THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MATEO GUDIEL PINTO as Heir of MANUEL GUDIEL GARCIA; GONZALO RAMIREZ TISTA, VICTORIA RAMIREZ TISTA and CELSO RAMIREZ TISTA as Heirs of CELSO RAMIREZ REYES; FEDERICO RAMOS MESA; MARTA CESAREA PEREZ RUIZ; VICTOR MANUEL TECU FLORIAN; MARTA LIDIA ORELLANA GUERRA; and Jane and John Does; all individually and on behalf of proposed Class Members, c/o Rudy Zuniga & Hiram Sosa Castaneda 37 Avenida 0-59, Zona 7 Edificio Fivico, 2do Nivel Ciudad de Guatemala, GUATEMALA Plaintiffs, v. KATHLEEN SEBELIUS, Secretary U.S. Department of Health & Human Services (DHHS) (formerly Department of Health, Education, and Welfare (HEW)) 200 Independence Ave., S.W. Washington, DC 20201 HOWARD K. KOH, M.D., MPH, Assistant Secretary for Health U.S. Department of Health & Human Services (DHHS) (overseer of the U.S. Public Health Service (PHS)) 200 Independence Ave., S.W. Washington, DC 20201 VICE ADMIRAL REGINA M. BENJAMIN, M.D., Surgeon General, U.S. Public Health Service (PHS) 5600 Fishers Lane, Room 18-66 Rockville, MD 20857 THOMAS FRIEDEN, M.D., MPH, Director, U.S. Center for Disease Control and Prevention ("CDC"), a center of U.S. Department of Health & Human Services (DHHS)	Civil Action No. 11-civ-00527-RBW FIRST AMENDED CLASS ACTION COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES Jury Trial Demanded

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)
and)
)
David Does 1-10,)
Defendants.)
_____)

CLASS ACTION COMPLAINT (FIRST AMENDED)

I. NATURE OF THE ACTION

1. Plaintiffs MATEO GUDIEL PINTO as Heir of MANUEL GUDIEL GARCIA; GONZALO RAMIREZ TISTA, VICTORIA RAMIREZ TISTA and CELSO RAMIREZ TISTA as the Heirs of CELSO RAMIREZ REYES; FEDERICO RAMOS MESA; MARTA CESAREA PEREZ RUIZ; VICTOR MANUEL TECU FLORIAN; MARTA LIDIA ORELLANA GUERRA; and Jane and John Does (hereinafter Plaintiffs), bring this action on behalf of themselves and all other similarly situated persons who were subjected to non-consensual human medical experimentation overseen by predecessor office holders of the Defendants or are the heirs of those so subjected. Plaintiffs bring this action against Defendants KATHLEEN SEBELIUS, Secretary of the U.S. Department of Health & Human Services ("DHHS"); HOWARD K. KOH, M.D., MPH, Assistant Secretary for Health, of the DHHS; VICE ADMIRAL REGINA M. BENJAMIN, M.D., Surgeon General, of the United States Public Health Services ("PHS"); THOMAS FRIEDEN, M.D., MPH, Director of the U.S. Center for Disease Control and Prevention ("CDC"); RIMA KHABBAZ, M.D., Director of the CDC's Office of Infectious Diseases; KEVIN FENTON, M.D., Ph.D., Director of the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention; GAIL BOLAN, Director of the CDC's Division of STD Prevention; HAROLD VARMUS, M.D., Director of The National Cancer Institute, a division of the DHHS; MIRTA ROSES PERIAGO, Director of the Pan-American Health Organization; and David Does 1-10 (collectively referred to as "Defendants") for equitable relief and damages.

2. This case addresses non-consensual human medical experimentation that took place in Guatemala from, as the U.S. Government has admitted, 1946 to 1953, and any

subsequent medical testing that lasted beyond 1953 at the hands of American and Guatemalan doctors and government officials ("the medical team," led by PHS) who were continuing the initial program.

3. The experiments at issue in this case have been compared to the infamous human medical experiments in Tuskegee, Alabama ("the Tuskegee experiments"), wherein African-American men were left untreated as researchers observed the impact of advanced stages of syphilis on their health, as discussed further below. While there indeed are many similarities, including the participation of the same division of the Public Health Service, the Venereal Disease Research Laboratory, one major distinction is that many of the victims in this case were *intentionally inoculated* with sexually transmitted diseases (also called venereal diseases). These victims did not begin the experiments with the diseases that the medical team wanted to study; instead the medical team intentionally infected their subjects.

4. The populations that the medical team selected for experimentation make these experiments all the more shameful; the medical team targeted children, prisoners, psychiatric patients, leprosy patients, commercial sex workers, and soldiers. The medical team selected several of these populations specifically because of their vulnerability. The complete inability of many of their subjects to give informed consent did not deter the medical team in the experiments in Guatemala; in fact, that vulnerability is precisely why those subjects were chosen.

5. These gruesome experiments finally came to light in the fall of 2010. On November 24, 2010, President Obama called for an investigation into the "intentional infection of vulnerable human populations" and, in no uncertain terms, noted: "The research was clearly unethical."

6. In response to the Presidential request, the Presidential Commission for the Study of Bioethical Issues ("the Presidential Commission") conducted an extensive investigation of the available records regarding the non-consensual human medical experimentation in Guatemala and, on September 13, 2011, released a devastating 201-page report outlining its results. In its letter to the President, the Presidential Commission concluded that:

> the Guatemala experiments involved gross violations of ethics as judged against both the standards of today and the researchers' own understanding of applicable contemporaneous practices. It is the Commission's firm belief that many of the actions undertaken in Guatemala were especially egregious moral wrongs because many of the individuals involved held positions of public institutional responsibility.

7. The Presidential Commission's Report repeatedly notes that the contemporaneous records of the medical team in the Guatemala experiments indicate that they clearly understood yet knowingly violated contemporaneous standards of ethics which, just like today, require that researchers obtain consent before subjecting humans to medical experimentation. As but one example, the Presidential Commission stated:

> None of the principles and requirements reflected in the standards [for the protection of human subjects set forth in the Report], were satisfied in the Guatemala experiments. And several – if not all – of these principles were known by the researchers in Guatemala at the time. Their behavior in a similar case – just two years earlier in the United States – and contemporaneous correspondence shows understanding of, and disregard for, generally accepted moral principles such as respect for human dignity in the course of their work in Guatemala. For these reasons, the Commission finds that many of the actions of the researchers were morally wrong and the individual researchers and institutional officials were morally blameworthy.

8. The Presidential Commission recognized how fundamental the requirement of consent is in human medical experimentation, noting:

> Obtaining informed consent of subjects is a cornerstone ethical requirement. So too are requirements for minimization of risks, a reasonable balance of risks and benefits, sound scientific justification, protection of privacy and confidentiality,

> and special protections for those who are especially vulnerable, including minors and those with impaired decision making.

9. The Findings and Recommendations of the International Research Panel of the Presidential Commission discussed the requirement of consent as well, noting that regardless of any variation in national practices, "almost all international codes and national laws and regulations governing research with human subjects seem to promote the basic principles of respect for persons, beneficence, and justice, and do agree specifically about *certain fundamental requirements*, such as minimizing risk, *obtaining informed consent*, and requiring independent review of research" (emphasis added).

10. In recommending a compensation fund for those harmed by human medical experimentation, the International Research Panel explained that "research is a socially collaborative project for the social good. If someone is injured in the course of research, in which they have served the social good, they should not be left to their own devices to pay for those injuries."

11. After reviewing the available records of these human medical experiments in Guatemala, the Presidential Commission noted, "Not only is there no record of consent to participation in the experiments, there are also several examples of active deceit on the part of the researchers." The Presidential Commission concluded that:

> the experiments in Guatemala starkly reveal that, despite awareness on the part of government officials and independent medical experts of then existing basic ethical standards to protect against using individuals as a mere means to serve scientific and government ends, those standards were violated. The events in Guatemala serve as a cautionary tale of how the quest for scientific knowledge without regard to relevant ethical standards can blind researchers to the humanity of the people they enlist into research.

12. The Presidential Commission reported that: 1) the medical team conducted tests on at least 5,128 subjects in the course of the human medical experimentation, 1,308 of whom

were intentionally exposed to venereal diseases, many of whom subsequently passed the disease along to spouses and family members; 2) of those victims, only 678 received any form of treatment for the venereal disease to which the medical team exposed them; and 3) there was no suggestion that any of the 5,128 subjects consented to being involved. To the contrary, the Presidential Commission found ample evidence of several subjects objecting to the harmful treatment they endured. The records reviewed by the Presidential Commission reveal that at least 83 victims died during the course of the experiments.

13. President Obama, Secretary Clinton, Defendant Sebelius, and now the Presidential Commission have all publicly recognized that the abhorrent research practices to which the Guatemalan victims, the Plaintiffs in this case, were subjected were socially and ethically unacceptable and unjustifiable.

14. This case is brought under the Alien Tort Statute ("ATS") and the U.S. Constitution and seeks to remedy the egregious violations suffered by those personally subjected to the non-consensual human medical experimentation and others who have lived with the devastating results. Defendants knowingly engaged in non-consensual human medical experimentation on highly vulnerable populations that resulted in the harms that Plaintiffs suffered.

II. JURISDICTION AND VENUE

15. This Court has federal question jurisdiction pursuant to 28 U.S.C. §1331 (federal question jurisdiction) as the claims are based on the ATS, 28 U.S.C. §1350, for the alleged violations of international human rights law and the U.S. Constitution.

16. This Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332 (a)(2). All Plaintiffs are citizens and domiciles of Guatemala, and all Defendants are U.S. domiciles with

their principal place of business and/or residence also in the United States. The amount in dispute between each Plaintiff and each defendant exceeds $75,000.

17. Venue properly lies in this Judicial District pursuant to 28 U.S.C. §1391(b) and (e).

III. PARTIES

A. Named Plaintiffs

18. There are currently a total of eight named Plaintiffs in this case. They are either the victims of or the legal heirs to victims of the non-consensual human medical experimentation that Defendants conducted in Guatemala.

19. Plaintiff **MATEO GUDIEL PINTO**, is the surviving child and legal heir of **MANUEL GUDIEL GARCIA**, who was a soldier at the Cuartel General between 1948 and 1950, a garrison that is now called "Cuartel Matamoros" in Zone 1 of Guatemala City. While serving as a soldier, Manuel was inoculated with venereal diseases by Defendants over the course of 18 months. Manuel has passed away since the filing of Plaintiffs' Initial Complaint in March 2011 and is now represented by his son.

20. Plaintiff **GONZALO RAMIREZ TISTA,** Plaintiff **VICTORIA RAMIREZ TISTA** and Plaintiff **CELSO RAMIREZ TISTA** are all surviving children and legal heirs of **CELSO RAMIREZ REYES**, who served in the Guatemalan military between 1948 and 1950 in the "Guardia de Honor." Celso Reyes was inoculated with venereal diseases by Defendants during six months of that service and suffered many diseases. When he left the military, Celso Reyes had sores, poor sight, gonorrhea, and was extremely lethargic. The venereal diseases with which Celso Reyes was infected have impacted his extended family as well. Plaintiff Victoria, the second child of Celso Reyes, has suffered many health problems since she was born,

including losing her vision at age 15. Plaintiff Victoria remains blind today. The daughter of Celso Reyes's oldest child, Plaintiff Gonzalo, also has canker sores on her head which have caused her to lose her hair.

21. Plaintiff **FEDERICO RAMOS MESA** was a soldier from 1948 through 1950 in the Guatemalan air force (Destacamento de la Fuerza Aerea Guatemalteca). Over a course of approximately 6 months during his service, he was inoculated with venereal diseases by Defendants every 15 days. These inoculations gave him uncomfortable feelings in the genital area along with secretions and hives. Before being inoculated, Federico had none of these symptoms. Each time he was inoculated, Federico had to stay in bed for one to three days, due to pain and fatigue. He was seen by Guatemalan and American physicians on the medical team during these months. After Federico left the military, the genital secretions continued and he had difficulty urinating. Federico continued to suffer pain in his bones, headaches, and fatigue. Federico has three children. Odilia Ramos Ruano, the youngest, was born with cankers on her head, which caused her total hair loss.

22. Plaintiff **MARTA CESAREA PEREZ RUIZ** is the wife of Oscar Perez Ruiz, who was abandoned at a young age and lived on the streets. In approximately 1960, Oscar was picked up by unknown persons working with Defendants and inoculated with syphilis. Oscar became so lethargic that people said "he should be buried." Years later, he married Marta and the two had seven children in total. The first was stillborn and the second, who is now 27 years old, has been severely disabled her entire life. In 1980, Oscar had a blood test and learned he had syphilis. Marta was then tested and learned that she also had syphilis. Marta and Oscar were treated with daily shots of penicillin for approximately 20 days. The treatment was very

painful and they could barely walk after receiving each shot. After the treatment, however, the couple had another last five children, all of whom are free of syphilis.

23. Plaintiff **VICTOR MANUEL TECU FLORIAN** was a soldier in the Guatemalan Army Corps of Engineers in Guatemala City from 1969 through 1971. During his 18 months of service, Victor received injections from members of a medical team every 15 days and thus contracted syphilis. Victor was not cured by the medical team before he left the Army Corps of Engineers – or after. Instead, Victor independently sought treatment at a health center. Though Victor was ultimately cured, he is unable to walk properly to this day due to the impact of the experiments.

24. Plaintiff **MARTA LIDIA ORELLANA GUERRA**, who lived in the Rafael Ayau orphanage after the death of her parents, was experimented upon when she was approximately nine (9) years old. Doctors that she had not previously met took her blood, performed a minor procedure on her arm, and later, began a series of injections. Initially, the injections were placed in Marta's arm, but later were given directly into her spine. While Marta had felt healthy and well prior to the injections, she felt sick once they began. Marta was never told why she was selected for these procedures, why the doctors were performing them, or what was being done to her. Marta has suffered various ailments in the decades following the injections. While she believes that the physical impacts of the experiments may have subsided in her old age, she continues to be mentally tormented by the fact she was never told what was being done to her or why.

25. As set forth herein, thousands of people were impacted by the non-consensual human medical experiments at issue in this matter. As word of the experiments spreads in Guatemala, additional people have come forward, realizing that they or their loved ones were

likely among the victims. While a listing of many, if not most, of the victims subjected to the experiments is available in the contemporaneous records of the medical team overseeing them, the names of the victims have been redacted from the public version of these records, which are maintained by the U.S. National Archives and Records Administration ("NARA").

26. Plaintiffs have diligently sought a copy of the unredacted list of victims to use in the course of this litigation. Despite an initial indication that NARA would provide Plaintiffs with such a copy, their request was later denied and efforts to negotiate with the Department of Justice, including an offer to review the unredacted list only under protective order, have been unsuccessful to date.

27. Further, in the course of its review of the medical team's contemporaneous records, the Presidential Commission created a master database of information regarding over 5,000 individual victims which, according to the Report, has been "saved and archived."

B. Plaintiffs' Class Action Allegations

28. Plaintiffs bring this action individually, and pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3), on behalf of the following class:

> All individuals who were subjected to non-consensual human medical experimentation in Guatemala ("test subjects") or were themselves infected to be used as vehicles for infecting the test subjects as part of Defendants' venereal disease experiments, and all children, domestic partners, and spouses of the test subjects who suffered serious, negative health conditions as a result of Defendants' non-consensual human medical experimentation.

29. The class is so numerous that joinder of all members is impractical.

30. As the Presidential Commission's Report confirms, there are thousands of potential class members; the non-consensual human medical experimentation involved over five thousand test subjects and thousands of others were impacted as a result of Defendants' non-consensual human medical experimentation.

31. There are questions of law and fact common to the class. Key common questions include, but are not limited to, the following:

a) Whether Plaintiffs and Proposed Class Members were unlawfully subjected to non-consensual human medical experimentation in violation of "the law of nations" provision of the Alien Tort Statute?

b) Whether Defendants caused and/or aided and abetted the non-consensual human medical experimentation imposed on Plaintiffs by either providing logistical support to the medical team performing the non-consensual human medical experimentation and/or failing to provide sufficient oversight and/or take adequate action to prevent and stop such non-consensual human medical experimentation in violation of international law, federal law and District of Columbia law?

32. The Plaintiffs' claims are typical of the claims of the class. They seek redress for the same conduct that has affected all class members and press legal claims which are the same for all class members.

33. The Plaintiffs named herein will fairly and adequately represent the class. These Plaintiffs do not have conflicts of interest with members of the class and have retained counsel in both the United States and Guatemala who are experienced in complex litigation, including class actions and international litigation, and will vigorously prosecute this action.

34. A class action is the superior method for adjudication of this controversy. In the absence of a class action, courts will be unnecessarily burdened with multiple, duplicative individual actions. Moreover, if a class is not certified, many meritorious claims will go un-redressed as the individual class members are not able to prosecute complex litigation against federal defendants and an international entity in a foreign court.

35. Finally, given the lack of an adequate forum for these claims in Guatemala, it would be logistically and financially impossible for the thousands of class members to each bring an individual action in the courts of the United States.

C. Defendants

36. Defendant **KATHLEEN SEBELIUS** is a United States citizen. Defendant Sebelius is currently Secretary of the U.S. Department of Health & Human Services ("DHHS"), which was formerly the Department of Health, Education, & Welfare ("HEW"). Defendant Sebelius is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

37. Defendant **HOWARD K. KOH, M.D., M.P.H.** is a United States citizen. Defendant Koh is currently Assistant Secretary for Health, which is part of DHHS, and oversees the U.S. Public Health Services ("PHS"). Defendant Koh is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

38. Defendant **VICE ADMIRAL REGINA M. BENJAMIN, M.D.,** is a United States citizen. Defendant Benjamin is currently Surgeon General, whose Office is part of the Office of the Assistant Secretary for Health in the Office of the Secretary and oversees the operations of the Commissioned Corps of the PHS. Dr. Thomas Parran, U.S. Surgeon General from 1936 through 1948, granted final approval for the grant funding the non-consensual human medical experiments in Guatemala and supported the research taking place there. Defendant Vice Admiral Benjamin is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

39. Defendant **THOMAS FRIEDEN, M.D., MPH,** is a United States citizen. Defendant Frieden is currently Director of the U.S. Center for Disease Control and Prevention, formerly the Communicable Disease Center, which absorbed VDRL in 1957. Defendant Frieden is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

40. Defendant **RIMA KHABBAZ, M.D.,** is a United States citizen. Defendant Khabbaz is currently Director of the Office of Infectious Diseases, of the U.S. Center for Disease Control and Prevention, which absorbed VDRL in 1957. Defendant Khabbaz is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

41. Defendant **KEVIN FENTON, M.D., Ph.D.,** is a United States citizen. Defendant Fenton is currently Director of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, a subdivision of the Office of Infectious Diseases, of the U.S. Center for Disease Control and Prevention. Dr. John R. Heller, the Chief of PHS' Venereal Disease Division from 1943 through 1948, was a member of the section that approved the grant for the non-consensual human medical experiments in Guatemala and regularly received reports on and oversaw the experiments. Defendant Fenton is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

42. Defendant **GAIL BOLAN** is a United States citizen. Defendant Bolan is currently Director of the Division of STD Prevention (formerly the Venereal Disease Research Laboratory ("VDRL"), formerly a division of HEW), a division of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, a subdivision of the Office of Infectious Diseases, of the U.S. Center for Disease Control and Prevention. Dr. John F. Mahoney, Defendant Bolan's predecessor as the Director of VDRL from 1929 through 1949, and who was the project leader of venereal disease experiments in Terre Haute, Indiana (which also focused on finding a successful prophylaxis and during which the requirement of obtaining informed consent was specifically and widely recognized by the medical community), secured funding for and oversaw the experiments at issue. Further, Dr. Richard C. Arnold, Director of Syphilis

Research at the VDRL from 1939-1951, was the secondary supervisor of the medical experiments at issue. Defendant Bolan is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

43. Defendant **HAROLD VARMUS, M.D.** is a United States citizen. Defendant Varmus is currently Director of the National Cancer Institute, a division of the National Institutes of Health, a division of DHHS. Harry Eagle, Defendant Varmus' predecessor as the scientific director of the National Cancer Institute from 1947-49 and a National Institutes of Health employee until 1961, created one of the serology tests for syphilis and was involved with the non-consensual human medical experimentation studies in Guatemala and even requested to do his own prophylaxis research on subjects in Guatemala. Defendant Varmus is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

44. Defendant **MIRTA ROSES PERIAGO** is a United States citizen and/or a United States resident. Defendant Periago is currently Director of the Pan-American Health Organization formerly the Pan-American Sanitary Bureau, which was at the helm of the non-consensual human medical experiments in Guatemala. According to an October 11, 2010 article in the Journal of the American Medical Association (JAMA), the Guatemala work was "funded with a grant from the National Institutes of Health (NIH) to the Pan American Sanitary Bureau . . . ." In addition to being the Assistant Surgeon General at PHS, Dr. Cutler, who ran the non-consensual human medical experiments at issue, was the Deputy Director of the Pan-American Sanitary Bureau. Dr. Joseph Spoto, the Chief of the Pan-American Sanitary Bureau from 1945 though 1946, who then moved to the Venereal Disease Division of the PHS through 1948, facilitated the research in Guatemala and introduced the medical team to the Guatemalan

officials who assisted in the non-consensual human medical experimentation. Defendant Periago is the successor office-holder for the person or persons who were directly responsible for the unlawful actions alleged herein.

45. All of these Defendants are liable under the principles of successor liability for the acts of their predecessor office-holders.

46. None of these Defendants enjoys immunity for the acts committed by their predecessor office-holders. Those predecessor office-holders implemented a medical policy or program that, as set forth below, violated clearly-established rights protected by the U.S. Constitution, as well as international law. In addition to being ethically unsound, this medical policy or program of non-consensual human medical experimentation was facially unconstitutional. The predecessor office-holders, the nation's top health officials, knew of the ethical and constitutional violations inherent to non-consensual human medical experimentation. Regardless of what motivated the predecessor office-holders to create, authorize, supervise, and enforce the non-consensual human medical trials in contravention of the Fifth and Eighth Amendments, as well as international law, their motivations do not presumptively immunize the program or them, the nation's chief medical officials, and others implementing and executing it, from complying with the rule of law.

47. Defendants David Does 1-10 are persons or corporations that were involved in the non-consensual human experimentation but whose identities are not known at this time.

IV. BACKGROUND FACTS CONCERNING CONTEMPORANEOUS NON-CONSENSUAL HUMAN MEDICAL EXPERIMENTATION IN TUSKEGEE, ALABAMA

48. The United States Public Health Service ("PHS") was established in 1798, and, with the 1944 Public Health Service Act, PHS became the primary division of the Department of

Health, Education and Welfare ("HEW"), now the Department of Health and Human Services ("DHHS"). PHS comprised all Agency Divisions of Health and Human Services and the Commissioned Corps, with the U.S. Surgeon General serving as the head of the PHS, overseen by the DHHS Assistant Secretary for Health.

49. It is now well documented that from 1932 through 1972, physicians from the Venereal Disease Research Laboratory ("VDRL") of the PHS conducted the highly controversial "Tuskegee Study of Untreated Syphilis in the Negro Male" on six hundred African-American men in Tuskegee, Alabama. According to the Centers for Disease Control and Prevention ("CDC"), the African-American men who participated in the Tuskegee experiments "did not receive the proper treatment needed to cure their illness." The men did receive free medical exams, free meals, and burial insurance in exchange for their participation, but "even when penicillin became the drug of choice for syphilis in 1947, researchers did not offer it to the subjects." Throughout those four decades, the 399 African-American participants in the Tuskegee experiments who tested positive for syphilis were never told that they had the debilitating and potentially fatal disease – instead, the PHS physicians merely observed as the disease crippled and killed many of the men.

50. After the whistle was blown on the study and the *New York Times* published a front-page account in 1972, the HEW appointed the Tuskegee Syphilis Study Ad Hoc Advisory Panel ("the Panel") to review both the study and the HEW's procedures. One member of the Panel expressed dismay over the researchers' deliberate efforts to "obstruct the opportunity for treatment."

51. The Panel concluded that the experiment was "ethically unjustified in 1932," noting that "one fundamental ethical rule is that a person should not be subjected to avoidable risk of death or physical harm *unless he freely and intelligently consents*" (emphasis added).

52. The Panel also found that "penicillin therapy should have been made available to the participants in this study especially as of 1953 [just a few years after the Guatemalan experiments began] when penicillin became generally available." The Panel's report did not detail the treatments other than penicillin that were available *prior* to 1953. In attaching Reservations to the final report, one member of the panel, Dr. Jay Katz, more strongly condemned the failure to obtain consent from the subjects and, in criticizing comments that a senior investigator wrote in 1936, noted that "syphilis was not a condition for which no beneficial treatment was available, calling for experimentation to learn more about the condition in the hope of finding a remedy."

53. The Panel's Report condemned the Tuskegee experiments but provided no concrete remedy for the victims.

54. The subjects of the Tuskegee experiments did not receive compensation until they filed a class action lawsuit.

55. While the Tuskegee experiments progressed, unbeknownst to the American public, whose tax dollars funded the PHS, the medical staff conducted other shorter-term venereal disease experiments on human subjects, such as a 1944 experiment on prisoners in a federal penitentiary in Terre Haute, Indiana. Assistant Surgeon General Dr. John Charles Cutler worked on the Terre Haute project, where attempts to infect prisoners with gonorrhea bacteria cultured from chancres (sores) of other prisoners with the disease proved ineffective.

56. Wanting a place where such experiments could be conducted with less scrutiny, the medical staff targeted Guatemala to continue its work.

V. BACKGROUND FACTS CONCERNING THE NON-CONSENSUAL HUMAN MEDICAL EXPERIMENTATION IN GUATEMALA

57. In October 2010, it was revealed that despite ongoing intense debates within the U.S. National Research Council over the ethics of the Terre Haute prison study and despite national and global attention to medical ethics following the Nuremberg Trials that had concluded eight months prior, the PHS also sanctioned non-consensual human medical experiments involving venereal diseases in Guatemala.

58. There are striking similarities between the Tuskegee experiments, which were deplored as one of the worst ever human rights violations on American soil, and the Guatemalan non-consensual human medical experimentation at issue in the present case. For example, both sets of non-consensual human medical experiments involved many of the same actors, including Surgeon General Thomas Parran, who oversaw and reviewed the whole endeavor, and Dr. John Cutler, who actually implemented the studies in Guatemala. Further, the experiments occurred concurrently, at a time of heightened global awareness of medical ethics and standards arising from the Nuremberg Trials of 1946 and 1947. In those trials, sixteen German doctors who conducted human experimentation during the Holocaust were indicted and sentenced as war criminals before an American military tribunal.

59. While the medical experimentation studies in Alabama and Guatemala had much in common, there are also marked differences making the Guatemala experiments more horrific. In Tuskegee, the PHS doctors did not infect the African-American subjects with syphilis, but rather, studied (and withheld full treatment from) subjects who were *already* infected with syphilis. In Guatemala, on the other hand, the PHS doctors actively infected the test subjects

with syphilis, gonorrhea, and chancroid either (a) by exposing them to infectious commercial sex workers, or (b) directly through inoculum made from tissue from human and animal infected gummas and chancres (i.e. pus of disease-filled sores.) In some cases, once the PHS learned what it wanted from each Guatemalan subject's induced exposure, it provided some treatment for the infection. However, the PHS did not provide treatment to all subjects nor did it follow-up with those who did receive treatment to ensure that the subjects were actually cured of their infection. How long the study continued and how long treatment, if any, was provided to those infected is not clear.

60. Informed consent of test subjects was widely regarded as an ethical norm long before the 1940s. This is evidenced by the cessation of studies like those at Indiana's Terre Haute federal penitentiary and the recognition in human experiments in the United States in the first half of the 20th century of distinct limitations in the scope of what doctors could ethically do to their human subjects. Unfortunately, the physicians who faced ethical limitations in what they were able to do at Terre Haute moved their work to Guatemala *for the explicit purpose* of pushing the boundaries of medical ethics beyond what they could do in the United States. After malaria specialist G. Robert Coatney, who had done prison malaria studies, visited the Guatemalan project in February 1947 and reported back to Surgeon General Parran, Coatney told Dr. Cutler that a "merry twinkle came into [Parran's] eye when he said 'You know, we couldn't do such an experiment in this country.'"

61. Dr. Cutler himself confided to his supervisors that "We are just a little bit concerned about the possibility of having anything said about our program that would adversely affect its continuation."

62. Nevertheless, from their offices in the United States, PHS and other U.S. entities decided to seek a location where they would be able to carry out more invasive methods of inoculation with venereal diseases without ethical scrutiny. This decision to move to Guatemala was part of a deliberate plan to continue the Terre Haute and Tuskegee-style experimentation offshore, where it would not be subject to the same level of oversight as in the United States.

63. Escaping from the ethical scrutiny in the United States, Dr. Cutler set up experiments in Guatemala where, from 1946 through at least 1953, in concert with Guatemalan government officials and PHS-trained doctors, PHS physicians conducted highly invasive medical tests on Guatemalan test subjects, including Plaintiffs listed herein, in the national penitentiary (Penitenciaría Central), the national orphanage (Puerto San José), State-run schools and rural areas, the military (including the Guardia de Honor), a leprosarium, and a mental institution (Asilo de Alienados). In addition, the medical team infected many commercial sex workers who were used to carry out inoculation of the test subjects.

64. The medical team and U.S. entities took advantage of the fact that ethical limitations in the United States were enforced, while in Guatemala, they were not. But, as the parties involved fully recognized, these ethical limitations were not unique to the United States nor did they apply only on U.S. soil; the ethical limitations were part of international law and, as such, transcend any particular country and apply to humans everywhere. As the Nuremberg trials made abundantly clear, all humans have the right to be free from non-consensual medical experimentation. The medical team and U.S. entities involved unquestionably violated that right by going to a country where they were less likely to be caught or punished for engaging in unethical practices. Trying to escape the law by violating it in a country known for weak enforcement is reprehensible.

65. Contemporary records note that because "the patients [were] frequently restless and not always cooperative it was sometimes noted that the needle [used in the experiments] was deeply inserted, at times so as to draw blood." As Dr. Arnold remarked in a letter to Dr. Cutler, "I am a bit, in fact more than a bit, leary [sic] of the experiment with the insane people," noting that they "cannot give consent" "do not know what is going on," and if "some goody organization got wind of the work, they would raise a lot of smoke." He then specifically told Dr. Cutler that "[his] first study could be done in a short time and none would be the wiser. In the report, I see no reason to say where the work was done and the type of volunteer."

66. While the research team often referred to the subjects as "volunteers," this term was a gruesome misnomer. At no time did the researchers inform the subjects as to what the medical team was doing or seek the test subjects' consent to participate in the venereal disease experiments. In short, these human medical experiments were performed without informed consent.

67. Dr. Cutler oversaw these non-consensual human medical experiments through at least 1948. It has not been established when the experimentation ended, although Dr. Cutler's files indicate clearly that the PHS continued work relating to the Guatemalan test subjects into the 1950s.

68. At no point in the medical experiments in Guatemala did the medical team obtain consent from the subjects involved; the people involved in these experiments did not give their informed consent to participate. Instead of consent from the subjects, the medical team sought cooperation from the institution in which their prospective subject pool resided. To gain that institutional cooperation, the medical team offered essential supplies, such as epilepsy medication to the mental asylum, malaria medication to the orphanage, and refrigerators for

medications, and even then, these essential supplies were not always provided without charge. For example, on November 15, 1948, Dr. Cutler wrote to his supervisors to ask permission to sell at-cost to the mental asylum the plastic plates, movie projector, and refrigerator recently ordered by the PHS lab. Furthermore, the bribes were not always medical supplies; reticent individual subjects were offered cigarettes in exchange for (uninformed) compliance – one single pack of cigarettes for inoculation, blood draws or spinal taps, or an individual cigarette for "clinical observation." Contemporaneous records noted that bribery with cigarettes was "valuable, even indispensable" to the experiments and was the test subjects' sole motivation to acquiesce: "the patients would often attempt to make numerous trips past the physician for blood letting, cisternal puncture or examination, just to augment their supply of tobacco." Worse still, most of the officials at the mental asylum thought at first that "inoculation" was just another type of drug, not an actively induced infection, and most of the inmates in the national penitentiary were quite reluctant to submit to the frequent blood sampling, which they thought weakened them.

69. When concerns over the ethical issues involved in the Guatemalan experiments grew following the Nuremberg Trials, Dr. Arnold recommended that the medical team should cease using psychiatric patients and children. The medical team also involved Guatemalan soldiers in its experiments and, even though this group was theoretically capable of consenting, the medical team never informed the soldiers of what the experiments entailed or sought consent from the soldiers involved. In other words, just like the orphans, children, psychiatric and leprosy patients, commercial sex workers, and prisoners, the soldiers who were subjects in the study never gave their informed consent to be experimented upon.

70. The medical team performed two types of experiments: 1) serological tests, as a diagnostic tool which did not involve exposure to venereal diseases; and 2) intentional exposure

experiments, which did. In total, the medical team intentionally exposed nearly 700 people to syphilis, nearly 600 to gonorrhea, and over 100 to chancroid – all serious venereal diseases. As some patients were involved in several experiments and the commercial sex workers involved may not have been tracked consistently, the total number of people personally subjected to this form of experimentation is not known.

A. Why Were the Experiments Undertaken?

71. The objective of the human medical experiments in Guatemala was to determine whether penicillin, then a recently-discovered cure for syphilis, could also be used as a prophylaxis. By the end of World War II, penicillin became more widely available and was making great strides toward becoming a cure for syphilis and other diseases. However, many syphilologists did not know for certain the correct dosages and limitations, and they sought a better chemical prophylaxis – like a morning-after cream – that a man could apply directly after possible exposure. Eager to know whether the new prophylaxis treatments could be safely given to the men in the United States Armed Forces and concerned that the syphilis animal research studies could not be translated to humans, the PHS researchers turned to human subjects in Guatemala.

72. Additionally, after the failed Terre Haute experiments, another goal was to find the most effective way to inoculate patients with the disease, an experiment that would not have been permitted in the United States.

73. While Dr. Cutler later reported that the "studies were designed to obtain information about methods of prophylaxis against syphilis; to increase understanding of the effects of penicillin in treatment of syphilis; to assist in a better understanding of the question of false positive serologic tests for syphilis; and to enhance knowledge of the biology and

immunology of syphilis in man," he also more privately recognized that many of his subjects "can not give consent," knew that the experiments raised serious ethical questions, and suggested that certain elements of the study not be publicly disclosed.

B. Why Guatemala?

74. The PHS had a long history of international work prior to the Guatemala experiments. In the 19th century, it participated in foreign quarantines and sanitary conferences focusing on infectious disease, which led to the 1945 establishment of the Office of International Relations. In 1901, PHS led a movement to organize the Pan-American Sanitary Bureau ("PASB"), which later became PAHO. The official heads of PHS served as the PASB Directors from 1902-1936, and were so involved that the PASB was a virtual branch of the PHS.

75. As noted in the Presidential Commission's Report, the non-consensual human medical experiments were conducted under the auspices of PASB, which was the "principal coordinating entity of international health activities in the Americas" at the time. In concluding that "the Guatemala experiments involved unconscionable violations of ethics, even as judged against the researchers' own understanding of the practices and requirements of medical ethics of the day," the Report made a conservative estimate that PHS provided the PASB approximately $223,032.91 for the purpose of conducting venereal disease research in Guatemala in 1946 and 1947.

76. Prior to the experiments, the purported main goal of PHS' involvement in the Guatemalan public health sector was to transfer laboratory materials, skills, and knowledge to the Guatemalan public health elite. The PHS trained Juan Funes, Guatemala's leading venereal disease public health official, which gave PHS close government contact when they needed domestic support.

77. In the 1930s, Harvard Medical School Tropical Medicine Professor, George Cheever Shattuck, conducted haphazard surveys in the Guatemalan highlands that showed little prevalence of syphilis either there or in the army ranks. Nevertheless, Shattuck carried racialized assumptions about syphilis from the United States to Guatemala, presuming that the disease was more frequent in persons of Latin descent than in others. Such assumptions were at the core of the non-consensual human medical experiments in Guatemala.

78. The medical team involved considered Guatemala the perfect place to conduct these human medical experiments that violated international law. The decade between 1944 and 1954 was one of relative peace until the U.S.-led coup of the democratically-elected government in 1954, after which Guatemala made strides toward labor protection laws, land reform, and democratic elections.

79. Further, as Dr. Cutler wrote, in Guatemala "prostitution was legalized to the extent that prostitutes [who were recognized to sometimes carry venereal diseases] were allowed to pay regular visits to men in penal institutions," which became integral to the design of the penitentiary portion of the experiments, as set forth below.

C. <u>The Non-Consensual Human Medical Experimentation</u>

80. From the beginning of the study, the PHS secured cooperation from the Guatemalan government, namely the Ministry of Health, the National Army of the Revolution, the National Mental Health Hospital, and the Ministry of Justice. The Guatemalan research was initially called "a series of experimental studies on syphilis in man." Dr. Cutler and the PHS medical team had two main goals: first, they sought to use "syphilization" to test the human response to infective material, enhance the response to disease, and understand superinfection and reinfection.

81. Second, the medical team sought ways to prevent syphilis immediately after exposure. Existing prophylaxis kits ("pro kits") given to American soldiers during World War II contained a calomel-sulpha-thiazole that was painful to use, so PHS wanted to determine if penicillin or some less noxious chemical could be used instead. In addition, they wanted to discover the cause for false positive syphilis tests and demonstrate more fully how and when differing dosages of penicillin actually cured infection.

i. The Subject Groups

82. Prisoners in the National Penitentiary: With cooperation from Guatemalan Ministry of Justice officials and the warden of Guatemala City's Central Penitentiary, which had nearly 1,500 inmates, the medical team began their experiments with inmates in the Guatemalan national penitentiary.

83. According to the Presidential Commission Report, 842 Guatemalan prisoners were involved in the serological portion of the non-consensual human medical experiments and at least 219 in the intentional exposure experiments. Only 92 of that 219 received any form of treatment.

84. The medical team first used the prisoners to study the effectiveness of four blood tests. This study also involved lumbar punctures (inserting a needle into the spine) to draw spinal fluid to confirm blood test results or find possible infection that blood tests would not reveal.

85. The medical team did not limit their use of the Guatemalan prisoners to serology tests; the prisoners were used in intentional exposure studies as well. In those experiments, the medical team tested inmates before they visited commercial sex workers, and then afterward, to see if infection had occurred. Commercial sex workers who tested positive for either syphilis or

gonorrhea were allowed to offer their services to prison inmates and were paid for by U.S. taxpayers, through PHS funds. These inmates were followed and their sexual activity recorded; after, they were tested. The men were divided into groups, and each group received different chemical and biological prophylaxis techniques after presumed infection.

86. In addition to using commercial sex workers as a means of exposure to venereal disease, the medical team used injections to infect the Guatemalan prisoners.

87. Four prohibitive problems arose throughout the course of the research. One researcher lamented over the low retention rate for commercial sex workers as subjects, noting that many left the profession once they were married. Not enough of the men in the prison were contracting syphilis, even when the physicians plied them with alcohol to induce them to seek the infected commercial sex workers. Thus, the sample pool was too small to create statistical significance. Additionally, there were a high number of false positives – too many men were testing positive for syphilis before exposure even occurred, although they exhibited no signs of actually having the disease. To decipher the false positives problem, researchers began to perform an intensive variety of blood tests, drawing blood weekly or bi-weekly.

88. The medical team did not seek consent from the inmates themselves (or even inform them), instead operating only with the cooperation and permission of the Guatemalan penal institutions. In Dr. Cutler's own words: "To increase the number of exposures we shall bring in the source of infection as indicated along with some not infected [commercial sex workers] so as to allay fears and suspicion. In that way, we shall be able to avoid political repercussions which are even now in the air, as the papers are complaining about conditions in the prison now. It is quite probable that we shall pay the man either nothing or a pack of cigarettes or some soap or other items for each extraction of blood."

89. Nor did the medical team seek to inform the prisoners, a large portion of whom were indigenous Guatemalans, whom the researchers called "Indians" and to whom they concluded that the experiments need not be explained. Rather than attempt to find a way to explain their work, the medical team blamed their victims, saying that the prisoners "[were] only confused by explanations and knowing what is happening." In fact, contemporary records reveal the medical team actively sought to deceive the inmates about the experiments.

90. Resistance from the inmates intensified over the course of the experiments, especially over the frequent blood withdrawals, which they believed would "weaken" them. Although the PHS doctors noted that they had more success inoculating the Guatemalan prisoners than those in Terre Haute, the persisting low rates of infection, resistance from the inmates, and other clinical complications encouraged them to use other test subjects – including children.

91. Children in the National Orphanage, in State-run Schools, and in Rural Areas: The medical team conducted the tests on children to understand the blood test results and in attempt to determine the cause of the false positives in other experiments.

92. According to the Presidential Commission Report, 1,384 Guatemalan children between the ages of 1 and 18 were involved in the non-consensual human medical experiments.

93. In accord with the racialized assumptions that the medical team carried with them from the United States, the PHS physicians believed that venereal diseases would manifest differently in each race, and thus, they wanted to analyze the blood of an uninfected Guatemalan test group – children.

94. According to the Presidential Commission Report, the medical team first started their testing on Guatemalan children in school in the Port of San José, Guatemala, and began

testing children in the National Orphanage soon thereafter. Later, the medical team expanded its experiments to include "Ladino" children from the highlands of Guatemala and "Indian" children.

95. Some reports suggest that the researchers did not give this group of children venereal diseases, but rather, put them through a barrage of blood tests to try and understand the difference between the minority of children who falsely tested positive for syphilis, and those who accurately tested negative for the disease. However, there is evidence to suggest some children were, in fact, actively infected. As the Presidential Commission reported, "The ages of subjects involved in the exposure experiments ranged from ***10*** to 72 years, with the average subject being in his/her 20s." (Emphasis added.)

96. In the course of the experiments, the medical team examined the children's mouths, skin, and lymph nodes, and it was documented that they examined the boys' genitals. In addition to blood draws, many children were also subjected to lumbar punctures in the course of the experiments. As Dr. Cutler reported to Dr. Mahoney, then head of the PHS' VDRL, "…we are going to bleed the children at San Jose next weeks [*sic*]… We then plan to draw bloods from the children once a month."

97. The medical team did not seek or obtain consent from the child test subjects themselves; the children did not consent to the experiments, nor did a parent or guardian consent on their behalf. Instead, the medical team cooperated with Guatemalan officials. To induce permission from the managers of the orphanage, the medical team offered substantial quantities of malaria medications and other essential medications that were in scarce supply for the orphanage.

98. Leprosy Patients: According to the Presidential Commission Report, the medical team also targeted Guatemalan leprosy patients, subjecting 51 of them (nearly the entire leprosarium population at that time) to serological experiments.

99. There is no indication that any of the leprosy patients consented to participating in the medical experiments.

100. Asylum Patients in Guatemala's Psychiatric Hospital: Seeking to continue their experiments in a regular and repeated fashion over a defined adult population over a long period of time, the medical team turned to Guatemala's one psychiatric hospital to use asylum patients as subjects.

101. According to the Presidential Commission Report, 642 Guatemalan psychiatric patients were subjected to the serological portion of the non-consensual human medical experiments and a minimum of 446 Guatemalan psychiatric patients were subjected to intentional exposure to syphilis to which they did not consent. Of those 446, only 294 received any form of treatment. The medical team also intentionally exposed numerous Guatemalan psychiatric patients to gonorrhea and chancroid.

102. The serological tests conducted on the psychiatric patients involved blood testing and lumbar punctures, as well as hundreds of cisternal punctures. As the Presidential Commission explained, "[c]isternal puncture, which involves the withdrawal of cerebral spinal fluid from the back of the skull, is particularly dangerous because of its proximity to the brain stem." Nevertheless, the medical team employed this procedure in its intentional exposure experiments, including in the psychiatric hospital. In other words, the medical team punctured patients' necks, removed their spinal fluid, injected venereal diseases into the patients' spinal columns, and ensured the presence of the disease by washing the spinal needle with some of the

individual patient's own spinal fluid. The Presidential Commission specifically noted that "[i]t would have been unclear at the time what types of reactions would occur from injection of foreign material, let alone infectious material, into the cerebral spinal fluid." As Dr. Cutler reported in 1955, the medical team rewarded the psychiatric patients for enduring this risk with "two packs of cigarettes." This was but one of the methods of planned inoculation that the medical team employed in the psychiatric hospital, where they could not bring commercial sex workers.

103. The tests on Guatemala's mentally ill patients are possibly among the most disconcerting in the non-consensual human medical experimentation at issue, both because the patients very clearly were unable to give consent and because of the vulgar methods used to inoculate them. Methods such as scraping the head of the penis with a needle and then introducing directly to the raw skin liquid bacteria cultured from the open genital sores of other men was unprecedented and certainly would never be sanctioned or replicated in the United States. Dr. Cutler's records even indicate that in at least one experiment, the medical team tested the transferability of syphilis through oral sex by making subjects drink water mixed with testicular tissue infected with syphilis.

104. The medical team used Guatemalan psychiatric patients in all of its intentional exposure experiments: syphilis, gonorrhea, and chancroid.

105. At least two of the psychiatric patients used in the chancroid experiments died, one only thirteen days after being inoculated.

106. Psychiatric patients used in the gonorrhea experiments were inoculated through their rectum, urethra and/or eyes. As the Presidential Commission reported, "One female [psychiatric patient] who was identified as having a terminal illness died four days after the

researchers inoculated her, without receiving any treatment for the gonorrhea or syphilis with which the researchers had infected her."

107. Another female psychiatric patient used in the experiments "was not treated for syphilis until three months after her injection. Soon after [ ] Dr. Cutler wrote that [she] appeared as if she was going to die, but he did not specify why. That same day he put gonorrheal pus from another male subject into both of [her] eyes, as well as in her urethra and rectum. He also reinfected her with syphilis. Several days later, [her] eyes were filled with pus from the gonorrhea, and she was bleeding from her urethra. Three days later, [she] died."

108. There are suggestions that the medical team was not forthcoming with the asylum staff, many of whom were compensated for their help with a pack of cigarettes or a few extra dollars, about the nature of the experiments.

109. There is no indication that the medical team sought consent from the asylum patients.

110. Soldiers in the Military: During their time in Guatemala, the medical team developed relationships with Guatemalan military physicians and eventually began conducting intentional exposure experiments on Guatemalan soldiers as well, including men in the Military Hospital, the Honor Guard, and the Second Army Company of Riflemen.

111. According to the Presidential Commission Report, over 500 Guatemalan soldiers were involved in the non-consensual human medical experiments. The medical team intentionally exposed at least 81 Guatemalan soldiers to chancroid, all of whom were purportedly later treated, and 518 Guatemalan soldiers to gonorrhea. The medical team provided only 202 of those 518 soldiers any treatment for gonorrhea.

112. The medical team exposed the Guatemalan soldiers to gonorrhea through methods such as sexual exposure, superficial inoculation into the penis, deep inoculation into the penis, and superficial inoculation following sexual exposure.

113. The medical team obtained the "ample supplies of pus" with gonorrhea bacteria that it needed for these experiments from syphilis patients at the Military Hospital; the researchers infected these syphilis patients with gonorrhea to "create a 'reservoir of infect[i]on' from which to draw."

114. The medical team exposed the Guatemalan soldiers to chancroid through scratches by a hypodermic needle done deep enough to draw blood. The chancroidal inoculum was then rubbed into the wound and, after several hours, different prophylaxes were applied to test their effectiveness.

115. Often, the Guatemalan soldiers involved in the experiments were isolated under careful control and supervision during the experiment. The medical team's files contain no discussion of financial compensation for the soldiers for their participation.

116. Nor do the medical team's files contain any evidence that the soldiers consented to participating in the experiments.

117. Commercial Sex Workers: While the medical team's records do not track all of the commercial sex workers that the medical team used in its experiments, at least four used in the gonorrhea experiments are identified in contemporaneous records of at least twelve who were involved.

118. As prostitution was legal in Guatemala during the time of the experiments at issue, commercial sex workers were supervised and had access to free treatment. Under Guatemalan regulations, commercial sex workers registered with the government and were

required to report twice weekly for an examination, suggesting that contemporaneous records would identify those working in this trade at the time of the experiments.

119. Relevant Guatemalan regulations, a copy of which Dr. Cutler had in his personal files, also set a minimum age of 18 for commercial sex workers. Contemporaneous records indicate that one commercial sex worker used in the intentional exposure experiments was only 16 years old.

120. One commercial sex worker used in the experiments was paid $25 to have sexual contact with seven men. In the year that followed, she was inoculated at least 11 times with various strains of gonorrhea and had at least 105 sexual contacts while infected.

121. Contemporaneous notes report that commercial sex workers were artificially inoculated by using a swab covered in pus from a man with an acute case of gonorrhea and applying it directly to the woman's cervix "with considerable vigor." The women were not allowed to wash between sexual encounters with the men.

122. In one gonorrhea experiment using the commercial sex workers, the medical team reported "us[ing] two girls over a four night period with four men exposed to them. Each man had as many contacts as *he* wanted during the evening. . . ." (Emphasis added.)

123. There is no record that any of the commercial sex workers used in the human medical experiments in Guatemala knew that they were being infected by the researchers, much less consented to being infected.

ii. Study Methods

124. One of the most obvious shortcomings of the study is that PHS only sought compliance from the institutions that housed the orphans, prisoners, leprosy patients, military, and mentally ill, and did *not* seek consent from the subjects themselves or a legal guardian.

Nonetheless, the subjects in the experiments were frequently referred to as "volunteers." In some cases, the PHS physicians lured participants by offering cigarettes – one single cigarette for "clinical observation," or an entire packet for inoculation, blood draws or spinal taps. The subjects were never given information about the procedures or their risks before accepting the exchange. In a similar tactic, the medical team bought institutional compliance with the offer of supplies, such as epilepsy meds to counter prevalent epilepsy problems in the asylum and needed medications at the orphanage. Items such as a refrigerator to store medications, a movie projector, and metal plates and cups were bartered for the use of human beings in medical experiments involving venereal diseases.

125. PHS used two methods to make the syphilis inoculums used to infect the "volunteers." The first was to grind up gummas (syphilitic growth) in the testes of rabbits infected with the Nichols & Frew strains of the syphilis bacteria and then use this to inoculate test subjects. The problem with this method was that it required that rabbits from the VDRL in Staten Island, New York be flown into Guatemala City. Many of the rabbits either didn't survive the trip, or did not develop enough of an infection to make the gummas sufficiently potent. The second method, and the one predominantly used in Guatemala, was to scrape open sores from the penises of infected asylum inmates or from Army soldiers who had a "Street" strain of syphilis, picked up from local commercial sex workers who were not involved in the study. After the sample was taken, there was only a narrow 45-90 minute turnaround time, because the spirochetes could not last longer than that outside a body. In that time, researchers had to remove the bacteria, centrifuge it with homemade beef broth, and deliver the inoculum to the subjects.

126. Men and women were inoculated in different ways. It was frowned upon in Guatemala for men, even physicians, to view a female body, so the PHS doctors used needles to abrade the women's forearms, faces or mouths, and then inserted the inoculum. The men underwent what they eventually referred to as a "short arm" inspection – doctors chose uncircumcised men (for purposes of keeping the mucus membranes moist) who could sit or stand in one place for multiple hours. The doctor held the subject's penis, pulled back the foreskin, abraded the skin just short of drawing blood by scraping it with a hypodermic needle, covered the abrasions with a cotton dressing, and finally dripped drops of the syphilitic emulsion onto the cotton-covered abrasions for between one and two hours. Other inoculation methods used in Guatemala included ingestion of syphilitic tissue mixed with distilled water; removal of spinal fluid, which was then infused with syphilitic mixture and re-injected into the body; and venipunctures of the mixtures into the medial cubital vein of the forearm. In the army barracks prophylaxis studies, the men had sexual intercourse with uninfected commercial sex workers, then the syphilitic inoculum was put into the meatus of the penis, and they were told to urinate an hour later and apply different kinds of chemical prophylaxis. Alternatively, the inoculum was placed on the cervixes of commercial sex workers before they were allowed to have sex with the prisoners or the soldiers.

iii. Limited Treatment of Infected Participants

127. It appears that most of the Guatemalan subjects began the study disease-free. Although some "volunteers" infected in the course of the study were given penicillin, the research files show no follow-up to determine if they were actually cured. Researchers claimed to be "scrupulous" about administering cures; however, Dr. Cutler admitted to experiencing great difficulty in keeping track of his subjects, especially the commercial sex workers and the

mentally-ill patients, even though his wife, Eliese Cutler, helped manage the records by photographing the subjects and their inoculations for the recorded files. As contemporary records reveal, one mentally ill subject who after scarification and the first emulsion application fled the room, was finally found two hours later with the emulsion still in place.

iv. Deception in the Guatemala Study

128. The medical team and U.S. government entities involved in the Guatemala experiments had experience working with other venereal disease experiments, which gave them an acute knowledge of the dangers of syphilis and other venereal diseases. Dr. Cutler admitted knowing that they were not telling many people that their inoculum contained syphilis and, in a June 27, 1947 letter, he reiterated his concerns, saying, "a few words to the wrong person here, or even at home, might wreck [the experiment] or parts of it…" Dr. Cutler acknowledged that keeping mum about the real reason for their medical work was a burden on the project, especially as the medical team experimented with methods of inoculation, various prophylaxis treatments and various therapies: "It is unfortunate that we have to work in such a guarded, even subterranean way, but it seems to be very necessary."

129. As the two years of rigorous and widespread testing in Guatemala progressed, the team balanced demands from the Guatemalan officials that were met in order to ensure the team's continued cooperation, as well as demands from PHS headquarters in the United States, where heightened concerns over the cost and the methods used decreased interest in and funding for continuing the experiments.

130. For the most part, the Guatemalan officials traded their cooperation with the PHS for medical supplies and services. They requested that the medical team test and treat the ill men in the army barracks and also requested a survey of disease in the Guatemalan lowlands. At the

time, penicillin was a fairly new and sparse medicine seen as a cure-all; Guatemalan officials sought from Dr. Cutler more penicillin for the country. At the orphanage, the medical team traded malaria drugs for compliance. When requesting instructions on how to transfer the movie projector and refrigerator to the Asylum, Dr. Cutler wrote to a colleague, "The suggestion has been made that the entire cost should be written off as professional services."

131. It is not clear from publicly available data how this non-consensual human medical experimentation in Guatemala ultimately ended. Dr. Mahoney, Dr. Cutler's supervisor, recognized *ex post facto* that Dr. Cutler's data was not sufficiently conclusive, and he analogized the Guatemala findings to those of the failed and highly criticized Terre Haute Penitentiary study. However, perceived racial immunological differences led the researchers to believe that tests of every race would have to be conducted in order for any results to have scientific weight. While such tests are neither logistically nor ethically possible, it is unknown how long researchers continued to collect data using unethical procedures to obtain more data before completely ending the non-consensual human medical experimentation in Guatemala.

VI. DEFENDANTS' VIOLATIONS OF LAW

132. Defendants' actions violate, and Plaintiffs' causes of action arise from, the following laws, agreements, conventions, resolutions and treaties, which constitute specific examples of the applicable law of nations or customary international law:

(a) Alien Tort Statute, 28 U.S.C. § 1350;

(b) The Fifth Amendment to the U.S. Constitution;

(c) The Eighth Amendment to the U.S. Constitution;

(d) The Law of Nations;

(e) Universal Declaration of Human Rights, G.A. Res. 217A(iii), U.N. Doc. A/810 (1948);

(f) International Covenant on Civil and Political Rights, G.A. Res. 2220A(xxi), 21 U.N. Doc., GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966);

(g) Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. res. 39/46, 39 U.N. Doc., GAOR Supp. (No. 51) at 197, U.N. Doc. A/39/51 (1984)(ratified 10/28/98);

(h) Declaration on the Protection of All Persons From Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452, 30 U.N. Doc., GAOR Supp. (No. 34) at 91, U.N. Doc. A/10034 (1976);

(i) Vienna Declaration and Programme of Action (World Conference on Human Rights, 1993);

(j) Article 3 of the Geneva Conventions;

(k) The Nuremburg Code;

(l) The Bilateral Treaty of Peace, Amity, Commerce and Navigation between the United States and Guatemala; and

(m) Statutes and common law of the District of Columbia.

VII. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

(Violation of Prohibition Against Medical Experimentation on Non-Consenting Human Subjects: Alien Tort Statute, 28 U.S.C. § 1350)

133. Plaintiffs incorporate by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

134. Plaintiffs bring this claim against all Defendants.

135. Defendants' acts described herein constitute medical experimentation on non-consenting human subjects in violation of the law of nations and are, therefore, actionable under the Alien Tort Statute, 28 U.S.C. § 1350. The customary international law prohibition of medical experimentation on non-consenting human subjects is expressed and defined in international treaties and declarations, international judicial decisions, and in the domestic legislation of numerous countries throughout the world, including the United States. It is widely-recognized that experimentation on unknowing human subjects is morally and legally unacceptable.

136. Defendants are liable for the alleged conduct in that Defendants (or their predecessors), acting under color of law and authority as United States officials, set the conditions for, committed, directed, ordered, confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated the medical experimentation on Plaintiffs, without Plaintiffs' consent. Defendants intended, knew or should have known, that the non-consensual human medical experimentation was being committed by their subordinates and failed to prevent such abuse or punish those responsible.

137. Non-consensual human medical experimentation, which violates one's rights to life, health, and personal integrity, is universally condemned as violation of customary international law, as reflected in various international instruments, such as the Nuremburg Code, which states as its first principle that "[t]he voluntary consent of the human subject is absolutely essential," the Universal Declaration of Human Rights ("UDHR"), and Article 7 of the International Covenant on Civil and Political Rights ("ICCPR"), which provides that "no one

shall be subjected without his free consent to medical or scientific experimentation." Other international documents prohibiting non-consensual human medical experimentation include the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, and the 2001 Directive passed by the European Parliament and the Council of the European Union. This prohibition is also recognized by the World Medical Association's Declaration of Helsinki, which sets forth global ethical principles for physicians and provides that human subjects should be volunteers who give informed consent to participate in research, and by the Council for International Organizations of Medical Services ("CIOMS") guidelines, which require "the voluntary informed consent of [a] prospective subject." The prohibition of non-consensual human medical experimentation is further demonstrated in the enactment of an explicit prohibition by no less than eighty-four countries. For its part, the U.S. Food & Drug Administration has long required informed consent for human medical research. Violations of this international prohibition are capable of impairing international peace and security, especially, as here, when the medical team of one country violates the rights of another State's citizens.

138. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have been subjected to severe physical and psychological injuries, have incurred expenses, and suffered damages. These injuries have caused, and will continue to cause, Plaintiffs great physical and mental pain and suffering.

139. Plaintiffs are informed and believe and thereon allege that Defendants' aforementioned acts were intentional, willful, malicious, oppressive and despicable, and/or were done in willful and conscious disregard of the rights, welfare, and safety of Plaintiffs, thereby justifying the awarding of punitive and exemplary damages against Defendants.

140. Plaintiffs have suffered severe physical and psychological pain and suffering, and are entitled to monetary damages.

SECOND CLAIM FOR RELIEF

(Violation of Prohibition Against Cruel, Inhuman, or Degrading Treatment:

Alien Tort Statute, 28 U.S.C. § 1350)

141. Plaintiffs incorporate by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

142. Defendants' acts described herein constitute cruel, inhuman, or degrading treatment of Plaintiffs in violation of the laws of nations and are, therefore, actionable under the Alien Tort Statute, 28 U.S.C. § 1350. The customary international law prohibiting cruel, inhuman, or degrading treatment is expressed and defined in international treaties and international and domestic judicial decisions, among other authorities.

143. Defendants are liable for the alleged conduct in that Defendants, acting under color of law and authority as United States officials, set the conditions for, committed, directed, ordered, confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated the medical experimentation on Plaintiffs, without Plaintiffs' consent. Defendants intended, knew or should have known, that the non-consensual human medical experimentation was being committed by their subordinates and failed to prevent such abuse or punish those responsible.

144. Cruel, inhuman, or degrading treatment is widely prohibited by a variety of international human rights instruments, including the UDHR (Art. 5), the ICCPR (Art. 7), as well as the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment ("CAT") (Art. 16). The United States is a party to the ICCPR, having signed on

October 5, 1977 and ratified the Covenant on June 8, 1992, and to the CAT, having signed on April 18, 1988, and ratified on October 21, 1994.

145. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have been subjected to severe physical and psychological pain and suffering, have incurred expenses, and suffered damages. These injuries have caused and will continue to cause Plaintiffs great physical and mental pain and suffering.

146. Plaintiffs are informed and believe and thereon allege that Defendants' aforementioned acts were intentional, willful, malicious, oppressive and despicable, and/or were done in willful and conscious disregard of the rights, welfare, and safety of Plaintiffs, thereby justifying the awarding of punitive and exemplary damages against Defendants.

147. Plaintiffs have suffered severe physical and psychological pain and suffering, and are entitled to monetary damages.

THIRD CLAIM FOR RELIEF

(Violation of Substantive Due Process: Fifth Amendment)

148. Plaintiffs incorporate by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

149. Plaintiffs bring this claim against all Defendants.

150. Defendants' acts described herein constitute a deprivation of life and liberty interests in violation of the Fifth Amendment of the United States Constitution.

151. At all times pertinent to the allegations herein, Defendants were acting under color of law of the United States.

152. Defendants are liable for said conduct in that Defendants, acting under color of law and authority as United States officials, set the conditions for, committed, directed, ordered,

confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated the medical experimentation on Plaintiffs, without Plaintiffs' consent, thus depriving Plaintiffs of their liberty. Defendants intended, knew or should have known, that the non-consensual human medical experimentation was being committed by their subordinates and failed to prevent such abuse or punish those responsible. Plaintiffs have had to live with the debilitating and destructive disease syphilis as a result of this non-consensual human medical experimentation, and have therefore been deprived of their liberty to live their lives free of such intrusive, harmful actions.

153. Plaintiffs, who had not been adjudicated guilty of any crime in accordance with due process of law and therefore were not subject to punishment, were subjected to harms through the medical experimentation that amounted to punishment by the government. Plaintiffs' treatment during the non-consensual human medical experimentation was without legitimate penological purpose; instead, the medical experimentation was imposed out of medical curiosity, without regard for the impact on its human subjects. The non-consensual human medical experimentation deprived Plaintiffs of their liberty in direct violation of their substantive and procedural due process rights under the Fifth Amendment.

154. As a direct and proximate result of Defendants' unconstitutional acts and omissions, Plaintiffs have been subjected to severe physical and psychological pain and suffering, have incurred expenses, and suffered damages. These injuries have caused and will continue to cause Plaintiffs great physical and mental pain and suffering.

155. Plaintiffs are informed and believe and thereon allege that Defendants' aforementioned acts were intentional, willful, malicious, oppressive and despicable, and/or were

done in willful and conscious disregard of the rights, welfare, and safety of Plaintiffs, thereby justifying the awarding of punitive and exemplary damages against Defendants.

156. Plaintiffs have suffered severe physical and psychological pain and suffering, and are entitled to monetary damages.

FOURTH CLAIM FOR RELIEF

(Violation of Cruel and Unusual Punishment: Eighth Amendment)

157. Plaintiffs incorporate by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

158. Plaintiffs bring this claim against all Defendants.

159. Defendants' acts described herein constitute cruel and unusual punishment in violation of the Eighth Amendment of the United States Constitution.

160. At all times pertinent to the allegations herein, Defendants were acting under color of law of the United States.

161. Defendants are liable for said conduct in that Defendants, acting under color of law and authority as United States officials, set the conditions for, committed, directed, ordered, confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated the medical experimentation on Plaintiffs, without Plaintiffs' consent, causing Plaintiffs to be subjected to cruel and unusual punishment, including those Plaintiffs who were prisoners at the time of the experiments. Defendants intended, knew or should have known, that the non-consensual human medical experimentation was being committed by their subordinates and failed to prevent such abuse or punish those responsible.

162. Defendants are further liable for their conscious disregard of the excessive risk of serious harm to Plaintiffs' health and safety.

163. As a direct and proximate result of Defendants' unconstitutional acts and omissions, Plaintiffs have been subjected to severe physical and psychological pain and suffering, have incurred expenses, and suffered damages. These injuries have caused and will continue to cause Plaintiffs great physical and mental pain and suffering.

164. Plaintiffs are informed and believe and thereon allege that Defendants' aforementioned acts were intentional, willful, malicious, oppressive and despicable, and/or were done in willful and conscious disregard of the rights, welfare, and safety of Plaintiffs, thereby justifying the awarding of punitive and exemplary damages against Defendants.

165. Plaintiffs have suffered severe physical and psychological pain and suffering, and are entitled to monetary damages.

VII. DEMAND FOR JURY TRIAL

166. Plaintiffs demand a trial by jury on all issues so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to:

(a) enter judgment in favor of Plaintiffs on all counts of the Complaint;

(b) declare that Defendants have violated Plaintiffs' human rights and the laws of the District of Columbia and the United States, as set forth herein;

(c) award Plaintiffs compensatory and punitive damages, including, but not limited to, Plaintiffs' medical expenses, lost earnings, and damages for pain and suffering, in an amount to be determined at trial;

(d) grant Plaintiffs equitable relief, permanently enjoining Defendants from further engaging in human rights abuses against Plaintiffs and other inhabitants of Guatemala;

(e) award Plaintiffs the costs of suit including reasonable attorneys' fees;

(f) award Plaintiffs such other and further relief as the Court deems just under the circumstances.

Respectfully submitted this 10th day of November, 2011,

/s/ Terrence P. Collingsworth

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing First Amended Complaint, filed per the Court's October 6, 2011 Order, was electronically filed with the Clerk of Court by emailing to: dcd_cmecf@dcd.uscourts.gov and that service was electronically made on the federal Defendants via email to Laura K. Smith, Department of Justice at Laura.Smith2@usdoj.gov, and that a copy will also be sent via certified U.S. first-class mail with delivery confirmation on November 10, 2011, to those on the service list below.

SERVICE LIST

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Signed and certified this 10th day of November, 2011 by:

/s/ Terrence P. Collingsworth

_____

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