

Statement on 1946-48 Guatemala Research
Submitted by
The Commissioned Officers Association of the U.S. Public Health Service, Inc.
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- The sexually transmitted disease (STD) research conducted by the US Government and the Government of Guatemala in Guatemala in the late 1940's judged by today's rules and standards for human subject protection cannot be justified.
- No more so than the initial US Government and public reaction to the onset of the AIDS epidemic in the 1980's can be morally or ethically justified by today's enlightened standards. Standards that came about largely because of the work of the U.S. Surgeon General at the time – Dr. C. Everett Koop. The same can be said for what were often considered appropriate and morally and ethically justified therapies for a whole host of medical and mental conditions over the ages, that are totally inappropriate, immoral, unethical and often illegal by today's standards.
- The first effort to establish a set of principles or guidelines to guide human experimentation was the Nuremberg Code delivered in 1947 -- and the PHS study in Guatemala was conducted from 1946-1948. The Helsinki Declaration followed in the 1960s (and has since been revised a few times). These two documents may be considered to really encompass the core and the birth of human experimentation research ethics.
- The STD research conducted in Guatemala in 1946-48 can only be fairly assessed in consideration of historical perspective and the state of medical ethics at the time. The priority need to address the issue of venereal disease is mirrored in the fact that venereal disease accounted for 16.3 % of the total appropriations for the Public Health Service in fiscal year 1947.
- Important to acknowledge that there is ample evidence the research project was conceived, approved, implemented and conducted in full accordance with the existing norms and standards in place at the time. The project was undertaken at the invitation of official representatives of the Government of Guatemala and approved by the leading public health authority in the United States. The review of the studies in Guatemala conducted by CDC indicates that the request for the conduct of the research was initiated by the Chief of the Venereal Disease Bureau of the Guatemala Health Agency "through the collaboration of the Pan American Sanitary Bureau", the precursor of the Pan American Health Organization, the WHO Regional Office for the Americas.
- Informed consent has emerged as the principal measure by which medical research involving human subjects are sanctioned. There is no evidence regarding the issue of

informed consent in the Guatemala program. And there is considerable debate about the role of cultural variations in providing informed consent.

- The history of STD prevention and treatment research programs in the US is one of peaks and valleys. The very first peak may indeed be the law that led to the founding of what would later evolve into the U.S. Public Health Service; the 1798 *Act for the Relief of Sick and Disabled Seamen* that established the Marine Hospital Service.
- Peaks and valleys continued throughout the 20th Century. STD's were such a serious threat to America's military in WWI that the public's moral and ethical disdain was overcome and under the leadership of the US PHS and in full cooperation with the Armed Forces, major strides were made in the prevention and treatment of STDs. "The entry of the US into WWII had served as a catalyst to the national program , again because of the high rate of rejection of draftees due to syphilis and because of the high rates of absence from duty of military manpower resulting from syphilis and gonorrhea (Venereal Disease control by Health Departments in the Past: Lessons for the Present, John Cutler et al, AJPH, April 1988)

Conclusion

In consideration of historical perspective, two themes are evident. The first is the role of the U.S. Public Health Service in leading the research to address these public health threats, operating fully within the moral, ethical, and legal constructs in place at the time. The second is the need to improve the existing constructs, which even today are inadequate to fully ensure the protection of human subjects in medical research, especially in international research programs. The U.S. Public Health Service today stands at the forefront of these efforts.