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Lessons Learned: A Half-Century of Experimenting on Humans.(U.S. Army experiments)
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Just a few months after Richard Nixon left the White House in disgrace, the country's confidence in its institutions was further undermined by news stories about clandestine CIA activities within the United States during the 1950s and 1960s. A congressional committee under Senator Frank Church of Idaho and a presidential commission under Vice President Nelson Rockefeller were established to investigate the charges. In the summer of 1975, the truth about domestic experiments with psychoactive drugs, most pervasively lysergic acid diethylamide (LSD), began pouring out.

Approximately 6,700 human subjects were used by the government in experiments involving psychoactive chemicals. In private contract research with universities and chemical companies, other agents were also used, including morphine, Demerol, Seconal, mescaline, atropine, and psilocybin.

One of those used in LSD experiments while he was in the army, James B. Stanley, was inspired to undertake a historic attempt to get the U.S. Supreme Court to recognize the Nuremberg Code--from the 1947 ruling in the trial of Nazi Germans who conducted experiments on concentration camp inmates--as having the force of law in the U.S. armed forces. In February 1958, Master Sergeant Stanley was stationed with his wife and children at Fort Knox, Kentucky. Responding to a posted notice, he volunteered to be a subject in a study advertised as developing and testing measures against chemical weapons. He then became one of thousands of men to be transferred to Edgewood Arsenal in Aberdeen, Maryland, for LSD experiments.

But Stanley was never told that the clear liquid he drank for the test contained a psychoactive drug, nor was he debriefed or monitored for the hallucinations that followed, nor did he understand the source of the emotional problems that disrupted his personal life, leading finally to his divorce in 1970. In 1975 Stanley finally learned the truth when he received a letter from the army asking him to come to the Walter Reed Medical Center in Washington, D.C., for a follow-up study of the LSD subjects.

Stanley was one of several veterans who sued the government for the suffering the LSD experiments caused them. His case went the furthest, all the way to the Supreme Court, which by a five-to-four decision found that, like all other current or former members of the armed forces, Stanley was barred from suing the United States for injuries incurred "incident to service"--a legal rule known as the Feres Doctrine. Justice William Brennan dissented:

The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects.... In defiance of this principle, military intelligence officials ... began surreptitiously testing chemical and biological materials, including LSD.

Justice Sandra Day O'Connor added her own dissent:

No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed, as Justice Brennan observes, the United States played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, and the standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the voluntary consent of the human subject is absolutely essential.

The irony of Stanley's defeat is that it shows how toothless the Pentagon's Nuremberg Code-based policy was. Rules were in effect during his participation in the LSD experiments, but even following the army's own study that concluded these rules were violated, someone victimized by the results of failed implementation could not recover damages in a court of law. What little regulation applied to military-medical experiments seemed largely worthless.

The Army Calls Itself to Account

The Church committee hearings and Rockefeller investigations were not only productive in themselves but also stimulated a significant internal army study of its own conduct concerning hallucinogenic drug testing with soldiers at Fort Detrick, Maryland. A long-time favorite object of demonstrations by peace advocates, Fort Detrick has been a scientific center since 1943 out of concern that German "buzz bombs" could be outfitted with biological agents. Its series of hallucinogenic drug experiments from 1953 through 1971 was second in length only to the Tuskegee Syphilis Study among major American research ethics scandals. Most importantly, a U.S. Inspector General's investigation forced a confrontation between the intent of the Pentagon's Nuremberg Code-based policy and the fact that the army had failed to act according to the intent of its own rules.

Entitled Use of Volunteers in Critical Agent Research, the IG report is a fascinating and generally frank assessment of the army's experimental program. It begins by acknowledging the "inadequacy of the Army's institutional memory" about the experiments, even though they had only taken place a few years before, and that written records had in many cases been destroyed as part of routine destruction schedules. To reconstruct the events surrounding the history of the experiments, the investigators interviewed sixty-five witnesses in thirty-two cities and the District of Columbia and assembled tens of thousands of pages of documents from several federal repositories and military installations.

The report includes a number of insights about the reception of the Wilson Memorandum, which formalized the Pentagon's human experiment policy for the Eisenhower administration, within the army and the chemical corps. After the memo was signed but before the army had prepared its implementing directive, top corps officials and advisers met at Edgewood Arsenal in March 1953 to interpret the policy. Among other things, the group agreed that only hazardous experiments fell within the policy, "blanket type approval" could be obtained rather than submitting individual experiment proposals for review, "line of duty" projects involving nonhazardous materials were not covered, voluntary consent involved such factors as the volunteer's age and mental capacity, and no coercion is permissible. These interpretations were reasonable and sound. Altogether, this approach to the use of human subjects was, with few exceptions, light years ahead of practices in the civilian world.

Official policy and actual practice did not mesh, however. For example, in 1955 a Defense Department Ad Hoc Study Group on Psychochemical Issues recommended that any subjects being administered LSD be given a training lecture to prepare for its effects. However, in

January 1956 an assistant chief chemical officer who was helping design an LSD experiment with a group of soldiers commented in response to the recommendation:

In view of the fact that a great many of the effects observed in the group may be the result of suggestion [placebo effect] it would appear desirable to have one control group which has neither been given a training lecture on LSD-25, nor any information as to the symptoms of the drug being administered.

The officer may have been engaged in sound scientific design but vacuous research ethics. The point of the Nuremberg Code and the Pentagon rules based on it was precisely that a desire for greater knowledge could not simply trump the subject's rights.

In another case, a former chemical corps officer told the Inspector General that he had volunteered for an LSD experiment, knew he was to receive the drug, but did not know when. Some time after volunteering he went to Fort Bragg to observe some tests being conducted with an airborne artillery corps. He reported:

I was there to observe what was going on and also to brief the CG [commanding general], Twenty-eighth Airborne Corps. I went to the site with CWL [chemical warfare liaison] project officer and a major; it was early and it was cold. I was asked if I wanted some hot coffee, which I did. I was given the coffee and apparently it had the LSD in it; they told me later, it had a dose of 200 micrograms of LSD.

Can this be called informed voluntary consent, or was it, as the Inspector General suggests, "an overly broad interpretation" of the requirement?

A carefully drawn policy framework was no match for the quest for information with eminently available human subjects. As the IG report comments, "In spite of clear guidelines concerning the necessity for `informed consent,' there was a willingness to dilute and in some cases negate the intent of the policy." Indeed, the report continues, "This attitude of selective compliance was more the norm than the exception."

The Inspector General concludes that the "volunteers were not fully informed, as required, prior to their participation; and the methods of procuring their services, in many cases, appeared not to have been in accord with the intent of Department of the Army policies governing use of volunteers in research." In other words, the men were lured into the experiment under false pretenses and never told what was planned or what they might face. They were not informed, nor did they have the opportunity to give signed, witnessed consent.

Operation Whitecoat

Illustrating how diverse the treatment of human subjects was in those days, another army program began at that time and **became a paradigm of research ethics**. Starting in 1954 and for nearly twenty years, a special arrangement between the army and the heads of the Seventh-Day Adventist church allowed soldiers who were church members to volunteer for medical research under what was called Operation Whitecoat. Seventh-Day Adventists believe in community service but not in combat. The conscientious objectors among them were sent to Fort Sam Houston in San Antonio, Texas, where they were recruited for voluntary assignment as potential human subjects in biological experiments at Fort Detrick. As many as 200 Adventists took part each year, for a total of 2,300 volunteers in about 150 experiments.

The first study exposed the soldiers and some prisoners to Q fever, which is similar to typhus but much milder and commonly accompanied by an atypical pneumonia. Thirty-eight participants became symptomatic and all responded to antibiotics administered eight to ten days following exposure, thus establishing the correct schedule for therapy. This favorable result appears to have been characteristic of Whitecoat. Through all the years of the project, there were no attributable deaths, one documented complaint of "undue suffering," and two alumni who said they suffered permanent injuries from experiments. One of them, Bob Kline of Burtonsville, Maryland, was discharged in 1956 after he had been part of a Q fever study. Kline's liver was inflamed, a possible effect of Q fever. His claim was denied.

What no one seems to dispute is that the Whitecoat soldiers were truly volunteers. Washington entrepreneur W. Jay Nixon, who served from 1969 to 1971, near the end of the project, said: "If they were pulling the wool over anybody's eyes, I don't think it was in the Whitecoat program, because there were too many civilians involved who had no allegiance to the army." There was intense interest in Whitecoat at the highest levels of the military-medical establishment and great solicitousness of the continued support of Seventh-Day Adventist leaders. An article in the November 3, 1955, Review and Herald, a church publication, celebrated the program:

Each [soldier] made his own personal decision whether or not to volunteer for the project. All that was promised to them was an opportunity to save the lives of others, and to add to the knowledge of medical science, by their own participation and probable suffering.

The publicity Whitecoat received from the very beginning helps to explain the careful arrangements that seemed always to characterize the program, in contrast to the LSD studies. A 1969 fact sheet describes the process for particular studies:

When a research study in volunteers is to be conducted, the required number of WHITECOAT personnel are given a comprehensive briefing by the Commanding Officer as to the purpose and nature of the project, the risk involved, and exactly what is expected of each participant. After answering any questions that might arise, each subject is interviewed individually, given an additional opportunity to ask questions, and then indicates his desires as to participation in that particular study. If he volunteers he is required to sign the standard consent form. When an individual indicates that he would prefer not to participate in a particular study it usually is for personal reasons such as his wife is having a baby, he is to be the best man at his sister's wedding, or some similar reason.

One objection to the Whitecoat system is that the church leaders' enthusiasm in a close-knit faith community made it hard for soldiers to turn it down. Yet some of them did not volunteer and those who did were not required to be Adventists. The men also had the advantage of mutual support and group solidarity, which could help them to resist being enrolled in a dubious experiment. This is something that few potential human subjects have today. The group aspect of Whitecoat survives in a modern project at Fort Detrick: the Medical Research Volunteer Subjects (MRVS) program.

91 Bravo

Of all the amazing things I learned while researching this article, nothing surprised me more than the fact that dozens of soldiers of both genders are still used as normal volunteers in biological experiments. Throughout the military-medical community, there exists the problem of where to find a group of healthy, bright, well-informed, scientifically sophisticated, and

uncoerced potential subjects who require very little money to be in an experiment. Probably the best answer is the men and women MRVS (pronounced "mervs") at Fort Detrick. They are a special group of medics--91 Bravo--who come as close to realizing the ethical ideal of true informed consent as any group of research subjects since Walter Reed's Yellow Fever Commission in 1900.

I interviewed seven young male and female soldiers from medical units assigned to Fort Detrick, all of whom had been recruited from Fort Sam Houston. Part of their assignment in Maryland was routine for the medical corps, as they were placed in laboratories to assist in various scientific studies. Another part of their assignment was decidedly more dramatic: they understood that occasionally they would be invited to serve as subjects in medical experiments having to do with the U.S. Army Medical Research Institute of Infectious Diseases.

One of my first interviews was with twenty-year-old Lee Rice, who grew up in Woodbridge, Virginia. Rice had long wanted to be a doctor but knew that it was too expensive for his family. After completing Bible college, he decided that the army could be the route to his dream, as both his father and grandfather had been in the service. For all his grit, Rice was not quite prepared to take the Fort Detrick recruiter's offer when he assembled with his fellow troops at Fort Sam Houston. He laughed as he recalled his reaction to the proposal that he be a test subject in army medical experiments.

As he learned more about the conditions at the Infectious Diseases Institute, including the opportunity to be "stabilized" at one duty station for several years and to work around highly trained medical scientists, the idea began to look attractive. Rice's mother was anxious about the prospect, his father somewhat amused; but after they checked with Pentagon friends on the institute's work, they felt reassured and Rice was on his way to suburban Maryland.

In fact, today the military's system for the review of research proposals with human beings is far stricter than in the civilian world. Army Regulation 70-25, "Use of Volunteers As Subjects of Research"--the descendent of the Wilson Memorandum--has evolved into a demanding set of rules that are well recognized. Today's A.R.70-25 requires multiple levels of review, from the local unit's "human use committee" to several other screens up the chain of command. There is one nearly verbatim vestige of the old Nuremberg Code-based rules in A.R. 70-25: "Voluntary consent of the human subject is essential," it says at one point, and goes on to state that soldiers may not be punished for refusing to be human subjects.

In contrast to the several levels of review in the military, in the civilian world a clinical study might only be reviewed by a single committee at the university or research center. Some critics of the system have questioned the independence and objectivity of these review panels. Most research studies involving human beings have to be approved by institutional review boards (IRBs) at universities, where colleagues of the scientists proposing the research are responsible for the review. Some IRBs have recently been established outside academia so that experiment proposals can be reviewed more quickly than usually happens in the university panels. These free-standing IRBs are perfectly legal and their conflicts of interest might be no worse than that of the university panels, where professors know that their colleagues' grants and careers are on the line if a study does not seem sound enough to pass muster.

By the time I spoke with Rice, he was nearly finished with his three-year tour of duty at Fort Detrick and had volunteered for three studies. When not in a study he was the company clerk, but his primary mission was to be available for research. Periodically he had been called into

the institute auditorium with his fellow MRVS to hear a presentation of the upcoming studies for which human volunteers were needed. The only obligation the MRVS have is to attend these sessions, which take place every two or three months.

Some of the studies involve protection against potential biological warfare agents, such as anthrax, while others are designed to improve the medical treatments of diseases that are common in military environments. The anthrax vaccine study only involves getting the vaccine and then having blood drawn regularly over a period of two years to see if it has still been protective. Other projects are not nearly so benign, however, and can involve two weeks on the inpatient unit at the institute and considerable discomfort. The MRVS refer to some of these projects as "shit protocols," a term that pretty much describes the experience.

Rice participated in some of the toughest studies. One involved a germ called campylobacter, which especially plagues the navy. An intestinal bacterium, campylobacter causes severe diarrhea. The navy is trying to develop a vaccine against it that uses a mutant form of an E. coli toxin (the one that causes travelers' diarrhea) to increase the natural immune response while also giving an oral vaccine. Rice described his role in the study as "the most grueling thing I've ever experienced." Though the first day wasn't bad, the next day he had an excruciating headache, couldn't look into any light, and generally felt just awful. But because he reached this endpoint so quickly he was also treated right away, and he soon felt much better following the administration of antibiotics.

Why would anyone volunteer for such a noxious task? It was a question I pressed hard during my interviews. The most obvious answer is that soldiers cannot really volunteer; at some point, they must be concerned about the consequences of resisting, especially considering they had agreed to be in the MRVS program in the first place. But one of the young men of 91 Bravo I interviewed had nearly completed his assignment and had not been in a single study. Instead, he was taking pre-med courses at the local community college--compliments of Uncle Sam--and his schedule did not permit him to participate. But as long as he attended the MRVS briefings, he met his obligation to the program.

Other MRVS I spoke with carefully avoided the shit protocols, opting instead for studies that didn't make them sick and for which they were paid $25 for each blood draw. And over a two-year period there are a lot of "bloods," making for a reasonable piece of change to add to an army salary. Could this be the suspicious part of the story of the MRVS--that they are unethically coerced with money?

I addressed this question to each soldier with whom I spoke. I found their responses consistent and persuasive. First, they pointed out, whereas civilian volunteers from the community can be paid for every day of residence at the study clinic and for every procedure that is done to them, the MRVS can be paid only for blood. If anyone is subject to undue influence by dint of money, it is the civilians from Frederick, Maryland, and the rest of the surrounding community. And, of course, the civilians usually lack the peer support and scientific training of the MRVS.

Second, as several MRVS pointed out to me, you're not going to get rich giving blood at $25 a draw. The extra money is welcome, especially for those with families or anticipating a three-day pass, but is certainly not enough to overcome the significant downsides of some studies. For example, a male MRVS with small children told me he was interested in the money but could not manage being debilitated when he went home to be with his kids.

Finally, the money issue has to be balanced against the need for the work to be done. Few would volunteer without the extra incentive, all the MRVS I spoke with admitted. Suppose we acknowledge that the world is a dangerous place and that the United States has legitimate interests and good reasons to maintain a system of national defense, including a bioprotection program. Then waiting for altruistic volunteers may be admirable but not morally necessary--so long, of course, as rigorous protections are in place and the MRVS are truly free to say no.

The more senior MRVS told me that they frequently discuss the potential side effects with volunteers. An older medic, twenty-nine-year-old Rob Colbert from Jonesboro, Arkansas, told me why:

A lot of the challenges [studies designed to provoke a reaction to a particular agent] that we have, I mean, there's a very high risk of getting severe diarrhea, nausea, cramping, headaches, which is basically the extent of any of the complications.... Some of them are worse than others as far as the enterics go.

Though they might not be anyone's idea of a good time, the protocols even attract non-MRVS in other units assigned to Fort Detrick. Nineteen-year-old Alissa Tevels is in an animal care unit, 91 Tango, but she has participated in the anthrax study and in another on shigella vaccine. Though not part of the MRVS meetings, she socializes with many of the participants and hears about studies of interest or sees them posted around the institute.

I found Tevels and the men and women of 91 Bravo to be both proud of their work and somewhat frustrated at the myths that surround it--myths they encounter inside as well as outside the service. One told me of the ribbing she got back in Houston after she decided to join the program. "From the drill sergeant on down: `You guys are going to be guinea pigs, I feel so sorry for you.' After we were here for three years we were just laughing," she told me. "We had it so good here."

William Frank Fowler, a Lafayette, Louisiana, native, said he is proud of his work at Fort Detrick. "I wish we could educate more people about [the institute]. It's actually a real good place to work," he told me. "It's given me a lot of experience that I feel I'll keep forever, that I'll always use."

Openness in Research

The openness that made my visit to Fort Detrick possible will be key to ensuring that the future of human experiments for national security purposes will be based on the model of the army's Infectious Diseases Institute rather than a repetition of the many sad mistakes of the past. The young MRVS did not know how hard-won were the enlightened policies that framed their experience. Theirs is the self-assurance of those who have never had reason to doubt that, even as members of the armed forces, they retain a measure of control over their lives. Such was not the case for earlier generations of research subjects.

But the MRVS' self-assurance would be illusory if it weren't supported by a system that makes them co-investigators with the research scientists themselves. For that to be the case, they must have access to relevant information about the purposes, risks, and potential benefits of studies. In a sense, the MRVS program is the army's payment on the promise made in 1953 when Secretary of Defense Charles Wilson signed his Nuremberg Code memo.

A persistent danger to ethical national security research, however, is presented by the argument that some experiments need to be conducted in tight secrecy. Under such circumstances not only is the public deprived of the right it normally has in a democracy to judge whether the research is justified under the circumstances, the subjects of the research may be deprived of their specific right to give informed consent.

The end of the Cold War has lessened the threat of cataclysmic conflict, but the simmering resentments of small groups around the world has left Americans feeling as exposed--or perhaps even more exposed--than they were when the world was neatly divided into two principal camps. The need to keep secrets from terrorist organizations can easily substitute for the former need to keep secrets from the Soviets (even though their security apparatus knew far more about what the U.S. armed forces were doing than did U.S. citizens). Confronted with several small-scale hot wars, the environment of national security research could easily slide again into the mentality demonstrated during much of the Cold War.

In its response to the 1995 recommendations of the president's Advisory Committee on Human Radiation Experiments, the Clinton administration took two important steps that should help to avoid both the temptation to future secrecy and the subsequent undermining of informed consent in national-security-related experiments. First, the president directed all federal agencies to permanently retain records related to classified human experiments. Records retention will make it possible to reconstruct what experiments have actually been done far more easily than was the case when the CIA's secret experiments were revealed in the 1970s. Because so many records have been destroyed, either deliberately or accidentally, the information took another twenty years and enormous effort by many people to piece together. The second step was to agree that

* all classified research must meet informed-consent requirements

* potential research subjects should be told what agency is sponsoring the research (some people might prefer not to be part of research for the CIA, for example) and if the project involves classified research

* all ethics review panels for secret projects include one non-governmental member with the appropriate security clearance

* an appeals process be established so that any ethics review panel member who disagrees with the panel's decision can go to the head of the agency or the president's science adviser.

An Avenue to Justice

There are seventeen federal agencies that currently conduct human subjects research. If there is a single lesson to be gleaned from the story of military-medical experiments it is that we can expect them to continue as long as nations and political movements are interested in novel weapons that might gain them at least a temporary strategic advantage over their adversaries. Accordingly, how those weapons can be rendered most effective and how they can be defended against will be important questions that can only be answered with human subjects.

If it is true that human experiments will continue to be attractive to some nations, I believe it is also true that they can be done ethically. The army's Infectious Diseases Institute could provide a model of such experiments. Its critical elements are fair recruitment practices, fully informed

consent with an educated group of potential subjects, peer support, no more than modest compensation, and careful review and minimization of risk factors. In principle, at least, the research should also be confined to defensive rather than offensive purposes, in spite of the admitted limitations of these categories.

It is also past time for the world to have some mechanism to identify unethical experiments and to sanction or at least censure governments that support them. There should be an internationally recognized system for identifying key individuals in positions of responsibility--medical scientists as well as political leaders--and a research ethics court that can implement the universal values that have been repeated time and again and apply the hard lessons learned through so many failures since World War II.

"Transparency" in the development of novel weapons is one way to sustain a global balance of power--and, admittedly, terror. In the future, openness in the conduct of human experiments could do more than help assure that they meet ethical standards against exposing human subjects to undue risks. It might also help ensure that the weapons themselves are kept at bay.

In the Name of Science, Medicine, and Defense

For decades the U.S. government has enthusiastically conducted or sponsored through civilian agencies and corporations unethical medical experiments, both domestically and abroad, using U.S. citizens as well as those from other countries. Foreign governments have done likewise, often violating the human rights of the subjects involved:

1932: Japan's "factories of death" began, eventually exploiting tens of thousands of people in China, including American prisoners of war, in biological warfare experiments led by Japanese army officer Dr. Ishii Shiro. Though Ishii escaped prosecution, the Soviet Union executed twelve of his associates in 1949.

1932-1972: The U.S. Public Health Service sponsored the Tuskegee Syphilis Study, involving over 400 uninformed, poor black sharecroppers.

1943: The U.S. Chemical Warfare Service constructed its flagship biological warfare center in Frederick, Maryland (at what is now called Fort Detrick), along with three other major facilities around the country.

1945: Eighteen patients at the Manhattan Project Army Hospital were secretly injected with plutonium to test the affects of the new metal over decades; other substances tested were radioactive strontium, polonium, radium, and uranium.

1946: Twenty-three Nazi German officials, twenty of them physicians, were tried in Nuremberg, Germany, on charges of conspiracy, war crimes, crimes against humanity, and membership in a criminal organization for complicity in medical experiments on men, women, and children in concentration camps. Seven were hanged, eight were given lengthy prison sentences, and the rest were acquitted.

1947-1973: The U.S. military recruited an estimated 1,600 German scientists, including several tried at Nuremberg.

1949-1969: More than 200 secret open-air tests of U.S. vulnerability to biological warfare attacks took place across the country, including the release of tons of zinc cadmium sulfide in 1957 and 1958.

1950s: The CIA created the Society for the Investigation of Human Ecology, a front organization to test mind-control agents at McGill University in Montreal, Quebec, and elsewhere.

1950s-1970s: After Nuremberg, the United States was the only Western country maintaining an extensive program of human experiments on prison inmates. By 1974, about three-quarters of all approved drugs had gone through prison research, and several drug companies had built facilities adjacent to prisons.

1963-1973: Prisoners had their testicles irradiated in a million-dollar Atomic Energy Commission study in Oregon and Washington state penitentiaries. Nine prisoners were awarded over $2 million in damages in 1979.

1975: Congressional hearings revealed the CIA's MKULTRA project, which used Fort Detrick staff to test mind-control drugs, including LSD.

1997: The Quaker Oats Company and the Massachusetts Institute of Technology announced a $1.85 million settlement for about thirty alumni of the "science club" at Fernald School for the mentally retarded in Waltham, Massachusetts, who from 1946 to 1973 were fed cereal containing radioactive tracers supplied by the Atomic Energy Commission.

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