

# Legal immunity set for swine flu vaccine makers

By MIKE STOBBE (AP) – July, 2009

ATLANTA — The last time the government embarked on a major vaccine campaign against a new swine flu, thousands filed claims contending they suffered side effects from the shots. This time, the government has already taken steps to head that off.

Vaccine makers and federal officials will be immune from lawsuits that result from any new swine flu vaccine, under a document signed by Secretary of Health and Human Services Kathleen Sebelius, government health officials said Friday.

Since the 1980s, the government has protected vaccine makers against lawsuits over the use of childhood vaccines. Instead, a federal court handles claims and decides who will be paid from a special fund. The document signed by Sebelius last month grants immunity to those making a swine flu vaccine, under the provisions of a 2006 law for public health emergencies. It allows for a compensation fund, if needed.

The government takes such steps to encourage drug companies to make vaccines, and it's worked. Federal officials have contracted with five manufacturers to make a swine flu vaccine. First identified in April, swine flu has so far caused about 263 deaths, according to numbers released by the Centers for Disease Control and Prevention on Friday.

The CDC said more than 40,000 Americans have had confirmed or probable cases, but those are people who sought health care. It's likely that more than 1 million Americans have been sickened by the flu, many with mild cases. The virus hits younger people harder than seasonal flu, but so far hasn't been much more deadly than the strains seen every fall and winter. But health officials believe the virus could mutate to a more dangerous form, or at least contribute to a potentially heavier flu season than usual.

"We do expect there to be an increase in influenza this fall," with a bump in cases perhaps beginning earlier than normal, said Dr. Anne Schuchat, director of the CDC's National Center for Immunization and Respiratory Diseases. On Friday, the Food and Drug Administration approved the regular winter flu vaccine, a final step before shipments to clinics and other vaccination sites could begin.

The last time the government faced a new swine flu virus was in 1976. Cases of swine flu in soldiers at Fort Dix, N.J., including one death, made health officials worried they might be facing a deadly pandemic like the one that killed millions around the world in 1918 and 1919. Federal officials vaccinated 40 million Americans during a national campaign. A pandemic never materialized, but thousands who got the shots filed injury claims, saying they suffered a paralyzing condition called Guillain-Barre Syndrome or other side effects. "The government paid out quite a bit of money," said Stephen Sugarman, a law professor who specializes in product liability at the University of California at Berkeley.

Vaccines aren't as profitable as other drugs for manufacturers, and without protection against lawsuits "they're saying, 'Do we need this?'" Sugarman said.

The move to protect makers of a swine flu didn't go over well with Paul Pennock, a prominent New York plaintiffs attorney on medical liability cases. The government will likely call on millions of Americans to get the vaccinations to prevent the disease from spreading, he noted.

"If you're going to ask people to do this for the common good, then let's make sure for the common good that these people will be taken care of if something goes wrong," Pennock said.

AP Medical Writer Luran Neergaard contributed to this report from Washington.