Manufacturers Brewing New Swine Flu Vaccine

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WASHINGTON (AP) — Attention is shifting to the world's five leading flu vaccine makers: How fast are they really producing swine flu vaccine, and just how do they plan to test that it works?

A meeting Thursday of the Food and Drug Administration's scientific advisers offers the first in-depth public progress report since U.S. scientists delivered the novel virus to manufacturers and asked them to turn it into usable vaccine.

They've succeeded to a degree. The National Institutes of Health on Wednesday called for a few thousand volunteers, from babies to the elderly, for studies to see if pilot batches are safe and protective. The first shots should go into adult volunteers' arms in early August, with child studies to follow quickly if there are no signs of immediate side effects.

Those government-directed studies — and more that manufacturers will run — are key as the government decides whether to offer swine flu vaccine to millions of Americans starting in mid-October, besides vaccinating against the regular winter flu. Health authorities in other countries are looking to the U.S. studies, too, as they make their own plans.

Assuming the studies show the vaccine is OK, a big question is how much will be available and when. Last week, the World Health Organization warned that production is going slower than predicted, with the strains now in use yielding only about half as much of the main vaccine ingredient as is usual.

Wednesday, London-based GlaxoSmithKline echoed that caution, saying it is "working as quickly as possible" but being hindered by those low yields.

"Some of us are skeptical that very much will be available by mid-October," said Dr. William Schaffner, a vaccine specialist at Vanderbilt University.

And the government has warned that any vaccination campaign will put higher-risk people in line for the first batches, as supplies gradually increase over time.

Manufacturers' vaccine studies are expected to largely mirror the NIH's plans: Volunteers will get two vaccinations, 21 days apart. By early September, the NIH should have blood tests showing how much immune protection the initial inoculation triggered, and if a low-dose or higher-dose version was needed. It will take another month to get information on the second inoculation.

Complicating the question: If plain vaccine doesn't spur enough protection or there

isn't enough supply, manufacturers could add immune-system boosters called adjuvants. That will pose a dilemma as the U.S. has never approved a flu vaccine containing those ingredients, although they are widely used in vaccine given to older adults in Europe.

But there's little information on their safety in children and pregnant women. Dr. Anthony Fauci, the NIH's infectious disease chief, said it's highly unlikely that flu vaccine with an adjuvant would be part of a children's immunization campaign. Part of FDA's debate Thursday, however, is how to do additional testing of that combination in various age groups.

The NIH's first studies will use flu shots made by France-based Sanofi-Pasteur and CSL Ltd., which on Wednesday began a much smaller study of its vaccine in its home country of Australia.

Also yet to be studied are shots made by Glaxo and Swiss-based Novartis, and a nasal-spray flu vaccine from Maryland-based MedImmune.

Food and Drug Administration: http://www.fda.gov/ [1]

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