

Bioethics commission meets at UM to - Miami Herald, The (FL) - January 22, 2013

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In "Dark Zephyr," fictional terrorists released a cloud of anthrax on San Francisco. Adults were successfully vaccinated, but doctors didn't know the safe dosage to give children.

Fortunately this was just a practice exercise in emergency response in 2011. But the realization that modern medicine had no protocol to protect children from a deadly bacterial pathogen prompted U.S. Secretary of Health Kathleen Sebelius to ask the **Presidential Commission for the Study of Bioethical Issues** to consider the ethics of using healthy children in anthrax vaccine research.

The discussion has taken the 13-person **commission** a full year. The central question is to find the balance between the hypothetical risk of not knowing how to treat children in an anthrax bioterrorism attack and the real risk to healthy children who would participate in a **study**.

The **commission**, composed of leaders in medicine, social policy and law, met at the University of Miami Miller School of Medicine this week for the last of four sessions to publicly ponder these ethical issues. The UM Ethics Program has long been identified by the World Health Organization as one of the six global "Collaborating Centres for Bioethics."

Amy Gutmann, the **commission's** chair, reminded participants the **commission's** role is advisory only. "The question we must address is whether the U.S. Government could ethically support a pediatric [anthrax vaccine] **study** under any circumstance," Gutmann said. "We will not render a final decision as to whether a particular **study** should move forward. Nor are we working to justify any particular protocol or outcome."

An existing vaccine is routinely administered to adults in the military and other fields to protect against anthrax spores that are deadly if inhaled. Before the vaccine can be ethically researched with children, new trials in young adults should occur, said Col. Nelson Michael, director of the U.S. Military HIV Research Program and member of the **commission**. These studies would administer lower doses of the vaccine to determine the safest dosage in 18- to 20-year old adults.

Such studies would not be efficacy studies, however, which have been done in animals. Researchers would never infect humans with anthrax for a **study**, according to Michael, who is an expert in vaccine research.

"It would be completely unethical to conduct an anthrax challenge trial in humans," Michael said.

The issues surrounding this research question are unprecedented in **bioethics** for a few reasons, according to Lisa M. Lee, the executive director of the **commission's** staff. First, testing an anthrax vaccine on healthy children is unlike other pediatric research because research subjects will

enjoy no direct benefit, as would, for example, a child with cancer who could be saved by previously untested treatment.

Second, weaponized anthrax is not naturally occurring, and the probability of an attack is “unknowable.” The capability to use anthrax as a biological weapon is widely acknowledged, since letters infected with anthrax spores were sent to politicians and media outlets in 2001, killing five people. (A 2010 FBI investigation blamed the attacks on an Army scientist who helped develop the anthrax vaccine and later committed suicide.) Security analysts have presented their interpretation of the likelihood of a bioterrorism attack, but even the best intelligence cannot put a percentage on the chance that terrorists will unleash anthrax on American cities.

Lee said the last factor that makes this research different is the hope that the results will never be used.

“This is an extremely unusual question, and we haven’t been able to find the perfect analogy,” Lee said. “It really is without precedent.”

In public meetings held in Washington D.C., Chicago and Miami, the commission has consulted scientists, representatives from the Food and Drug Administration, pediatricians, vaccine researchers and other academics. Monday, the commission heard the testimony of two philosophy professors who specialize in bioethics.

Tom Beauchamp, a professor of philosophy at Georgetown University, spoke to the commission via video chat. Beauchamp was one of the authors of the Belmont Report, the 1979 paper that established the first ethical guidelines for conducting research on humans.

He questioned the commission on informed consent, both for minors who by legal definition can’t give consent and also for their parents. He recommended the consent process be observed by an independent person who is knowledgeable about the research but does not have a personal interest in the research going forward.

Dennis Thompson, professor of public policy at the Harvard University Kennedy School of Government, raised questions about minimal risk, pointing out that “risks of government-sponsored experiments are not of the status ethically as the risks to which parents expose their children in daily life.”

While commending the commission for the ethical heavy lifting they’d already done, Thompson also pointed out that ethical questions are unlike case law, which is based on legal precedents.

“This is not a judicial proceeding or process – too much respect for precedent, especially when the history of cases is so short and probably too permissive,” Thompson said. “That can lead to underestimating risks or getting distorted, I think, a misleading set of standards and examples for what should be permitted.”

The commission’s job was not to definitively answer these questions, but rather to provide ethical guidance for the government’s decision on future research. They left Miami Tuesday with consensus on some of the stickier issues like the definition of “minimal risk” and the “de-

escalation" of research that would begin with adolescents.

The commission will fashion its year-long deliberation into a report destined **for the desks of the U.S. president and his secretary of health**, who will then decide if this research should be pursued.

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