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

Fact Sheet

Flu Vaccine Crisis: FDA's Response to Early Warning Signs

In late August, the flu vaccine manufacturer Chiron, which has a manufacturing facility in Great Britain, announced that it had discovered several contaminated lots of vaccine. On October 5, the company announced that it would not be able to provide any of its flu vaccine this year. As a result, an estimated 40 million Americans who would otherwise have been immunized against the flu will not be.

When asked about FDA's oversight of the Chiron facility, acting FDA Commissioner Lester Crawford said that even with the benefit of hindsight, there was nothing FDA should have done differently. He said, "This is the way we've always done it, and it's worked very well in the past. So, no, we would not have altered the procedures."[1]

Contrary to FDA's assertions, there are serious questions about how FDA responded to early warning signs of problems at the Chiron facility. These are being investigated by the House Government Reform Committee.

Chronology

In June 2003, FDA conducted a full inspection of the Chiron facility in Liverpool, England. FDA's chief enforcement official told the *Wall Street Journal* that the visit identified "'systemic quality-control issues'" that "led inspectors to conclude that Chiron wouldn't necessarily be able to discover problems, identify the root cause and take steps to prevent similar issues from arising again."[2] FDA has not released specific information about these problems or the agency's response.

In August 2004, Chiron announced that as many as several million doses of vaccine may have been contaminated with bacteria. After this announcement, FDA did not conduct its own full inspection. While the agency sent several inspectors who happened to be in Great Britain for a brief visit on the day of Chiron's announcement, FDA appears to have relied primarily on the company's investigation of the problem. Dr. Crawford stated, "We at FDA were waiting for Chiron's report to determine if further action, such as on-site inspection, was needed."[3]

The British response to the same August 2004 announcement was quite different. The British government sent a team of inspectors to the plant and identified serious manufacturing deficiencies. Based on this inspection, the regulators shut the plant down for three months, suspending vaccine distribution.

FDA did not contact British regulators to find out their plans for oversight, even though, according to Dr. Crawford, the two agencies discussed a variety of regulatory topics.[4]

Only after the shutdown did FDA send a team to inspect the facility. That team found serious problems with manufacturing standards — too late to avoid a problem.

ENDNOTES

[1] *FDA Denies Knowing Scope of Plant's Mess*, USA Today (Oct. 12, 2004).

[2] *U.S. Uncovered Problems at Chiron Plant in 2003; 'Quality Control Issues' Were Similar to Concerns*, Wall Street Journal (Oct. 11, 2004).

[3] Conference call with Acting FDA Commissioner Lester Crawford and media (Oct. 11, 2004).

[4] *Id.*