

Panel debates bioterrorism protection for children

May 17 2012, By LAURAN NEERGAARD , AP Medical Writer

(AP) -- The Obama administration is asking a presidential commission to help decide an ethical quandary: Should the anthrax vaccine and other treatments being stockpiled in case of a bioterror attack be tested in children?

"We can't just assume that what we have for adults works for children," Health and Human Services Secretary [Kathleen Sebelius](#) told the panel Thursday.

Controversy over whether to open pediatric studies of the [anthrax vaccine](#) led Sebelius to ask the Presidential Commission for the Study of [Bioethical Issues](#) to tackle the question. The commission began its deliberations Thursday; recommendations are expected by year's end.

Sebelius made clear that the question is far broader than anthrax.

"There are serious [ethical issues](#) around the development of medical countermeasures for children" in general, she said.

Developing protections for youngsters is critically important, but in a way that puts "our children's safety as our highest priority," Sebelius said.

A decade after the anthrax attacks in the United States, the government has a multibillion-dollar stockpile of tools to fight back against some of the threats that worry defense experts. Notably missing is information on

how to treat children in various emergencies - whether the same drugs their parents will get will work or be safe for them, and even what dose [youngsters](#) should receive.

Thus the debate on whether to conduct studies now, before millions of children might need to try an untested product in an emergency. Even if those studies were offered, there's no way to know how many parents would agree to enroll their children.

Testing medications in children always requires extra [safeguards](#). It's fairly straightforward to test a potential treatment for cancer or some other childhood disease. But if a child won't receive a direct medical benefit, federal regulations say studies are allowed only if testing adults can't provide the answers and if the risks to participating children are minimal.

Anyone exposed during an anthrax attack would require 60 days of powerful antibiotics, or antibiotics until a vaccine could kick in. Last fall, the National Biodefense Safety Board, which advises the government, recommended child testing of the anthrax vaccine, but only if outside ethical experts agreed such studies could be done appropriately.

The shots have been widely used in adults, including U.S. troops, and are considered safe for them, said the board chairman, Dr. John Parker, a retired Army major general who has been vaccinated.

Side effects include shot-site soreness and redness, muscle aches, fatigue and headache. Rare but serious allergic reactions have been reported.

The bioethics commission wrestled with how to define "minimal risk" when there is no imminent emergency, and the chairwoman, Dr. Amy Gutmann, wondered whether people urging such testing would enroll

their own children.

Parker responded that he's discussed that with first-responders and some in the military. "There are groups out there that would want their families protected as much as they are protected as they do their job, in fear of bringing something home," he said.

Other doctors told the panel that 60 days of antibiotics can cause bad side effects for [children](#), including diarrhea, other infections and dangerous allergic reactions. Plus there's concern that many people wouldn't take the full course, Parker said.

More information: Presidential Commission for the Study of Bioethical Issues: <http://www.bioethics.gov>

National Biodefense Safety Board: <http://tinyurl.com/7c79bbd>

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