

Citizens for Responsible Care and Research, Inc. (CIRCARE)
(A wholly independent, volunteer, nonprofit, tax-exempt organization,
incorporated under the laws of the State of New York)

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June 5, 2012

Public Commentary
Presidential Commission for the Study of Bioethical Issues
1425 New York Avenue NW, Suite C-100
Washington, DC 20005

VIA info@bioethics.gov

In re: Presidential Commission for the Study of Bioethical Issues, Ninth Public Meeting, May 17, 2012, chair's request for post-meeting comments and supplementary statements.

We appreciate the chair's request for post-meeting comments and supplementary statements. We comment here on both sets of issues at the Commission's Ninth Public Meeting.

1. Pediatric trials of anthrax vaccine in children:

We join in opposition to these proposed trials. Direct benefit to test subjects is highly unlikely. Circumstances in which consent would be sought are unlikely to be conducive to true, informed, voluntariness. Reasonably foreseeable hazards are not negligible, and effective remedies for research injury are unlikely.

In particular:

- In discussion and colloquy, some Commission members appeared to accept the view that the vaccine in question could be expected to be less harmful than therapeutic antibiotics. The Food and Drug Administration's labeling information strongly suggests the contrary.
- In that same discussion, some Commission members seemed to believe that research injury could be remedied by the National Vaccine Injury Compensation Program. But there are major problems here. Three stand out: First, the program applies only to government-required vaccinations, not to research. Second, adverse effects may not show up immediately or dramatically. Third, the program has

worked in some respects but nevertheless has been found seriously defective. The most scholarly legal appraisal of the program has found it hostile to petitioners and so slow as to render effective remedy a nullity. See Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 *Administrative Law Review* 785, 851 (2011).

2. Human genome data and privacy and confidentiality issues in research and medical practice:

- We reaffirm our submission of May 11.
- The Commission confined its discussion almost entirely to uses of these data in biomedical research and medical practice. Again, we urge the Commission to realize that some of the most serious abuses of privacy and confidentiality of identifiable genomic data are coming from other interests—particularly in cross-linking studies and in invasions of personal privacy, without legal warrant, for the purposes of predicting behavior on the basis of genetic information. Wrongheaded and possibly unlawful as these activities might be, they are nevertheless irremediable for all practical purposes in this day of data mining, data aggregation, intensive unconsented behavioral science research, and employer and law enforcement use of such information.

Citizens for Responsible Care and Research, Inc. (CIRCARE) is the oldest human research protection organization in the United States and is entirely independent. We advocate conscionable research and are dedicated to responsible medicine and effective protection of human subjects in behavioral and biomedical research. We will be pleased to be of further assistance.

Sincerely,

For Citizens for Responsible Care and Research:

Gerald S. Schatz, J.D.

(Of the Bars of the District of Columbia and Pennsylvania)

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