

**VACCINE PURCHASE AND DISTRIBUTION:
PROPOSED CHANGES IN VACCINE SUPPLY AND DELIVERY
POLICIES**

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INTRODUCTION

Immunizations are a fundamental component of preventive medicine. Before vaccines, diseases such as diphtheria, pertussis, and measles were rampant in America. In 1900, 120 out of every 1000 infants died from preventable diseases before the age of 18 months. (Infectious diseases in children, 2002) For more than a decade efforts have been made to strengthen the infrastructure for effective delivery of vaccine to children and adults who need them. Immunization rates have risen to about 90 percent for most vaccines for children.

The recent shortages, which have taken providers, policymakers, and parents by surprise, have also undermined efforts to fully vaccinate the current cohort. Shortages of routinely administered vaccines against 8 of the 11 vaccine-preventable childhood illness have occurred. The affected vaccines include Diphtheria, Tetanus, & Pertussis (DTaP); Measles, Mumps, Rubella (MMR); Varicella and pneumococcal conjugate vaccines; adult tetanus and diphtheria toxoids have also been in short supply and delays in adult influenza vaccine have occurred in the past.(Mason, CDC Presentation July 17, 2002) These shortages have led the ACIP to recommend deferral of certain immunizations (the fourth doses of both DTaP and pneumococcal conjugate) until the supply of vaccines is restored.

The vaccine shortages have had serious consequences “on the ground” in physicians’ offices. An estimated 11,000 babies are born each day in the United States, each requiring 20 doses of vaccine by age 18 months to be protected against the 11 childhood diseases. Immunization is an essential part of preventing disease for primary care physicians and requires predictable delivery of safe and effective vaccines. Yet, according to recent testimony by a pediatrician representing the American Academy of Pediatrics (AAP), physicians are having to turn away parents when they bring in their children for shots because they do not have vaccine available. The situation is particularly acute for pneumococcal conjugate vaccine, with some pediatricians completely out of the vaccine, according to the testimony. Children who miss their dose at the scheduled time might not be brought back at a later date to get the shot. The same holds true for adults who are unable to get vaccinated; adults needing flu shots, if unable to receive shots in October or November, might forget the whole thing until next year.

In order to ensure patients come back for their vaccination, physicians have had to implement call back and tracking systems specifically for vaccines as well as strategies to more carefully monitor inventory, as not to have patients come back repeatedly when vaccines are not available. These are added administrative procedures caused by the shortage and requires valuable staff time and resources.

The inability to provide a vaccine when a parent comes into the office also hurts the patient doctor relationship. Physicians spend a significant amount of time trying to reassure parents of vaccine safety and the benefits of vaccinating their children. Not being able to follow through with administering the vaccine after emphasizing the importance of it disrupts the confidence that parents have in their pediatricians.

The level of concern about the shortage is high among the major stakeholders, many of whom have gathered data, convened committees and put forth recommendations for solutions. This paper gathers together these recommendations and presents them with underlying rationales. Problems of vaccine supply and delivery were first made prominent by the shortages. However, other factors, such as threat of bioterrorism, put development of new vaccines in the national interest, and give new urgency to issues around development as well as supply and distribution. Further, tight budgets, especially at the state level, influence the level of support available for vaccine purchase.

The formulation of the problem is different from the vantage point of those who develop and produce the supply, those concerned about disease in the population, and those concerned about delivery of vaccine to patients. Proposed solutions, likewise, vary according to these three points of view. To get a complete picture, we solicited information from and interviewed all major stakeholders. A complete list of interviewees is in Appendix A, and includes:

- Professional organizations, including
 - American Academy of Pediatrics (AAP),
 - American Academy of Family Physicians (AAFP),
 - American College of Physicians/American Society of Internal Medicine (ACP-ASIM),
 - American Medical Association (AMA)
- Association of State and Territorial Health Officials (ASTHO),
- American Public Health Association (APHA),
- American Association of Health Plans (AAHP),
- Representatives of the pharmaceutical industry, including
 - Pharmaceutical Research and Manufacturers for America (PhRMA),
 - GlaxoSmithKline,
 - Chiron UK,
- staff people for key members of Congress,
- representatives from Centers For Disease Control and Prevention (CDC) and the National Immunization Program (NIP).

This report is divided into three sections. In the first we report on recommendations dealing with protection of the public's health and national security; in the second we report on recommendations to ensure an adequate supply of vaccine, and in the third on recommendations to ensure equitable delivery of vaccine to the children and adults who need it. Recommendations discussed in this report are summarized in Table 1. Appendices B, C and D give supplementary information of the stakeholders' recommendations. Appendix B gives an overview, in tabular form, of the key points of recommendations by stakeholder group, while Appendix C gives recommendations organized within major issue category. Appendix D gives a brief description of key legislation.

Table 1

SUMMARY OF RECOMMENDATIONS

MEETING THE COUNTRY'S PUBLIC HEALTH AND NATIONAL SECURITY NEEDS

1. Create a National Vaccine Authority to ensure adequate development and manufacture of needed vaccines. (IOM)
2. Transfer responsibility to the Federal government for the development, manufacturing and financing of vaccines for both military and civilians. Give states and local agencies responsibility for distribution of vaccines. (APHA)

ENSURING AN ADEQUATE SUPPLY OF VACCINES

3. Provide adequate price to manufacturers to produce vaccines
 - § Establish an independent, multi-disciplinary group (possibly under the auspices of IOM) to determine the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines.
 - § Guarantee manufacturers a market price.
 - § Explore the feasibility of contracts between government and manufacturers that reward performance, such as delivering an adequate supply of vaccine in a predictable manner.
4. Review the implementation of the Current Good Manufacturing Practice (CGMP) standards.
 - § Review the implementation of the Current Good Manufacturing Practice (CGMP) standards so that they do not have a negative impact on supply. The review should ensure science-based regulatory processes and decisions.
 - § Provide tax relief for new facilities or reconstruction of old facilities or other forms of subsidy.
 - § Require government agencies and advisory committees to provide adequate advance notice whenever manufacturing changes are necessary
5. Improve communication between regulating agencies and manufacturers pertaining to supply disruptions.
 - § Require manufacturers to provide advanced notice if they plan to pull out of the market so that authorities can plan to mitigate against shortages
 - § Revise the rules for proprietary information sharing; CDC should provide information to other manufacturers to permit increased capacity to compensate for impending shortages
6. Harmonize and streamline the regulatory process to accelerate the licensing and approval process.
 - § Harmonize the content and format need for regulatory submissions of license application in the context of the International Committee on Harmonization (ICH) and working with other regulatory authorities to achieve mutual recognition of lot release tests for various vaccines
 - § Streamlining the process to licensure of vaccines can be enhanced by early and frequent communication with sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs
 - § Center for Biologics Evaluation and Research (CBER) should have adequate resources to review the scientific evidence that supports the safety, efficacy and quality of manufacture of vaccines and to conduct research to support the regulatory process.
7. Strengthen the Vaccine Injury Compensation Program (VICP).
 - § Strengthen the Vaccine Injury Compensation Program (VICP) to clarify definition of vaccines and include provision for the adjudication of parent and third party claims separate from awards to the vaccine-injured child
8. Expand the current stockpile
 - § Expand the current stockpile

9. Invest in improving public opinion and education about vaccines

ENSURING EQUITABLE DELIVERY OF VACCINE TO CHILDREN AND ADULTS

10. Increase administrative reimbursement fees to cover adequately the costs associated with vaccine delivery in an office or center.
11. Expand VFC to cover vaccinations for SCHIP children.
12. Bring about better coordination and shorter time frames between licensing of the vaccine by the FDA, approval by the ACIP, and purchasing.
 - Vaccine manufacturers and large purchasers should strive to agree on a public and private price within 60 days
 - Emergency funds should be supplied by the Federal government to buy newly recommended vaccines for public programs during the interim after recommendation and before expenditures can be incorporated in the regular budget cycle.
13. Assure full funding for 317 infrastructure, particularly to provide infrastructure for oversight of adult immunizations

MEETING THE COUNTRY'S PUBLIC HEALTH AND NATIONAL SECURITY NEEDS

Recommendations

- § Create a National Vaccine Authority to ensure adequate development and manufacture of needed vaccines. (IOM)
- § Transfer responsibility to the federal government for development, manufacture and financing of vaccines for both military and civilians. Give states and local agencies responsibility for distribution of vaccines. (APHA)

Call for a National Vaccine Authority

Delays in production of the routine vaccines, lack of sufficient incentives in the marketplace for development of some vaccines, combined with threats of bioterrorism involving vaccine-preventable diseases, prompted the Council of the Institute of Medicine to calling for the creation of a National Vaccine Authority (NVA) (IOM, November 5, 2001), an integrated management structure within the federal government for acquiring vaccines as well as a facility for developing and producing vaccines with government support. This latest call for a NVA, issued in November 2002, reiterated two earlier recommendations in 1992 (Lederberg, 1992) and 1993 (Mitchell, 1993) for establishment of such an Authority, but this latest call has heightened urgency for two reasons. First, evidence for the inability of the private sector to meet the country's needs for vaccines has accumulated substantially since the 1993 report, as manufacturing companies have gone out of business and needed vaccines are in short supply. Second, events after September 11, 2001 have reemphasized the serious defects in America's capacity to deal with biological agents used in terrorist attacks.

Specifically, there are only four major manufacturing companies in the world today, and only two are in the United States. There were four times as many only 20 years ago. Further, market forces are not reliable enough to guarantee development and production of vaccines against infectious diseases which may never be needed in large enough supply to be profitable in peacetime, but which may be needed for large segments of the population in the event of a bioterrorist attack. Currently, the United States has one licensed anthrax vaccine product, manufactured by a single plant, which has been closed for FDA-required manufacturing renovations since 1998. No new lots of anthrax vaccine have been cleared for release since that time. Delays and problems in procuring a cell-culture smallpox vaccine also argue for major changes at the federal level to ensure that these agents be available in sufficient supply at a time of national need (IOM, November 5, 2001). Statement from the Council follows:

The Council of the Institute of Medicine of the National Academies believes that the development of a National Vaccine Authority is long overdue. It could be created within the Department of Health and Human Services, in collaboration with the Department of Defense of as a joint effort of the two departments.

Moreover, the Council believes that establishment of a government-owned, contractor-operated facility for research, development, and production of vaccines is essential to meeting the country's public health needs, particularly those related to bioterrorism and protection of our armed forces. This facility also should play a role in development and production of other vaccines required for the public health that are not currently available in the open market. The Council encourages the president of the United States, the secretary of health and human services, secretary of defense, and the director of the Office of Homeland Security to evaluate these recommendations as critical elements in maintaining the country's health.

The American Public Health Association has not issued a formal statement, but in a letter stated its strong opinion that the current system does not adequately protect the health of our nation's citizens. They stress that APHA's focus is on what is best for the health of the people and that all of their recommendations come from that perspective. They report that their views and the level of urgency for addressing them have changed because of the threat of bioterrorism, which came at a time when the manufacturing of even routine vaccines was inadequate. The APHA, like the IOM Council, would make the federal government responsible for the development and research for vaccines; APHA calls for creation of a Center for Vaccine Development to that end. In APHA's view, the federal government could contract with a private firm to manufacture the vaccine, but the government would pay for the production.

APHA also recommends replacing the current system of federal, state and private purchase of vaccines with one in which the federal government alone is responsible for purchasing vaccines, including both the routine childhood and adult vaccines as well as other more specialized vaccines and vaccines against agents of bioterrorism. They believe this is necessary to overcome the inequities in the delivery of routine vaccines to all children and adults (to be discussed at greater length subsequently in this paper) and to protect the population against vaccine-preventable bioterrorism threats. APHA would give states and localities responsibility for the distribution of the vaccines.

There has been opposition from some quarters to the establishment of an NVA on the grounds that it is another layer of administration, which will add to the bureaucracy and may not solve problems. A further objection is that such an organization would be redundant because the ACIP, AAP and the AAP already set recommendations for vaccine use. In addition, the pharmaceutical industry opposed a "government-owned, contractor-operated" (GOCO) system for manufacturing vaccines, citing that government involvement in vaccine production would stifle the entry of new vaccines and would not guarantee any more of a supply (PhRMA testimony, June 12, 2002).

ENSURING AN ADEQUATE SUPPLY OF VACCINES

Recommendations

- § Provide adequate price to manufacturers to produce vaccines
 - § Establish an independent, multi-disciplinary group (possibly under the auspices of IOM) to determine the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines.
 - § Guarantee manufacturers a market price.
 - § Explore the feasibility of contracts between government and manufacturers that reward performance, such as delivering an adequate supply of vaccine in a predictable manner.
- § Review the implementation of the Current Good Manufacturing Practice (CGMP) standards.
 - § Review the implementation of the Current Good Manufacturing Practice (CGMP) standards so that they do not have a negative impact on supply. The review should ensure science-based regulatory processes and decisions.
 - § Provide tax relief for new facilities or reconstruction of old facilities or other forms of subsidy.
 - § Require government agencies and advisory committees to provide adequate advance notice whenever manufacturing changes are necessary
- § Improve communication between regulating agencies and manufacturers pertaining to supply disruptions.
 - § Require manufacturers to provide advanced notice if they plan to pull out of the market so that authorities can plan to mitigate against shortages
 - § Revise the rules for proprietary information sharing; CDC should provide information to other manufacturers to permit increased capacity to compensate for impending shortages
- § Harmonize and streamline the regulatory process to accelerate the licensing and approval process.
 - § Harmonize the content and format need for regulatory submissions of license application in the context of the International Committee on Harmonization (ICH) and working with other regulatory authorities to achieve mutual recognition of lot release tests for various vaccines
 - § Streamlining the process to licensure of vaccines can be enhanced by early and frequent communication with sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs
 - § Center for Biologics Evaluation and Research (CBER) should have adequate resources to review the scientific evidence that supports the safety, efficacy and quality of manufacture of vaccines and to conduct research to support the regulatory process.
- § Strengthen the Vaccine Injury Compensation Program (VICP).
 - § Strengthen the Vaccine Injury Compensation Program (VICP) to clarify definition of vaccines and include provision for the adjudication of parent and third party claims separate from awards to the vaccine-injured child.
- § Expand the current stockpile
 - § Expand the current stockpile
- § Invest in improving public opinion and education about vaccines

Background

There are many factors that have contributed to the shortage in vaccine supply. The withdrawal of manufacturers from the market, interruptions in production, policy changes, economics and the marketplace all have significant impacts on vaccine supply. Some have directly resulted in the shortage while other factors act as disincentives for manufacturers to enter the market, therefore allowing for the possibility of future shortages. There are relatively few manufacturers producing vaccines and disruption in one manufacturer's production has a major impact on supply. In addition, low returns on investment have forced manufacturers to make the business decisions of pulling out of the vaccine market. Vaccines are not as profitable as other pharmaceuticals and manufacturers can not sustain their business. The withdrawal of Wyeth, ending their production of DTaP and Td was an important immediate factor leading to the shortage in DTaP and Td. Also, required changes or disruption in the manufacturing process, have lead to short supply, as was the case for MMR when Merck's production process was interrupted.

Vaccine supply was also affected by the decision in mid-1999 to eliminate the preservative thimerosal from vaccines as a precautionary measure. In fact, the story of the thimerosal controversy is an example of not only disrupted supply due to required production and packaging changes, but also concern about liability, adequate time to respond to change and return on investment for the vaccine industry. Thimerosal is a derivative of ethylmercury and has been used as an additive to vaccines since the 1930's because it is effective in killing and preventing bacterial contamination. It was particularly useful in protecting open multi-dose vials of vaccine.

The concern over thimerosal began when the Food and Drug Administration (FDA) Modernization Act of 1997 required the FDA to review and assess the risk of all mercury containing food and drugs. The review concluded that the use of thimerosal as a preservative in vaccines could result in an intake of mercury within the first 6 months of life that exceeded the Environmental Protection Agency's guidelines for methylmercury intake, which is a related compound of ethylmercury. More studies have been done on methylmercury so standards have been based on this compound. This amount however did not exceed the guidelines set by the FDA, the Agency for Toxic Substances and Disease Registry, or the World Health Organization. The FDA found no evidence of harm caused to children by thimerosal in vaccines except for minor local reactions (National Immunization Program website, Thimerosal and Vaccines). The public reaction to the questions over thimerosal opened up manufacturers to liability suits and created great concern over the safety of vaccines. As a precaution, steps were taken to begin the removal of thimerosal from vaccines, adding to the disruptions in supply and fueling many of the concerns and proposals manufacturers have supported to improve the system.

The nature of vaccine production is different from that of pharmaceutical manufacturing. Vaccines are produced from or use living cells and organisms as well as complex growth materials taken from living sources, which require careful monitoring

for purity and quality. Subtle changes in materials, process or environment, change the final vaccine, and affect its safety and or effectiveness. Each lot must be carefully tested for composition and potency through a lot release process. Unlike other drugs, vaccines are used on healthy people to prevent disease and for this reason vaccine production is subject to higher standards (FDA testimony June 12, 2002).

The Food and Drug Administration monitors the process before and after approval of the drug. The FDA provides guidance for trials done under an Investigational New Drug Application (IND). To receive a license for the product, a manufacturer needs to submit a biological licensing application and show that the product is “safe, pure, and potent” (FDA testimony June 12, 2002). The FDA also assesses compliance with Current Good Manufacturing Practices before and after licensure. Once a vaccine is licensed, the product is continually monitored for safety and effectiveness through ongoing review of adverse events, post-licensure inspection, and other post-marketing activities. Lot release is also used to help ensure the potency and quality of the final vaccine and serves as a quality control process (FDA testimony June 12, 2002).

These regulations and procedures were set in place to ensure safe and efficacious vaccines. However, these regulations and changes often require manufacturers to make changes in their process which, in turn, effects the amount of vaccine they are able to produce while the changes are taking place and the cost to them of producing the vaccine. Pricing, then is one of the key issues to examine in an analysis of vaccine supply.

Issues Around Vaccine Pricing

Recommendations: Provide adequate price to manufacturers to produce vaccines

- *Establish an independent, multi-disciplinary group (possibly under the auspices of IOM) to determine the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines.*
- *Guarantee manufacturers a market price.*
- *Explore the feasibility of contracts between government and manufacturers that reward performance, such as delivering an adequate supply of vaccine in a predictable manner.*

Currently, the CDC purchases at least 52% of all vaccines doses, and some estimate that the proportion might even be as high as 60%.¹ This figure includes vaccines purchased for states, the 317 and the Vaccines for Children (VFC) program. Vaccine is sold to the government for public programs at a steeply discounted price. The revenue gained from selling to the private sector subsidizes the vaccines sold to the government at discounted prices. The large market share held by the government offers substantial leverage in price negotiations. From the manufacturers’ perspective an appropriate

¹ Peter Paradiso, PhD testimony to the Subcommittee on Public Health and Safety, Committee on Labor and Human Resources, United States Senate May 6, 1997. Dr. Paradiso’s of Wyet-Lederle Vaccines and Pediatrics discusses the reauthorization of 317.

balance between public and private sector is necessary to ensure sufficient revenue for the manufacturers. Manufacturers contend that the addition of VFC program upset the equilibrium that was achieved with the 317 program, and caution that federal vaccine purchasing policies can influence the viability of the market for manufacturers (Peter Paradiso testimony May 6, 1997).

In addition to concerns about the expansion of the public market under VFC, manufacturers also express concerns about price caps the CDC imposed on older vaccines (those under contract on May 1, 1993) that permitted price increases only as much as the consumer price index. Manufacturers contend that the combination of price caps and expansion of public market have resulted in slowed investments in new facilities and new research programs (Peter Paradiso testimony May 6, 1997).

Companies will leave the marketplace when a product no longer provides an appropriate return on investment for them. Policies need to offer manufacturers an appropriate profit for the research, development, approval, and distribution of vaccines for the public well-being.

The National Vaccine Advisory Committee (NVAC) recommended that the Department of Health and Human Services establish an independent, multi-disciplinary group (possibly under the auspices of IOM) to determine the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines. NVAC also suggests a guaranteed market price. Finally, NVAC also recommended exploring the idea that contracts between government and manufacturers reward performance, such as delivering an adequate supply of vaccine in a predictable manner.

Issues around modifying manufacturing plants to comply with Current Good Manufacturing Practice (CGMP) standards.

Recommendations: Review the implantation of the Current Good Manufacturing (CGMP) standards

- *Review the implementation of the Current Good Manufacturing Practice (CGMP) standards so that they do not have a negative impact on supply*
The review should ensure science-based regulatory processes and decisions.
- *Provide tax relief for new facilities or reconstruction of old facilities or other forms of subsidy.*
- *Require government agencies and advisory committees to provide adequate advance notice whenever manufacturing changes are necessary*

Current Good Manufacturing Practices (CGMP) are established by current industry processes and FDA regulations. Conformity to the standards are determined through inspection and surveillance before and after licensure. These standards were put into place to help ensure vaccines meet the requirements for safety and have not technically changed since their implementation. However, the industry argues that the

guidelines are broadly stated and that interpretations by individuals enforcing the regulations change. Representatives assert that constant changes require significant financial investment as well as time on the part of the manufacturers. The cost of plant changes to meet regulatory requirements has resulted in manufacturers choosing to cease production rather than making the investment. The following table, prepared by *Infectious Diseases in Children* gives vaccines in short supply in 2001. According to this table, shortages in five vaccines are attributable to CGMP issues.

| VACCINE NAME | REASON FOR SHORTAGE |
|-------------------------|---|
| DT, Td, tetanus Toxoids | One manufacturer dropped production |
| DtaP | Tetanus toxoids shortage due to manufacturer dropping production |
| Pneumococcal conjugate | Rapid implementation; Good Manufacturing Practice Issue (CGMP); grantee funding shortage |
| Varicella | Good Manufacturing Practice Issues (CGMP) |
| MMR | Good Manufacturing Practice Issues (CGMP) |
| Hib (Merck) | Good Manufacturing Practice Issues (CGMP) |
| Hep B-Hib (Merck) | Good Manufacturing Practice Issues (CGMP) |
| Influenza | In 2000, difficulty in production. In 2001, one manufacturer dropped production; uneven distribution. |

According to representatives of the vaccine industry, changes are sometimes put into effect, even when there is no evidence of concern about the vaccines that are produced in those facilities. Not only are the changes required, but often they are required without adequate time for supply adjustments.

Recommendations address compensation for plant renovations necessitated by the CGMP as well as notification. NVAC calls for reviewing implementation for CGMP standards so they do not have a negative impact on supply. The review should ensure science-based regulatory processes and decisions. (NVAC paper May 30, 2002). In addition, NVAC recommended offering tax relief for new facilities or reconstruction of old facilities or other forms of subsidy.

With respect to recommendations around notification, the pharmaceutical industry advocates for government agencies and advisory committees to provide adequate advance notice whenever manufacturing changes are necessary (PhRMA testimony June 12, 2002). Advance notice would allow for all involved to take into consideration the time it would take to make the change as well as understand what the change would do to the immediate supply. It will help to expedite the process for minor changes, allowing for minimal disruption in the production process (NIP interview August 6, 2002). The goal is to have standards that incorporate current technological advances and improvements but also remain flexible enough to ensure the continued vaccine production (NIP interview August 6, 2002).

Issues around notification of withdrawal from market and sharing of information

Recommendations: Improve communication between regulatory agencies and

manufacturers pertaining to supply disruption

- *Require manufacturers to provide advanced notice if they plan to pull out of the market so that authorities can plan to mitigate against shortages*
- *Revise the rules for proprietary information sharing; CDC should provide information to other manufacturers to permit increased capacity to compensate for impending shortages*

Withdrawal from the market is both a symptom of a problem and a problem in and of itself. While it is important to address the fundamental, root-cause, underlying problems associated with a marketplace that does not offer sufficient returns, some improvements in the communication of intents could help cushion the impact.

The problems caused by withdrawal from the marketplace are particularly acute when there is only one manufacturer for a vaccine, as is the case for three of the vaccines in short supply. (CDC testimony, June 12, 2002). However, even when there is more than one manufacturer, withdrawal by any can leave a shortfall. When one manufacturer stopped making adult tetanus diphtheria toxoids (adult Td), the remaining company was unprepared to fulfill the supply needs on short notice, resulting in a decrease in adult Td from 16.1 million doses in 1998 to 9.7 million doses in 2001. (NVAC paper May 30, 2002). Two manufacturers dropped production of DTaP, leaving only two companies to cover the entire United States, creating another unexpected drop in doses. Then, one of these two companies made changes in production as part of an effort to remove thimerosal, which further interrupted supply.

Legislation, S.2049, sponsored by Senator Dewine, Senator, Dodd, Senator Clinton and Senator Schumer, introduced on March 21, 2002 called for manufacturers to provide advanced notice if they plan to pull out of the market². Some in the industry support this idea while other representatives argue that in certain circumstances, they may not be able to give a great deal of notice. For example, if they need to upgrade a production facility to be CGMP compliant, they may decide to withdraw rather than upgrade. Some have also pointed out that even if they gave advanced notification, there may be little that could be done about the shortage because another manufacturer may not be able to increase production to fill the gap immediately.

Another approach to advanced notification, advocated by manufacturers and NVAC, is providing the CDC with the ability to share proprietary information on supply concerns in light of a pending shortage. Supply information has always been considered confidential because it provides insight into a manufacturer's capacity. However, in light of a shortage it would be beneficial for CDC share, in confidence, this information to

² S.2049 Sponsor: Sen DeWine, Michael (introduced 3/21/2002) Childhood Vaccine Supply Act of 2002 – Amends the Federal Food, Drug, and Cosmetic Act to require a sole manufacturer of a biological product (currently, a drug) subject to licensure to notify the Secretary of Health and Human Services no later than one year before discontinuing its manufacture. Permits a shorter notification period if the manufacturer can continue the distribution of the product involved for one year. Authorizes the Secretary to purchase pediatric and adult vaccines for national stockpiles using preventive health services project grant funds.

prevent a large disruption in supply. The availability of this information would allow for a more open discussion among manufacturers to determine how the gap could be filled based on existing capacity of various producers, before the shortage occurs.

Issues around licensing and approval of vaccines in a global marketplace

Recommendations: Harmonize and streamline the regulatory process to accelerate the licensing and approval process

- *Harmonize the content and format need for regulatory submissions of license application in the context of the International Committee on Harmonization (ICH) and working with other regulatory authorities to achieve mutual recognition of lot release tests for various vaccines*
- *Streamlining the process to licensure of vaccines can be enhanced by early and frequent communication with sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs*
- *Center for Biologics Evaluation and Research (CBER) should have adequate resources to review the scientific evidence that supports the safety, efficacy and quality of manufacturing vaccines and to conduct research to support the regulatory process.*

Before the 1980's and 1990's, established producers of vaccines were regionally dominant and rarely pursued global markets. However, expanded opportunities for development of new vaccines, and the higher cost of exploiting these opportunities have led leading vaccine manufacturers to seek entry into new markets through direct foreign investment, acquisitions, and strategic alliances (Mowery and Mitchell, 1995). Now, vaccine manufacturers research, develop and produce their products for a global market. At the same time as the industry was becoming more international and seeking global markets, laws and regulations for reporting and evaluating the data on safety, quality and efficacy of new medical products were becoming more stringent in individual countries. The need to rationalize and harmonize regulation was impelled by the need to reduce duplication, save costs, and bring new treatments to patients in need with minimum delay. Harmonization of regulatory requirements began in Europe, as the European Union moved towards the development of a single market for pharmaceuticals.

The European nations moved towards harmonization³ through the development of the European Agency for the Evaluation of Medicinal Products (EMA). The EMA works as a network using the scientific resources of the European Union and the

³ The concept of harmonization began with the European Community in the 1980's when the European Union began moving towards the development of a single market for pharmaceuticals (ICH website: www.pharmweb.net/pwmirror/pw9/ifpma/ich8.html). The European Agency for the Evaluation of Medicinal Products (EMA) was established in 1993 and its main responsibility was to protect the health of the public and animals (<http://www.emea.eu.int>). During the 1980's the United States, Japan, and Europe had also been discussing possibilities of harmonization, but it was not till the World Health Organization Conference of Drug Regulatory Authorities (CDRA) when discussions began to formalize and in 1990 the International Conference on Harmonization was put together.

European Economic Area - European Free Trade Association Member States to evaluate and supervise medicinal products for both human and veterinary use. This allows for a manufacturer to use one process for approval and licensure for a vaccine in the participating countries.

In the United States the current licensing process for vaccines is complex, labor intensive, expensive, time consuming and considered one of the most stringently regulated industries in the United States (NVAC paper May 30, 2002). Industry representatives report that the approval and licensure process takes longer and is more cumbersome than it is in other countries. Since this process is so complex, time consuming and costly it can act as a disincentive for manufacturers, especially when they have already been able to release a product in the other countries.

Harmonization of the licensing and approval process could open up doors for having more manufacturers in the market place as well as help address shortage issues. As an example, the following vaccines from GlaxoSmithKline are all licensed in Europe and could be introduced into the United States if licensure and approval was harmonized (Interview Dr. Zink August 19, 2002).

- § Priorix for measles, mumps, and rubella
- § Varilrix for chicken pox
- § Boostrix a booster against Diphtheria, Tetanus, Pertussis for adolescents or adults
- § Fluarix for flu
- § Infanrix HeXa combines Diphtheria-Tetanus-Pertussis-Hep B-Inactivated Polio Vaccine and Haemophilus influenza type b⁴

Bringing these vaccines into the United States would have significantly reduced the supply shortage for DTaP, MMR, and Varicella.

This concept has been encouraged not only by manufacturers in the vaccine industry but by the National Vaccine Advisory Committee (NVAC). NVAC suggested that “harmonizing the content and format need for regulatory submissions of license application in the context of the International Committee on Harmonization and working with other regulatory authorities to achieve mutual recognition of lot release tests for various vaccines” should be done to help streamline and enhance the regulatory process. (NVAC paper May 30, 2002). The goal of such a program is not to lower the standards through which products are deemed to be safe and efficacious, rather prevent repetitive work for manufacturers, and pool resources to prevent shortages that can be caused when one manufacturer is no longer able to supply what is needed.

In addition, ”streamlining the process to licensure of vaccines can be enhanced by early and frequent communication with sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs” (NVAC paper May 30, 2002). NVAC states that adequate resources are needed to facilitate accurate and

⁴ This is a standard vaccine in Germany and Italy (over 15 million doses already administered)

timely review of vaccine licensure and approval. For this reason NVAC recommends increasing funding for the Center for Biologics Evaluation and Research (CBER) could help to ensure that adequate resources are available to review scientific evidence used to establish safety, efficacy, and quality⁵.

Issues around liability

Recommendation: Strengthen the Vaccine Injury Compensation Program (VICP)

- *Strengthen the Vaccine Injury Compensation Program (VICP) to clarify definition of vaccines and include provision adjudication of parent and third party claims separate from awards to the vaccine-injured child*

The Vaccine Injury Compensation Program (VICP) was put into effect in 1988 after the number of lawsuits brought against manufacturers began to increase, specifically pertaining to adverse reactions to the DTP vaccine. The legal system was time consuming, costly, and difficult to manage for both petitioners and manufacturers. In addition, the affordability and availability of product liability insurance began to concern manufacturers. This concern and cost in turn effects the manufacturer's decisions to withdraw from the market because vaccine production would no longer be a profitable business. The government at this point realized the implication this would have on vaccine supply and the VICP was established to address the issue.

This system called for individuals who had been injured by a vaccine covered by the program to file a petition for "no fault" compensation with the U.S. Court of Federal Claims rather than filing a lawsuit against the vaccine manufacturer or administrator in the civil tort system. If a petition is dismissed, judged to be noncompensable under the program and the petitioner rejects this judgment, if the award granted by VICP is rejected by the petitioner, or if the vaccine is not covered, a lawsuits can be filed against the manufacturer or health care provider. To assure that this program is accessible for all, the attorney fees and costs for the petitioner, regardless of the ruling, is paid for through the program (Dr. Evans interview, August 15, 2002; GAO Report 12/1999). There are two ways that a petitioner can qualify for compensation. The petitioner must show that a vaccine caused the injury they are claiming or the petitioner must have an injury that is listed on the vaccine injury table (GAO Report 12/1999).

After the enactment of this program concerns were eased and in fact lawsuits against DTP manufacturers decreased dramatically. In 1986 the number of suits filed against manufacturers for DTP was 255, in 1988 the number was 114 and continued to decrease with 4 suits being filed in 1997 (HRSA website). However, the recent the upsurge in suits due to thimerosal brought back manufacturers concerns over liability. Individuals, contending that thimerosal was an additive and not part of the vaccine, sued

⁵ Previous legislation has been implemented to enhance the review process. In 1992 the Prescription Drug User Fee Act (PDUFA) was implemented to increased levels of resources for the FDA to review human drug applications. This money was to be used to reduce the amount of time required to evaluate biologics. This act expired in 1997 and was renewed with the FDA Modernization Act (FDAMA) of 1997 extending it for five more years (FDA website: <http://www.fda.gov/oc/pdufa/reports.html>).

manufacturers directly, rather than going through the VICP, as they would have needed to do with an injury caused by the vaccine itself. The ambiguity in the definition of a what was included in a vaccine, allowed individuals to circumvent the system.

Another way in which the liability protection needed to be strengthened involved compensation for parents or third parties. The issue of compensation for parents and third parties was initially raised during the drafting of the VICP in the 1980's, but was rejected to maintain the focus of the Act on providing appropriate and just compensation for the vaccine-injured child (AAP Letter to Senator Frist July 19, 2002). Thus, currently families of children injured by vaccines may sue manufactures directly.

AAP, NVAC and PhRMA all take the position that strengthening the VICP is necessary. All support clarifying the definition of what a vaccine. The definition of vaccines should include the active ingredients as well as preservative, additives and excipients and is seen as especially important due to the recent thimerosal discussion. The AAP also supports the inclusion of language allowing for compensation for family counseling and feels that it would not be in the best interests of the child to separate the claims of the parents from that of the child. For this reason, they would also recommend the addition of provisions within the VICP to provide for the loss of consortium that would be separate from what is awarded to the vaccine injured child (AAP letter to Senator Frist July 19, 2002).

This attention that has been drawn to the VICP has resulted in legislative attempts to address the areas of concern⁶. Legislation S.2053 sponsored by Senator Frist, Senator Bunning, Senator Hutchinson, and Senator Gordon was introduced on March 21, 2002

⁶ S.2053 Sponsor: Sen Frist - Improved Vaccine Affordability and Availability Act amends the Public Health Service Act and addresses the following in the VICP:

Vaccine Injury Compensation Program, including provisions regarding: (1) equitable relief; (2) third party petitions; (3) jurisdiction to dismiss improperly brought claims; (4) vaccine-unrelated injury; (5) an increase in the award for pain and suffering in the case of vaccine-related death; (6) the basis for calculating projected lost earnings; (7) compensation for family counseling and establishing guardianship expenses; (8) payment of interim costs; (9) procedures for paying attorney's fees; (10) extending the statute of limitation ; (11) the composition and meeting schedule of the Advisory Committee on Childhood Vaccines; and (12) standards of responsibility and the definitions of manufacturer, vaccine related injury or death and vaccine.

H.R.3741 Sponsor: Representative Burton - National Vaccine Injury Compensation Program Improvement Act of 2002 - Amends the Public Health Service Act addressing the following:

(1) revise the basis for calculating the projected lost earnings of a person who sustained a vaccine-related injury; (2) increase the award for a vaccine-related death; (3) allow compensation for expenses for family counseling and establishing guardianship; (4) allow payment of interim attorneys' fees and costs; (5) establish a procedure for paying attorneys' fees; (6) extend from two to six years the statute of limitations for injuries or death from a vaccine set forth in the Vaccine Injury Table; (7) revise the membership and meeting schedule of the Advisory Commission on Childhood Vaccines; and (8) direct the Secretary of Health and Human Services to conduct a public service announcement campaign about the availability of the Program.

Amends the Internal Revenue Code to increase the limit on Vaccine Injury Compensation Trust Fund administrative expenses.

specifically touching upon on many of the issues brought up around strengthening the VICP. The bill clarifies definitions of vaccines and manufacturers, provides provisions to improve the ability of individuals to make claims and at the same time attempts to slow the process of individuals bringing derivative claims against manufacturers. From the industry's perspective, the Frist's bill makes the system more user friendly and it reiterates the initial intent of the program which states that claims proceed initially through VICP. PhRMA's testimony to the Governmental Affairs Committee on June 12, 2002, states that they strongly support the provisions of the Frist bill and (PhRMA testimony June 12, 2002).

Smoothing out disruptions in supply

Recommendation: Expand the current stockpile

Creating stockpiles of vaccines can help smooth out temporary problems in production, and the concept of stockpiling is endorsed by virtually all the major groups. There is disagreement over what vaccines should be in the stockpile, length of time stockpile should cover, and how the stockpile should be paid for. Stockpiles will not solve problems of shortages; these are caused by fundamental problems in the marketplace. Nor are they the solution for all vaccines; influenza vaccine, for example, is produced annually to immunize against the specific strain of influenza virus expected to circulate the next winter. Because it changes annually, and last year's vaccine is not effective against this year's viruses, it would not be effective to create a stockpile of influenza vaccine. However, even though stockpiles will not solve problems in vaccine manufacture, and even though not all vaccines can be stockpiled, stockpiles will provide a cushion to help with short-term supply problems. For this reason, they are endorsed by virtually all major stakeholders.

Currently, CDC maintains a stockpile of MMR, e-IPV, and DT using funds through the VFC program. The AAP position is that stockpiles should include all routine childhood vaccines for 6 to 12 months. CDC estimates cost of six-month stockpile supply of all routinely administered pediatric vaccines to be \$705 million, not including the annual maintenance costs (estimate provided by Kim Lane of CDC). The industry as well as those at the CDC agrees that single-source and multi-source vaccines should be stockpiled. Abrupt shortages occur for many reasons and it is no longer possible to create a stockpile on the assumption that if one manufacturer is not able to meet their supply demand, that another manufacturer will be able to fill the gap. The CDC is in the process of negotiations for including all recommended pediatric vaccines in the stockpile. Due to capacity of manufacturers and production time the process is long and vaccines will be phased in (Kim Lane interview August 13, 2002).

Along with the expansion of which vaccines are stockpiled is how to pay for the stockpiles. The vaccine manufacturers have said that while they maintain stockpiles to maintain supply during a disaster, they do not maintain routine 6-month or longer supplies of vaccine. They state that it is not in their economic interest to do so. When

they come out with a product, they do not want the old stockpiled product to compete with it. Thus they would be ‘stuck’ with the vaccines in the stockpile.

It is generally agreed that the federal government, through the CDC, would purchase and maintain the stockpiles. ASTHO is firm, in wanting the stockpiles to be part of the VFC program and not compete with other infrastructure needs in the 317 program. However, the current bills addressing the stockpile call for an amendment to 317 of the Public Health Service Act, allowing the Secretary of Health and Human Services to purchase childhood and adult vaccines for national stockpile⁷. It is the internal opinion at the CDC that the VFC stockpile currently purchases vaccines for all children, not just VFC children. When the stockpile is drawn down, based on who receives the vaccine, the appropriate funding source replaces the vaccine.

Currently, the CDC contracts with manufactures to warehouse and maintain the stockpile of the vaccine they produce. Based on lessons learned from the stockpiling process and in light of current bio-terrorism concerns, there is discussion of moving towards having multiply third party vendors warehouse and maintain the vaccine stockpiles. In addition, it is felt that the best way to store vaccines is labeled and in a vile (final form). If for example, if the disruption in supply was due to a problem in the filling line of a manufacturing plant, having a vaccine stored that was not already in final form would not be of any use. These decisions have major cost implications. This initial investment for expanding the stockpile will be great, but in the opinion of most stakeholders it is a step that should be taken.

Issues around public’s concerns about vaccines and value public places on immunization

Recommendation: Invest in improving public opinion and education about vaccines

In order for the vaccine market to remain attractive for manufacturers, the demand for vaccines needs to be strong. An integral part of this is public opinion about vaccines and their importance. Safety and efficacy are important issues that are addressed in the regulation of vaccines, but their safety and efficacy must be communicated to the public as well. Manufacturers firmly believe that the government holds an important role in

⁷ S.2049 Sponsor: Sen DeWine, Michael - Childhood Vaccine Supply Act of 2002

The bill Authorizes the Secretary to purchase pediatric and adult vaccines for national stockpiles using preventive health services project grant funds using the following language:

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

(3) The Secretary may purchase pediatric and adult vaccines for national stockpiles utilizing a portion of the funds made available under this subsection.

S.2053 Sponsor: Sen Frist - Improved Vaccine Affordability and Availability Act amends the Public Health Service Act and addresses the following pertaining to stockpiling:

Directs the Secretary to: maintain a 6 months supply of prioritized vaccines

making sure the public is fully informed and supports immunization efforts. They need to understand the risks and benefits of vaccines and when concerns arise about vaccine safety, the government should provide information to answer questions. Manufacturers can not effectively provide this service because the information will not be perceived as objective and unbiased, due to business interests.

NVAC suggests that current efforts be enhanced in a national campaign, emphasizing safety and efficacy of vaccines. If the people do not value vaccines, there will be a reluctance to pay for them, and vaccines will continue to be undervalued.

ENSURING EQUITABLE DELIVERY OF VACCINE TO THE CHILDREN AND ADULTS

Recommendations

- § Increase administrative reimbursement fees to cover adequately the costs associated with vaccine delivery in an office or center.
- § Expand VFC to cover vaccinations for SCHIP children.
- § Bring about better coordination and shorter time frames between licensing of the vaccine by the FDA, approval by the ACIP, and purchasing.
 - § Vaccine manufacturers and large purchasers should strive to agree on a public and private price within 60 days
 - § Emergency funds should be provided by the federal government to buy newly recommended vaccines for public programs during the interim after recommendation and before expenditures can be incorporated in the regular budget cycle.
- § Assure full funding for 317 infrastructure, particularly to provide infrastructure for oversight of adult immunizations

Background

The goal of equitable distribution is made more challenging because policies for both purchasing vaccines and reimbursing costs for their administration differ according to the insurance status of the child or adult needing the vaccine. The vaccine delivery system is actually four or possibly five delivery systems, with different policies depending on whether the child is covered by Medicaid, SCHIP, a private insurance company or is uninsured. For adults, Medicare is also involved.

For children covered by Medicaid, the federal government supplies recommended vaccines to physicians through the Vaccines for Children (VFC) program up-front and without cost to the state Medicaid program or physician, and the state Medicaid program reimburses them for the costs of administration (either directly or as part of a capitated payment). For children covered through SCHIP policies vary according to whether the states used SCHIP funds to expand their Medicaid programs (19 states), to institute separate SCHIP programs (15 states), or a combination of the two (17 states) (Edmunds, Teitelbaum, Gleason, 2000). SCHIP children who are covered through a Medicaid expansion program are entitled to VFC-purchased vaccine, while those who are covered through a separate SCHIP program are not. States policies to supply vaccine to SCHIP children in separate state programs differ; some states purchase vaccine in bulk and supply to the physicians, whereas in other states physicians purchase the vaccine and are reimbursed after-the-fact. For privately insured children, physicians typically purchase

the vaccine and either seek reimbursement from the insurance company. For some managed care companies, the cost of the vaccine might be included in the capitated payment, but according to the American Association for Health Plans (AAHP), most managed care companies are moving towards fee-for-service reimbursement for immunization delivery. Uninsured children are eligible for federally-purchased vaccine under the VFC program, but typically there is no reimbursement to a physician for administration costs.

Policies for purchasing vaccine and reimbursement for the administrative costs of its delivery have a profound impact on a private physician's ability and willingness to administer immunizations to all children in the practice. Not surprisingly, then, all of the provider organizations have taken strong positions on purchase and reimbursement of vaccines. The next sections review the evidence on effect of reimbursement policies on physician practices and then give the specific recommendations offered by the provider organizations. These recommendations are followed by recommendations for expanding the VFC program and for fully-funding 317 infrastructure funding.

Impact of Funding Policies on Vaccine Delivery

The change in physician immunizing practice after the introduction of the VFC program offers a dramatic illustration of the impact of purchasing and reimbursement policies on physician practice. Although the VFC program targets mainly Medicaid and uninsured children, the lessons of its impact have far broader implications. In fact, inadequate reimbursement rates for vaccine delivery have also been associated with low immunization rates among Medicare providers (Poland and Miller , 2000).

Before the introduction of the VFC program in 1994, physicians usually purchased vaccine for both Medicaid and privately-insured children. They were reimbursed by the State Medicaid programs or private insurance companies after-the-fact for the vaccine and were also reimbursed for the administrative costs of delivery. For Medicaid children the state-reimbursed fee was unrealistically low in many states, in some states as low as \$1.00 or \$2.00 per immunization (Wood and Halfon, 1996). The VFC program brought about several changes. First, the federal government purchased vaccine and supplied it to physicians up-front for Medicaid and uninsured children. Second, some states, especially those with particularly low rates, used the savings from vaccine purchase in their Medicaid programs to enhance the reimbursement for administrative costs. As a result, reimbursements that had been at \$1.00 or \$2.00 levels increased to \$10.00 or even higher. Increases in New York were particularly sharp, rising from \$2.00 to \$17.85.

The combination of up-front, "free" vaccine (at least to the physician) and enhanced administrative fees had a dramatic impact on vaccine delivery. Whereas before VFC, private physicians had often referred Medicaid children to public clinics because of the expense, delay, and hassle in getting reimbursed, now they began to vaccinate in their own practices. The change in delivery of childhood vaccines from public to private sector has been documented extensively. For example, between 1994 and 1998 National

Immunization Survey reported a decrease in the proportion of families who report receiving all immunization from public clinics from 24 to 17 percent. In some states the shift was even more pronounced. Washington State saw a particularly dramatic trend. In 1994 the public sector accounted for 80% of the vaccine delivery and the private sector for 20 percent. However, by 1999 the figures had completely reversed. In Alabama the trend was also pronounced. Before VFC the public sector delivered 70% of the states immunizations, but by 1999 only that number had dropped to 35% (Fairbrother, Kuttner, Miller et al., 2000). Other states, such as Minnesota and Pennsylvania, also reported reduced doses delivered in the public sector (Zimmerman, Norwalk et al., 2001), while some states, like Maine and New Jersey reported that virtually all immunizations –90%-- take place in the private sector (Fairbrother, Kuttner, Miller et al., 2000). Not surprisingly, given these trends, in national surveys of physicians (Zimmerman, Medsger et al., 1997) and nurse practitioners (Zimmerman, Van Cleve et al., 2000) reported that they were referring fewer children to public clinics and were vaccinating more in their own offices.

In New York, which had one of the largest increase in administrative fee, the proportion of private physicians who reported that they referred some or all of children to public clinics for immunization decreased from 51% in 1993 to 18% in 1997 (Szilagyi, Humiston et al., 2000). This shift was reflected in coverage rates: in the inner city of New York; in private offices seeing the poorest children coverage rates for DTP, Polio and MMR rose 24 percentage points – from 18% to 42% (Fairbrother, Friedman, Hanson, Butts, 1997).

Vaccine Delivery in the Medical Home

It is clear, then, that VFC led to a shift in delivery from public delivery to private doctor's office, by making it financially viable for physicians to vaccinate children in their own offices, rather than referring them to public clinics. The American Academy of Pediatrics strongly recommends care for a child in a regular "Medical Home"⁸ (AAP Policy Statement 2002). For immunizations, having a child's regular doctor administer vaccinations is important in ensuring that a child becomes fully immunized and yet does not receive duplicate doses.

Approximately 5 visits are needed to administer all 20 required doses of routine childhood vaccinations (Recommended Childhood Immunization Schedule, 2002) before 18 months of age. Management of this aspect of the child's care can be daunting when immunizations are given at multiple sites. The child's physician keeps track of the up-to-date status and advises the family when the next vaccination visit should occur. Families also often keep track of their children's vaccination status through individual immunization cards, brought to each vaccination visits. When children receive their

⁸ The American Academy of Pediatrics policy statement urges physicians to strive to attain a medical home for every child in their community. AAP believe that care should be delivered or directed by physicians who provide primary care and help to manage and facilitate essentially all aspects of pediatric care. They physician should be known to the child and family and should be able to develop a partnership of mutual responsibility and trust with them. (AAP Policy Statement 2002.)

immunizations at different sites -- at a public immunization clinic and at their regular provider's office, for example -- both providers update their own records from the family immunization card and add any new immunizations given at the current visit. In theory, then, it is possible to keep accurate records and for the child's regular physician to manage vaccination coverage. Practice differs from theory: cards may be left home or lost or hard to read; records may be transcribed improperly. Studies have shown that receiving vaccinations from different sources leads not only to "record scatter" (Joffe, Rodewald, Herbert, Barth, and Szilagyi, 1999), but also to substantial underestimation of true coverage at the various provider offices (Stokley, Rodewald, and Maes, 2001). Not surprising, then, different providers give duplicate doses of vaccine (Feikema Klevens, Washington and Barker, 2000) because each thinks their patients need it, and the children wind up "extraimmunized". Annual costs for extraimmunizations were estimated conservatively at \$26.5 million, in an era before introduction of the very expensive pneumococcal conjugate vaccine (Feikema Klevens, Washington and Barker, 2000). Costs associated with extraimmunization can only be expected to increase with the addition of more and more expensive vaccines.

The issue may be less acute for adult vaccinations, because only one immunization is required annually for influenza, but it still pertains. Physicians are best able to keep track of the immunizations received if they are given in the office. While influenza vaccinations are frequently administered in vans, senior centers, drug stores and the like, physicians are still held accountable for the immunization status of their patients (NCQA HEDIS 2002). Adults may be well able to keep track of a once-a-year influenza immunization, but may be less able to remember whether they need a pneumococcal vaccine, which is given less frequently (commonly at five year intervals for those 65 and older). Thus, provider involvement in management of coverage is important, even for adults.

Issues and Recommendations Around Reimbursement

Recommendation: Increase administrative reimbursement fees to cover adequately the costs associated with vaccine delivery in an office or center.

Because vaccine reimbursement policies have such a strong impact on the financial viability of administering a vaccine in the private office, it is not surprising that the provider groups have recommendations designed to ensure appropriate reimbursement for the services.

Although the issues are slightly different for pediatric and adult vaccine delivery, all groups are concerned about the Medicare Resource-Based Relative Value Scale (RBRVS) physician fee schedule, which the Centers for Medicare and Medicaid Services (CMS) introduced in January 1992⁹ (AAP, RBRVS Brochure, 2002). Although this fee

⁹ The Centers for Medicare and Medicaid Services (CMS) developed a Resource-Based Relative Value Scale (RBRVS) physician fee schedule based on the relative value of the service they provide and the resources that are used. The relative value of the service is derived from the idea that there are three

schedule was developed for Medicare services, it is used by Medicaid and private insurers as well. It was recently estimated that 63 percent of all private and public payors, including Medicaid, have adopted components of the Medicare RBRVS to determine reimbursement fees for physicians and other payors are exploring its implementation as well.

The RBRVS system recognizes three components of each service: the amount of physician work that goes into the service, the practice expense associated with the service, and the professional liability expense for the provision of the service¹⁰. CMS has taken the position that no physician work is involved in administering vaccines, since, in their view, nurses often provide this service. The key professional organizations have challenged this view, citing that the Relative Value Scale Update Committee (RUC) concluded that immunization administration services include physician work equivalent to the work required in the lowest level office visit (ACP-ASIM Statement to NVAC July 15, 2002). ACP-ASIM, along with AAP and AAFP, strongly supports the work of RUC showing that physician work is required in the administration of vaccines and feel that their work should be sufficient proof to include this value in vaccine reimbursement rates (AAP letter to CMS December 21, 2001; AAFP letter to CMS December 19, 2001; ACP-ASIM letter to CMS September 26, 2001 and December 21, 2001).

The ACP-ASIM has voiced the opinion for several years that CMS reimbursement rates for vaccine administration have been inadequate and that Medicare reimbursement rates do not cover the actual cost of administering a vaccines. ACP-ASIM conducted a survey as part of their Adult Immunization Initiative and found that 85% of general internal medicine physicians believe that reimbursement for

components to each service: physician work, administrative costs, and professional liability (AAP RBRVS Brochure 2002; ACP-ASIM interview July 25, 2002).

¹⁰ Physician work, administrative costs and professional liability each makes up a certain percentage of the total relative value unit (RVU). This unit is then multiplied by the Geographic Practice Cost Indices (GPSI). This factor represents the relative cost compared to the national average relative cost for physician work, malpractice, and practice expenses. A cost of living GPCI is applied to physician work RVU, a malpractice GPCI is applied to the liability RVU, and a practice cost GPCI is applied to the practice expense RVU. In the final step the annually updated Conversion Factor (CF), as specified by the Balanced Budget Act of 1997, is used to convert the RVU into a dollar amount (AAP RBRVS Brochure 2002).

Physician work represents approximately 54% of the total RVU for each service (AAP RBRVS Brochure 2002). Physician work includes work done before, during and after the service and value is assigned based on the time required to perform the service, the technical skill and physical effort required, mental effort and judgement, and psychological stress associated with concern over iatrogenic risk to the patient. These values are updated by CMS with input from AMA/Specialty Society Relative Value Scale Update Committee (RUC) which is composed of representatives from major medical specialty societies. The recommendations made by RUC are reviewed, modified if necessary, and then used to establish payment policy. Practice expenses are established using many sources and methodologies and Professional Liability Insurance (PLI) is approximately 3% of the physician's fee schedule payment (AAP RBRVS Brochure 2002).

immunization is inadequate and that it is a barrier to their practice's ability to provide immunizations (ACP-ASIM Statement to NVAC July 15, 2002).

In addition, the AAP has cited other costs besides physician work, which it wants included in the reimbursement fees. For example, the recent ruling by OSHA that "safe sharps" (retractable needles) be used for that administration of childhood vaccines, rather than current non-retractable version will add an estimated \$14 million to administrative costs annually (AAP letter to OSHA, July 25, 2001). AAP has recommended that the reimbursement be raised to cover this expense of safe sharps. In addition, they call for an increased reimbursement to cover the costs of reporting to immunization registries (AAP interview July 24, 2002). These costs – currently not covered – have been estimated to run from \$1.47 to \$3.24 per immunization for reporting through manual data entry (as would be the case in most offices and centers) and \$.24 per immunization if reporting is through an automated registry interface. (Rask, Wells, Kohler, Rust, Cangialose 2000).

Issues and Recommendations Involving VFC Coverage for SCHIP children

Recommendation: Expand VFC to cover vaccinations for SCHIP children.

The SCHIP program was enacted as Title XXI of the Balanced Budget Act in 1997, four years after enactment of the VFC program. As stated earlier, the states implemented the SCHIP program in a variety of ways, including expanding their Medicaid programs to higher-income children, establishing separate SCHIP programs, or doing both. The motivation for states to establish a separate SCHIP program was to permit more generous eligibility and to move child health insurance out of the public assistance arena with its rigid rules and stigma. Medicaid is an entitlement program; thus, states which used SCHIP funding to increase income eligibility threshold would be bound to cover all children who met the criteria. On the other hand, separate programs could offer more generous income eligibility and offer insurance as long as the funds held out. It is not surprising, then, that the states that used SCHIP funds to expand their Medicaid program set low income eligibility thresholds than those that set up separate programs (Edmunds, Teitelbaum, Gleason 2000). Furthermore, Medicaid had been part of the public assistance environment, with rules and procedures consistent with that environment. Enrollment procedures at that time were considered by families and observers to be burdensome and even humiliating (Stoakley, Wessler, 1994). States wanted to create a new environment for their SCHIP programs.

States did not anticipate the ramifications of this decision on vaccine for the SCHIP children. As enacted, the VFC program provided vaccines for children covered by Medicaid, uninsured children, Native American children, and underinsured children in some settings. In the four years after the enactment of VFC but before the enactment of SCHIP, the children who would later be covered by SCHIP were eligible for VFC vaccines by virtue of being uninsured. Under Title XXI, states must cover age appropriate immunizations for all enrolled SCHIP children, including those in separate programs, but did not address VFC eligibility for the children that would be covered. However, many states assumed that these children would continue to receive VFC-

purchased vaccines. Some states, most notably California, made budgetary decisions on this assumption and negotiated contracts with health plans with rates that did not take into account the cost of vaccine. California sought a ruling from CMS (then HCFA) that would resolve the dilemma. In a letter to California Medical Care Services (dated March 16, 1998), CMS ruled that children enrolled in State CHIP programs are not eligible for free federal vaccines through the VFC program.

As a result of the ruling, states were left with two options to meet the SCHIP immunization requirements: require SCHIP health plans to purchase vaccines at commercial rates, or purchase vaccines at the Federal contract rate. Both of these options added costs to state-only SCHIP programs which are not costs in the Medicaid expansion SCHIP plans because Medicaid children remain VFC eligible (ASTHO Critical Issue Brief, March 20, 1998). States have taken both of these options, but continue to press for VFC coverage of SCHIP children.

The inability to offer VFC vaccines to SCHIP children creates problems for providers at the practice level as well and may lead to referral to the public clinic for vaccinations (Fairbrother, Kuttner, Miller, 2000). Because VFC requires assurance that ensures that the vaccine is only give to eligible children, providers need to set up extra accounting mechanisms and need to be aware of children's insurance status at the time the vaccine is given.

Not surprisingly, given the level of controversy, most provider groups have a position on this matter. In addition, legislation has been introduced in the Senate (S.573 introduced by Senator Feinstein on March 20, 2001)¹¹ to extend the VFC coverage to SCHIP children. ASTHO had recommended in a formal policy statement that exclusions in VFC for underinsured and children in the SCHIP program be removed (ASTHO Policy ID-1 Immunizations). Most providers strongly endorse having VFC vaccines available for SCHIP children; the AAP reports a sense of the membership in this direction, but has not taken a formal position¹². AAFP policy position endorses the position that all children and adults should be able to receive recommended vaccines *without cost* in their own physician's office. The AAFP does not specify through which explicit mechanisms funds would be provided for, but does say that they should come through government purchase or other payers. (AAFP Immunization Policy)

Issues and Recommendations Involving Delays Between Vaccine Licensure, Approval, and Availability of Funds to Cover the Service

Recommendation: Bring about better coordination and shorter time frames between licensing of the vaccine by the FDA, approval by the

¹¹ Bill S.573 Sponsored by Senator Feinstein Amends title XIX (Medicaid) of the Social Security Act (SSA) to allow children enrolled (under SSA title XXI) in the State Children's Health Insurance Program to be eligible for benefits under the pediatric vaccine distribution program.

¹² AAP has not taken a formal position on the inclusion of SCHIP in the VFC program because of concern over opening up VFC for discussion. The ability to provide vaccines to the population currently covered by VFC may be harmed if the program is opened up for debate.

ACIP, and purchasing

- *Vaccine manufacturers and large purchasers should strive to agree on a public and private price within 60 days*
- *Emergency funds should be provided by the federal government to buy newly recommended vaccines for public programs during the interim after recommendation and before expenditures can be incorporated in the regular budget cycle.*

Currently, the sequence of events leading to vaccination delivery to patients begins with FDA approval for licensure. Following that, the ACIP decides whether the vaccine should be recommended for inclusion in the routine childhood series, based on results of extensive testing. The provider organizations (AAP and AAFP) also make recommendations on inclusion and timing of the vaccine, however, after approval by the ACIP, the vaccine is available for administrations by physicians. Families may seek immunizations and /or physicians may wish to give vaccines based on new recommendations at this point, but families insurance may not cover it. Again, the speed with which a funding mechanism is available depends on the insurance status of the child or adult. Private insurance companies generally provide the vaccine as soon as it is approved by ACIP (AAHP interview July 25, 2002), but funding for children who are not privately insured usually takes longer. To provide funding for VFC-eligible children, the CDC needs to contract with pharmaceutical manufacturers to purchase the vaccine at a discounted price negotiated in the course of the contracting process (called the “contract price” or “federal discounted price”). Funding for vaccine for SCHIP children comes either through the state directly or from the state through the health plan. While vaccines purchased through VFC are available relatively quickly, there may be significant delays in state- or plan-purchased vaccines. States may need to request funds through the annual budget appropriation process, and this may account for some elapse of time. Then, if funding for the new vaccine is to come through the health plan, it then needs to be negotiated in the state contracts with health plans. This also could result in significant delays.

These delays in funding being available for the new vaccine have caused significant problems in physicians’ offices. The problems were especially acute in recent years as the cost of vaccine have risen and are now about \$600 per child (Calvin, 2002). The introduction into the schedule of heptavalent pneumococcal conjugate vaccine (PCV-7, Prevnar) costs \$58 per dose or \$232 (Scheifele, 2000) for the recommended four-dose series, adding to the total costs and exacerbating an already difficult situation. The AAP reported that in the past pediatricians began offering a vaccine as soon as it had been approved, even though details of funding had not been worked out. This approach worked in the past with the introduction of less expensive vaccines because many payors reimbursed for the vaccine after the fact, and pediatricians were able to absorb the residual cost. However, with such an expensive vaccine as Prevnar and with the delays in funding, pediatricians have not been able to absorb the costs not covered by the system.

AAP reports that they have heard from pediatricians who owe significant balances for Prevnar, which they ordered anticipating eventual third party reimbursement. Many have found that reimbursement did not adequately cover the cost of the vaccine or that third party payors were not providing coverage at all. The AAP also reported that they have heard from physicians who have had to take out lines of credit to meet payroll costs and remain open because of the loss of income they have experienced through providing this vaccine. Also, the AAP reported that they have learned of physicians who are contemplating referring children to the public clinic rather than provide the vaccine in the medical home, due to cost.

Beyond the problems of paying for the vaccine, pediatricians are also faced with an interim period during which some children are covered for the vaccine, but not others and the need to either provide differential service depending on the insurance status or find a way to pay for the children not covered in the interim. The problems this situation engenders go beyond the problems of bookkeeping.

To address these problems, AAP has recommended closer coordination of licensing, approval and purchasing, with a target of 60 days after licensure for establishment of public and private price. AAP also recommends that the federal government provide emergency funds to buy the newly licensed vaccines for public programs with fixed annual appropriations in the interim between the time recommendation by ACIP, AAP and AAFP and the time the expenditures are incorporated in the regular budget cycle.

Issues and Recommendations Around Vaccine Infrastructure

Recommendations: Assure full funding for 317 infrastructure, particularly to provide infrastructure for oversight of adult immunizations

The State and Territorial Health Officers urge full funding for immunization infrastructure, especially in order to adequately oversee adult immunizations. They point out that of the 64 current CDC state and urban immunization grantees, only 43 have a coordinator of adult immunization activities, and that additional resources will be needed to develop adult immunization plans, identify and target those at highest risk for complications of vaccine-preventable diseases, establish community partnerships and coalitions, and work with nursing homes to establish standing orders and vaccination protocols (ASTHO testimony, November 27, 2001).

CONCLUSION

Although recommendations offered by the major stakeholders differ, there is broad consensus that major changes are needed in development, pricing and delivery. The problems these recommendations address affect reliable supply of vaccines, ability of “usual source of care” physicians to immunize and manage up-to-date status of patients, health of the public and national security. It is important to arrive at consensus on what

steps should be taken and begin reforming the structure for supply and delivery of vaccinations.

References

- American Academy of Family Physicians Policies on Health Issues. Cost of Immunization. website: <http://www.aafp.org/x6884.xml>
- American Academy of Family Physicians. Letter Richard Roberts, MD, JD, FAAFP, to Administrator Thomas Scully. Centers for Medicare and Medicaid Services. Comment on Revisions to Payment Policies and Five Year Review of Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002. December 19, 2001
- American Academy of Pediatrics. Letter from Louis Cooper, MD, FAAP President, to Administrator Thomas Scully. Centers for Medicare and Medicaid Services. RE: Medicare Programs; Revisions to Payment Policies and Five Year Review of Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule; CMS-1169=FC. December 21, 2001.
- American Academy of Pediatrics. Letter from Louis Cooper, MD, FAAP President, to Senator Frist. The Improved Vaccine Affordability and Availability Act. July 19, 2002.
- American Academy of Pediatrics. Letter from Steve Berman, MD, FAAP President, to National Vaccine Program Office. RE: Request for Input on Vaccine Financing. May 30, 2001.
- American Academy of Pediatrics. Letter from Steve Berman, MD, FAAP President, to Occupational Safety and Health Administration (OSHA). RE: Needlestick Prevention Act and Childhood Immunization. July 25, 2001.
- American Academy of Pediatrics Policy Statement: The Medical Home. *Pediatrics*. 2002 July; 110(1): 184-186.
- American Academy of Pediatrics. RBRVS: What is it and How Does it Affect Pediatrics? Brochure, 2002.
- American Academy of Pediatrics. Testimony Before United States Senate Committee on Governmental Affairs by Timothy Doran MD, FAAP. Protecting Our Kids: What is Causing the Current Childhood Vaccine Shortage? June 12, 2002.
- American College of Physicians/American Society of Internal Medicine (ACP-ASIM). Letter to Administrator Thomas Scully. Centers for Medicare and Medicaid Services. Inaccurate and inadequate Vaccine Administration Payments. December 21, 2001.

- American College of Physicians/American Society of Internal Medicine (ACP-ASIM). Letter to Administrator Thomas Scully. Centers for Medicare and Medicaid Services. Recommendations to Revise Medicare and Medicaid Vaccination Policies. September 26, 2001.
- American College of Physicians/American Society of Internal Medicine (ACP-ASIM). Statement to National Vaccine Advisory Committee on Reimbursement for Vaccine Administration. July 15, 2002.
- Association of State and Territorial Health Officials (ASTHO). Cheryl Beversdorf, RN, MHS, CAE, Executive President. Critical Issues Brief-VFC Coverage in CHIP Plans. March 20, 1998.
- Association of State and Territorial Health Officials (ASTHO). Immunization Policy. ID-1,1.1-1.4.3 Expires December 31, 2003.
- Association of State and Territorial Health Officials (ASTHO). Letter from Donald Williamson, MD, to Secretary Shalala. U.S. Department of Health and Human Services. Vaccines for Children. February 24, 1998.
- Association of State and Territorial Health Officials (ASTHO). Letter from George Hardy Jr., MD, MPH Executive Director, To Administrator Scully. Centers for Medicare and Medicaid Services. Reimbursement Rates. April 3, 2002.
- Association of State and Territorial Health Officials (ASTHO). Testimony before the Committee on Health, Education, Labor and Pensions by FE Thompson JR., MD, MPH. November 27, 2001.
- Calvin K, Black R, Kieu Q. Healthy Families Vaccine Problems. Updated August 2002.
- Centers for Disease Control and Prevention (CDC). Testimony Before United States Senate Committee on Governmental Affairs by Walter Orenstein, MD. Protecting Our Kids: What is Causing the Current Childhood Vaccine Shortage? June 12, 2002.
- Cohen J. U.S. Vaccine Supply Falls Seriously Short. News Focus. *Science*. 2002 March;295
- Edmunds M, Teitelbaum M, Gleason C. All Over the Map: A Progress Report on the State Children's Health Insurance Program (CHIP). Health Division of the Children's Defense Fund. Washington DC. 2000 July.
- European Agency for the Evaluation of Medicinal Products. Website: <http://www.emea.eu.int/>.
- Fairbrother G, Friedman S, Hanson KL, Butts GC. Effect of the Vaccines for Children

- Program on Inner-city Neighborhood Physicians. *Arch Pediatr Adolesc Med.* 1997;151(12):1229-1235.
- Fairbrother G, Kuttner H, Miller W, et al., Findings from Case Studies of State and Local Immunization Programs. *Am J Prev Med.* 2000;19(3S):54-77.
- Feikema SM, Klevens RM, Washington ML, Barker L. Extraimmunization Among US Children. *JAMA* 2000; 283 (10): 1311-7.
- Food and Drug Administration (FDA). Prescription Drug User Fees. Website: <http://www.fda.gov/oc/pdufa/reports.html>
- Food and Drug Administration (FDA). Testimony Before United States Senate Committee on Governmental Affairs by Lester Crawford, D.V.M, PhD. Protecting Our Kids: What is Causing the Current Childhood Vaccine Shortage? June 12, 2002.
- General Accounting Office (GAO). Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily. December 1999.
- Health Resources and Services Administration. Office of Special Programs. Vaccine Injury Compensation Program. Website: <http://www.hrsa.gov/osp/vicp/abdvic.htm>
- Institute of Medicine (IOM). Statement on Vaccine Development Council of the Institute of Medicine. November 5, 2001. Website: <http://www.iom.edu/iom/iomHome.nsf/Pages?Vaccine+Development>
- International Conference on Harmonization. Website: <http://www.pharmweb.net/pwmirror/pw9/ifpma/ich8.html>
- Joffe GP, Roedewald LE, Herert T, Barth R, Szilagyi PG. Scattering of Primary Care: Doctor switching and Utilization of Health Care by Children on Fee-for-Service Medicaid. *Journal of Urban Health.* 1999; 76:322-334.
- Joseph CL, Giblin PT, Kallenbach LR, Jacobsen G, Davis RM. Visiting Multiple Sites for Immunization and Vaccine Coverage Levels of Preschool Children in 3 Urban Clinics: Potential Indicator of Record Scatter? *Clin Pediatr (Phila).* 2002 May; 41(4):249-56.
- Lederberg J, Shope RE, Oaks SC, eds. Emerging Infections: Microbial Threats to Health in the United States. Washington, DC: National Academy Press, 1992.
- Mason, Dean. An Update on DTaP, Td, MMR, PCV-7, Varicella, and Other Vaccines for the U.S. Market. Presentation to Colorado Health Officials. July 17, 2002.

- Mitchell VS, Pilipose NM, Sanford JP, eds. *The Children's Vaccine Initiative: Achieving the Vision*, Washington, DC: National Academy Press, 1993.
- Mowery D, Mitchell V. Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives. *Journal of Health Politics, Policy and Law*. 1995;20(4):973-1000.
- National Committee for Quality Assurance. HEDIS 2002.
- National Immunization Program. Thimerosal and Vaccines. What are Federal Government Recommendations. Website: <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/faqs-thimerosal.htm#3>
- National Vaccine Authority Committee on Strengthening the Supply of Routinely Recommended Vaccines in the United States. Jerome Klein, MD. May 30, 2002 Draft.
- Paradiso, Peter, PhD. Vice President of Scientific Affairs Wyeth-Lederle Vaccines and Pediatrics. Reauthorization of Section 317 of the Public Health Services Act. Subcommittee on Public Health and Safety. May 6, 1997.
- Pharmaceutical Research and Manufacturers of America (PhRMA). Testimony Before United States Senate Committee on Governmental Affairs by Wayne Pisano. Statement. June 12, 2002.
- Poland GA, Miller SM. Funding Mechanism and Infrastructure for Deliver of Adult Vaccine in the United State: the undeclared public health emergency. Paper prepared for the Institute of Medicine Committee on Immunization Policies and Practices. Washington DC, 2000.
- Rask K, Wells K, Kohler S, Rust C, Cangialose C. The Cost to Providers of Participating in an Immunization Registry. *Am J Prev Med*. 2000;19(2):99-103.
- Recommended Childhood Immunization Schedule United State, 2002. National Immunization Program. website: <http://www.cdc.gov/nip/recs/child-schedule.htm#Printable>
- Scheifele D. New Vaccines and the Rising Costs of Caring. Editorial. *Pediatrics and Child Health*. 2000;5(7)371-372.
- Stokely S, Rodewald LE, Maes EF. The Impact of Record Scattering of the Measurement of Immunization Coverage. *Pediatrics*. 2001;107(1):91-6.
- Stoakley D, Wessler J. Medicaid barriers: a qualitative view of the need for change. New York: Children's Defense Fund/New York Child Health Project, January, 1994.

Summary of Adolescent/Adult Immunization Recommendations. National Immunization Program. website: <http://www.cdc.gov/nip/recs/adult-schedule.htm#pdf-format>

Szilagyi PG, Humiston SG, Pollard Shone L, Kolasa MS, Rodewald LE. Decline in physician referrals to health department clinics for immunizations: the role of vaccine financing. *Am J Prev Med.* 2000;18(4): 318-24.

Tan L. Strengthening the Supply of Routinely Recommended Vaccines in the United States: A Perspective from the American Medical Association. *Infectious Diseases.* (In Press)

Wood DL, Halfon N. The Impact of the Vaccine for Children's Program on Child Immunization Delivery: A Policy Analysis. *Arch Pediatr Adolesc Med.* 1996 Jun; 150(6): 577-81.

Zimmerman RK, Medsger AR, et al., Impact of Free Vaccine and Insurance Status on Physician Referral of Children to Public vaccine Clinics. *JAMA.* 1997; 27(12): 996-1000.

Zimmerman RK, Meieczkowski TA, et al., Effects of the Vaccines for Children Program on Physician Referral of Children to Public Vaccine Clinics: A Pre-Post Comparison. *Pediatrics.* 2001 Aug; 108(2): 297-304.

Zimmerman RK, Norwalk MP, et al., The Vaccine for Children Program Policies, Satisfaction and vaccine Delivery. *Am J Prev Med.* 2001;21(4): 243-249.

Zimmerman RK, Van Cleve SN, Medsger AR, Raymund M, Ball JA. Does the Vaccines for Children Program Influence Pediatric Nurse Practitioner Referral of Disadvantaged Children to Public Vaccine Clinics? *Matern Child Health J.* 2000; 4(1): 53-8.

Appendix A

Conducted Interviews with the Following Stakeholders

PROVIDER GROUPS

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Appendix B

**RECOMMENDATIONS FROM
PROVIDER GROUPS**

| | <u>American Academy of Pediatrics (AAP)</u> | <u>American Academy of Family Physicians (AAFP)</u> | <u>American College of Physicians American Society of Internal Medicine (ACP-ASIM)</u> | <u>American Medical Association (AMA)</u> |
|---|--|--|---|---|
| ENSURING AN ADEQUATE SUPPLY OF VACCINES | | | | |
| Adequately Price Vaccines | | | | |
| Review Implementation of CGMP | | | | |
| Improve Ability to Assess Supply Prior to Shortage | | | | § Earlier notification from manufacturers of a shortage to the FDA § Improved notification to physicians (LJ Tan paper) |
| Harmonize and Streamlining Regulatory Process | | | | § Faster approval for new vaccine § Streamline production, FDA approval, and distribution of vaccine lots (LJ Tan paper) |
| Strengthen VICP | § Clarify definition of vaccines to include all components and ingredients listed vaccine licensee, as well as definition of manufacturer and vaccine related injury or death § Provisions for compensation to parents or third party adjudication through VICP § Allowing compensation for family counseling (Letter to Senator Frist 7/19/02) | | | § Strengthen VICP but keep in mind impact of negative consumer perception § Keep in mind liability issues for administrators of vaccines (LJ Tan Paper) |
| Expand Stockpile | § National stockpile for 6 to 12 months § Include all routinely recommended pediatric vaccines (Letter to Senator Frist 7/19/02) | | | § National stockpile for 6 to 12 months (LJ Tan Paper) |
| Improve Public | | | | |

| | | | | |
|--|---|--|--|--|
| Confidence in Vaccines | | | | |
| ENSURING EQUITABLE DELIVERY OF VACCINES TO CHILDREN AND ADULTS | | | | |
| Increase Administrative Reimbursement Fees | <p>§ Include physician work as part of reimbursement (Letter to CMS 12/21/01)</p> <p>§ Include cost of immunization registry</p> <p>§ Include cost of safe sharps (AAP Interview 7/24/02)</p> | <p>§ Include physician work as part of reimbursement</p> <ul style="list-style-type: none"> • Recommend CMS simplify coding methodology (Letter to CMS 12/19/01) | <p>§ Include physician work as part of reimbursement</p> <p>§ Recommend CMS simplify coding methodology (ACP-ASIM letters to CMS 9/26/01 and 12/21/01; ACP-ASIM website)</p> | |
| Expand VFC to Include SCHIP | <p>§ Does not have formal position but sense of member ship is SCHIP children should be covered by VFC (AAP Interview 7/4/02)</p> | <p>§ Recommends states allow intermingling of VFC and other vaccine supplies. (AAFP immunization policy)</p> | | |
| Prevent Delays Between Licensing, Approval and Purchasing of Vaccines | <p>§ agree on a public and private price within 60 days after FDA licensure</p> <p>§ The federal government provide emergency funds during interim, before expenditure incorporated into budget cycle (AAP to NVPO 5/30/01)</p> | | | |
| Assure Full Funding for 317 Infrastructure | | | | |

**RECOMMENDATIONS FROM
PROFESSIONAL ORGANIZATIONS**

| | <u>American Public Health Association (APHA)</u> | <u>Association of State and Territorial Health Officials (ASTHO)</u> | <u>American Association of Health Plans (AAHP)</u> | <u>Pharmaceutical Research and Manufacturers for America (PhRMA) and Industry Representatives</u> | <u>National Vaccine Advisory Committee (NVAC)</u> |
|---|---|---|---|--|---|
| ENSURING AN ADEQUATE SUPPLY OF VACCINES | | | | | |
| Adequately Price Vaccines | | | | | § Establish independent multi-disciplinary group to determine incentives § Guarantee market price § Reward performance through contracts (NVAC paper 5/30/02) |
| Review Implementation of CGMP | | | | § Adequate advance notice for manufacturing changes (Testimony 6/1202) | § Advanced notification for required changes § Reviewing the implementation of GMP § Tax relief for required changes (NVAC paper 5/30/02) |
| Improve Ability to Assess Supply Prior to Shortage | | | | § Allow CDC to share proprietary supply information § Manufactures should provide advanced notice when manufacturer leaves market (Interviews with industry representatives) | § Revise rules for proprietary information so CDC can share information if there are supply limitations (NVAC paper 5/30/02) |
| Harmonize and Streamlining Regulatory Process | | | | § Harmonize the licensure and approval process with other countries (Interviews with industry representatives) | § Harmonizing the content and format need for regulatory submissions of license applications § Increase funding for Center for Biologics Evaluation and Research § Enhance licensure of vaccines through communication with |

| | | | | | |
|--|--|---|--|---|--|
| | | | | | sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs (NVAC paper 5/30/02) |
| Strengthen VICP | | § Request changes in VICP made in consultation with states (ASTHO Policy ID-1 Immunizations, 1.3.4) | | § Clarify definition of vaccines to include all components and ingredients listed vaccine licensee, as well as definition of manufacturer and vaccine related injury or death § Support Frist legislation (Testimony 6/12/02) | § Should recognize that "vaccines" include the active ingredients as well as preservatives, additives and excipients (NVAC paper 5/30/02) |
| Expand Stockpile | | § National stockpile for 6 months using VFC (Interview July 24th, 2002) | | § Expand stockpiles for both single and multi-source products. (Testimony 6/12/02) | § Stockpile a larger number and greater quantity of routinely administered vaccines. (NVAC paper 5/30/02) |
| Improve Public Confidence in Vaccines | | | | § Bring the public into the process and boost its confidence (Testimony 6/12/02) | § National campaign to emphasize safety and efficacy (NVAC paper 5/30/02) |
| ENSURING EQUITABLE DELIVERY OF VACCINES TO CHILDREN AND ADULTS | | | | | |
| Increase Administrative Reimbursement Fees | | § Include physician work as part of reimbursement (Letter to CMS 4/3/02) | | § Rates should reflect administrative work (Testimony 6/12/02) | § Reimbursement rates should include administrative work (NVAC paper 5/30/02) |
| Expand VFC to Include SCHIP | | § Advocate including SCHIP children in VFC (ASTHO Policy ID-1 Immunizations, 1.3.2 and Letter to DHHS 2/24/98) | § Not a concern for plans because does not directly effect them (Interview 7/25/02) | | |
| Prevent Delays Between Licensing, Approval and Purchasing of Vaccines | | | | | |

| | | | | | |
|---|--|--|--|--|--|
| Assure Full Funding for 317 Infrastructure | | § Full funding of section 317 programs (ASTHO Policy ID-1 Immunization 1.3. 1) | | | |
|---|--|--|--|--|--|

Appendix C

Recommendations By Issue

ENSURING AN ADEQUATE SUPPLY OF VACCINE

Adequately Price Vaccines

Without appropriate pricing and financial incentives, manufacturers will pull out of the industry because profit will not be great enough for them to sustain their business. Pricing appropriately includes taking into account research and development costs. The cost of developing a new product includes that of the other products that were created in the process but failed. Inadequate pricing effects manufacturer's ability to invest in research and facilities (Peter Paradiso testimony may 6, 1997). Therefore, pricing or financial incentive should take into account failed products.

§ The National Vaccine Advisory Committee (NVAC) suggests that an independent, multi-disciplinary group be established to help develop recommendations look into the matter of appropriate incentives for manufacturers to sustain the supply of existing vaccines and the development of new ones.

§ NVAC also suggests guaranteeing a market price and to consider incorporating performance reward into the contracting process

Review Implementation of Current Good Manufacturing Practice (CGMP) Standards.

Current Good Manufacturing Practices (CGMP) are established by current industry processes and FDA regulations. Conformity to the standards are determined through inspection and surveillance before and after licensure. These standards were put into place to help ensure vaccines meet the requirements for safety and have not technically changed since their implementation.

§ The industry advocate for government agencies and advisory committees to provide adequate advance notice whenever manufacturing changes are necessary (PhRMA testimony June 12, 2002).

§

§ NVAC also supports providing advanced notice when manufacturing changes are required as well as providing tax relief for new facilities or reconstruction of old facilities.

§ NVAC also sets forth a proposal to review the implementation of CGMP standards so they do not have a negative impact on supply (NVAC paper May 30, 2002). Establishing which standards are still relevant.

The goal is to have standards that incorporate current technological advances and improvements but also remain flexible enough to ensure the continued vaccine production (NIP interview August 6, 2002; NVAC paper May 30, 2002).

Improve Ability to Assess Supply Prior to Shortage

In addition to disruptions in production, a manufacturer pulling out of the vaccine market has instigated shortages.

- § Bill S.2049 was sponsored by Senator DeWine, Senator Dodd, Senator Clinton and Senator Schumer, introduced 3/21/2002, the Childhood Vaccine Supply Act of 2002 Amends the Federal Food, Drug, and Cosmetic Act to require a sole manufacturer of a biological product (currently, a drug) subject to licensure to notify the Secretary of Health and Human Services no later than one year before discontinuing its manufacture. Permits a shorter notification period if the manufacturer can continue the distribution of the product involved for one year.
- § Some in the industry support this idea while other representatives argue that advanced notification may alert of a shortage but it is unlikely that another manufacturer can increase production quickly enough to prevent the shortage.
- § Manufacturers and NVAC also advocate providing the CDC with the ability to share proprietary information on supply concerns in light of a pending shortage. In light of a shortage, it would be beneficial for CDC to confidentially share this information to prevent a large disruption in supply. The availability of this information would allow for a more open discussion among manufacturers to determine how the gap could be filled based on existing capacity of various producers, before the shortage occurs.

Harmonize and Streamline Regulatory Process

Harmonization of the licensing and approval process with other countries could open up doors for having more manufacturers in the market place as well as help address shortage issues. Currently, regulatory requirements vary from country to country, which may result in unnecessary obstacles and delays in development, approvals and introduction of products around the world. Harmonization of technical and regulatory requirements can help to decrease costs and expedite the process of getting products to the public.

- § The National Vaccine Advisory Committee (NVAC) advocates “harmonizing the content and format need for regulatory submissions of license application in the context of the International Committee on Harmonization and working with other regulatory authorities to achieve mutual recognition of lot release tests for various vaccines” (NVAC paper May 30, 2002).
- § The industry supports the harmonization of the licensing and approval process to decrease duplication of work and providing them with the ability to get needed products out to the public more quickly.
- § NVAC and the AMA suggests enhancing streamlining of licensure through communication with sponsors; regulatory research that facilitates product development; and fast track and accelerated approval programs.

- § In addition NVAC suggest increasing funding for the Center for Biologics Evaluation and Research (CEBER) to assure they have the resources needed to establish safety efficacy, and quality.

Strengthen Vaccine Injury Compensation Program (VICP)

Manufacturers once again face liability issues due to the recent upsurge in suits for thimerosal. Families have sued manufacturers for thimerosal, an added preservative, without going through the VICP. The unclear definition of a vaccine allowed individuals to circumvent the system. In addition, families of children injured by vaccines have sued manufactures, asking to be compensated for the effect the vaccine injury has had on the family.

- § AAP, NVAC and PhRMA all take the position that strengthening the VICP is necessary. All support clarifying the definition of what a vaccine. The definition of vaccines should include the active ingredients as well as preservative, additives and excipients and is seen as especially important due to the recent thimerosal discussion.
- § The AAP also supports the inclusion of language allowing for compensation for family counseling and feels that it would not be in the best interests of the child to separate the claims of the parents from that of the child. For this reason, they would also recommend the addition of provisions within the VICP to provide compensation to parents or third parties (AAP letter to Senator Frist, July 19, 2002).
- § Legislation S.2053 sponsored by Senator Frist, Senator Bunning, Senator Hutchinson, and Senator Gordon, introduced on March 21, 2002, the Improved Vaccine Affordability and Availability Act amends the Public Health Service Act and addresses VICP. The bill clarifies definitions of vaccines and manufacturers, provides provisions to improve the ability of individuals to make claims and the same time attempts to slow the process of individuals bringing derivative claims against manufacturers.
- § PhRMA's testimony to the Governmental Affairs Committee on June 12, 2002, states that they strongly support the provisions of the Frist bill and (PhRMA's testimony June 12, 2002). The industry feels the Frist's bill makes the system more user friendly and it reiterates the initial intent of the program which states that claims proceed initially through VICP.
- § Legislation H.R.3741 sponsored by Representative Burton and co-sponsored by 39 representatives was introduced 2/13/2002. This bill, the National Vaccine Injury Compensation Program Improvement Act of 2002 , amends the Public Health Service Act addressing mostly compensation issues. The language is as follows:

- (1) revise the basis for calculating the projected lost earnings of a person who sustained a vaccine-related injury;
- (2) increase the award for a vaccine-related death;
- (3) allow compensation for expenses for family counseling and establishing guardianship;
- (4) allow payment of interim attorneys' fees and costs;
- (5) establish a procedure for paying attorneys' fees;
- (6) extend from two

to six years the statute of limitations for injuries or death from a vaccine set forth in the Vaccine Injury Table; (7) revise the membership and meeting schedule of the Advisory Commission on Childhood Vaccines; and (8) direct the Secretary of Health and Human Services to conduct a public service announcement campaign about the availability of the Program.

- § ASTHO asks that any changes made to the program are made in consultation with states.

Expand Stockpile

Creating stockpiles of vaccines can help to smooth out temporary problems in production, and the concept of stockpiling is endorsed by virtually all the major groups. There is disagreement over what vaccines should be in the stockpile, the length of time the stockpile should cover, and how the stockpile should be paid for. Stockpiles will not solve problems of shortages; these are caused by fundamental problems in the marketplace however, stockpiles will provide a cushion to help with short-term supply problems. AAP, AMA, PhRMA, NVAC and ASTHO all have formal positions on stockpiling.

- § The AAP's position is that stockpiles should include all routine childhood vaccines for 6 to 12 months.
- § AMA supports a national stockpile without specifying the size of the stockpile and for what vaccines.
- § PhRMA supports expanding the stockpile for both single and multi-source products.
- § NVAC asks for a stockpile larger in number and quantity of routinely administered vaccines.
- § ASTHO support a national 6 month stockpile of all vaccines, funded through VFC. They believe the stockpile should be part of the VFC program and not compete with other infrastructure needs in the 317 program.

The current bills addressing the stockpile call for an amendment to 317 of the Public Health Service Act, allowing the Secretary of Health and Human Services to purchase childhood and adult vaccines for national stockpile.

- § Bill S.2049 sponsored by Senator DeWine, Senator Clinton, Senator Dodd, and Senator Schumer, the Childhood Vaccine Supply Act of 2002 authorizes the Secretary of Health and Human Services to purchase pediatric and adult vaccines for national stockpiles using preventive health services project grant funds by providing an amendment Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) to purchase pediatric and adult vaccines for national stockpiles.

- § Bill S.2053 Sponsored by Senator Frist, Senator Bunning, Senator Hutchison, and Senator Smith introduced 3/21/2002, Directs the Secretary to maintain a 6 months supply of prioritized vaccines.

Improve Public Confidence in Vaccines

Safety and efficacy are important issues that are addressed in the regulation of vaccines, but their safety and efficacy must be communicated to the public as well. They need to understand the risks and benefits of vaccines and when concerns arise about vaccine safety, the government should provide information to answer questions.

- § Manufacturers firmly believe that the government holds an important role in making sure the public is fully informed and supports immunization efforts.
- § NVAC suggests that current efforts be enhanced in a national campaign, emphasizing safety and efficacy of vaccines.

ENSURING EQUITABLE DELIVERY OF VACCINES TO CHILDREN AND ADULTS

Increase administrative reimbursement fees

Although the issues are slightly different for pediatric and adult vaccine delivery, all groups are concerned about the Medicare Resource-Based Relative Value Scale (RBRVS) physician fee schedule, which the Centers for Medicare and Medicaid Services (CMS) introduced in January 1992 (2002 RBRVS brochure AAP). CMS has taken the position that no physician work is involved in administering vaccines, since, in their view, nurses often provide this service.

- § ACP-ASIM, AAP, AAFP strongly supports the work of RUC showing that physician work is required in the administration of vaccines and feels that their work should be sufficient proof to include this value in vaccine reimbursement rates (AAP letter to CMS 12-21-01; AAFP letter to CMS 12-19-01; ACP-ASIM letter to CMS 9-26-01 and 12-21-01).
- § ASTHO supports including physician work as part of reimbursement.
- § PhRMA and NVAC advocates that the reimbursement rates should reflect the administrative work.
- § AAP has cited other costs besides physician work, which they would like included the reimbursement fees. These costs include the expense for safe sharps (retractable needles) which OSHA requires the use of and the costs of reporting to immunization registries (AAP interview July 24, 2002).

In addition to amount, which is reimbursed the CMS coding methodology is of concern.

§ ACP-ASIM and AAFP recommend that CMS no longer require the use of G. codes.

Expand VFC to Include SCHIP children

The inability to offer VFC vaccines to SCHIP children creates problems for providers at the practice. Because VFC requires assurance that ensures that the vaccine is only give to eligible children, providers need to set up extra accounting mechanisms and need to be aware of children's insurance status at the time the vaccine is given. Most providers strongly endorse having VFC vaccines available for SCHIP children.

§ ASTHO advocates for including SCHIP children in the VFC program.

§ AAFP recommends the intermingling of VFC vaccines with other vaccine supplies.

§ The AAP reports a sense of the membership in this direction, but has not taken a formal position

§ Legislation S.573 sponsored by Senator Feinstein and co-sponsored by six senators, was introduced 3/20/2001. This bill calls for the inclusion of SCHIP children in the VFC program using the following language:

Amends title XIX (Medicaid) of the Social Security Act (SSA) to allow children enrolled (under SSA title XXI) in the State Children's Health Insurance Program to be eligible for benefits under the pediatric vaccine distribution program.

Prevent Delays Between Licensing, Approval and Purchasing of Vaccines

Currently, the sequence of events leading to vaccination delivery into patients begins with FDA approval for licensure. Following that, the ACIP decides whether the vaccine should be recommended for inclusion in the routine childhood series, based on results of extensive testing. The provider organizations (AAP and AAFP) also recommend on inclusion and timing of the vaccine, however, after approval by the ACIP, the vaccine is available for administrations by physicians.

Families may seek immunizations and /or physicians may wish to give vaccines based on new recommendations at this point, but families insurance may not cover it. These delays in funding being available for the new vaccine have caused significant problems in physicians' offices.

§ AAP has recommended closer coordination of licensing, approval and purchasing, with a target of 60 days after licensure for establishment of public and private price. AAP also recommends that the federal government provide emergency funds to buy the newly licensed vaccines for public programs with fixed annual appropriations in the interim between the time recommendation by ACIP, AAP and AAFP and the time the expenditures are incorporated in the regular budget cycle.

Assure Full Funding for 317 Infrastructure

Out that of the 64 current CDC state and urban immunization grantees, only 43 have a coordinator of adult immunization activities, and that additional resources will be needed to develop adult immunization plans, identify and target those at highest risk for complications of vaccine-preventable diseases, establish community partnerships and coalitions, and work with nursing homes to establish standing orders and vaccination protocols (ASTHO testimony, November 27, 2001).

§ ASTHO urges full funding for immunization infrastructure, especially in order to adequately oversee adult immunizations.

Appendix D

Key Legislation

Bill S.2049 (DeWine)

Title: A bill to amend the Federal Food, Drug and Cosmetic Act to include a 12 month notification period before discontinuing a biological product, and for other purposes.

Sponsor: Senator DeWine (introduced 3/21/2002)

Cosponsors:

Senator Clinton, Senator Dodd, Senator Schumer

Summary:

Childhood Vaccine Supply Act of 2002 - Amends the Federal Food, Drug, and Cosmetic Act to require a sole manufacturer of a biological product (currently, a drug) subject to licensure to notify the Secretary of Health and Human Services no later than one year before discontinuing its manufacture. Permits a shorter notification period if the manufacturer can continue the distribution of the product involved for one year.

Authorizes the Secretary to purchase pediatric and adult vaccines for national stockpiles using preventive health services project grant funds.

Bill S.2053 (Frist)

Title: A bill to 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, and for other purposes.

Sponsor: Senator Frist (introduced 3/21/2002)

Cosponsors:

Senator Bunning, Senator Hutchison, Senator Smith

Summary:

Improved Vaccine Affordability and Availability Act - Amends the Public Health Service Act to authorize additional appropriations for grants to States to increase influenza immunization rates in high risk populations, including medically underserved adults and adolescents, and extend vaccine availability.

Requires the Secretary of Health and Human Services to provide for a program of research, demonstration projects, and education to ensure that immunizations are routinely offered to adults and adolescents by public and private health care providers. Requires such program to collect data on adverse impacts associated with immunizations.

Directs the Secretary to: (1) develop and disseminate information concerning certain diseases and their vaccines, including bacterial meningitis and hepatitis A and B; and (2) maintain a 6 months supply of prioritized vaccines.

Revises provisions governing the National Vaccine Injury Compensation Program, including provisions regarding: (1) equitable relief; (2) third party petitions; (3) jurisdiction to dismiss improperly brought claims; (4) vaccine-unrelated injury; (5) an increase in the award for pain and suffering in the case of a vaccine-related death; (6) the basis for calculating projected lost earnings; (7) compensation for family counseling and establishing guardianship expenses; (8) payment of interim costs; (9) procedures for paying attorney's fees; (10) extending the statute of limitations; (11) the composition and meeting schedule of the Advisory Committee on Childhood Vaccines; and (12) standards of responsibility and the definitions of manufacturer, vaccine-related injury or death, and vaccine.

Requires the Secretary to contract with the Institute of Medicine of the National Academy of Science to conduct an ongoing, comprehensive review of new scientific data on childhood vaccines.

Bill H.R.3741 (Burton)

Title: To amend the Public Health Service Act with respect to the National Vaccine Injury Compensation Program.

Sponsor: Representative Burton (introduced 2/13/2002)

Cosponsored:
by 39 Representatives

Summary:

National Vaccine Injury Compensation Program Improvement Act of 2002 - Amends the Public Health Service Act to (1) revise the basis for calculating the projected lost earnings of a person who sustained a vaccine-related injury; (2) increase the award for a vaccine-related death; (3) allow compensation for expenses for family counseling and establishing guardianship; (4) allow payment of interim attorneys' fees and costs; (5) establish a procedure for paying attorneys' fees; (6) extend from two to six years the statute of limitations for injuries or death from a vaccine set forth in the Vaccine Injury Table; (7) revise the membership and meeting schedule of the Advisory Commission on Childhood Vaccines; and (8) direct the Secretary of Health and Human Services to conduct a public service announcement campaign about the availability of the Program.

Amends the Internal Revenue Code to increase the limit on Vaccine Injury Compensation Trust Fund administrative expenses.

Bill S.573 (Feinstein)

Title: A bill to amend title XIX of the Social Security Act to allow children enrolled in the State children's health insurance program to be eligible for benefits under the pediatric vaccine distribution program.

Sponsor: Senator Feinstein (introduced 3/20/2001)

Cosponsors:

Senator Boxer, Senator Brownback, Senator Chafee, Senator Durbin, Senator Murray,
Senator Reed

Summary:

Amends title XIX (Medicaid) of the Social Security Act (SSA) to allow children enrolled (under SSA title XXI) in the State Children's Health Insurance Program to be eligible for benefits under the pediatric vaccine distribution program.