

## **U.S. PUBLIC HEALTH SERVICE SEXUALLY TRANSMITTED DISEASES INOCULATION STUDY OF 1946-48**

### **Background**

While conducting historical research on the Tuskegee Study of Untreated Syphilis, Professor Susan Reverby of Wellesley College recently discovered the archived papers of the late Dr. John Cutler, a U.S. Public Health Service medical officer and a Tuskegee investigator. The papers described another unethical study supported by the U.S. government in which highly vulnerable populations in Guatemala were intentionally infected with sexually transmitted diseases (STDs). The study, conducted between 1946 and 1948, was done with the knowledge of Dr. Cutler's superiors and was funded by a grant from the U.S. National Institutes of Health to the Pan American Sanitary Bureau (which became the Pan American Health Organization) to several Guatemalan government ministries. The study had never been published.

The initial intent of the study was to look for new ways to prevent STDs, including gonorrhea, chancroid, and syphilis. The first experiments in Guatemala involved infecting female commercial sex workers with gonorrhea or syphilis, and then allowing them to have unprotected sex with soldiers or prison inmates. When few of these men became infected, the research approach changed to direct inoculation of soldiers, prisoners, and mental hospital patients. Gonorrhea was transmitted by inoculations into the urethra; chancroid by skin injection; and syphilis by a variety of means including skin injection and exposing the foreskin of the penis to infectious material. About 1,500 study subjects were involved. Although institutional officials were aware of the study, the study subjects were not informed of the purpose of the study and did not provide consent. The researchers indicated that they treated the vast majority of persons who contracted gonorrhea and chancroid, and most who contracted syphilis. However, the research suggests that some of the persons infected with syphilis were prescribed only partial treatment or not treated at all. At least one patient died during the experiments, although it is not clear whether the death was from the experiments or from an underlying medical problem. There are inadequate records to determine if the commercial sex workers were treated. The ethical violations included: 1) use of study subjects who were members of highly vulnerable populations, 2) research without valid informed consent, and 3) deception in conducting the experiments. Correspondence between the investigators indicates that they, and their superiors, also recognized the unethical nature of the research studies.

Such abuses could not occur today in research funded or conducted by the U.S. government. A series of safeguards established over the past 40 years provide protection for human participants, whether in the United States or overseas, in medical research from these types of abuses.

### **What is being done as a result of the discovery of this study?**

The U.S. Government is asking the Institute of Medicine (IOM), part of the National Academy of Sciences, to convene a committee of independent experts to conduct a fact finding investigation, by reviewing the conduct of the Guatemala experiments and issue a report establishing all of the facts of the study.

Separately, through the Presidential Commission for the Study of Bioethical Issues, the U.S. Government will convene an international group of experts to review and report on the most effective methods to ensure that all human medical research conducted around the globe today meets rigorous ethical standards and how training of researchers will ensure such abuses do not occur.

The United States will work with the Guatemalan Government to ensure that our respective responses to the discovery of this historical research aberration are transparent and responsible.