



Rx: Health Care FYI #13

Subject: *Ensuring a Stable Vaccine Supply*

From: *Rep. Tim Murphy (PA-18)*

The problem: A low-bid process combined with the threat of lawsuits has forced many domestic manufacturers to stop producing vaccines in the United States. This contributed to the recent flu vaccine shortage, when 30 million fewer doses of vaccines were available due to a contaminated supply from a foreign manufacturer. Encouraging more U.S. based manufacturers to produce vaccines will avoid future vaccine shortages. Vaccines include immunization against such diseases as influenza, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio, pneumonia, Hepatitis B, chickenpox, and meningitis.

- The number of companies making vaccines was 26 in 1967 but only 5 in 2004.¹
- The federal government is the largest single purchaser of vaccines and has implemented a low-bid process which has created a functioning price cap for vaccines, reducing the chance for profit.
- With slim profit margins for vaccines, if faced with lawsuits companies fear bankruptcy. This concern is heightened in the case of the flu vaccine, which has a limited shelf-life. Manufacturers had to absorb a \$12 million financial loss for the unused and returned vaccines in 2003.²
- Vaccine prices are increasing. For example, costs to fully immunize a 2-year-old has risen to about \$700.³

A fear of lawsuits is discouraging the production of vaccines:

- The cost to develop and make many vaccines is greater than that to make most drugs, because vaccines are given to healthy people with higher standards of safety than those given to people who are sick. Before vaccines are licensed, the FDA requires they be extensively tested to ensure safety. This process can take 10 years or longer.
- The reward from one lawsuit against a Diphtheria, tetanus and polio (DTP) vaccine manufacturer was \$1.13 million, which was equivalent to more than half of the entire market for the vaccine. Congress created the National Vaccine Injury Compensation Program (NVICP), to protect companies from lawsuits not supported by scientific evidence. The program covers a limited number of vaccines and allows lawyers to reject the NVICP findings and go to trial. Processing NVICP claims can take more than 2 years.⁴

Vaccines save money and lives:

- Vaccinations save more than \$52 billion in total health care costs and 33,000 childrens' lives annually.⁵
- Hepatitis B vaccines save \$14 in health care costs in children for every dollar spent.⁶

¹ Offit, Paul. Why Are Pharmaceutical Companies Gradually Abandoning Vaccines? Health Affairs. May/June 2005.

² Offit, Paul. Why Are Pharmaceutical Companies Gradually Abandoning Vaccines? Health Affairs. May/June 2005.

³ Landers, Susan. IOM highlights financing needs: More vaccines, higher cost. American Medical News. August 2003.

⁴ Offit, Paul. Why Are Pharmaceutical Companies Gradually Abandoning Vaccines? Health Affairs. May/June 2005.

⁵ Orenstein, Walter. Comparison of the 20th Century Annual Morbidity and Current Morbidity, Vaccine-Preventable Diseases. The Centers for Disease Control. 2003.

⁶ Centers for Disease Control and Prevention. National Infant Week Immunization Week. Talking Points. 2003.

- Measles-mumps-rubella (MMR) vaccines save \$23 in health care costs for every dollar spent or about \$9 billion each year.⁷
- Diphtheria, tetanus and polio (DTP) vaccines save \$6 in medical costs for every dollar invested.⁸
- Pneumonia vaccinations of persons 65 and older saves \$8 per person and over \$194 million in health-care costs due to fewer hospitalizations and by saving 60,000 seniors' lives annually.⁹
- Meningitis vaccines save \$2 billion in health care costs and over 665 childrens' lives annually.¹⁰

The federal government role:

- Congress created the Vaccine for Children program, which purchases vaccines from manufacturers in bulk including \$40 million in 2005 for the flu vaccine, and then provides the vaccines free of charge to public clinics and registered private providers who immunize millions of American children each year. Eligible individuals include children in families on Medicaid, the uninsured, American Indian or Alaska Natives and the underinsured.
- The Immunization Grant Program or the Section 317 program of the Centers for Disease Control provided \$479 million in 2005 discretionary federal grants to state, local, and territorial public health agencies for program operations and vaccine purchases.
- The National Vaccine Program Office (NVPO) at HHS has responsibility for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities. NVPO is supporting a new initiative to provide \$97 million for a 5-year contract designed to ensure year round influenza vaccine capacity and to incentivize the accelerated development, licensing and domestic production of cell-culture influenza.
- The Project Bioshield Act of 2004 authorized \$877 million for 75 million doses of an anthrax vaccines and treatments with future procurement targets for next generation smallpox and plague vaccines, botulinum anti-toxin and anti-radiation treatments against a terrorist attack.
- The Centers for Disease Control runs the National Immunization Program (NIP) to coordinate all planning, coordination, and conduct of immunization activities nationwide. In their 2000-2005 strategic plan, the NIP states that *"the public health sector must make certain that it provides support to the private sector in order to maintain the record high immunization coverage rates achieved over the past several years."*

Recommendations:

- Reevaluate the low-bid process and the functioning government price caps on vaccines to encourage the production of vaccines in the United States.
- Support new research and development through the creation of private-public partnerships to discover new vaccines.
- Reevaluate the National Vaccine Injury Compensation Program to ensure that those who are injured receive just and timely compensation.
- Educate the public on the benefits of vaccination in preventing future medical costs.

⁷ Centers for Disease Control and Prevention. National Infant Week Immunization Week. Talking Points. 2003.

⁸ Centers for Disease Control. An Ounce of Prevention...What are the returns. October 1999.

⁹ Sisk, J. Et. al. Cost-effectiveness of vaccination against pneumococcal bacteremia among elderly people. October 1997.

¹⁰ Zhou, Fangjun. Impact of Universal *Haemophilus influenzae* Type b Vaccination Starting at 2 Months of Age in the United States: An Economic Analysis. Pediatrics. October 2002, pp. 653-661.

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