

COMMITTEE ON GOVERNMENT REFORM
TOM DAVIS, CHAIRMAN



MEDIA ADVISORY

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Government Reform Committee to Examine
Nation's Flu Vaccine Shortage

Shortage Presents Serious Health Risks As Flu Season Nears
Half of Nation's Supply Will Potentially Go Unmet

What: Government Reform Committee Oversight Hearing:
"The Nation's Flu Shot Shortage: How it Happened and Where We Go from Here"

When: FRIDAY, OCTOBER 8, 2004, 10:00 a.m.

Where: ROOM 2154, RAYBURN HOUSE OFFICE BUILDING

Background:

The Committee will conduct an emergency hearing regarding recent developments concerning the severe shortage in the U.S. influenza vaccine supply. On October 5, 2004, British health authorities suspended the Chiron Corporation from manufacturing its influenza vaccine, Fluvirin, for three months because of manufacturing problems. The suspension prohibits Chiron from manufacturing, shipping, or marketing Fluvirin. Chiron was to export between 46-48 million flu shots this year to the United States, almost half of our nation's supply. The Department of Health and Human Services (HHS) had planned for a vaccine supply of about 100 million doses this season, after a demand of about 87 million doses last flu season. The loss of the Chiron flu vaccine poses a serious challenge to the U.S. vaccine supply and raises serious health risks right before the upcoming flu season. This hearing will examine the contributing factors that led to the influenza vaccine shortage, the public health implications of the vaccine shortage, and the U.S. government and vaccine manufacturer's plan to address this problem.

The public health implications of this development are enormous. Every year approximately 36,000 people die and 200,000 people are hospitalized due to complications from influenza. With a shortage of vaccines, the number of people to die

from or be hospitalized for influenza could increase drastically this year. The Centers for Disease Control and Prevention (CDC) issued interim recommendations for influenza vaccination on October 5, 2004. The interim recommendations give priority for vaccination to the “high-risk” population. Those among that population include: young children, the elderly, expecting mothers, persons with chronic medical conditions, and healthcare workers. As a result of the shortage, millions of healthy people and thousands of people in the high-risk population will have to forego vaccination.

HHS announced on Wednesday, October 6, 2004, that U.S. Food and Drug Administration (FDA) representatives would travel to England to meet with British regulators. FDA will use the meeting to assess if there is possible flexibility with regard to the suspension of Chiron. On Friday, October 8, 2004, FDA will meet with Chiron officers and tour Chiron’s facility over the weekend. CDC’s immediate focus will be on making sure the vaccine supply reaches those who are most vulnerable.

Chiron is the fifth-largest vaccines producer in the world, with sales of \$678 million in 2003. Chiron’s Fluvirin influenza vaccine is one of only two injectable flu vaccines approved by FDA. Fluvirin is manufactured in the United Kingdom at an FDA licensed facility, as Chiron does not currently have a manufacturing site located in the U.S. Both Chiron and Aventis Pasteur (the other major flu vaccine manufacturer) had anticipated providing between 45-50 million doses each to the U.S. vaccine supply this year. There is a third flu vaccine manufacturer, Medimmune. However, Medimmune only expects to produce between 1-2 million doses of its FluMist vaccine this year. FluMist is an inhaled vaccine containing a live but weakened flu virus.

At a Committee hearing in February 2004, “A Review of This Year’s Flu Season: Does Our Public Health System Need a Shot in the Arm?” witnesses discussed the possibility of a similar situation happening. The Committee was concerned that Chiron did not have a manufacturing plant located within the U.S. Should a flu pandemic occur, it was theorized that the UK could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply. With only a few vaccine manufacturers producing flu vaccines each year, we must consider what can be done to strengthen the market and increase production capabilities. The hearing on Friday, October 8, 2004 will consider the factors contributing to the flu vaccine shortage, how the government and vaccine manufacturers will respond to and manage this crisis, and what steps must be taken to be prepared for next year’s flu season.

WITNESSES

Panel One:

Dr. Julie L. Gerberding, Director, Centers for Disease Control and Prevention

Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases

Dr. Lester M. Crawford, Acting Commissioner, Food and Drug Administration

Panel Two:

Ms. Christine Grant, Vice President for Public Policy and Government Affairs, Aventis Pasteur, Inc.

Dr. James Young, President, Research and Development, Medimmune, Inc.

Dr. Robert Stroube, State Health Commissioner, Virginia Department of Health

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