National Institutes of Health says it made a mistake

By THOMAS D. WILLIAMS Courant Staff Writer

The National Institutes of Health says it made a mistake in announcing it would be using children to conduct anthrax vaccine test trials.

But the agency has not ruled out using children in future tests.

"Approval was not granted to enroll children in [the anthrax testing trial]. The Web announcement ... was in error. It has since been corrected," said Robert Bock, a NIH spokesman. "Any planning to test anthrax vaccine on children in [that trial] can be viewed only as a contingency."

The NIH was sharply criticized in June when it posted an Internet announcement that 350 healthy adults and 100 healthy children in the first and second grades were being sought as volunteer test subjects.

A new vaccine NIH is developing and the one currently in use by the military, manufactured by BioPort Corp. of Lansing, Mich., are being compared in the NIH test trials.

Days after news stories surfaced on the NIH's announcement, Sen. Jeff Bingaman, D-N.M., wrote Mike Leavitt, secretary of the U.S. Department of Health and Human Services, to express "grave concern" about clinical anthrax vaccine trials for children.

"Surely considerable information regarding the safety of the new vaccine, as well as about its potential effectiveness, should be obtained in adults long before any consideration is given to providing it to children," Bingaman wrote. "And, based on what already is known about the adverse event profile of the older vaccine, it should not be `tested' in children at all."

The NIH does do trials on children for other vaccines, Bock said. "[It] is currently conducting a study of a vaccine for typhoid fever in infants, in Vietnam. The institute is also conducting a study of a vaccine for shigella among 1- to 4-year-olds in Israel."

In its initial announcement, posted on its website, the NIH stated:

"Adults who are in good health and children who are in good health may be eligible for this study. ... On a random basis, patients will receive either the rPA dose or the licensed vaccine, for comparison of the properties of both vaccines.

"Rare but severe reactions could occur if there is extreme sensitivity to a vaccine. However, such an occurrence is extremely rare following a vaccine, and if there are any dangerous symptoms, they can be effectively treated by medications available to patients while they are at the clinic."

BioPort's vaccine, used almost exclusively on soldiers, has shown an adverse reaction rate 100 times the figure initially stated on the label. Adverse reactions include immune disorders, muscle and joint pain, headaches, rashes, fatigue, nausea, diarrhea, chills and fever. At least half a dozen deaths and a number of birth defects have been attributed to its use.

The six-shot vaccine plus annual booster is being used to eventually protect all 2.4 million in the armed services against anthrax spores that can be inhaled after being spread or fired by terrorists or enemies of the United States.

The NIH and U.S. Health and Human Services Department are calling for development of the vaccine to protect civilians from terrorist or other attacks. Hundreds of millions of dollars have been spent on developing a new vaccine, in addition to the new one NIH is testing.

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