

# Inmates Sue to Keep Research in Prisons

*ACLU and bioethicists argue against use of prisoners in biomedical research*

"My favorite expression is that we've got Mondays here—7 days a week. Everyday's the same," says 37-year-old Cecil Cone, an inmate at the State Prison of Southern Michigan at Jackson. Because of sheer boredom and the chance to make extra money, Cone says he volunteers to be tested with radioactive tracers, tuberculosis tests, medicated skin lotions, and antacids. The experiments are conducted in two clinics at the prison and are run by The Upjohn Company and Parke-Davis.

The drug testing provides "a change of pace. It's like a little vacation," says Cone in a telephone interview. But he adds, "The main incentive is money."

A federal regulation was to go into effect on 1 June that would ban all biomedical research in prisons largely because the very incentives Cone finds so appealing are believed to compromise his ability to give truly free and informed consent as a volunteer research subject. The federal regulation has been hailed by bioethicists and civil liberties groups. But in a twist in the history of the issue of whether biomedical research should be conducted in prisons, four inmates at Jackson, including Cecil Cone, are suing the federal government to retain the right to volunteer.

The prisoners allege that their constitutional rights to due process and equal protection were denied. Four months after the inmates filed suit last July, Upjohn, which is based in Michigan, also brought suit against the government on similar grounds and became another plaintiff in the case. The federal rule to ban clinical testing in prison—which is promulgated by the Food and Drug Administration—is stayed until the court decides the case known as *Fante and The Upjohn Company v. The Department of Health and Human Services*.

Public sentiment on the issue of testing drugs on prisoners has swung widely over the past four decades. Before 1940, drugs that did not directly improve the subjects' health were rarely tested on prisoners. But during World War II, prisoners frequently volunteered to test treatments for infectious diseases that handicapped American troops. "Their involvement was considered to be not only acceptable, but praiseworthy," says a 1976 report, "Research Involving

Prisoners," from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. After extensive study, the commission concluded, nevertheless, that research on prisoners should be banned. The federal regulation now under contention was written as a response to the commission's study.

The United States is the only country in the free world that has not prohibited research on prisoners. In 1975, 16 phar-

maceutical firms conducted clinical trials in prisons. Now only three do—Upjohn, Parke-Davis, and Hoffmann-La Roche, Inc. However, Parke-Davis plans to close its clinic on or before 1 July because of the "cloud of uncertainty" with the FDA regulation, a company spokesman says.

The drug companies maintain that the prison population provides a large test group that can be more closely monitored than volunteers who are not incarcerated. But during the late 1960's and early 1970's, many companies stopped doing research on prisoners because of mounting public mistrust that followed several exposés of abuses. The Atomic Energy Commission, for example, confirmed news reports that the testicles of prisoners in Oregon and Washington were irradiated during the 1960's to test the effects on sperm production. A *New York Times* article in July 1969 revealed careless procedures in a blood program at an Alabama state prison that resulted in almost 550 cases of hepatitis and four deaths. At the Maryland House of Corrections, researchers at the University of Maryland School of Medicine tested vaccines for diseases including malaria and shigella. In 1974, the prisoners filed a lawsuit, claiming that they had been lured into the clinical trials. In a class action suit, *Bailey v. Lally* (1979), the inmates charged that poor prison conditions, idleness, and attractive wages of

Rhodes, the lawyer who is representing the inmates at the court's request. "My clients say they were not coerced [into volunteering]," says the lawyer representing the four prisoners at Jackson.

The national commission was well aware that the Jackson prisoners favored retaining the drug-testing programs. In preparing its report, commission members made a site visit to Jackson and interviewed dozens of prisoners. About 800 of the 5100 prisoners comprise the research pool. The commissioners found that the clinical research there and at other prisons offer overly tempting incentives to the inmates that could sway them into signing up for the drug trials. At Jackson, for instance, the medical care and living conditions were much better in the clinics than in the prison. The routine medical care provided by the prison "was appalling," says Barbara Mishkin, who was a staff member of the national commission and is now deputy director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

Payment for the prisoners' participation has never been comfortably settled. If the wages are too high, it might be considered an inducement. Wages that are too low are said to be exploitive because the inmates would be paid more for the same work outside the prison walls. Upjohn pays its subjects wages that are intended to be comparable to

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prison employment such as working in the laundry or in the license-plate factory. But Cone says, "I can make more money in the clinic than in the other jobs. It don't compare." The good prison jobs may pay \$70 to \$100 a month, whereas in the clinic, he can clear \$100 a month. And there is more that the clinic offers. "The beds are better and there are only 12 inmates in the cell block," Cone says. In the prison complex, Cone is surrounded by as many as 300 other prisoners.

The pharmaceutical companies argue that finding an alternative population for clinical testing outside the prison would be both costly and difficult. They say that unlike earlier testing in prisons, research now includes better safeguards against potential abuse because the protocols are reviewed by academicians and community physicians to oversee the research. In the 20 years of experiments at Jackson, Upjohn reports that only nine prisoners were injured. Eight of them have fully recovered and the remaining inmate suffered a hip disability for which he received a settlement, an Upjohn spokesman says.

But a good record avoids the main issue, says Alvin Bronstein, director of the National Prison Project of the American Civil Liberties Union. "The potential for abuse is there. The question is, 'Should the state make prisoners available for research?'"

"The argument is that the experiments are for the greater good and there's where the danger lies." Indeed, 2 weeks ago, the ACLU national board approved a resolution that calls for a halt of biomedical research on prisoners if there is no direct benefit for the subject.

On the other hand, Robert Levine, editor of the Hastings Center journal *IRB* and a Yale professor, argues that the prisoners should be free to join in the testing. "Prison is an inherently coercive atmosphere. The best way to show respect for these people is not to limit their range of options."

Aside from the ethical issues, the belief of the drug companies that prisons offer an ideal scientific setting is challenged as well, especially by a physician, John D. Arnold. After 29 years of conducting prison research, Arnold made an about-face in the early 1970's and spoke out against experimentation on inmates. "Personally, I don't have any uneasiness about the ethics of it. But there is a profound mistrust by the public of what goes on in prisons. It is dangerous to be so precariously balanced in the public eye," he says. So for this reason and the prospect of stricter federal regulations,

Arnold quit prison research and opened a private clinic, the Quincy Research Center, in Kansas City, Missouri. The clinic contracts out services to conduct drug trials for several pharmaceutical firms.

Arnold says a private clinic, of which there are now five or six in the country, provides better data than a prison. The researcher can select a test group from a diverse population instead of a homogeneous group of prisoners. Private volunteers, Arnold contends, also comply better with the protocols. The wide use of illicit drugs in prison complicates any testing there, he says.

The trade-off is cost. Arnold says private volunteers may be paid 10 to 15 times more than prisoners. But the expense is insignificant in the total price tag of bringing a new drug to market, he argues.

The prisoners at Jackson see the government and civil liberties groups as overzealous protectors. "They've stepped beyond their bounds," says Cone. "We're tired of people telling us what to do. Why is everyone jumping on the bandwagon?"

With the change of Administration, Secretary of Health and Human Services Richard Schweiker or the new FDA Commissioner, Arthur Hayes, can withdraw the rule. But with only Hoffmann-La Roche and Upjohn left among the companies that seek to continue prison research, a move to change the rule may have difficulty gaining political momentum. Whether the rule to ban prison research ever goes into effect will most likely be decided by the U.S. District Court in Michigan when it considers the lawsuit filed by the prisoners at Jackson.—MARJORIE SUN



Gail Light/Michigan Department of Corrections

### **Prisoners in a cell block at Jackson**

"Should the state make them available for research?"