“Three months after the CDC announced there would be a flu vaccine shortage for the 2004-2005 flu season, it announced that there would probably be a vaccine surplus.”

In October 2004, British regulatory authorities closed down production and distribution of influenza vaccine made by the Chiron Corporation, an American company with factories in Liverpool that supplies approximately half of the vaccine used in the United States. This action right before the start of the 2004-2005 flu season led to unprecedented shortages and caused public health officials to scramble to address the shortage. The public announcement of this shortage also revealed major weaknesses in the nation’s public health preparedness, led to increased scrutiny of the American public health system, and provoked public anxiety, resulting in long lines and lengthy waits for the available vaccine. Indeed, the flu vaccine shortage became an issue in the 2004 presidential race, prompting Dr Julie Gerberding, director of the Centers for Disease Control and Prevention (CDC), to comment, “I’m sorry that this is becoming a political issue. This is a health issue.” However, an examination of the vaccine shortage clearly demonstrates that public health is inextricably linked to national politics and policies.

ROOTS OF THE VACCINE SHORTAGE

Influenza has enormous public health implications. It strikes an estimated 10% to 20% of Americans each year, hospitalizing 114,000 and killing 36,000. At-risk groups include young children aged 6 to 23 months; the elderly aged 65 and older; healthcare workers involved in direct patient care; women who will be pregnant during the influenza season; and persons with chronic diseases. Public health officials also fear that a flu pandemic will strike the United States in the near future.

Vaccine is the primary prevention strategy against the disease. However, for a variety of reasons American pharmaceutical companies have largely abandoned vaccine production. First, the influenza virus mutates easily, which means that unlike most vaccines, flu vaccine requires a new formula every year. This makes it difficult to save unused doses; the frequent result is that large amounts of the unused vaccine are destroyed, which adversely affects manufacturers’ profits. For instance, in April 2003 Wyeth stopped manufacturing the vaccine because of continued losses due to unused or unsold vaccine that had to be destroyed. And, in light of recent efforts by the pharmaceutical industry to develop recombinant processes for making the vaccine more cheaply and efficiently, companies are hesitant to invest time and dollars in a process that could soon become obsolete. Fears of litigation, despite passage of the National Childhood Vaccine Injury Act of 1986 that created no-fault compensation for those injured by vaccines, also have influenced manufacturers’ decisions to pull out of the market. Another disincentive for US companies to manufacture the vaccine is the very labor-intensive, long manufacturing process necessary to meet stringent Food and Drug Administration (FDA) standards. Companies in Europe and Canada encounter less stringent regulatory hurdles. Finally, most of the US supply is bought at a fixed price by the federal government, essentially destroying the private market for the vaccine.

The vaccine shortage did not begin with the 2004 flu season. During the 2003 flu season, 83 million vaccine doses were manufactured, but 100 million were needed. Yet, the events of 2004 represented a major setback in protecting the American public. In August 2004, the Chiron Corporation discovered the contamination of its vaccine producing plant that supplies approximately half of the vaccine used in the United States. This created a major shortage of flu vaccine, which led to the suspension of production by the company. Another disincentive for US companies to manufacture the vaccine is the very labor-intensive, long manufacturing process necessary to meet stringent Food and Drug Administration (FDA) standards. Companies in Europe and Canada encounter less stringent regulatory hurdles. Finally, most of the US supply is bought at a fixed price by the federal government, essentially destroying the private market for the vaccine.

The FDA may have missed several opportunities to avert the 2004 crisis. They had examined and inspected the Chiron plan in June 2003 and reported no major problems, even though the inspection did raise concerns about quality control. Despite these concerns, the FDA never returned to the plant to ensure that these deficiencies had been corrected; instead, they relied on the manufacturer’s assurances. Even after the August 2004 contamination discovery, the FDA did...
not schedule an inspection. It was not until after British authorities took action that the FDA became involved.

**ADDRESSING THE VACCINE SHORTAGE:**
**PUBLIC HEALTH AND POLITICS**

Why was the influenza vaccine shortage not foreseen? Perhaps American governmental officials felt confident in the manufacturer’s quality assurance procedures for vaccine production. Perhaps other pressing public health issues—emerging infectious diseases such as severe acute respiratory syndrome and emerging public health priorities such as bioterrorism—have superseded immunization as a public health priority. Certainly, public health planning has emphasized increased and adequate immunization of at-risk populations, as well as racial and ethnic minority populations. Yet, influenza immunization rates for African Americans (52%) and Hispanics (46%) aged 65 and older remain much lower than those for whites (70%).

After the announcement of the vaccine shortage, the CDC quickly moved to address the problem and began aggressive surveillance of vaccine need and prioritization at the local, county, and state levels. It urged that the vaccine be given only to those in the high-risk categories and used its BioSense software to map delivery trends and optimize the allotment of available vaccine. It also made plans to increase the stockpile of vaccine by contracting with other pharmaceutical companies. For example, US government officials approved GlaxoSmithKline to supply up to 4 million flu vaccine doses from a German-based plant.

These measures, however, represent stopgap responses to the overall issues of improving the implementation of public health measures and strengthening the public health infrastructure, especially in light of a feared global flu pandemic and threats of bioterrorism. Initiatives to advance public health preparedness may involve policies that will be politically controversial. After the announcement of the flu vaccine shortage, the CDC called for voluntary measures to limit vaccination to members of high-risk groups. However, these rationing measures were not entirely successful. Reports surfaced of the vaccination of politicians, celebrities, and professional athletes who did not fit any of the high-risk profiles.

In order to ensure that limited amounts of vaccine get to those who truly need them, the federal government may need to adopt additional powers to mandate who should receive them. Such a step would be at odds with the current political system that favors free markets, voluntary programs, and individual states’ responsibility in matters of public health. Even efforts to increase vaccine production would involve political considerations. For example, the federal government may need to set a price for vaccines that is high enough to encourage more companies to enter the market. Of course, such a step would undoubtedly raise questions about price controls.

But something needs to be done. Three months after the CDC announced there would be a flu vaccine shortage for the 2004-2005 flu season, it announced that there would probably be a vaccine surplus—further indication that current public health policies are woefully inadequate to safeguard the nation’s health.

**References**