

U.S. could potentially use controversial adjuvants in swine flu vaccine

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The World Health Organization estimates that a worldwide production capacity of 3 billion doses of pandemic H1N1 vaccines will be used to prevent the outbreak and spread of the 2009 H1N1 flu, or "swine flu," as it is better known. This ambitious plan for widespread vaccine use, albeit inadequate for a total population of 6.8 billion people, has drawn criticism regarding the vaccine's safety, and the use and potential use of vaccine adjuvants.

In the alternative health community, chiropractor Ginger Mills, DC, of Redwood City, is concerned that adjuvants, especially squalene, will be added to vaccines used in the U.S., should the number of cases rise. "Squalene is an oil that is found in olives and in certain other foods, and is perfectly healthy when you ingest it — but when injected into the bloodstream, it can have adverse effects."

Adjuvants enhance or "supercharge" the immune response, reduce the number of vaccines needed, and allow supplies to last longer. Currently, aluminum salts are the only approved vaccine adjuvants for use in the United States. The use of adjuvants has been suspected, but not confirmed, in the development of illnesses in Gulf War veterans who may have received squalene-containing anthrax vaccines.

However, the current stock of U.S. swine flu vaccines does not contain adjuvants, according to Anne Schuchat, MD, in an informational video produced by the Centers for Disease Control and Prevention (CDC).

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Schuchat does acknowledge that there is an emergency provision to use them — should the pandemic accelerate.

Adjuvants are being used in swine flu vaccines in countries outside of the United States, including Canada, Europe and Australia. However, even though Canada is using an adjuvanted vaccine, it has also ordered 1.8 million doses of the unadjuvanted vaccine for use in pregnant women and children under the age of 3.

Maine physician Meryl Nass, MD, has written widely on the use of vaccines. "If novel adjuvants do get added (in the U.S.) — only if conditions change — it would preclude the quick licensure process that took place for the licensed H1N1 vaccines. Recipients would need to sign an informed consent for an experimental product," said Nass. "I do not believe they would be 'secretly' added."

The World Health Organization has tried to allay concerns about the vaccine and states that clinical trials suggest this vaccine is as safe as the seasonal influenza vaccines, and that most countries have vaccine monitoring systems in place. Without specifically addressing the use of adjuvants, WHO states that any vaccine side effects are expected to be of short-term duration, such as injection site soreness, swelling and redness, and possibly, headache, fever and muscle aches. However, WHO also has a disclaimer that "even very large clinical trials will not be able to identify possible rare events that can occur when pandemic vaccines are administered to many millions of people."

With a pivotal and profitable role played by the pharmaceutical industry in vaccine production, Nass suggests that there is a lack of "unconflicted data" available about adjuvants. "Nearly all of the MF59 (adjuvant) data were derived from the manufacturer of MF59, for example," said Nass. "It is more the lack of reliable data, and gives the impression that something is being hidden. Those of us who are familiar with the subject are concerned that if these adjuvants were used en masse, we would face some bad outcomes. The FDA has been sitting on them for 10 years, and usually, that means that the FDA is aware of significant problems."

Nass testified before Congress in 2001 that the FDA needed to make a decision on the safety of adjuvants, so manufacturers could know whether they could include them in vaccines or not. "It seems that the FDA and the manufacturers have been waiting for a pandemic to solve the problem for them," said Nass. "It was going to be avian flu — an adjuvanted vaccine for H5N1 avian flu was approved in many countries, but the disease never spread person to person. Then swine flu came along, and Glaxo and Novartis got another bite at the cherry. You see, once these adjuvants get into licensed products in the U.S., they will become part of all sorts of novel vaccines for cancer and non-infectious diseases, whose antigens are waiting in the wings."

The adjuvant question may not be answered in this pandemic go-round either. In the latest CDC FluView assessment of influenza activity in the United States, there is swine flu activity in 26 states — but many of the cases are mild and are not included in the count. The U.S. government has ordered 195 million vaccines that will be distributed through coordination with states and distribution centers.

While the official influenza season began Oct. 4, cases of swine flu appeared earlier — even in a number of pandemic experts themselves. And when it becomes personal, the use of a vaccine may seem like a good idea.

Author of "The Coming Plague," Laurie Garrett wrote in Newsweek about her September bout with swine flu, and described its symptoms as "days of semi-delirium, muscle aches, fatigue, nausea, and stomach twisting."

Another pandemic expert and Google executive, Larry Brilliant, led the WHO team that was responsible for smallpox eradication in Southeast Asia and India. Brilliant, a physician and epidemiologist, is now president of the Skoll Urgent Threats Fund, and recently became one of the expected 100 million Americans to develop the swine flu.

"But while I was never sick enough to consider going to see my doctor or going to an ER, I would not wish this disease on anyone and I certainly would have preferred a vaccination to this teeth-rattling bug," wrote Brilliant on Huffington Post.

"Most poignantly, even though I tried to stay isolated, I infected one of my children who also spent a lousy sweat-soaked, teeth-chattering week dancing with the swine. No loving parent would ever want to spread this disease to his or her kids. If the sole reason to get vaccinated were to prevent my spreading this disease to my family and community, that alone would make getting vaccinated an easy choice for me."

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