



REP. HENRY A. WAXMAN
RANKING MINORITY MEMBER
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
OCTOBER 18, 2004

Fact Sheet

Flu Vaccine Crisis: The Role of Liability Concerns

During the presidential debate on October 13, 2004, President Bush blamed liability concerns for the vaccine shortage facing the nation. He asserted: “Vaccine manufacturers are worried about getting sued and so therefore they have backed off from providing this kind of vaccine.” The President’s campaign has also claimed that the passage of legislation granting liability waivers to certain medical products (H.R. 5) would have averted this year’s flu vaccine crisis.

In fact, nonpartisan experts who have studied the fragility of the vaccine supply — and the companies themselves — do not consider liability a major contributing factor:

- Between May 2001 and September 2004, the Government Accountability Office issued a series of reports on our country’s fragile vaccine supply. Not one of these reports cites liability concerns as a reason why there are so few vaccine manufacturers in the United States. GAO did not recommend liability waivers for vaccine manufacturers.¹
- In a 2003 report, the Institute of Medicine (IOM) assessed why some companies have stopped making vaccines, including the influenza vaccine. IOM did not cite liability as a reason why vaccine manufacturers have left the market since the passage of the Vaccine Injury Compensation Act in 1986. IOM did not recommend liability waivers for vaccine manufacturers.²
- The two manufacturers who recently stopped making flu vaccine — King Pharmaceuticals in 2000 and Wyeth in 2002 — cited the expense of meeting safety standards and the relatively small size of the U.S. market as the reason for dropping out. Neither blamed liability concerns.³

There are several key steps to securing an adequate supply of vaccines. According to the IOM and GAO, there should be a streamlined FDA approval process for important vaccines, a guarantee of a reasonable return on investment, and central coordination within the Administration of vaccine supply issues.⁴ In addition, effective oversight of vaccine manufacturers like Chiron is needed to identify and resolve potential problems. These measures,

which have been recommended by the independent experts, should be the priority — not liability waivers.

One reason liability issues have little impact on vaccine availability is that most manufacturers of vaccine are already shielded from liability under the Vaccine Injury Compensation Program (VICP), which was established by Congress in 1986. Under this program, a no-fault compensation program gives vaccine manufacturers broad liability protection, while at the same time assuring adequate compensation for those injured by vaccines. The VICP covers an extensive list of vaccines, including the vaccines against diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, pneumococcal disease, Hepatitis B, chickenpox, and hemophilus influenzae type b. As had been expected for the two years, on October 11, 2004, Congress enacted legislation to add the flu vaccine to the VICP.

Section 10 of H.R. 5, the legislation promoted by President Bush, expressly provides that the legislation does not apply to the vaccines covered by VICP. By its own terms, the legislation that Administration officials cite as the answer to the shortage of flu vaccine would not apply to the flu vaccine or any other vaccine covered under the VICP.

ENDNOTES

¹ See, e.g., GAO, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People* (May 2001); GAO, *Childhood Vaccines: Ensuring Adequate Supply Poses Continuing Challenges* (Sept. 2002); GAO, *Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 9, 2003); GAO, *Federal Challenges in Responding to Influenza Outbreaks* (Sept. 28, 2004).

² IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003).

³ See, e.g., *With Few Suppliers of Flu Shots, Shortage Was Long in Making*, New York Times (Oct. 17, 2004) (“King said it would stop making Fluogen rather than commit more money to trying to bring the plant into compliance”); *How U.S. Got Down to Two Makers of Flu Vaccine*, Washington Post (Oct. 17, 2004)(quoting a Wyeth executive saying, “We were finding that there was not, in fact, a market for our product”); *Wyeth Ceases Production of Its Injectable Influenza Vaccine and Pneumococcal Polysaccharide Vaccine* (Nov. 19, 2002) (online at www.wyeth.com/news/Pressed_and_Released/pr11_19_2002_09_52_07.asp).

⁴ See, e.g., IOM Council, *Statement from the IOM Council on Vaccine Development* (Nov. 5, 2001); GAO, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges* (Sept. 2002); IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003).