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Vaccine Policy Issues for the 108th Congress

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Summary

The President's decision to proceed with smallpox immunization of military personnel and front-line civilian public health workers has galvanized public and congressional attention to federal vaccine policy. The issues raised by smallpox vaccination are essentially the same as those for vaccines for seemingly more mundane diseases. Vaccines are biologics: their basic components begin as living material. They introduce dead or weakened viruses or bacteria 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 authority for vaccine policy within the federal government. 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 the Department of Health and Human Services (e.g., the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), and the Departments of Defense, Veterans Affairs, and Homeland Security.

Concerned about bioterrorist attacks in the United States, the 107th Congress approved several bills that included vaccine-related issues. Dozens of other vaccine-related bills did not pass; some issues will likely be revisited during the 108th. The issues can be characterized as availability, safety and effectiveness, and access.

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, such as fast-track approvals.

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; it has already worked to improve 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 threats such as HIV/AIDS, malaria, and tuberculosis.

This report will be updated as warranted.

Contents

Vaccine Policy Issues for the 108th Congress

For most Americans, vaccines mean routine childhood immunizations and annual adult flu shots. There are other uses as well; military personnel and travelers also use vaccines to protect against diseases rare in the United States. In 2002, one unusual decision galvanized awareness of the federal vaccine policy issues that the 108th Congress would face: the President's decision to proceed with the immunization of military personnel and front-line civilian public health workers against the risk of hostile use of smallpox.

Although the nation's focus on homeland security may be new, the issues raised by smallpox vaccination are essentially the same as those for vaccines for seemingly more mundane diseases: these include vaccine development, production, availability, safety, effectiveness, and access. Hence, this report's focus is on vaccination, one of the most cost-effective methods available to prevent infectious diseases.

Background

What Is A Vaccine?

Vaccines are *biologics* — their basic components begin as living material — that introduce dead or weakened viruses or bacteria into a person or animal to stimulate an immune reaction that the body will remember if assaulted by 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. The Advisory Committee on Immunization Practices defines *vaccination* as "the physical act of administering any vaccine ..." and *immunization* as a "more inclusive term denoting the process of inducing or providing immunity artificially by administering an immunobiologic."[1]

Forty-seven vaccines are FDA-licensed and available for public use in the United States.[2] Dozens more are in active development; research teams worldwide

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[1] Centers 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).

[2] Vaccines Licensed for Immunization and Distributed in the U.S., information last updated

(continued...)

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 and its Advisory Committee on Immunization Practices, issues recommended immunization schedules for children, adolescents, and adults in the United States.[3]

Stakeholders

Many groups have a stake in vaccine-related issues, including the government entities responsible for research and development, licensing, post-licensing surveillance of side effects, 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 Food and Drug Administration (FDA) is responsible for the regulation of vaccines and other biologics.[4] The National Institutes of Health conducts intramural vaccine research and development and funds research in universities, for example. The Centers for Disease Control and Prevention (CDC), charged with protecting the health and safety of the population, houses the National Vaccine Program and the National Immunization Program and its Advisory Committee on Immunization Practice, which work to coordinate nationwide activities.[5] The Vaccine Injury Compensation

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[2] (...continued)
December 2002 [http://www.fda.gov/cber/vaccine/licvacc.htm], visited May 22, 2003.

[3] For 2003, National Immunization Program recommendations, which vary by age and chronic medical conditions of potential recipients, include vaccines for hepatitis B, diphtheria, tetanus, pertussis, *Haemophilus influenzae* Type b, polio, measles, mumps, rubella, varicella (chicken pox), pneumococcal disease, hepatitis A, influenza, and meningococcal disease [http://www.cdc.gov/nip], visited May 22, 2003.

[4] In the United States, FDA 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 and regulations concerning the surveillance of side-effects 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 RL30980, *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.

[5] Following 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 (continued...)

Program, which is jointly administered by the Health Resources and Services Administration, 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."[6]

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, and the National Strategic Stockpile, which includes some vaccines, is in the portfolio of the newly established Department of Homeland Security. State and local governments conduct vaccine activities within their public health role.

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 U.S., 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. 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 Secretary of Health and Human Services to undertake specific activities with regard

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[5] (...continued)
production and procurement across federal agencies. Transferred organizationally in 1994 to CDC, 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.cdc.gov/od/nvpo/who.htm], visited May 22, 2003.

[6] The National Vaccine Injury Compensation Program fact sheet is at [http://www.hrsa.gov/osp/vicp/fact_sheet.htm], visited May 22, 2003.

to national stockpiles of drugs and vaccines and the accelerated approval of high-priority countermeasures (Sections 121-126).

The Homeland Security Act 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); transfers overall authority for maintaining national stockpiles of drugs and vaccines to the Secretary of the new Department of Homeland Security (Section 1705); and covers adverse effects attributed to thimerosal, a mercury-containing vaccine preservative, within the National Vaccine Injury Compensation Program (Sections 1714-1716).[7,8]

Legislative Issues for the 108th Congress

The 108th Congress has already considered some of the issues addressed in the dozens of vaccine-related bills that did not pass during the 107th Congress and will likely revisit others. For this report, the range of legislative issues that may be considered during this session are organized into three groups:

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

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[7] These CRS reports, produced to support discussion of homeland security, address vaccine-related issues: CRS Report RL31694, *Smallpox Vaccine Stockpile and Vaccination Policy*, by Judith Johnson; CRS Report RL31354, *Possible Impacts of Major Counter Terrorism Security Actions on Research, Development, and Higher Education*, by Genevieve J. Knezo; CRS Report RL31649, *Homeland Security Act of 2002: Tort Liability Provisions*, by Henry Cohen; 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; and CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Angie A. Welborn.

[8] The 108th Congress repealed the thimerosal liability provision in the Homeland Security Act of 2002 Amendments in H.J.Res. 2 (P.L. 108-7, Division L, Section 102).

Availability

Thirty-seven American companies made vaccines in 1967; in 2002, there were ten.[9] 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,[10] requiring great financial reserves to sustain a company through the trial and error process. Once a vaccine is licensed and in the field, its continued production remains complex.

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. Every lot produced must be inspected.

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 manufacturing practice standards, and demonstrate the safety and effectiveness of the new vaccines — all before they can make the vaccine available to the public.

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 protecting 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

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[9] Rino Rappuoli, Henry I. Miller, Stanley Falkow, The Intangible Value of Vaccination, *Science*, v. 297, Aug. 9, 2002, p. 937.

[10] Pharmaceutical Research and Manufacturers of America, 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 [http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29], visited May 22, 2003.

for safety. Neither the interested manufacturer nor DOD has been willing to bear the expense of those trials.[11]

Malaria, tuberculosis, and HIV kill 5 million and sicken 300 million worldwide each year.[12] 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.

Planning. Finally, even licensed vaccines can become temporarily unavailable. In 2002, supply shortages of licensed vaccines for eight of the 11 vaccine-preventable diseases caused significant concern among public health officials.[13]

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.

In the 107th Congress, several bills 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 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

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[11] U.S. Army Medical Material Development Activity Information Paper, Tick-Borne Encephalitis Virus Vaccine, dated March 31, 2003 [http://www.usammda.army.mil/info335.pdf], visited May 22, 2003.

[12] World Health Organization, HIV, TB and Malaria — Three Major Infectious Disease Threats, Backgrounder No. 1, July 2000 [http://www.who.int/inf-fs/en/back001.html], visited May 22, 2003.

[13] Robin J. Strongin, U.S. Childhood Vaccine Availability: Legal, Regulatory, and Economic Complexities, National Health Policy Forum Issue Brief, no. 785, November 15, 2002.

countermeasures to bioterrorism threats. The Senate and the House are each considering legislation based on that proposal.[14]

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 possible 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 efficacy — procedures. Some, including the Institute of Medicine, have suggested establishing a National Vaccine Authority.[15] An Institute of Medicine committee, in a DOD-sponsored report, recommended better coordination within the DOD vaccine acquisition programs and between DOD and other entities, particularly HHS.[16] These groups anticipate that a coordinated decision and budget authority could present a coherent front to private manufacturers and within government. After those reports, DOD assigned vaccine acquisition responsibilities to a higher administrative level.[17] It is too early to assess whether the changed organizational focus will yield better coordination. 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 its budget limits the scope and timeliness of its activities and how current reorganization activities within FDA might affect its scientific responsibilities.

Sometimes all the necessary pieces of potential solutions exist, but without an organizing force. For years, various representatives of HHS, DOD, and private

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[14] See CRS Report RS21507, *Project BioShield*, by Frank Gottron, for a fuller discussion of the legislative activity on S. 15, introduced by Senator Judd Gregg, and H.R. 2122, introduced by Representative Billy Tauzin.

[15] Council of the Institute of Medicine, Statement on Vaccine Development, Nov. 5, 2001 [http://www.iom.edu/iom/iomhome.nsf/pages/Vaccine+Development?OpenDocument], visited May 22, 2003.

[16] Institute of Medicine, *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.

[17] First 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 May 22, 2003; and DOD briefing (by COL David Danley and others) to CRS staff, Apr. 30, 2003.

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.

Ensuring Safety and Effectiveness Delays Availability. It takes a long time from the start of clinical trials to FDA licensure. Many observers consider much of that time as necessary to ensure that vaccines produced and sold are safe and effective. FDA regulators have expressed some interest recently in two legislative proposals that address ways to shorten time-to-approval — all under limited and strictly controlled conditions. These are fast-track approvals and alternatives to randomized controlled trials.

Fast Track Approvals. The 108th Congress may discuss what fast-track mechanisms FDA might consider for its approval of new vaccines, specifically, and, more generally, possible regulatory changes to expedite standard approvals. Congress could include these issues in any oversight of laws that direct HHS and DOD to accelerate research and development and approval of bioterrorism countermeasures (e.g., P.L. 107-107 and P.L. 107-188).

Alternatives to Randomized Controlled Trials. Clinical trials designed to test vaccines for most infectious diseases usually involve random assignment of individuals to groups — members of one group are given vaccine and members of the other (the control group) are not — followed by intentional challenge with the causative agent. When the disease under study has no known treatment and has severe outcomes (including death), it is unethical to challenge human research subjects: if the vaccine is not effective, the subjects are irreparably harmed. For that reason, researchers and regulators now seek alternative models for demonstrating vaccine effectiveness.

In 2002, FDA published its long-debated final animal rule. The regulations would apply only "when adequate and well-controlled clinical studies in humans cannot be ethically conducted and field efficacy studies are not feasible." The regulations now 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.[18] Although no vaccine has yet been approved under this new rule, FDA used the rule for the first time in February 2003 to approve a drug.[19] Congress may follow the implementation of this rule and discuss alternative actions in its oversight of safety, effectiveness, and availability goals.

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[18] 21 CFR, Parts 314 and 601; *Federal Register*, vol. 67, no. 105, pp. 37988-37998, May 31, 2002 [http://www.gpoaccess.gov/fr/advanced.html], visited May 22, 2003.

[19] FDA Approves Pyridostigmine Bromide as a Pretreatment Against Nerve Gas. *FDA News*, February 5, 2003 [http://www.fda.gov/bbs/topics/NEWS/2003/NEW00870.html], visited May 22, 2003.

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. Congress probably will be called upon this year 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 considering assessing effectiveness in terms of value-for-cost.

Safety is assessed by the nature and frequency of adverse effects 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. Effectiveness is judged, 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.

FDA monitors safety and effectiveness. The Vaccine Adverse Event Report System (VAERS), administered by FDA and CDC, assembles reports from parents, clinicians, and manufacturers that may involve post-vaccination problems. Another FDA program, MedWatch, informs the public with clinical information about safety issues involving vaccines and other medical products.

Problems

Side-Effects. Some scientists, parents, and consumer advocates raise concerns that U.S. vaccine policy, with its required 20 shots to infants by age two, 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 recent focus has been on thimerosal, a mercury-containing preservative used in some vaccines. In this case, even though the science is not definitive,[20] 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

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[20] Institute of Medicine, *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*, Kathleen Stratton, Alicia Gable, Marie C. McCormick, editors, Washington, D.C., National Academies Press, 2001.

of the data, the ACIP withdrew its earlier recommendation that the rotavirus vaccine be given to infants.[21]

Insufficient Knowledge and Inadequate Risk Communication. Often, decisions of vaccine safety revolve around perceptions of risk, limits on the science of risk assessment, and communication of what is known about risks. Scientists, clinicians, Members of Congress, and public policy analysts continue to face choices — 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 (reportedly based on misinformation about side effects) recently in India,[22] 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.

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 format 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?

Vaccines have not been prime candidates for generic production in part because of the complex manufacturing procedures required. Comparisons between branded and generic vaccine products, therefore, have not been relevant, although the issue may arise within congressional debate on generic drugs.

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[21] ACIP's rotavirus vaccine fact sheet is at [http://www.cdc.gov/nip/publications/fs/Rotavirus.htm], visited May 22, 2003.

[22] Amy Waldman, Distrust Reopens the Door for Polio in India, *The New York Times*, January 19, 2003.

Possible Legislative Solutions

Post-Licensure Adverse-Event Surveillance. When it comes to smallpox, Congress has acknowledged the need for the consistent documentation of administration and side effects along with coordination of the many related federal, state, and local activities.[23] As the smallpox immunization program proceeds, Congress may want to review the completeness of the surveillance programs and the usefulness of its output.

Congressional approval of the National Childhood Vaccine Injury Act of 1986 (P.L. 99-660) set into motion the VAERS activities in FDA and CDC. 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.

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."[24]

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. As Congress returns to debating Medicare prescription drug benefits, questions of cost will likely come up. Some legislators have expressed interest in broadening this 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. Others may feel such analysis is too fraught with uncertainty for government decisions and is best left to individual physicians. As research methods evolve, they can be applied as well to questions regarding vaccines.

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)[25] has made many awards, primarily to families of children, following injuries deemed to have been associated with CDC-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 has proposed changes to VICP in his

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[23] For example, in P.L. 107-188, Title XXVIII, Section 2801.

[24] The National Immunization Program website is at [http://www.cdc.gov/nip], visited May 22, 2003.

[25] The National Vaccine Injury Compensation Program fact sheet is at [http://www.hrsa.gov/osp/vicp/fact_sheet.htm], visited May 22, 2003.

Improved Vaccine Affordability and Availability Act (S. 754, introduced April 1, 2003).

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.

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.

Problems

Vaccines fare better than prescription drugs in health benefits coverage in the United States. Even so, only 76% of U.S. children less than 3 years old had completed the recommended series of vaccinations in 2000 despite the HHS Healthy People 2000 and 2010 objectives of 90%. Recommended adult immunization rates are even farther from HHS goals: 65% of adults at least 65 years of age report receiving a flu vaccine within the past year, far less than the HHS goal of 90% by 2010.[26] 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.[27]

As federal and state agencies coordinate options and plans for smallpox vaccination, weaknesses in the U.S. public health infrastructure have become apparent. These include the need for improvements in technology, training, hospital and laboratory capacity, and communication among participants.[28] Outside of the United States, inadequate public health infrastructure overshadows any question of access. Some Members of the 107th Congress went beyond a domestic focus and

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[26] These and other data collected and analyzed by CDC are available at [http://www.cdc.gov/nchs/data/hp2000/hp2k01.pdf] and [http://www.healthypeople.gov/document/html/objectives/14-22.htm], visited May 22, 2003.

[27] Institute of Medicine, *Calling the Shots: Immunization Finance Policies and Practices*, Washington, D.C., National Academy Press, 2000.

[28] CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Bioterrorism*, by Holly Harvey.

showed legislative interest in the lack of access to vaccines in less developed areas around the world.

Possible Legislative Solutions

The 108th Congress may 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 Programs. Individual states and assorted federal programs work toward childhood immunization. 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 publically funded vaccine programs, such as Medicaid, the State Child 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 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, specifically the smallpox vaccine, to bioterrorism attacks, 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.

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 of the 107th Congress, noting concern for public health needs of developing countries worldwide, introduced some bills to assist those countries in fights against, for example, HIV/AIDS, tuberculosis, and malaria. Their concern stemmed from both humanitarian impulses and a growing awareness of the links between poor health and economic and political instability. Consideration of this issue continues in the 108th Congress; the House and the Senate have passed different versions of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (H.R. 1298). Legislators may want to increase access for already-existing vaccines and, an issue of both availability and access, spur the development of affordable new vaccines for which the technology already exists, and consider increased long-term investment in vaccine development for these diseases.