Human Beings, although the guidelines "have provided some significant controls over research practices . . . they are inadequate and . . . the problems remain unsolved".

Those sentiments were echoed by several other witnesses at the hearings, and in particular by Dr Bernard Barber, chairman of the Department of Sociology at Columbia, who outlined the results of a survey of some 350 medical researchers engaged in 424 different studies involving human subjects. Dr Barber found that information supplied by the researchers themselves indicated that eighteen per cent of the studies involved more risk than benefit for the subjects, and even after the possible long-term benefits to society were included in the analysis, 8 per cent of the experiments involved more risk than benefit. Moreover, 9 per cent of the respondents in the survey volunteered the information that their research had not been subjected to peer review.

What steps should be taken to tighten control over human experimentation? Both Dr Barber and Dr Katz suggested that Congress should pass legislation setting up a board with authority to regulate at least federally funded research involving human subjects. Last year, the Senate passed a resolution sponsored by Senator Walter Mondale calling for a commission to study and make recommendations in the general area of medical ethics, but the proposal died in the committee rooms of the House of Representatives. Katz and Barber believe, however, that Congress should go one step further and set up a regulatory, rather than simply a study, organization.

The idea would be for the board to consist of people drawn from several disciplines and to include lay members. It would formulate detailed policies on such issues as the selection of subjects, informed consent and the application of risk-benefit criteria, and it would firmly guide the work of peer review committees in research institutions. Katz also suggested that the board should be independent of HEW so that it could have control over research sponsored by agencies such as Defense.

Other suggestions aired at the hearings included an immediate moratorium on research involving prisoners. Such experimentation is more extensive in the United States than in any other Western country, and it involves special issues such as the difficulty of obtaining genuinely free informed consent from a person who effectively has little freedom of choice. A number of serious abuses of medical ethics in prison research were detailed at the hearings last week (see box). It was also suggested that scientific journals should refuse to publish research results derived from studies involving unethical practices.

PRISON RESEARCH

Ethics Behind Bars

by our Washington Correspondent

IN April 1971 another priceless piece of information was added to the scientific literature with the publication of a paper describing the effects of vitamin deficiency in prisoners in Iowa State Penitentiary. To obtain the information, five prisoners were fed a diet deficient in vitamin C for up to three months, and the onset of scurvy was carefully monitored. The clinical signs included swollen and bleeding gums, loss of hair, haemorrhages in the skin and eyes, pain in the joints, loss of dental fillings and depression.

That is just one particularly outrageous example of research conducted on prisoners, described last week during hearings on human experimentation held by Senator Kennedy's Senate Health subcommittee — but the hearings also brought out the fact that the majority of preliminary drug testing in man in the United States is done behind prison walls.

According to Dr C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, about 70 per cent of Phase I drug tests — the preliminary safety studies which follow immediately after animal testing—are carried out on prisoners.

Dr Stetler defended the use of prisoners for drug testing on the grounds that the food and drug laws in the United States require extensive clinical trials of drugs before they can be approved, and that prisoners provide an ideal test group because of their particularly well controlled environment and diet. He also maintained that tests on healthy subjects are better, from both a scientific and ethical point of view, than trials on sick people. In many European countries, including Great Britain, where clinical trials are often carried out just on the sick, prisoners are seldom if ever used and Dr Stetler even went so far as to say that such testing is less scientifically rigorous.

Scientific justification and good medical practice apart, the drug companies also have a financial incentive to use prisoners for their testing. A typical payment to a prisoner for taking part in a drug trial is about \$20 or \$30 a month, which is less than one tenth of the going rate outside the prisons. Moreover, because a prisoner is less able to exercise his legal rights, the cost

of claims for damages is likely to be smaller.

Why do prisoners consent to the use of their bodies for the testing of new drugs? Therein lies the chief ethical question posed by prison research. Although low in comparison with fees outside, the \$20 or \$30 a month provides a great financial incentive to a prisoner who would normally earn only between \$2 and \$10 a month on regular prison duties. Moreover, the promise of escape from the tedium of prison life and the fact that a prisoner has little chance to exercise free will in prison surroundings also contribute to his decision to take part in trials.

With such incentives, and with such constraints on prisoners, are they in a position to give their consent to taking part in medical experiments freely, and with full understanding of the possible risks? Several witnesses at the hearings last week said that they believed not, and some recommended that an immediate moratorium should be placed on medical research involving prisoners.

Others, particularly the representatives of the Pharmaceutical Manufacturers Association, however, said that they believe that existing guidelines for the conduct of research on human subjects are sufficient to ensure good medical practice, provided that they are rigorously enforced. Drug trials involving prisoners are regulated by the Food and Drug Administration, which must ensure that the trials are carried out in accordance with the Department of Health, Education and Welfare's guidelines for human experimentation, and similarly, other medical research on prisoners funded by the federal government should conform to the guidelines (see accompanying article). But it came out in the hearings that the FDA does not have a full record of drug trials carried out in prisons, and that in any case such information would not be available to the public because it would involve trade secrets.

If a moratorium were imposed on prison research, where would the drug companies find their volunteers? Dr Capron suggested that they should look to educated people outside the prisons, who are better placed to evaluate the risks involved in, and the justification for, such experiments. And Miss Jessica Mitford, the author came up with the novel suggestion that since the stockholders of drug companies stand to benefit most from the development of new drugs, they should volunteer.