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Flu Vaccine Shortage: Another Example of How Bush Dis-Torts the Truth About Lawsuits

“Vaccine manufacturers are worried about getting sued, and therefore they have backed off from providing this kind of vaccine.”
-- President Bush, Presidential Debate, October 13, 2004

President Bush has argued that lawsuits against drug companies have resulted in a shortage of flu vaccines. This assertion overlooks what health experts have been telling the government for years – that the production of flu shots is a long and complicated process based on old technology that is fraught with the potential for error. Despite the growth in recent years of the flu vaccine market (due to new recommendations as to who should receive a flu shot) the number of flu vaccine manufacturers has dwindled. With the recent contamination of flu shots at one of Chiron Corp.’s factories, there is now only one manufacturer of flu vaccines for the United States. Conversely, there are no shortages in European countries or in Canada where governments are more involved in ensuring a stable supply of flu shots and they typically rely on more manufacturers. Although President Bush argues that it is the fear of lawsuits that deters pharmaceutical companies from joining the vaccine market, the truth is that there is no economic incentive for them to do so and lawsuits are not a factor in the current shortage.

- **Making flu vaccine is a risky business that is based on 50-year-old technology.** Flu vaccines require that a new formula be created every year because flu strains mutate. This is a much riskier prospect than developing other drugs that stay on the market for years. Vaccine production from start to finish takes six to eight months.¹ The process begins with public health officials predicting which type of flu to treat. Once a strain of flu is selected, the vaccine is made by injecting the virus into chicken eggs by hand and slowly growing it. One egg provides enough vaccine for only four or five doses.² In the case of an error, there isn’t enough time to replace the lost supply during the same flu season. More advanced and efficient production technologies do exist but have not yet been implemented by any drug company.³
- **Market demand is unpredictable – and an inaccurate estimate can lead to heavy losses.** The experience of the pharmaceutical company Wyeth, which dropped out of the market last year, illustrates that it is lost profits, not liability, which leads manufacturers to get out of the vaccine business. Wyeth had a surplus of 7 million doses in 2003 – but because flu strains mutate each year, the doses could not be used the next year. Wyeth lost \$30 million that year, and \$50 million over the course of three years.⁴ Facing required improvements to its plant by the Food and Drug Administration, Wyeth decided to drop out of the flu vaccine market.

- **There is little financial payoff given the market risks, especially when compared to other drugs.** Flu shots for half of all children and nearly all elderly patients (the two groups who receive the most flu shots) are paid for by public health insurance or government vaccine programs, typically at a very low price. Medicare, for instance, will pay no more than \$18 per flu shot this year.⁵ Unlike payments for medications, which are often taken daily and refilled monthly, payments for flu shots occur only once each flu season. According to an Institute of Medicine report, “vaccines frequently generate lower revenues than drugs and, thus, provide a less attractive opportunity for private investment by the pharmaceutical industry.”⁶
- **Lawsuits and the Vaccine Supply.** In the early 1980s there were concerns that lawsuits related to the DTP vaccine forced drug companies to leave the market. To address these concerns, Congress passed a carefully crafted protection for vaccine companies against litigation. The Vaccine Injury Compensation Program (VICP), enacted in 1986, is a no-fault alternative to the traditional tort system. The program covers all vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. Before filing a lawsuit against a vaccine manufacturer or health care provider, claimants are required to file for federal compensation. If the claimant is turned down or rejects the award they can then file a lawsuit.

Flu vaccines are about to be covered by the VICP. Although there are few risks of injury from flu vaccines and there have been very few lawsuits based on flu vaccine injuries, a provision recently signed into law by President Bush⁷ charges flu vaccine manufacturers an excise tax to pay claims under the VICP. It is highly unlikely that this action will address flu vaccine shortages as it has not prevented shortages for 8 of the 11 vaccines currently included in the program.⁸ Rather, as the Institute of Medicine recommends, “financial incentives that ensure an adequate rate of return on investment are necessary” if future vaccine shortages are to be averted. It also reported that, “current government strategies have not addressed the relationships between financing vaccine purchases and the stability of the U.S. vaccine supply.”⁹

- **Solutions.** In 2003 the Institute of Medicine, the nation’s primary source for advice on matters of public health, released the definitive report *Financing Vaccines in the 21st Century: Assuring Access and Availability*. This report did not cite liability as a cause of vaccine shortages nor did it recommend that changes be made to the tort system. Instead, it recommended a new and different approach to vaccine financing by the government. The approach that it considered best able to improve access and availability of vaccines contains the following three elements:
 - A mandate that all private and public health insurance plans cover all recommended vaccines.
 - A universal government subsidy for reimbursing vaccination providers and insurers.
 - A government voucher for uninsured patients to receive immunizations through any provider.¹⁰

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- ¹ Testimony of Janet Heinrich, Director, Health Care – Public Health Issues of United States Government Accountability Office, Before the Special Committee on Aging, U.S. Senate, September 28, 2004.
- ² David Brown, “How U.S. Got Down to Two Makers of Flu Vaccine,” *Washington Post*, October 17, 2004.
- ³ Lisa Rapaport, “Flu Shot Crisis Shows Ailing System; One Vaccine Maker’s Woes Shouldn’t be Such a Problem, Observers Say,” *Sacramento Bee*, October 10, 2004.
- ⁴ Brown, *supra* note 2.
- ⁵ Medicare, available at http://medicare.custhelp.com/cgi-bin/medicare.cfg/php/enduser/std_adp.php?p_faqid=1570&p_created=1097878393&p_sid=BC2Thwoh&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MTgmcF9jYXRfbHZsMT02NiZwX2NhdF9sdmwyPSZwX3BhZ2U9MQ**&p_li=
- ⁶ Committee on the Evaluation of Vaccine Purchase Financing in the United States, Institute of Medicine, “Financing Vaccines in the 21st Century: Assuring Access and Availability,” August 2003.
- ⁷ The American Jobs Creation Act of 2004, signed on October 22, 2004.
- ⁸ National Vaccine Advisory Committee, “Strengthening the Supply of Routinely Recommended Vaccines in the United States,” January 2003, page 1.
- ⁹ IOM report, *supra* note 6.
- ¹⁰ *Id.*