The United States Needs a National Vaccine Authority

Barry R. Bloom

Viewed globally, vaccines are the most cost-effective medical intervention to prevent death and disease (*1*). Not solely a good in itself, childhood immunization represents the gateway to provision of comprehensive health care to which all children ought to be entitled. Although many poor developing countries, such as India, Indonesia, the Philippines, Vietnam, and Tanzania, vaccinate over 80% of their children against six childhood diseases by the age of 1 (*2*), in the United States we truly do not know how many children have their required immunizations. A 1992 report by the Centers for Disease Control (CDC) revealed the shocking statistic that, in most cities surveyed, fewer than 50% of the children were fully immunized by the age of 2 (*3*). With the recent passage by Congress of the president's Childhood Immunization Initiative, a major commitment has been made to begin to address the egregious neglect of childhood immunization in the United States, and to vaccinate at least 90% of our children by 1996 (*4*). With these new resources and expectations, questions of leadership, coordination, and accountability should compel our attention. Here, I argue that immunization is a complex and fragile enterprise and that it is both necessary and possible, within existing legislation and funding mechanisms, to establish a national vaccine authority with the capacity to facilitate coherent planning, coordination, public information, government-industry cooperation, and resolution of immunization issues.

Current Vaccine Players

The development, testing, production, distribution, and use of vaccines in the United States depend on the proper functioning of over 20 federal agencies (*5*), as well as state departments of health, vaccine companies, biotechnology companies, professional medical societies, voluntary organizations, and large numbers of public and private health care personnel. Within the government, the FDA and its advisory committees have regulatory authority over safety and licensing. The CDC, through the Advisory Committee for Immunization Practices (ACIP), has responsibility for deciding which vaccines will be universally used, which will be purchased in the public sector, and what the appropriate schedules will be for vaccine use (*6*). The CDC also oversees the public distribution of vaccines and allocates to the states the federal resources for immunization. Under the National Vaccine Injury Compensation Act (NVICP), the ACCV makes recommendations on compensation for adverse effects of vaccines. The NIH is principally responsible for the research and scientific development of new and improved vaccines. The DOD is concerned with military vaccine needs and global emergencies. The USAID works to promote infrastructure development and self-sufficiency in immunization in developing countries. Ultimately, industry is the critical partner in determining which vaccines and combinations will—and will not—be developed and manufactured, and in setting their prices. This enormously complex distribution of responsibilities has produced an enterprise in which the major government agencies tend to compete with each other for resources and power, the vaccine industry seeks to maximize profitability, and the public is ill-informed and often confused.

The author is in the Howard Hughes Medical Institute, Albert Einstein College of Medicine, Bronx, NY 10461, USA.

Some Key Vaccine Issues

One crucial issue is government-industry cooperation. In the early 1980s there were 14 vaccine companies in the United States; in 1989, largely because of problems with liability and profitability, only four major producers remained. Paradoxically, recent scientific developments offer unprecedented opportunities for new vaccines and simplified delivery of existing ones. It is new technology that has been the driving force behind the recent resurgence of interest in vaccines, not only for infectious diseases but also for autoimmune diseases and some forms of cancer. Vaccines represent a federal enterprise valued at $1.2 billion in the United States and $3 billion globally (*7*). To plan intelligently, vaccine companies must estimate market size, ability to pay, manufacturing costs, security of market share and competition, liability, dividends, and R&D on future products. They are concerned that the government has not been a reliable partner. For example, at the same time Vice President Gore is leading an effort to strengthen science and technology in this country, the 1993 Omnibus Budget Reconciliation Act (OBRA), which represents a major step in furthering childhood immunization (*8*), has also established price caps on vaccines purchased by the government and has allowed states the option of purchasing all their vaccines at a lower fixed price, which could account for as much as 80% of all vaccines in the United States. The vaccine companies are concerned that this will reduce their resources for R&D, and the biotechnology industry argues that OBRA will savage their ability to raise venture capital for new vaccines, perhaps driving many out of the vaccine business.

The climate in industry has changed dramatically, with consolidation and the remarkable formation of private sector alliances between former competitors (*9*). Recognizing that monopolies inevitably place the public interest at risk, I believe that interest is best served by multiple manufacturers and competition, not by monopsonistic or universal government purchase, which will limit development of new and improved vaccines. All parties—the companies, the federal and state governments, and the public—need a new, more stable, and predictable environment, if the scientific potential of new vaccines is to be realized. This is particularly important because however complex the safety, efficacy, and regulatory issues surrounding today's very simple vaccines (*10*) may seem, they are child's play in comparison to the issues we will encounter with the vaccines on the horizon (*11*).

Another priority in current vaccine efforts is the establishment of a national immunization registry to improve access to immunization and to minimize missed opportunities when children contact the health care system but are not checked for immunization status (*12*). This registry, conceived as part of the National Vaccine Plan (see below), would track the effectiveness of childhood immunization programs, send immunization reminders, and establish a systematic basis for evaluating the adverse effects of vaccines. In the frenzy to ensure public sector purchase and distribution of vaccines under OBRA, of the $464 million of government funds provided to CDC for childhood immunization only $9.2 million (of the $50 million required to set up the registry) was allocated. If one believes that improving access and finding children left out of the system are major problems in this country, and if one believes that immunization programs are a crucial first step in providing comprehensive health care to all the nation's children, this is a major initiative that must not be allowed to falter.

A third issue for discussion, and one with global as well as domestic implications,

is the Children's Vaccine Initiative (*13*). This program was established in 1990 with the goal of immunizing all the world's children with existing vaccines and developing new and improved vaccines by the year 2000. UNICEF purchases vaccines at discounted prices from about 12 manufacturers in Europe, Canada, and Japan and supplies ~40% of all the vaccines in developing countries. No U.S. companies bid on UNICEF tenders, in part because when they indicated their willingness to do so at discounted prices, they were excoriated in congressional hearings for charging higher prices in the United States and lower prices to the Third World (*14*). This position is both shortsighted and destructive. A UNICEF study (*12*) has concluded that a multi-tiered pricing system is good for everybody: it enables developing countries to obtain at humanitarian prices the most cost-effective intervention to protect the health of their children; and it enables the companies to benefit from economies of scale and to produce vaccines at lower unit cost, which should result in gains in industrialized countries both in jobs and in lower prices than would be possible in the absence of the UNICEF market.

A National Vaccine Authority

One of the best kept secrets in America, though an extraordinarily enlightened piece of legislation, is Title XXI of the Public Health Service Act (P.L. 99-660), passed in 1986. This statute quietly codifies some visionary innovations in preventive health care and vaccines, including "no-fault" health insurance for vaccine-related injuries. Some health care professionals believe that this provision could serve as a basis for more general "no-fault" compensation in health care reform considerations. Because there are inevitably a very small number of children who suffer adverse effects from required childhood vaccines, the law established the NVICP to enable families of such children to receive compensation for pain and suffering, lifetime medical expenses, and lost earnings (*15*). Compensation can be obtained by filing a valid claim with special Masters of the Court, without the need for expensive and protracted litigation. The program is financed by a trust fund created by an excise tax on every dose of vaccine (*16*).

Another provision of the law calls for the secretary of HHS "to establish a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." Specifically, the director of the program is assigned responsibility for coordinating and providing direction for research, development, safety, and efficacy testing of vaccines, and for developing a National Vaccine Plan (*17*). Finally, the legislation establishes a National Vaccine Advisory Committee (NVAC) to recommend ways to increase the availability of vaccines in the United States, to recommend research priorities, and to identify important areas where government and nongovernment cooperative action is required. The committee reports to the assistant secretary of health and is required to submit an annual report on its activities to the Congress. The NVAC is currently the only forum in which all of the players involved in childhood immunization are represented at the same table.

I wish to argue that, without creating new legislation or a new bureaucracy, the NVAC currently within the National Vaccine Program, preferably redesignated the National Vaccine Commission (NVC), has the potential, if given a redefined mandate and limited budgetary authority, to provide the leadership and coordination envisioned by the law and essential to an effective national immunization program. In the first few years of its existence, the NVAC did not exert the leadership expected because it lacked the authority or budget to get things done. More recently, it has made significant contributions to identifying problems and solutions (*18*). Broadly defined, the responsibilities of the new NVC would be to provide the highest level of scientific expertise and guidance to the various government agencies in the National Vaccine Program and accurate information to the public about immunization policies and practices. To assure that level of expertise, its membership should be appointed, as specified in the statute, in consultation with the National Academy of Sciences.

The mission of the NVC should be to assume the leadership role in policy oversight and coordination for which the NVAC was originally authorized. Specifically, it should (i) serve as a forum in which major vaccine players can be brought to the same table to discuss vaccine-related policy issues; (ii) formulate recommendations on policy and priorities with respect to the development, supply, and provision of vaccines; (iii) interact with the global Children's Vaccine Initiative; (iv) provide, in the face of fluctuating health budgets, support and continuity for the efforts already under way in the various government agencies and industry; (v) promote cooperation between the government and private sector in vaccine efforts; and (vi) assure that government gets good value for the public funds it invests. Such an authority is also needed to provide a mechanism for overcoming government or industry inertia that could seriously impede implementation of new vaccine technologies; for surmounting barriers to the delivery of current vaccines to all children and adults who are at risk (*19*); and for responding rapidly to vaccine emergencies and new infectious threats, for which current mechanisms are inadequate.

To carry out such a mandate, the NVC must represent the key participants, which include the major government agencies involved in research, regulation, and distribution of vaccines, the vaccine and biotechnology companies (*20*), clinical and biomedical experts in childhood and adult immunization, health economists, community practitioners and health care providers, and parents, whose concerns, understanding, and support are essential.

The question will inevitably be raised: how can an independent group have a significant impact if it cannot control government agency budgets? The answer is that, in fact, it is the congressional subcommittees and committees involved in authorization and appropriation that have real authority over the government agency budgets. It is hardly realistic to expect the congressional staff to have sufficient knowledge and experience to understand and effectively manage the complexities of immunization. Ultimately, the authority of an NVC would derive not from control of government agency budgets, but from the power of an independent group with wide vaccine expertise and experience charged with representing the public (domestic and global) interest.

To have clout, the NVC must have a budget, though not the major funds for immunization programs, which clearly belong in the agencies. A budget is required to maintain a small, competent staff to research major policy, innovation, and implementation issues. The NVC must be able to act to protect the public interest if government or private sector action is not being taken. To support that continuing function, the secretary of HHS should exercise her existing statutory evaluation authority (*21*) to spend 1% of PHS expenditures relating to vaccines on evaluation of vaccine programs by the NVC. Beyond the commission's continuing research and administrative functions, the NVC must have access to funds that can be rapidly mobilized when there are national needs or emergencies. Such "no-year" funding is the most difficult to obtain from Congress, but it is precisely the basis for the NVICP trust fund derived from excise taxes on each dose of vaccine purchased (*16*). From actuarial data, the NVICP is able to specify an amount each year that will guarantee that all valid claims are covered. This same trust fund should be used to finance actions recommended by the NVC. Specifically, I propose that funds be accumulated in the trust beyond the

level needed to assure coverage of all valid injury claims, with the expressed intent that the additional trust funds be used by the NVC in the national interest to address critical or urgent problems. When emergent microbial threats or opportunities to facilitate immunization are identified, the NVC, representing the best judgment of all the major parties, should have the authority to direct incremental funds to the appropriate government agencies, private or community organizations—not only to "address" the problem, but to solve it.

A recent Institute of Medicine report (*22*) urged that a national vaccine "authority" be established, and recommended that one of its functions be to provide a governmental (public sector) capacity to produce, at least to a pilot stage, vaccines that are urgently needed for use in developing countries. The time has come when it should be possible to achieve this goal by developing a mechanism for cooperation between government and industry, enabling use, when needed, of existing or underutilized private sector production capacity, available in vaccine-manufacturing facilities domestically or internationally. The NVC, if there is no obvious commercial interest, should have the authority and resources suggested here to initiate the production of vaccines urgently required for developing countries and for emergent microbial threats to the United States (*23*). Clearly, our ability to respond to emergent infectious diseases must be assured whether the vaccines required are perceived by industry to be profitable or not.

To such a complex challenge, an NVC would represent an appropriately complex response—an authority that could coordinate public and private resources, ensure cooperation where it is both possible and indispensable, and provide resources when a national response is essential (*24*).

REFERENCES AND NOTES

1. World Bank, *World Development Report: Investing in Health* (Oxford Univ. Press, New York, 1993); Commission on Health Research for Development, *Health Research: Essential Links to Equity in Development* (Oxford Univ. Press, New York, 1990); UNICEF, *State of the World's Children, 1990* (Oxford Univ. Press, New York, 1990). For a summary of cost-benefit studies on immunization in the United States, see (*17*), pp. 125–126.
2. UNICEF, *State of the World's Children, 1993* (Oxford Univ. Press, New York, 1993); WHO, *Expanded Programme on Immunization. Immunization Information System* (WHO, Geneva, 1994). The standard childhood immunizations include vaccines for diphtheria, tetanus, pertussis, polio, measles, and tuberculosis.
3. Centers for Disease Control, *Morbid. Mortal. Wkly. Rep.* **41**, 104 (1992). The survey was undertaken after an epidemic of 28,000 cases of measles occurred in the United States in 1990.
4. In the president's budget request for fiscal year 1995, the Childhood Immunization Initiative would receive ~$888 million. Part of the funds are channeled through CDC to the states for public health immunization, infrastructure development, and some vaccine purchase, and part through HCFA for purchase of vaccines for populations without insurance coverage or under Medicaid.
5. Department of Health and Human Services (DHHS) [Agency for Children and Families (ACF), Advisory Committee for Immunization Practices (ACIP), Advisory Committee for Childhood Vaccines (ACCV), Agency for Health Care Policy Research (AHCPR), Centers for Disease Control and Prevention (CDC), Health Care Financing Administration (HCFA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), National Vaccine Injury Compensation Program (NVICP), National Vaccine Program Office (NVPO), Office of Minority Health (OMH), Office of the Surgeon General (OSG), and Public Health Service (PHS)]; Department of Defense (DOD); Department of Education (DOED); Department of Housing and Urban Development (HUD); Department of State (DOS) [Agency for International Development (US-AID)]; Department of Treasury (DOT) [National Vaccine Injury Trust Fund]; and Department of Agriculture (USDA). The judiciary and congressional authorization and appropriations committees also participate.
6. The American Academy of Pediatrics Committee on Infectious Diseases also makes recommendations on pediatric immunization, although their recommendations do not fully coincide with those of the CDC's ACIP. There is a pressing need to harmonize the recommendations for vaccine schedules and use.
7. UNICEF, *A Commercial Perspective of Vaccine Supply: Summary* (New York, 1994). It is sobering to note that worldwide sales in 1993 of a single anti-ulcer drug, Zantac (totaling ~$3.5 billion), exceeded global sales of all vaccines.
8. It does so by providing additional funding for vaccines for uninsured and underinsured children and for Native Americans under Medicaid; by providing for more rapid inclusion of new vaccines into immunization programs; and by encouraging participation of private physicians in childhood immunization.
9. Pasteur-Mérieux-Connaught-Rhône-Poulenc; Chiron-Sclavo-Ciba-Geigy (Biocine); Merck-Pasteur; see D. Mowry and V. Mitchell, *An Assessment of the Feasibility and Market Impact of Expanded Foreign-Firm Participation in the U.S. Vaccine Market* (National Vaccine Program Office, Department of Health and Human Services, Washington, DC, 1993).
10. The childhood vaccines commonly used consist of two purified proteins (diphtheria and tetanus toxoids, DT), a carbohydrate-protein conjugate (*Haemophilus influenzae* B, HiB), one killed bacterium (*Bordetella pertussis*), and two live attenuated virus vaccines (polio and measles).
11. N. R. Rabinovich, B. F. Hall, D. L. Klein, P. McInnes, *Science* **265**, 1401 (1994).
12. National Vaccine Advisory Committee, *Developing a National Childhood Immunization Information System: Registries, Reminders and Recall* (Department of Health and Human Services, Washington, DC, 1994).
13. This is an international effort to immunize the world's children and bring modern science to the development of new and improved vaccines for children, initiated by an extraordinary session of the United Nations that brought together 71 heads of state for the Children's Summit in 1990. It is cosponsored by the United Nations International Children's Emergency Fund (UNICEF), United Nations Development Program (UNDP), Rockefeller Foundation, World Bank, and World Health Organization (WHO).
14. U.S. Senate Hearing to review Federal and State Expenditures for the Purchase of Children's Vaccines (Subcommittee on Investigations and General Oversight, Committee on Labor and Human Resources, Washington, DC, 1982).
15. Between 1990 and 1993, an average of 150 injury or death claims were filed each year, with about 40% ruled compensable, resulting in annual payments from the trust of about $42 million.
16. At the end of fiscal year 1993, the trust contained $629 million. The excise tax is based on crude assessments of risk for each vaccine; it ranges from $0.06 for diphtheria plus tetanus to $4.56 for diphtheria, tetanus, and pertussis vaccines. The ACCV has recommended that a flat $0.50 tax be levied on each dose of vaccine. A flat tax would significantly lower the cost of vaccines, add $100 million each year to the trust, and still fully guarantee compensation for all injuries.
17. *Disease Prevention through Vaccine Development and Immunization: The National Vaccine Plan–1994* (Department of Health and Human Services, National Vaccine Program Office, Washington, DC, 1994).
18. National Vaccine Advisory Committee, *J. Am. Med. Assoc.* **226**, 1547 (1991); *Access to Childhood Immunizations: Recommendations and Strategies for Actions* (Department of Health and Human Services, Washington, DC, 1992); *State and Local Impediments to Immunization Services: Recommendations and Strategies for Action* (Department of Health and Human Services, Washington, DC, 1994); *J. Am. Med. Assoc.* **269**, 1817 (1993).
19. Although effective vaccines exist for pneumococcal disease and influenza, they are not reaching adult populations, especially the elderly. Improved distribution of these vaccines could save 70,000 lives and perhaps as much as $10 billion annually [National Vaccine Advisory Committee, *Adult Immunization* (Department of Health and Human Services, Washington, DC, 1994].
20. It is noteworthy that the NVAC may be the only forum in which representatives of vaccine companies can come together to discuss policy issues; if the major producers were to meet among themselves, they would be in violation of antitrust laws.
21. Section 241 of the Public Health Service Act states "Such portion as the Secretary may determine, but not more than 1 per centum, of any appropriation for grants, contracts or other payments . . . shall be available for evaluation (directly or by grants or contracts) of any program authorized by this Act. . . ."
22. Institute of Medicine, *The Children's Vaccine Initiative: Achieving the Vision* (National Academy Press, Washington, DC, 1993).
23. See: Institute of Medicine, *Emerging Infections* (National Academy Press, Washington, DC, 1993); and Centers for Diseases Control, *Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States* (Department of Health and Human Services, Washington, DC, 1994).
24. Ironically, such a commission has been recommended previously: after the swine-flu episode in 1977 by the National Immunization Work Groups; in 1986 by the Institute of Medicine, *Vaccine Supply and Innovation* (National Academy Press, Washington, DC, 1986); and again in 1993 by the Institute of Medicine (*23*). Reauthorization of the National Vaccine Program is due in 1995; designation of an NVC, with specifications of its functions and budget authority, could be readily formalized in that reauthorization.

25. I thank G. Evans and B. Johnson for valuable information on vaccine injury compensation; A. Robbins for information about the National Vaccine Act and Program; C. J. Clements for data from the WHO Expanded Programme for Immunization; J. Cordero for information on immunization funding; A. Fauci, D. A. Henderson, G. Douglas, T. M. Vernon, and E. Marcuse for helpful comments on the manuscript; and especially R. Widdus for valuable ideas, criticism, and information.