromise On Child Vaccine Compensation Bill, *CQ Weekly*, May 17, 2003, p. 1192, at [<http://www.cq.com>], visited Nov. 10, 2004.

⁵⁷Smallpox Vaccine Injury Compensation Program: Smallpox (Vaccinia) Vaccine Injury Table, Interim Final Rule, Health Resources and Services Administration, *Federal Register*, vol. 68, no. 166, Aug. 2003.

⁵⁸Smallpox Vaccine Injury Compensation Program: Administrative Implementation; Interim Final Rule, HRSA, *Federal Register*, vol. 68, no. 241, Dec. 16, 2003.

Problems

Vaccines fare better than prescription drugs in health benefits coverage in the United States. In 2002, 75% of U.S. children between 19 and 35 months old had completed the recommended series of vaccinations, not yet reaching the HHS Healthy People 2000 and 2010 objectives of 80%. Recommended adult immunization rates are even farther from HHS goals: 66% of non-institutionalized adults at least 65 years of age reported receiving a flu vaccine within the past year, far less than the HHS goal of 90% by 2010.⁵⁹ Also, there are regional and economic disparities in access to immunization services. Reasons given for these problems include insufficient coordination of varying eligibility rules among private insurers and government vaccine programs; incomplete documentation of immunizations achieved; and inadequate financing.⁶⁰

As federal and state agencies coordinated options and plans for smallpox vaccination, weaknesses in the U.S. public health infrastructure became apparent. These include the need for improvements in technology, training, hospital and laboratory capacity, and communication among participants.⁶¹ In many developing countries, inadequate public health infrastructure overshadows any question of access. Congress has gone beyond a domestic focus and showed legislative interest in the lack of access to vaccines in less developed areas around the world.

Possible Legislative Solutions

Congress has the opportunity to touch on access to safe and effective vaccines in its consideration of prescription drug benefit bills and broader issues involving global health.

Coordination of Government Financing Programs. Individual states and assorted federal programs work toward increasing childhood immunization rates. To improve immunization rates among U.S. children as well as the financial efficiency of the efforts, legislative discussions could address difficulties of coordination among the publicly funded vaccine programs, such as Medicaid, the State Children's Health Insurance Program, and Vaccines for Children.

Adult immunization insurance coverage and government financing is less complete. Although Medicare covers the major, recommended vaccines for adults, such as influenza and pneumococcal infections, many younger adults have no

⁵⁹These and other data collected and analyzed by CDC are available at, for example, [<http://www.healthypeople.gov/document/html/objectives/14-24.htm>] and [<http://www.cdc.gov/nchs/data/hsr/tables/2003/03hus051.pdf>], both visited Nov. 10, 2004.

⁶⁰IOM, *Calling the Shots: Immunization Finance Policies and Practices*, Washington, D.C., National Academy Press, 2000; and IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability*, Washington, D.C., National Academies Press, 2003.

⁶¹CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Bioterrorism*, by Holly Harvey and Sarah Lister.

coverage for these routinely recommended vaccines. Congress may consider funding levels and financing strategies for vaccine-related care in the United States.

Payment for Vaccination and Follow-Up Care. In the context of medical countermeasures to bioterrorism attacks, such as the smallpox vaccine, Congress may consider questions about the payment for the vaccine administration and, then, for follow-up and treatment, if necessary, of vaccine-related illness. As other vaccine countermeasures are developed, Congress may need to consider who would have access to that continuum of medical care.⁶²

Global Health. Concerns about access to vaccines are not limited to biodefense and domestic use. Many government agencies and private groups work toward international health objectives, such as eradicating polio. Some Members noted concern for public health needs of developing countries worldwide and the need to assist those countries in fights against infectious diseases. Their concern stemmed from both humanitarian impulses and a growing awareness of the links between poor health and economic and political instability. Their work resulted in P.L. 108-25, the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003. Legislators may want to increase access to existing vaccines, spur the development of affordable new vaccines for which the technology already exists — an issue of both availability and access, and consider increased long-term investment in vaccine development for these diseases

⁶²See also: National Vaccine Advisory Committee, Strengthening the Supply of Routinely Recommended Vaccines in the United States: Recommendations from the National Vaccine Advisory Committee, *Journal of the American Medical Association*, vol. 290, no. 23, Dec. 17, 2003, pp. 3122-3128; R. Giffin et al., Childhood Vaccine Finance And Safety Issues, *Health Affairs*, vol. 23, no. 5, Sep./Oct. 2004, pp. 98-111; and F.A. Sloan et al., The Fragility of the U.S. Vaccine Supply, *New England Journal of Medicine*, vol. 351, Dec. 2, 2004, pp. 2443-2447.