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First, Do No Harm: The US Sexually Transmitted Disease Experiments in Guatemala

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Abstract

Beginning in 1946, the United States government immorally and unethically—and, arguably, illegally—engaged in research experiments in which more than 5000 uninformed and unconsenting Guatemalan people were intentionally infected with bacteria that cause sexually transmitted diseases. Many have been left untreated to the present day.

Although US President Barack Obama apologized in 2010, and although the US Presidential Commission for the Study of Bioethical Issues found the Guatemalan experiments morally wrong, little if anything has been done to compensate the victims and their families.

We explore the backdrop for this unethical medical research and violation of human rights and call for steps the United States should take to provide relief and compensation to Guatemala and its people.

Today, Guatemala has a total population of 14.76 million people; 53.7% live in poverty.¹ The average level of education was 4.1 years in 2011,¹ and Guatemala is considered a lower-middle-income country.¹ In 1946, these demographic characteristics were even more dismal and without the benefit of more than 60 years of national, economic, and cultural development.

In the context of these inequalities in 1946, Public Health Service investigators in a study funded by the National Institutes of Health, with the cooperation of Guatemalan authorities, engaged in a series of immoral and unethical human medical experiments conducted without the participants' informed consent. The study involved at least 5128 vulnerable people, including children, orphans, child and adult prostitutes, Guatemalan Indians, leprosy

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patients, mental patients, prisoners, and soldiers. Between 1946 and 1948, health officials intentionally infected at least 1308 of these people with syphilis, gonorrhea, and chancroid and conducted serology tests on others. The study originally began in the United States but was moved to Guatemala when researchers were unable to consistently produce gonorrhea infections in prisoners at a Terre Haute, Indiana, prison. The public had no knowledge of the experiments for more than half a century, and even today little is known about these violations of medical ethics and human rights.²

It is important to emphasize the facts surrounding the Guatemala sexually transmitted disease (STD) experiments to properly evaluate the moral, ethical, and legal implications of the experiments. The experiments were not conducted in a sterile clinical setting in which bacteria that cause STDs were administered in the form of a pin prick vaccination or a pill taken orally. The researchers systematically and repeatedly violated profoundly vulnerable individuals, some in the saddest and most despairing states, and grievously aggravated their suffering. For example:

Berta was a female patient in the psychiatric hospital. Her age and the illness that brought her to the hospital are unknown. In February 1948, Berta was injected in her left arm with syphilis. A month later, she developed scabies (an itchy skin infection caused by a mite). Several weeks later, [lead investigator Dr. John] Cutler noted that she had also developed red bumps where he had injected her arm, lesions on her arms and legs, and her skin was beginning to waste away from her body. Berta was not treated for syphilis until three months after her injection. Soon after, on August 23, Dr. Cutler wrote that Berta 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 Berta's eyes, as well as in her urethra and rectum. He also re-infected her with syphilis. Several days later, Berta's eyes were filled with pus from the gonorrhea, and she was bleeding from her urethra. On August 27, Berta died.³

In 2010, US President Barack Obama apologized to Guatemalan President Alvaro Colom and the people affected, expressing the United States' commitment to the ethical and legal conduct of contemporary human medical studies.⁴ The US Presidential Commission for the Study of Bioethical Issues (hereafter the Commission) has since issued 2 reports: "*Ethically Impossible*" *STD Research in Guatemala from 1946–1948*³ and *Moral Science: Protecting Participants in Human Subjects Research*.⁵

The Commission's first report condemned the experiments as "impossible" under current ethical standards. The second report acknowledged an inability by the United States to confirm that all federally funded research provides optimal protections against avoidable harms and unethical treatment today⁵; the report also recommended reforms, none of which have been implemented as of yet. No mention of reparation or compensation for the victims was made in either report. In addition, little was said about the violations against human rights, which, when considered in conjunction with medical ethics, should provide protection to vulnerable populations.⁶

By contrast, the Guatemalan government issued a separate report, *Consentir el Daño: Experimentos Médicos de Estados Unidos en Guatemala* (To Agree to the Harm: Medical

Experiments by the United States in Guatemala), which went beyond the US reports to state that the experiments were “a crime against humanity” and that racism and discrimination were present throughout the experiments in an explicit and conscious way.⁷ The Guatemalan report called for reparation and compensation for the victims. In addition, 2 independent reports, written by the United Nations⁸ and the Catholic Church⁹ on human rights violations and genocide in Guatemala from the 1950s to the 1990s, bolster the Guatemalan commission’s declarations with respect to discrimination, reparations, and human rights and highlight weaknesses in the US reports.⁷ There is little evidence that the US government, the public health community, academic publications, or the media have acknowledged the Guatemalan report.

In spring 2012, when the case against the US government was considered by a federal district court as a class action lawsuit brought on behalf of the Guatemalan victims and their survivors, the court dismissed the case on grounds of sovereign immunity.¹⁰ Plaintiffs relied on the *Ethically Impossible* report in reciting the facts in the class action complaint. The US Justice Department did not dispute the facts in moving to dismiss the case, raising only technical arguments about sovereign immunity and the plaintiffs’ failure to exhaust administrative remedies before filing suit. The district court is required to assume the veracity of the plaintiff’s allegations when there is a motion to dismiss for failing to state a legally cognizable claim. The case was never heard on its merits and was dismissed on June 12, 2012, even though the court had set a hearing on the matter for July 26, 2012.

The court wrote that

the Guatemala Study is a deeply troubling chapter in our Nation’s history. Yet... this Court is powerless to provide any redress to the plaintiffs. The pleas are more appropriately directed to the political branches of our government, who, if they choose, have the ability to grant some modicum of relief to those affected by the Guatemala Study.¹⁰

To date, the political branches have provided no relief to the plaintiffs.¹¹

However, on January 10, 2012, one day after the Justice Department moved to dismiss the case in *Gudiel v Sebelius*,¹⁰ the Department of Health and Human Services announced funding of approximately \$1.8 million to improve treatment and prevention of HIV and other sexually transmitted infections (STIs) in Guatemala and to further strengthen ethical training on human research protections.¹² In addition, the Centers for Disease Control and Prevention was tasked with developing a case study on the unethical research conducted in Guatemala. The study will include learning objectives focused on scientific and ethical issues in designing a field investigation. Legal training appears to be missing from the Department of Health and Human Services directive.¹² General funding of global human research protections and STI health initiatives in Guatemala is no substitute for treatment of and compensation to the victims.

Despite the Department of Health and Human Services’ announcement and the Commission’s reports, the lack of publicity received by the Guatemalan case is startling. The American public is largely unaware of these experiments and the outrageous treatment

of Guatemalans, the reports by the US and Guatemalan commissions, or the victims' lack of reparations, compensation, and access to justice through the courts. The media has devoted little attention to the case. Unlike other cases in which human rights were violated in human subjects research (e.g., the Tuskegee syphilis experiments), few, if any, organizations have taken up the cause for human justice with respect to this vulnerable Guatemalan population.

The wrongful actions by US officials can be characterized by several facts. First, US officials intentionally infected victims with bacteria that cause STDs without informed consent. Second, they have failed to provide victims with treatment or compensation. Finally, they covered up and did not publish or disclose the experiments, including the intentional infections and their failure to provide treatment.

In summary, the US and Guatemalan commissions have documented many of the facts of the STD experiments and are in agreement on many salient points. Each report has determined that the Public Health Service investigators violated contemporaneous medical research ethics standards, and the Guatemalan report determined that the experiments violated human rights law. Given the state of the records, the few judicial precedents, the increasingly unreceptive attitude of the US Supreme Court toward class actions, and the complicated questions of sovereign immunity, the plaintiffs' quest for access to justice through the courts will be long and uncertain.

VIOLATION OF CUSTOMARY INTERNATIONAL LAW

A significant omission of the Commission's reports is the lack of an explicit discussion of legal responsibility and accountability. The Guatemalan report asserts that the investigation was immoral and constituted a crime against humanity.⁷ The report states that it focuses on the moral plane because most of the responsible principals are surely dead. The report refers to international human rights authorities and ethical principles such as the United Nations Declaration of Universal Human Rights (ratified by both the United States and Guatemala), the Interamerican Declaration on the Rights and Responsibilities of Man, the Rights of Man in the Charter of the Organization of American States, the 1978 Belmont report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and the Declaration of Helsinki. It also references the Nazi Nuremberg trials and the Tuskegee syphilis experiments.⁷

The Obama administration has not conducted a public analysis to determine whether the experiments violated US or international legal standards. There is judicial precedent, however, to support the proposition that the Guatemala experiments violated international human rights standards. In the 2009 case of *Abdullahi v Pfizer*,¹³ the United States Court of Appeals for the Second Circuit held that nonconsensual medical experimentation on human beings violates customary international law because, among other reasons, the prohibition is sufficiently specific and focused and is accepted by nations around the world.

The relevant question with respect to the Guatemala STD experiments is "At what point in time did customary international law first prohibit nonconsensual medical experimentation?" The Nuremberg code, prohibiting human medical research without informed consent, was upheld with the conviction of German doctors on August 19, 1947; a case can be made that

the intentional STIs in Guatemala violated this code beginning on that date, at a minimum, when US sexually transmitted disease investigators in Guatemala would have known of these developments in human rights law.³

Whereas US legal standards govern US-led research but do not necessarily protect residents of other nations, international laws protect all citizens of the world and should be closely considered in this case. For example, according to Article 7 of the International Covenant on Civil and Political Rights,¹⁴ “no one shall be subjected without his free consent to medical or scientific experimentation.” This covenant, adopted in 1966 and put in force in 1976, is monitored by the United Nations Human Rights Committee and is part of the International Bill of Rights. Some might argue that the Guatemalan case should be heard by the United Nations governing body to speed up the process of bringing compensation and relief to the victims. Other international human rights authorities and laws, including several articles from the 1948 Universal Declaration of Human Rights, also provide international standards for human subjects research, standards that surely were violated in the Guatemalan experiments.

Not only should human rights laws have been applied to the Guatemalan experiments; medical research is also governed by principles of biomedical ethics¹⁵ that call for patient safety, respect, beneficence, justice, and nonmaleficence (“first do no harm”). Today’s medical professionals and researchers are trained in these biomedical values and ethics. Most notably, the International Ethical Guidelines for Biomedical Research Involving Human Subjects, promulgated by the Council for International Organizations of Medical Sciences, define how the principles of the Declaration of Helsinki can be applied to developing countries in light of their socioeconomic circumstances. Although these guidelines were developed after the Guatemalan experiments, they recognize that, even in developing countries, informed consent and other basic principles of research ethics clearly apply. Surely, the researchers involved in the Guatemalan experiments were not abiding by many of these principles of biomedical research ethics.

International human rights standards provide one avenue to address structural injustice and institutional and national responsibility, including discrimination based on gender, race, and class in Guatemala and the complex of political, economic, military, and social relations between Guatemala and the United States. The actions in Guatemala went beyond domestic crimes such as rape, battery, assault, and conspiracy and violated international law.¹⁶

UNEQUAL JUSTICE AND DISCRIMINATION

The Commission reports^{3,5} generally allude to the possibility that discrimination played a role in the Guatemala investigations, but the reports do not address the issue adequately¹⁶ or systematically. For example, in *Ethically Impossible*,³ the authors discuss why the investigators selected Guatemala as a setting: “A possible remaining but clearly unacceptable explanation for choosing Guatemala would reflect the notion that the Guatemalans were a suitable, if not preferable, experimental population by virtue of poverty, ethnicity, race, remoteness, national status, or some combination of these factors.”³ The

Moral Science report makes only a passing, ambiguous reference to racism in a footnote, stating simply, “The Commission here focuses on the issues of justice.”⁵

By contrast, the Guatemala report discusses discrimination in much stronger terms. The report states that racism and discrimination were present throughout the experiments in an explicit and conscious way. The report recommends strengthening compliance with the constitutional requirements of equality among human beings to combat discrimination and racism.

Ultimately, the nonconsensual human experiments and serology tests conducted, the process of intentionally infecting people with bacteria that cause STDs, and the failure to provide treatment were immoral and unethical and violated both US and international legal standards, regardless of the race, color, national origin, or socioeconomic status of the victims here. Discrimination in the context of the Guatemalan experiments includes discrimination by US officials against Guatemalan people and discrimination within Guatemalan society by elites against lower-class indigenous and nonindigenous people. Discrimination is an aggravating, unacceptable factor that warrants additional review and discussion.

The US equal protection principles and laws are relevant when examining evidence of discrimination and the inferences to be drawn from the facts. The laws also provide guidance on how to address discrimination in other human research contexts with respect to underrepresented, minority, and vulnerable populations. The US Supreme Court and other authorities recognize that the following factors are relevant in evaluating a claim of intentional discrimination based on race, color, or national origin: the impact of the action and whether it bears more heavily on one group than another, a pattern or history of discrimination, departures from substantive norms, departures from procedural norms, and knowledge of the harm discrimination will cause (see, e.g., *Village of Arlington Heights v Metropolitan Housing Dev. Corp.*¹⁷ and *Guardians Ass’n v Civil Serv. Comm’n*¹⁸).

Under these parameters, evidence of discrimination abounds in the Guatemalan experiments. First, these experiments were limited to the Guatemalan people. Second, the United States has a history of discrimination and oppression against the people of Guatemala. For example, the Cold War and the war on drugs by the United States devastated Guatemala’s civic society and economy for decades. In 1954, the United States overthrew the country’s democratically elected government.¹⁹ Military dictatorships, backed by the United States, assassinated almost 200 000⁸ people in the next 40 years. The Guatemalan government engaged in mass killings of Mayans, obliterating entire villages.^{8,9} Bishop Juan Gerardi was bludgeoned to death in 1998 for publishing a report by the Catholic Church documenting the killings.²⁰

Third, the United States and Guatemala reports document departures from substantive and procedural norms in the Guatemala investigations. Fourth, the investigators knew of the harms they caused. Finally, civil rights statutes and federal regulations also prohibit unjustified discriminatory actions without requiring a showing of intent or individual racial animus.^{17,18} These standards of discrimination provide an analytic framework to evaluate

evidence of discrimination in the context of the Guatemalan experiments. Indeed, these are the kinds of evidence that the Guatemala commission report cites in concluding that discrimination and racism were present throughout the experiments.⁷

UNEQUAL JUSTICE: GUATEMALA AND TUSKEGEE

The Tuskegee syphilis experiments, involving recompense for past injustice, are directly relevant to the Guatemala injustices. In both the Guatemala and the Tuskegee experiments, directed by the same principal investigator, the US government engaged in concededly immoral and unethical actions: conducting nonconsensual human medical experiments, not treating infected victims, and deceiving victims and the public. In Guatemala, researchers intentionally infected the victims and generally left them without treatment or compensation for the remainder of their lives. In Tuskegee, the nearly 400 victims were already infected but were left without treatment beginning in the 1930s.

The United States eventually provided treatment and compensation for victims, families, and heirs in Tuskegee, including funding to locate the victims and pay attorneys' fees. The ethical principle of equal justice strongly suggests that similar relief should be provided for the Guatemalan victims. However, reparation in Tuskegee was made only after organizations championed the cause, made the wrongful acts known to the general public, sought access to justice through the courts, and applied pressure on the government to take action.² This has not occurred in the context of the Guatemalan STD experiments.

REPARATIONS AND COMPENSATION

Academicians have long noted that, in addition to a duty of justice, an obligation of reparation arises from one's wrongful acts.²¹ Scholars note that such compensatory action is morally essential not only to "repair" the harm but also to render victims their due and thereby acknowledge them as agents worthy of respect and entitled to atonement.²² The authors of the Guatemalan report also articulated the principles of compensation and reparations (as did Cohen and Adashi¹¹), which remain valid and extend to the need to address legal issues. A summary of these principles as they apply to the Guatemalan victims is informative.

First, as a matter of corrective justice, surviving participants or their affected contacts should be compensated in full for injuries sustained. Surviving family members should also be made whole for harm incurred, whether direct (e.g., disease transmission) or indirect (e.g., emotional distress, loss of a family member at a younger age) in nature. A political solution between the US government and the Guatemalan government can make this happen. Second, a compensation and reparations program would more concretely and permanently acknowledge the wrongful nature of the conduct in question, in keeping with the expressive function of both US and international law. Such a program would also reaffirm the legal and ethical standards undergirding human participant research.

Third, compensation and reparations would advance healing and reconciliation and constitute an important, tangible, goodwill gesture to the Guatemalan people and nation. Fourth, compensation and reparations could be tailored to enhance the legal and ethical

training of current and future investigators, mitigating potential educational shortcomings and preventing future misconduct. Finally, as a matter of deterrence, compensation and reparations may obviate legal and ethical violations in the future.

History has provided a few models of compensation programs that the US response to Guatemala may do well to emulate. For example, in response to a class-action lawsuit (*Allen v United States*²³), the US Congress passed the Radiation Exposure Compensation Act of 1990.²⁴ As of October 2011, more than \$1.5 billion had been disbursed to more than 23 000 approved claimants exposed to ionizing radiation during US-based nuclear experiments.²⁵

It is this type of compensation that is required to correct the injustices suffered by the Guatemalan people, not the mere \$1.8 million set aside for prevention programs and ethical training on human research protections. The Tuskegee payment structure^{26,27} (\$37 500 for each living participant, \$15 000 for each surviving dependent, \$16 000 for each living control group participant, \$5000 to heirs of deceased members of the control group) totaled \$10 million in 1974 (approximately \$47 million in 2013 currency). A similar payment structure applied to the Guatemalan victims would still be a relatively small amount in comparison with the \$1.5 billion already awarded to victims of radiation research.

CONCLUSIONS

In its *Ethically Impossible* report addressing the Guatemalan experiments, the Commission expressed the need to be ever vigilant to ensure that such reprehensible exploitation of our fellow human beings is never repeated. As such, it is critical to adopt legal and ethical reforms to provide treatment and compensation for individuals involved in improperly conducted human experiments, waive sovereign immunity for federally funded human research in the United States and abroad, ensure that parallel protections apply to privately funded research, and respect autonomy and equality for all. Greater application of legal strategies may promote a stronger structural foundation for preventing such unethical acts in the future.

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