NEW WORLD

Human Experimentation and Medical Ethics

by our Washington Correspondent

FOR the past 40 years, a number of poor uneducated black men in Alabama have been taking part in a medical experiment without their knowledge or consent. They were all found to have syphilis in 1932, but treatment has been withheld from them—even after penicillin became available—because the investigators wanted to determine the clinical effects of untreated syphilis. The experiment, known as the Tuskegee Study after the Alabama town in which it took place, was brought to light last year by a reporter working for the Associated Press, and it has become perhaps the most visible scandal involving medical research in the United States.

When the Tuskegee study first hit the headlines, government officials pointed out that although the study was carried out by the Public Health Service, they were unaware of it. They promised to provide free health care to the survivors (a promise which has yet to be kept) and pointed out that the study was initiated 40 years ago, when medical practice and social conditions were very different—guidelines and controls on medical research are now sufficient to prevent such abuses taking place, it was suggested. But several witnesses who testified before the Senate Health subcommittee during hearings on human experimentation last week were much less sanguine.

The hearings brought to light a number of abuses of medical practice which Senator Edward Kennedy, the chairman of the subcommittee, described as "outrageous". The committee was told, for example, of a study carried out last year in San Antonio, Texas, in which a number of Mexican-American women who went to a family-planning clinic were given placebos instead of oral contraceptives as part of a study to determine whether the side effects of the pill are physiological or psychological. Although told to continue practising whatever form of birth control they usually used, at least ten of the women quickly became pregnant.

In another case, an experimental method of inducing abortion was carried out on 15 women in Philadelphia in May last year, as a result of which one eighteen-year-old woman had to have a complete hysterectomy and eight others had complications. According to Dr Sidney Wolfe, a doctor associated with an organization called the Health Research Group which is linked with Ralph Nader, the method, known as the supercoil, had previously been condemned as scientifically unsound and the women on whom it was used were not adequately informed of the risks involved. In a previous set of hearings, (see *Nature*, **242**, 7 ; 1973), Kennedy's subcommittee had also brought to light incidences of routine prescribing of drugs for uses not approved by the Food and Drug Administration.

Fortunately, such cases of seemingly obvious abuse of medical ethics in research involving human subjects are rare, but several witnesses suggested last week that they simply represent the tip of an iceberg of questionable research practices and studies which have dubious scientific merit. Such a situation led many to recommend that controls over human experimentation should be strengthened.

In 1971, the Department of Health, Education and Welfare (HEW) published a set of guidelines for all the research involving humans which it supports. The guidelines reflect the objectives spelled out in the Nuremberg Code promulgated by the judges at the trial of Nazi war criminals. In short, they specify that three chief criteria must be fulfilled in any experiments on human subjects. First, the risks to the subject must be outweighed by the potential benefit to him or by the importance of the knowledge to be gained. Second, the subject must be fully informed of the possible risks, and he should give his consent without any coercion. And third, committees should be set up in institutions in which research on humans takes place to review the necessity for the research and to ensure that it is carried out ethically.

In theory, those applying for research grants from agencies in HEW must comply with the guidelines and, similarly, drug companies which apply to the Food and Drug Administration for permits to conduct drug trials should also comply with the guidelines. But, according to Dr Jay Katz of the Yale University School of Law and author of a book on *Experimentation with*

HEALTH RESEARCH

White House Lunacy

by our Washington Correspondent

THE Nixon Administration's plans for cutting back in some areas of biomedical research and for phasing out the NIH training grants and fellowships were described last week as "lunacy" by Professor James D. Watson, director of the Cold Spring Harbor Laboratory and professor of molecular biology at Harvard University. Testifying at the Senate Health Committee hearings on human experimentation, Watson also castigated the Administration for concentrating on research likely to have a quick payoff at the expense of more basic research. "This way of proceeding," he said, "represents a puerile understanding of both how good science is done and how its discoveries have been directed toward human application."

The object of Dr Watson's remarks was the Administration's budget for 1974, which proposes cutbacks in funding for every institute in the National Institutes of Health except the National Cancer Institute and the National Heart and Lung Institute, and the phasing out of all grants and fellowships administered by the NIH for training new researchers.

But Watson was not alone in his concern, for no less an authority than Dr Michael DeBakey, the renowned Houston heart surgeon, and Dr Lewis Thomas, dean of the Yale School of Medicine, told the subcommittee of their misgivings. And Senator Edward M. Kennedy, the subcommittee's chairman, did not miss the opportunity to criticize the Nixon Administration, promising that he would do what he can to restore some of the money.

But it is not simply the cutbacks that concern Dr Watson, for he also expressed strong reservations last week about the trend towards more targeted research and in particular the use of contracts instead of grants for scientific programmes. He pointed out that "almost every important new discovery comes from someone under thirty-five and who at the moment of his breakthrough is essentially unknown to the outside world", and such people are thus unlikely to receive contracts "from a government that looks with distaste on the unpredictable".

As for the phasing out of training grants and fellowships, Watson predicted that "not only will all the money be tightly held by middle-aged entrepreneurs, but the science itself will have for the most part to be done by an age-group not noted for working into the night". Asked by Kennedy where the Administration gets its advice for the plans for biomedical research, Watson said that none of his colleagues supports the plans, and that the National Cancer Board, the chief advisory body for cancer research of which Watson is a member, "is not listened to".