A Radical Ethical Deviation: Using "Bioethics" to Subvert

Statutory Protections for Children

Vera Sharav

The greatest threat to legitimate medical research, the integrity of medicine, and the preservation of a democratic society, is the alarming pressure exerted by academic, commercial and government stakeholders to weaken, if not eliminate, medical ethics standards embodied in the Hippocratic Oath, "First, do no harm," the *Nuremberg Code*, mandating "the voluntary, informed consent of the human subject is absolutely essential," and the *Declaration of Helsinki*, "*the well-being of the individual research subject must take precedence over all other interests."*

American Medical Association journals have published at least three articles endorsing mandatory vaccination. The latest article endorses mandatory participation in clinical vaccine trials to overcome "*a distressing decline in the numbers of healthy volunteers who participate in clinical trials*," which the authors say, "*has a potential to become a key rate-limiting factor in vaccine development.*" The authors—both from the Jenner Institute at Oxford University— recommend, what they term, "***mandated choice***."[1] Their position, buttressed by linguistic acrobatics is grounded in dubious utilitarian bioethics:

> *"the debate boils down to a consideration of the 'greater good' or the 'lesser evil.' A key consideration is the risk benefit ratio—risk to the individual volunteer balanced against the benefit to society."*

The erosion of medical ethical standards that have stripped the rights of vulnerable individuals—has been facilitated by a cadre of academic bioethicists whose semantic deconstructions provide a blueprint for redefining ethical-legal standards to circumvent statutory prohibitions against exposing children to unjustifiable risk with no benefit.

> *"**In real ethics, there are some things that must never be done.** Bioethics is "procedural." Where it can, it leaps ahead, and where it cannot, it inches ahead, enticed onward by the question, Why not? If it can be done it should be done, or in any event it will be done, and, if it will be done, why not by us rather than by the competition? This is ethical reasoning of a very low order. There is no sure way of protecting society against it.*
> *But **we might begin by asking the experts who advocate the crossing of the next moral line, What's in it for you?"*** [2] Richard John Neuhaus

Two current examples of egregious unethical, government-sponsored experiments involving children are radical "game changers" that threaten to lower the ethical and scientific bar that defines legitimate medical research involving human subjects.

Inasmuch as children are incapable of giving informed consent, they are vulnerable to exploitation; therefore, statutory protections were enacted to restrict the use of children in non-therapeutic experimental research. Each of the following examples violates the permissible parameters of research by using children as subjects in experiments that are against their best interest. **A. Proposal to test Anthrax Vaccine in children and more broadly, to test "medial countermeasures". B. Randomized oxygen supplementation experiment in extremely premature babies.** (This case example will be addressed in a follow-up post).

Experiments such as these constitute a far-reaching departure from legitimate medical ethics.

In these government-sponsored experiments children are used as means to an end—as if they were laboratory animals, who are disposed of at the end of the experiment. Neither of these experiments is designed to provide clinically useful scientifically valid information: yet, both have been declared "ethical" by prominent bioethicists who disingenuously claim that the primary driving force for conducting these experiments is "Safeguarding Children."

It is worth bearing in mind that bioethicists are valuable handmaidens for the biomedical industry which is why industry is pouring millions of dollars into bioethics centers. Bioethicists hired by the pharmaceutical companies, have served the industry faithfully in a number of capacities, including, for example, writing industry-funded research articles, acting as 'key opinion leaders' in promotion of marketing, sitting on for-profit institutional review boards and justifying clinical drug research on vulnerable populations such as homeless people. The same corporate-friendly bioethicists testify as experts in high-level governmental meetings, formulate ethical guidelines for public policy, and regularly appear in the media, counseling the public on bioethical issues. For these services, academic bioethicists are handsomely rewarded by both industry and government.

Indeed, Nobel Laureate, Dr. James Watson, an avowed eugenicist who headed the Human Genome Project, is quoted to have assured those in attendance at an economic conference in Davos that no one need worry about the morality of what the Genome Project was doing since the project had allocated millions of additional dollars "***to get the best ethicists that money can buy.***"[2]

Academic bioethics has no moral compass and its practitioners have no shame: in 2012 bioethicists at the University of Pennsylvania accepted funding from *Merck*—the company that famously had developed a physician's "*hit list*"—much like a Maffia hit-list—targeting doctors who told the truth about the risks of Vioxx. The Merck grant funded a 10-day crash course in China about bribery and corruption. The cost of the course was reported as $9,200 per student.[3]

A radical proposal is being aggressively pursued by Kathleen Sebelius, the Secretary of Health and Human Services (HHS), who seeks an "ethical permission slip" to use healthy children as human subjects of an anthrax vaccine experiment, and more broadly, to test "medical countermeasures" against speculative bioterror attacks.[4] [5]

Children who lack legal capacity to volunteer or to consent to medical research are protected under Federal statutes which prohibit the inclusion of children to medical research that involves more than a "minor increase over minimal risk" unless:

> **"***The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of* ***vital importance*** *for the understanding or amelioration of the subjects' disorder or condition*" [45 CFR46.406]
>
> "*...the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children*."[45 CFR 46.407]

There is no doubt that the anthrax vaccine experiment poses greater than minimal risk. In the absence of an imminent anthrax risk for children, the experiment is unapprovable under federal statutes. Nevertheless, HHS officials are intent on exposing healthy children, who are not otherwise at risk, to the highly controversial anthrax vaccine (*BioThrax*) whose safety and efficacy in humans following exposure to anthrax has never been proven despite decades of testing in adults—nor has a reliable animal model been developed. The FDA-approved label clearly states:
"The safety and efficacy of BioThrax in a post-exposure setting have not been established." [6]

The stated rationale for testing such products in children is to facilitate stockpiling of "medical countermeasures to protect the nation from bioterror attacks."[5] [5] The documented risks posed by such "countermeasure" products are significant—potentially disabling, and even lethal.[7] [7] Indeed, manufacturers and everyone involved in conducting the tests or in administering "medical

countermeasures" are protected by an iron-clad shield from any legal liability for any harm under the Public Readiness and Emergency Preparedness Act (PREP Act).[8]

Neither Secretary Sebelius, nor any government official has cited any evidence of a bioterrorist threat; such claims are entirely speculative, based on a simulated exercise, a war game called "Dark Zephyr." While the Secretary claims that "*the safety of our children is paramount,"*[5] this proposal would subject healthy children to known serious risks—not to mention significant pain and additional unknown risks—in experiments testing drugs and vaccines that the Secretary classifies as "medical countermeasures"—and that the Secretary has shielded from all liability for harm. This shield denies a child who may be injured in countermeasure research the right to seek compensation through any state or federal judicial court.

In a speech published in *The Hastings Center* in 1996, Daniel Callahan, a founding father of bioethics, admonished bioethicists who are *easily co-opted into the service of biomedical* stakeholders:
"*In this country those who would legitimate morally controverted scientific research long ago learned how to put together commissions and panels to include sympathetic ethicists."* [9] Indeed, endorsement for the morally abhorrent anthrax vaccine experiment in children has been sought through two such panels: the **National Biodefense Science Board**[10] and the **Presidential Commission on the Study of Bioethical Issues**.[11]
Callahan eschewed bioethicists who agree to serve "*on any national or public commission where there is a reasonable certainty that its political aim is to legitimate a controverted research or policy proposal…It is the formal and official legitimation of ethical expertise that should be avoided."*
Though he recognized that *"that is usually just what some commissions and panels are after."*

The Alliance for Human Research Protection has been in the forefront protesting against exposing children to risk of harm in experiments that have no potential benefit for them—absent any evidence of an anthrax threat. We noted that such experiments violate bedrock medical ethics and Federal statutes and cautioned against the influence of "bioethicists" who would subvert statutory protections for children. Indeed members of AHRP have issued numerous written and oral reports documenting both the lack of evidence for the anthrax vaccine's efficacy following a speculative attack, and the body of evidence documented in government reports corroborating the serious risks posed by the vaccine.[12] [13] [14] [15] Furthermore, we have pointed out that the safety and efficacy of antibiotics following exposure to inhaled anthrax spores is undisputed, whereas the vaccine's safety and efficacy following exposure is

unproven and controversial. Nevertheless, despite the documented serious risks—including the FDA-required warning about harm to the unborn fetus; despite the documented severe adverse effects among vaccinated military personnel—*"between 1 and 2% of immunized individuals may experience severe adverse events which could result in disability or death,"*[7] the proposed anthrax vaccine experiment was endorsed by the NBSB (provided an ethics panel agrees); and it was given a "nuanced" endorsement by the Presidential Commission for Bioethics, Chaired by Amy Gutmann, President of the University of Pennsylvania.

This Presidential Bioethics Commission under the Chairmanship of Amy Gutmann served its government retainer by lending an "ethical" veneer of legitimacy to "a *controverted research proposal*." It did so **by deliberately misrepresenting the known facts.**
The Commission report misrepresented the vaccine as posing only "minimal risk in adults"; by misrepresenting "immunogenicity" (the ability to induce antibodies) as evidence of "efficacy" (the ability to prevent disease and death) which has never been demonstrated in humans. And it succeeded in confusing the media; resulting in some media reports indicating that the Commission nixed anthrax vaccine tests in children, while others reported that the Commission gave a tentative green light for the experiment to proceed. **The Commission sanctified a wide range of non-therapeutic pediatric experiments to test "medical countermeasures."**

Furthermore, the Commission continues to help prepare the groundwork for the experiments to proceed. The following May 14, 2013 post on the Commission's website states:

> *"In the context of pediatric medical countermeasure (MCM) research, the ethical case for compensation is particularly acute. Children who enroll in pediatric MCM research cannot legally or ethically provide informed consent for participation.* ***These children could also be asked to bear greater risk than ordinarily permitted in pediatric research****—although no more than a minor increase over minimal risk—for the benefit of children exposed to a potential future attack. For these reasons, children injured as a result of their participation in pediatric MCM research should receive necessary medical care and appropriate compensation for their injuries."*

In a speech announcing a major public policy shift, President Obama stated on May 24, 2013:

> *"No nation could preserve its freedom in the midst of continual warfare…This war, like all wars, must end. That's what history advises. It's what our democracy demands..."*
>
> "*There have been no large-scale attacks on the United States, and our homeland is more secure...In sum, we are safer*."[16]

With these words, **the President of the United States validated AHRP's position that there is no credible evidence of a pending bioterror attack on the US—thereby eliminating the justification for exposing children to risks in "medical countermeasures" research.**
See AHRP's letter to President Obama.[17]

Given the unproven efficacy of the anthrax vaccine in adults; given the lack of an animal model after decades of trials; and given the known serious risks of the vaccine in adults; exposing children to the vaccine cannot possibly "safeguard children." Nor can such a trial provide any useful information—the very fundamental requirement of ethical research—such an experiment is unethical on every level.

There is, however, a **scientifically full proof method for ascertaining the vaccine's efficacy** by conducting an experiment in adult volunteers: one group would be vaccinated, and then exposed to weaponized anthrax, while the other group would be exposed to anthrax and treated with antibiotics. Such an experiment might best be conducted by following the "Fair Selection" criteria recommended by the Commission in its Report on p. 73: *"researchers should seek to enroll research participants who are best equipped to understand the consequences of participation…[those] who are particularly well informed about the purpose and limits of pediatric MCM research, for example, could mitigate some of the heightened concerns about such research. This might include children of MCM researchers, policy makers, and subject matter experts.*"

In the spirit of fairness, first in line, for anthrax exposure experiment would surely be Dr. Gutmann and the Commissioners who recommended the "Fair Selection" criteria.

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