

Tarasoff, Vitaly v. The Regents of the University of California, 529 P.2d 553, 118 Cal. Rptr. 129 (1974); 17 Cal.3d 425, 551 P.2d 334, 131 Cal.Rptr. 14 (1976).

PRISONERS AS RESEARCH SUBJECTS

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Since the 1980s, virtually no prisoners in the United States have been used in biomedical experimentation that does not benefit prisoners as individuals or as a class. A principal reason is that ethical reflection on this topic in the 1970s not only decisively affected public policy but also shaped an enduring moral consensus in society.

A crucial year in that process was 1976. The Federal Bureau of Prisons announced an indefinite moratorium on nontherapeutic biomedical experimentation conducted in any federal prison. That same year, the board of directors of the American Correctional Association—the professional organization of U.S. prison officials at all levels of government—officially adopted a statement urging responsible bodies at federal, state, and local levels to eliminate the use of prisoners as subjects of medical pharmacological experimentation.

Most important, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) recommended to the secretary of the Department of Health, Education and Welfare (now the Department of Health and Human Services, DHHS) that a moratorium on approving and funding prisoner experimentation be declared until certain specified minimum standards had been met by any prison allowing experimentation on inmates. The work of the National Commission deserves special attention because it was pivotal, at a critical moment in the 1970s, in articulating connections between moral principles and public policies concerning prisoner experimentation (U.S. National Commission, 1976a, 1976b).

Some debate continued over government regulations implementing the National Commission's recommendations, but by the 1980s, experimentation that was not therapeutic for the individual prisoner or prisoners as a class had virtually come to an end. With the crucial help of the National Commission, American society had reached a moral consensus already achieved by the rest of the world.

Practices

Such a consensus did not always exist. Rulers in ancient Persia permitted physicians to use prisoners as experimental subjects. Rome tested poisons on prisoners. European physicians in the eighteenth century used prisoners in experiments, exposing them—sometimes through injections—to venereal disease, cancers, typhoid, and scarlet fever.

In the United States, prisoners were used for experimentation from at least 1914, when white male convicts in Mississippi were used in pellagra experiments. During World War II, prisoner experimentation assumed a morally favorable aura when prisoners, to show their patriotism, signed up in large numbers for experimental studies. After reviewing this experimentation, several state commissions encouraged the use of prisoners (Beecher).

The American Medical Association (AMA) underscored the degree to which participation in medical experimentation was viewed as morally admirable. It adopted a resolution disapproving of the practice of permitting prisoners convicted of murder, rape, arson, kidnapping, treason, or other heinous crimes to participate in medical experimentation. They were not considered sufficiently virtuous to be part of such a noble enterprise (Katz).

After World War II, when it became known that Nazi physicians had used concentration camp prisoners in medical experiments that mutilated and killed their subjects—innocent Jewish citizens of all ages—Europe found the use of any incarcerated persons in experimentation morally repugnant. An early draft of the Declaration of Helsinki included the following provision: “Persons retained in prisons, penitentiaries, or reformatories—being ‘captive groups’—should not be used as subjects of experiment; nor persons incapable of giving consent because of age, mental incapacity, or being in a position in which they are incapable of exercising the power of free choice” (U.S. National Commission, 1976a, essay 16, p. 4).

However, the provision was deleted from the final version of the 1964 Declaration, reportedly because of pressure from the United States. Not only did the United States have an extended history of approving prisoner experimentation, but during the post-World War II years there was a substantial increase in biomedical experiments, including those using prisoners.

The federal government funded a wide variety of biomedical and behavioral experiments using prisoners, including numerous studies on infectious diseases, and the Atomic Energy Commission (later absorbed by the Department of Energy) conducted experiments involving radiation of male prisoners' genitals. From 1970 to 1975, five of the six government agencies that supported experimentation—all

within the Public Health Service of the Department of Health, Education and Welfare—used prisoners in 125 biomedical studies and 19 behavioral research projects (U.S. National Commission, 1976b).

The greatest use of prisoners was in initial tests of drugs, performed primarily by private drug companies. In 1962, following the thalidomide tragedy, the U.S. Congress passed legislation requiring that before drugs were released for therapeutic use, their safety and efficacy must be tested on humans. To ensure an increased and steady supply of experimental subjects, pharmaceutical companies built facilities within prisons.

Prisoners became the principal subjects in the United States for testing new drugs. By 1975, according to a survey conducted by the Pharmaceutical Manufacturers Association (whose members develop most of the prescription drugs in the United States), at least 3,600 U.S. prisoners were the first humans on whom the safety of new drugs was tested. Prisoners in the United States were even being used to test drugs for researchers in other countries.

Principles

When the National Commission conducted its deliberations on prisoners, the Department of Health, Education and Welfare was already on record as being enthusiastic about the advantage of using prisoners in research. The president of the Pharmaceutical Manufacturers Association testified before the National Commission that his organization believed there were few alternatives to using prisoners in drug tests. Given that factual assumption, the moral argument was made that the good of society required the use of prisoners.

In its *Report and Recommendations* the National Commission moved beyond the moral appeal to the good of society by challenging the factual assumption that prisoners were necessary for at least initial drug trials. The commission found several drug-testing programs in the United States that successfully used healthy, nonincarcerated volunteers (U.S. National Commission, 1976b). Thus prisoners were not essential for biomedical experimentation. Having established that empirical fact, the National Commission then devoted considerable attention to two of the three ethical principles it said should govern experimentation with human subjects.

RESPECT FOR PERSONS. According to the National Commission, the fundamental moral principle of respect for persons includes respect for their dignity and autonomy. Experimentation with autonomous persons demands obtaining their consent to participate. The basic principle of

respect for persons thus justifies the bioethical guideline of informed consent. Debates arising from the moral principle of respect for persons revolve around whether prisoners can provide a sufficiently voluntary consent to participate in experimentation.

One line of reasoning argues that prisoners obviously are competent to volunteer for experiments. After all, conviction for a crime presupposes that the citizen has been found sufficiently competent to be held accountable for his or her acts. Also, the citizen who enters prison has had certain rights legally recognized, such as the right to sue for freedom of worship and even to obtain compensation for injuries sustained in prison jobs (McDonald).

According to this line of thinking, prison inmates participate in remunerated occupations that put them at some risk. No one challenges the capacity of prisoners to volunteer for these tasks—for example, stamping license plates in prison factories. Why should there be moral outrage at prisoners' choosing (they are permitted to refuse) to participate in medical experiments that admittedly provide financial inducements but also may do less physical harm?

Those who oppose prisoner experimentation argue that the relationship of persons to their bodies is very different from their relationship to their productive goods; the former comprises their relationship to themselves. There is a distinction between activities in which impinging on a person's body is accidental or unavoidable, as in a job, and those in which it is the very purpose of the activity, as in experimentation (Fried). The argument runs that since consent to a job is different from consent to experimentation, prisoners may be sufficiently free to consent to prison jobs but not sufficiently free to consent to experimentation.

Among those who cite the principle of free and informed consent as part of their opposition to the use of prisoners in experimentation, some argue that prisoners cannot in principle give a sufficiently free consent (American Civil Liberties Union). Others who oppose the use of prisoners in experimentation admit that in principle it might be possible for an inmate in some ideal correctional institution to give a sufficiently free and informed consent. However, they argue that in fact either the structure or the administration of the penal system in the United States makes it impossible for prisoners to give a sufficiently free consent to experimentation.

This argument relies on analyses of the basic structure of American prisons made by historians and sociologists. According to historians, the coercive structure of the American prison and its powerful impact on the attitudes of prisoners are not accidental. After the 1820s, foreign officials

came to the United States to observe the unique lengths to which the country went in creating new institutions called *penitentiaries*. They were designed not only to incarcerate criminals but also to shape their behavior and their character (Rothman).

Those opposed to prisoner participation in experimentation argue that medical experiments cannot remain unaffected by the social environment of what sociologist Erving Goffman calls a “total institution,” such as a penitentiary. In a total institution a single authority tightly controls the entire space and time of each person within it, including a series of abasements, degradations, and humiliations designed to convince inmates to accept the single authority’s view of them. In such institutions the entire social environment is designed to elicit cooperation with the central authority. It is argued that in total institutions even the attractive and beneficial features of an activity such as experimentation can overcome the inmates’ ability to give a sufficiently free consent (Goffman).

The National Commission’s investigations revealed that in U.S. prisons there appeared to be limited alternatives to experimentation among available prison activities. Other activities were not conducted in comparably secure surroundings, and there appeared to be a paucity of meaningful, alternative ways for prisoners to express any altruism they might have. Most importantly, no other prison activity paid comparably. The National Commission learned of differences in payment between experimentation and other prison activities that ranged to well over ten to one. Not surprisingly, surveys showed that 70 percent of prisoner research subjects volunteered primarily for the money (Arnold et al.).

Ethicists who served on the National Commission, or as staff and consultants, have subsequently emphasized that the commission believed prisoners were able to consent to experimentation under some conceivable conditions. However, the actual and likely conditions of American prisons raised genuine questions concerning prisoners’ being able to give sufficiently free and informed consent. A distinction between coercion and manipulation of a prisoner’s consent may be useful, although even a manipulated consent to participation in experimentation may be impermissible (Beauchamp and Childress; Faden et al.).

JUSTICE. A significant contribution of the National Commission was making not only respect for persons but also justice central to ethical considerations of prisoner experimentation. A few voices defended the use of prisoners as a form of reparative justice. Prisoners, they said, have committed crimes against society, and it is inherently appropriate, as an act of reparation for those crimes, for prisoners to serve

society by being used in research. Opponents of prisoner experimentation responded that society, through its legal system, had already pronounced sentence on prisoners for whatever crime they committed, and medical experimentation should not be considered a form of punishment.

The National Commission brushed past discussions of reparation to questions raised by comparative justice. The essence of comparative justice is that like cases or classes are to be treated alike, and different cases or classes are to be treated differently (Feinberg). Problems of remuneration immediately came to the fore. Considerations of justice would require paying prisoners participating in experiments the same as free volunteers. However, the amounts would be so much greater than remuneration otherwise available in prison that the payments could become so irresistible as to be coercive. Thus, in its final report, the National Commission included suggestions that researchers pay the same rate for prisoners to participate in experiments as they did for nonincarcerated volunteers; however, individual prisoners would receive the same amount they received for other prison jobs. The excess would go into a fund for the general benefit of prisoners, or into escrow accounts paid to each participant at the time of his or her release from prison (Branson).

Comparative justice leads in biomedical ethics to considerations of the selection of subjects for experimentation. With respect to nontherapeutic experimentation in particular, risks and benefits should be distributed equitably among classes and groups of experimental subjects. The implications of comparative justice specifically for the gender and race of prisoners selected for experimentation received some attention from the National Commission. It heard testimony from black prisoners that they did not have equal opportunity to participate in experiments. Better-educated whites were disproportionately enrolled in prisoner experimentation. In its report the National Commission also noted that less research was conducted in women’s prisons than in men’s.

More fundamental were concerns about the justice of selecting prisoners at all for research benefiting society generally. A principal moral concern was that prisoners bore a disproportionate share of the burdens of research benefiting society as a whole—for example, initial drug trials on humans.

Comparative justice refers not only to similarities but also to differences between groups. Unequal treatment—for example, permitting free subjects, but not prisoners, to participate in experimentation—can be justified when individuals or groups are different in relevant respects. Prison populations are significantly different from the free society.

Prisoners live in an institutional environment that is more coercive than that of free-living volunteers, and prisoners are less likely to receive equivalent healthcare. They also receive a minuscule percentage of the financial benefits given to free research subjects.

That prisoners are considered to be in so many relevant respects different from, and unequal to, the rest of society is a principal reason they are considered to be treated justly if they do not participate in research that does not benefit them directly.

Policies

In 1976, the National Commission recommended that research involving prisoners that posed more than minimal risk, that was not studying the process of incarceration, and that did not directly improve the health or well-being of individual prisoners should not be conducted unless the reasons for the research were compelling and “a high degree of voluntariness on the part of the prospective participants and openness on the part of the institution(s) to be involved would characterize the conduct of the research.” The National Commission included a long list of acceptable prison conditions. Showing its concern for justice, the commission also said that research would have to satisfy “conditions of equity” (1976b, p. 16).

In 1978, the DHHS published final regulations on research involving prisoners that were more restrictive than the recommendations of the National Commission. The department threw up its hands at trying to find prisons that met the commission’s conditions of openness, and prohibited research on prisoners that did not benefit them as individuals or as a class (“Additional DHHS Protections”).

DHHS limited research involving prisoners to: (1) studies, involving no more than minimal risk or inconvenience, of the possible causes, effects, and processes of incarceration and criminal behavior; (2) studies of prisons as institutional structures, or of prisoners as incarcerated persons; (3) research on particular conditions affecting prisoners as a class; and (4) research involving a therapy likely to benefit the prisoner subject. Minimal risk was defined as risk normally encountered by nonprisoners (“Additional DHHS Protections”).

The Federal Bureau of Prisons has maintained a policy that is even more restrictive. It prohibits biomedical research and drug testing on its inmates unless an individual, sick federal prisoner could benefit directly from an experimental therapy. Even then, a federal prisoner can be enrolled in a relevant clinical trial only if the responsible physician recommends it, the experiment has been approved by the DHHS,

the prisoner consents, and the medical director of the Federal Bureau of Prisons approves the individual case.

The U.S. Food and Drug Administration (FDA), which has authority over private drug companies, announced regulations in 1980 that were essentially the same as those of DHHS. But in 1981 the FDA “stayed indefinitely” its proposed regulations concerning use of prisoners. As a result, as of 1993, no regulations were in place that would prevent private drug companies from arranging with somewhat less than half the state prisons of the United States to resume using prisoners as subjects of initial drug trials (Penslar).

However, drug companies have evidently taken to heart the view expressed in the FDA’s proposed regulations that sponsors of research could never establish a compelling need to use prisoners (“Protection of Human Subjects”). Ethical discussion, most notably that of the National Commission, not only affected public policy. It also created a persistent moral consensus in society that prisoners should not be used in experimentation that does not specifically benefit them as individuals or as a class.

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SEE ALSO: *Autonomy; Bioethics, African American Perspectives; Coercion; Eugenics: Historical Aspects; Freedom and Free Will; Holocaust; Informed Consent: Consent Issues in Human Research; Justice; Minorities as Research Subjects; Research, Human: Historical Aspects; Research, Unethical; Rights, Human; Utilitarianism and Bioethics*

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PRISONERS, HEALTHCARE ISSUES OF

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"It is but just that the public be required to care for the prisoner, who cannot, by reason of the deprivation of his liberty, care for himself" (*Spicer v. Williamson*, 1926).

Because of incarceration, the legal context of providing medical, dental, and mental health services is different in prisons and jails from that in the outside community. In no other setting are such services constitutionally guaranteed. Drawing upon the prohibition against "cruel and unusual punishment" in the Eighth Amendment to the Constitution (and the Due Process Clauses of the Fifth and Fourteenth Amendments for juveniles, pre-trial detainees, and federal prisoners), the courts require that institutions with custody of human beings provide for their basic necessities, including healthcare.

It was not always so. Historically, the correctional system in the United States has been largely protected from public scrutiny. Prisons were built far from population centers, and courts adopted a "hands off" doctrine regarding their administration (*Procurier v. Martinez*, 1974). Early cases in the 1970s, however, revealed horrendous medical conditions in which inmates were used without supervision to perform medical care on their fellows, including pulling teeth, suturing, and surgery. Dramatic instances were illustrated in which prisoners died neglected, covered in maggots, and lying in their own filth (*Newman v. Alabama*, 1974).

The present legal framework was established in the 1976 landmark decision of *Estelle v. Gamble*, in which the Supreme Court ruled that prisoners have a right to be free of "deliberate indifference to their serious health care needs." Although there has been some fine-tuning, the legal landscape has remained largely unchanged since that ruling.