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Human Experiments and National Security: The Need to Clarify Policy

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The New Environment of Biodefense Research

On September 4, 2001, press reports indicated that the Defense Intelligence Agency of the U.S. Department of Defense (DOD) planned to reproduce a strain of anthrax virus suspected of being held in Russian laboratories. According to the same reports, the Central Intelligence Agency (CIA), under the auspices of Project Clear Vision, is engaged in building replicas of bomblets believed to have been developed by the former Soviet Union. These small bombs were designed to disperse biological agents, including anthrax. Government attorneys were said to be confident that, because these projects were designed to develop defensive measures, they were not in violation of the 1972 Biological and Toxin Weapons Convention.[1]

Whatever eyebrows might have been raised by these news stories quickly dropped within a week of their publication, when the September 11 catastrophes and the subsequent anthrax attacks suddenly placed bioterrorism defense at the top of the national agenda. Other developments occasioned by the new "War on Terror" have elicited little reaction in the legal, medical, and health policy communities, even though they portend the repetition of historic violations of the public trust. In combination and absent certain policy reforms, these developments could lead to human experiments for national security purposes that are conducted without widely acknowledged protections. We are in danger of retracing depressingly familiar territory and thereby reawakening a legacy of mistrust that burdens the attitudes of many Americans toward their government.

Several other developments lead to the conclusion that events are moving in an ominous direction, though separately none may excite great concern under the current circumstances. On December 23, 2001, the Bush administration granted the Secretary of the Department of Health and Human Services (DHHS) the authority to classify information as secret. The announcement associated this authority with the role of DHHS in the domestic security effort. No DHHS secretary has been granted this authority before, yet there has been virtually no analysis of the significance of this policy shift. For example, once such authority is granted, a process must be put in place for the assignment of security clearances within that agency, and a chain of custody, storage, and access to sensitive documents must be put in place, as well as the establishment of criteria for classification.

Other current policy initiatives also relate to secrecy in science. Besides the withdrawal of various documents

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from public access, the Bush administration is drafting a new information security policy. This policy is expected to restrict the communication of certain scientific results. Whatever the ultimate nature of the policy, research institutions will likely be obliged to accept expanded restrictions on their management of information acquired or retained by their faculty.[2]

All this is not to imply that the new classification authority and federal scrutiny over research activities is unjustified. The nature and location of vaccine stockpiles has long been a matter of national security, and is so now more than ever. Similarly, we should celebrate recent reports that efforts to vastly increase the supply of smallpox vaccine through dilution have apparently succeeded, with a "take" having been achieved among the normal, healthy volunteers in the study.[3] There is no inconsistency in acknowledging that the ultimate effect of this effort may be to boost public morale rather than protect against a smallpox attack. It is commonly understood among epidemiologists that a mass vaccination of 300 million Americans would result in hundreds, if not thousands, of deaths from the vaccine due to immune system disorders in the general population. The federal Centers for Disease Control (CDC) have effectively decided that mass vaccination for smallpox is not part of their disaster plan.[4]

New Arguments for Secret Research

But in the context of the new international crisis, the smallpox vaccine dilution trial is an undertaking worth noting. It requires little imagination to foresee an intelligence finding that a certain hostile power or terrorist group has acquired an agent that defeats current vaccines and is resistant to antibiotics. One concern is that a modified microbe, perhaps a variant anthrax strain I have mentioned as of concern to U.S. defense officials, may be made available by disaffected Russian scientists who still have access to bacterial or viral stores. There are other grim possibilities. The former Soviet biological weapons officer Ken Alibek has suggested that Russian scientists may have continued a program to insert DNA from Venezuelan equine encephalitis into the genetic structure of the smallpox virus, thus triggering two diseases simultaneously.[5]

How could defensive preparations proceed under such a scenario? Traditional approaches, which include inferences drawn from systematically acquired primate data or historic experience with a disease and a therapy, may be judged inadequate to the security threat at hand. For example, I served as a consultant to the Food and Drug Administration's Infective Drugs Advisory Committee when it met on July 28, 2000, to consider the Supplemental New Drug Application for Ciprofloxacin as therapy for inhalational anthrax. In this case, there was an enormous body of data from which to draw, both in the routine clinical use of Cipro for lower respiratory tract infection and in clinical trials. Inhalational anthrax was also considered to be a well-understood disease, though its epidemiology is obviously more informed in light of the 2001 attacks through the postal system.

Unlike the factors that applied in this case, including a much-studied agent and a familiar medication, the scenario I have sketched would present authorities with a novel weaponized pathogen and a speculative potential therapy. Even if an adequate animal model were available, officials may be reluctant to accept the implications of relying only on primate data for the protection of military personnel and first responders. Clinical trials of a

potential therapy, perhaps including the exposure of human subjects to the suspected agent, may turn out to be very desirable. Secrecy would evidently be preferred in order to protect information about either the success or failure of the trial. The study subjects may be drawn from Special Forces personnel or from units of medical technicians. In the event that conscription is revived, conscientious objectors or those who prefer noncombat duties on grounds of religious principle could be engaged.

The Burdens of History

The history of the use of military personnel and others in medical experiments for national security purposes is complex.[6] In general, since the 1930s there has been both reluctance to treat those who wear the uniform as "human guinea pigs" as well as instances in which they were found to be the most appropriate subjects. At times there have been no formal protections; at other times there have been formal protections that were inadequately administered. Today the policies and practices governing the participation of military personnel in medical research are in some respects even more stringent than those in the civilian world. But the success of these arrangements depends on an atmosphere of transparency and scrutiny. Under the cover of secrecy, policies and practices can be rapidly altered under the assumption that they are and will always be immune to inspection. In some instances, that assumption has proven to be warranted, as documents have intentionally or unintentionally been destroyed, making a complete historical reckoning impossible.

Yet rumors of past exploitation have a way of surfacing, whether accurate or not, and succeeding generations acquire an underlying skepticism that is corrosive of national institutions. Thus we recall that sailors were required to endure painful mustard-gas chamber tests during World War Two, tens of thousands of soldiers and airmen were exposed to atomic bomb tests in the 1950s and early 1960s, and thousands more were given LSD in the mid 1960s. Of these incidents only the last seems to have been covered by the Pentagon's own policy at the time, and on the Army's own account was in violation of that policy. But at least we know the main outlines of these incidents and can come to terms with the truth. Other episodes, such as the CIA's MK-ULTRA project that tested hallucinogens on hapless bystanders, including hospitalized patients, or the recruitment of German medical scientists after World War Two, some with dubious backgrounds, will never be fully understood because the records were sanitized.

It can hardly be surprising that the spillover effect of these kinds of incidents has extended into the post-cold war era. The DOD has curtailed its effort, initiated in 1998, to vaccinate all active-duty and reserve soldiers for anthrax. Although the official reason for the policy change was a shortage of vaccine and doubts about its efficacy,[7] there was also great concern in Congress about the program's ill effects on morale, as well as its safety.[8] Hundreds of men and women refused to accept vaccination and were disciplined. Many complained of health problems they associated with the questionable quality of the vaccine. Many more accepted vaccination but expressed their anxiety and resentment privately and in Internet chat rooms. They were influenced by the suspicions among some Gulf War veterans that they were used as human guinea pigs for the anthrax vaccine and other agents during Desert Shield/Desert Storm, sometimes alleged as a factor

in their subsequent illnesses. The Gulf War vets, in turn, grew up amid the controversy about Agent Orange, which, though it was not a human experiment, also had the flavor of government secrecy. This chain of cultural suspicion is one that should be broken.

An Available Policy

Perhaps the most frustrating aspect of the current situation is that a carefully developed policy to govern classified research involving human subjects was adopted in principle by the Clinton administration. During 1994–1995 I served as a staff member of the Advisory Committee on Human Radiation Experiments (ACHRE). In 1997, following the ACHRE recommendations, President Clinton issued an executive memorandum that instructed all agencies to propose modifications in federal policies for secret projects, including IRB review with at least one nongovernmental member, an appeals process for any dissenting IRB member, and permanent record-keeping by the sponsor. Subjects would have to be informed of the sponsoring agency, except in cases of minimal risk, and that the project involves classified research. Another presidential directive released at the time of the response to the ACHRE report required the heads of federal agencies to disclose annually the number of secret human research projects undertaken by the agency and the number of human subjects participating in each project.[9]

These requirements were to be added to the federal Common Rule on human subjects research. Although imperfect, the rules would at least provide a measure of protection to the subjects and ensure that posterity does not lose the opportunity to achieve an accurate accounting. Yet nearly 6 years after they were proposed, the standards for secret research have not been written into the rules of a single federal agency, including the DHHS with its new classification authority.

The low priority accorded this matter prior to September 11 is no longer acceptable. In its final report to the President, his human radiation experiments advisory committee concluded that, too often, our government failed to implement the moral values it espoused.[10] If appropriate requirements that build on the hard lessons of the past are not adopted before the renewal of secret national security experiments, future generations of Americans will be justified in concluding that we, too, succumbed to hypocrisy.

Notes

1. U.S. germ warfare research pushes treaty limits. *The New York Times* 2001 Sep 4.
2. U.S. tightening rules on keeping scientific secrets. *The New York Times* 2002 Feb 17.
3. Study suggests smallpox-vaccine supplies could be stretched safely with dilution. *Wall Street Journal* 2002 Feb 6.
4. A nation challenged: bioterrorism; plan for smallpox rules out mass vaccination. *The New York Times* 2001 Nov 27.
5. Alibek K. *Biohazard*. New York: Delta; 1999:258–60.
6. Moreno JD. *Undue Risk: Secret State Experiments on Humans*. New York: Routledge; 2001.
7. Shortage forces Pentagon to cut anthrax vaccinations. *The New York Times* 2000 Jul 11.
8. Committee calls for suspension of military's anthrax shots. *The New York Times* 2000 Feb 18.
9. Human Radiation Interagency Working Group. *Building Public Trust: Actions to Respond to the Report of the Advisory Committee on Human Radiation Experiments*. Washington, D.C.: Department of Energy; 1997:18–9. Available at: http://tis.eh.doe.gov/ohre/roadmap/whitehouse/index.html.
10. Advisory Committee on Human Radiation Experiments. *The Human Radiation Experiments*. New York: Oxford University Press; 1996.