



UNITED STATES MISSION  
TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS  
IN GENEVA

September 11, 2015

Ms. Mireille Fanon Mendes-France  
Chair-Rapporteur of the Working Group of Experts  
on People of African Descent  
Geneva, Switzerland

**OHCHR REGISTRY**

Mr. Dainius Puras  
Special Rapporteur on the right of everyone to the  
enjoyment of the highest attainable standard of  
physical and mental health  
Geneva, Switzerland

**15 SEP 2015**

Recipients: *RKD/SPB*  
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Mr. Baskut Tuncak  
Special Rapporteur on the implications for human rights  
of the environmentally sound management and disposal  
of hazardous substances and wastes  
Geneva, Switzerland

Dear Ms. Mireille Fanon Mendes-France, Mr. Puras, and Mr. Tuncak:

Thank you for your inquiry of May 11, 2015, concerning allegations that Mr. Chester Noel, Ms. Helen Noel, and members of their family, who are persons of African descent, have suffered and continue to suffer from the adverse effects of mercury as a result of participating in a late 1920s-early 1930s clinical study on the treatment of syphilis (also known as the "Rosenwald Fund Study").

The United States government provides the attached response to your joint inquiry.

Sincerely,

Keith M. Harper  
Ambassador  
U.S. Representative to the United Nations  
Human Rights Council

**1. Please provide any additional information and any comments you have on the above-mentioned allegations.**

The United States government takes the opportunity to provide clarification of its understanding with respect to certain allegations raised or reflected in the joint communication:

To clarify, though characterized as a “study,” the work undertaken in the selected southern states of the United States in the late 1920s and early 1930s was a demonstration project for the control of syphilis. In other words, it was a project to demonstrate the feasibility of controlling syphilis in the rural South. The treatment regimens used were standard for the time of the project. As indicated in the report generated in 1932, *The Control of Syphilis in Southern Rural Areas* (see footnote 1) (hereinafter “the Report”), the study was intended to do the following: 1) allow cooperation between the United States Public Health Service (PHS) and state and local health departments in the control of venereal diseases; 2) act as a study and demonstration of “the most practicable and efficient methods of applying existing knowledge” to these conditions; 3) direct work toward syphilis specifically, as it offered an opportunity to “accomplish more prompt results” at control of this condition; 4) have as a primary interest the development of a more effective and accessible medical service to infected individuals as a means of preventing the spread of the disease and promoting a cure; and 5) provide training and opportunity to work to health care providers, regardless of race, better distribution of medications and diagnostic laboratory facilities, and better services to employees of industrial corporations (pp. 7-8).

The work done as part of this study was undertaken as a collaboration between the PHS, the Rosenwald Fund, and the state and local health departments of the six selected southern states in the United States from 1929 through 1932. The studies ended at varying times in each respective state. The termination dates appear to have been impacted by the amount of funding available, as the Rosenwald Fund anticipated providing only a portion of the financial support for the study, with additional funds to be provided by the respective states.

At the time the study was being conducted, the concepts of “informed consent” and “human subjects protections” had not been codified in United States law, nor were they as common in the scientific standard practice as they are currently. As such, while such matters are of clear import to the United States today, the work done should be considered in light of the standards of care and consideration in place during that time period.

Most patients treated for syphilis at that time received combination therapy with nearsphenamine injections and mercury ointment applied to the skin. This

combination therapy was not considered an experimental treatment; rather, in the pre-penicillin era of the 1930s, the standard of care for syphilis was an arsenical (such as neoarsphenamine) and a heavy metal (such as mercury). (See J.H. Stokes, et al., *Standard treatment procedure in early syphilis*. JAMA 1934; 102: 1267-72.) Consequently, it appears that the study involved standard treatments for syphilis. As such, it was not intended to experiment with the use of mercury as a form of treatment for syphilis or involve a form of treatment that was unusual and being tested for its efficacy, but was instead intended to demonstrate the feasibility of controlling syphilis in the rural South using standard treatments.

It is alleged that Mr. Chester Noel and members of his family were part of the study; that they suffered from the adverse effects of mercury; and that multiple generations of the Noel family continue to suffer health effects as the result of exposure to mercury. To the best of its knowledge, the United States government is not aware of records related specifically to the Noel family or that any records are available to document participation of individuals or their family members. Also, to the best of its knowledge, the United States government is not aware of any documented instances of the adverse effects of mercury being passed between generations.

It is alleged that although mercury was used as a treatment for syphilis, the risk of serious adverse effects was known. Again, as noted above, in the pre-penicillin era of the 1930s, the standard of care for syphilis was an arsenical (such as neoarsphenamine) and a heavy metal (such as mercury). The Report appears to address the known risks, stating that clinicians and health officers were provided guidance for monitoring and treating drug toxicities that might occur in treated patients (pp. 26, 64).

It is alleged that patients were not informed about syphilis or the use of mercury and its risk and were informed that they were being tested for “bad blood.” Though the Report contains little information about what information was provided to patients, there are “Instructions to Patients” included that state “If you feel sick – stop all treatment until you can see the doctor or a nurse” (p.67). In addition, “bad blood” appears to have been a commonly used term for syphilis at the time of the project. (See A. Brandt, “Racism and Research: The Case of the Tuskegee Syphilis Study,” at <http://www.med.navy.mil/bumed/Documents/Healthcare%20Ethics/Racism-And-Research.pdf>.)

It is alleged that African-American patients cooperated because it was the first time that many of them received what they perceived to be “legitimate government-sponsored healthcare.” While no specific information is available regarding the reasons that individual patients may have participated in the study, one reason the project was undertaken according to the Report was the

“...inadequacy of medical service for Negroes in practically all rural communities...” (p. 6).

It is alleged that ten Noel family members passed away from symptoms consistent with mercury poisoning, with the adverse effects detected for four generations. Again, while no records are available concerning members of the Noel family and their participation in the study, as noted, to the best of its knowledge, the United States government is not aware of any documented instances of the adverse effects of mercury being passed between generations.

It is alleged that members of the Noel family were not adequately informed of the risks of the experiment. As noted, no information is available concerning members of the Noel family and what they may have been told.

It is alleged that members of the Noel family suffered from conditions genetically linked to the impact of mercury and from vitamin B12 deficiency consistent with adverse effects of mercury poisoning. Medical records of the Noel family are not available to the United States government at this time. Mercury toxicity is not known to cause vitamin B12 deficiency, and these appear to be separate conditions.

It is alleged that Ms. Noel and her family members were denied their right “to access information regarding the Rosenwald Fund Study in general and in particular, information on the adverse impact of experimenting with the use of mercury on human subjects.” The United States government received email requests from Ms. Noel and provided responses to those emails. Specifically, the Centers for Disease Control and Prevention (CDC), an agency in the United States Department of Health and Human Services (HHS), received an email from her in March 2012 and responded in May 2012, attempting to explain the study and the lack of evidence that mercury toxicity could be passed between generations. The CDC also responded to another inquiry from Ms. Noel in October 2012, which referred to the May 2012 CDC response and addressed Ms. Noel’s inquiry regarding the link between her ancestor’s mercury exposure and her vitamin B12 deficiency. In addition, the Department of State received an email from Ms. Noel in September 2014, which was forwarded to and responded to by the HHS Food and Drug Administration (FDA) in December 2014, acknowledging the CDC response. However, the United States government is not aware of any other or pending requests for information. In addition, Ms. Noel can submit any additional requests for information from the various United States agencies pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

**2. Please provide information on the process of how the Rosenwald Fund Study was carried out, including the following:**

**a. the decision and criteria used to select the subjects of the Study, namely 40,000 African-Americans;**

According to the Report, the leadership of the Rosenwald Fund formulated a policy "to include, among its other activities, cooperative efforts to improve hospitals and health services for Negroes." In furtherance of such policies, the leadership made a decision to enter the "slightly explored field of Negro health." Also, there was "accumulated evidence" of an "excessive prevalence of venereal diseases" among this population, "complicated by the inadequacy of medical service for Negroes in practically all rural communities" due to a host of factors (pp. 5-6). Based on these, and other factors, in October 1929, the PHS requested that the Rosenwald Fund cooperate with the PHS and state and local health departments to demonstrate control measures focused on syphilis in "Negro populations" (pp. 5-7). In November 1929, the Rosenwald Fund agreed to support demonstration projects for "control of venereal diseases in the rural south" during the calendar year 1930 (p. 8).

Health officers in southern states were given the opportunity to "enter into a cooperative arrangement" with the Fund and the PHS for the proposed demonstration projects (p. 8). Based on criteria including the "relative density of the Negro population," local interest, and availability of local budget support and personnel, a county from each of six southern states was selected for participation (pp. 9-11).

Following efforts to publicize the projects in each of the six counties, blood samples for syphilis testing were "taken at any convenient place accessible to relatively large numbers of individuals" (p. 24). A total of 33,234 persons were screened for syphilis, of whom 5,905 were diagnosed and treated (p. 28).

**b. the information that was provided to the subjects of the Study, including, but not limited to, the purpose and process of the Study;**

This information is not stated in the Report, though there is an indication that individuals were provided some instruction about their treatment (p. 67).

**c. the procedure to obtain consent from the subjects;**

This information is not stated in the Report, though there is an indication that individuals were provided some instruction about their treatment (p. 67).

As indicated above, though the concept of "informed consent" is now a vital and integral aspect of research conducted today, that concept was less prevalent and formalized at the time of the Rosenwald Fund treatment study. The Nuremberg Code, formulated several years after the study in 1947, articulated that informed

consent should be obtained for experiments; that experiments should be scientifically necessary and conducted by qualified personnel; that human trials should be preceded by animal studies and surveys of a disease's natural history; and that benefit to science should be weighed against risks and suffering of experimental subjects. (See "*Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*," Vol. 2, pp. 181-82. Washington, D.C.: U.S. Government Printing Office, 1949; see, e.g., [http://www.loc.gov/rr/frd/Military\\_Law/NTs\\_war-criminals.html](http://www.loc.gov/rr/frd/Military_Law/NTs_war-criminals.html) ). The Nuremberg Code "is generally regarded as the first document to set out ethical regulations in human experimentation based on informed consent." (See J. Vollmann, et al. *Informed consent in human experimentation before the Nuremberg code*. Brit. Med. J. 1996; 313: 1445-7).

**d. the information on the decision to deviate from the standard Rosenwald Fund study in Tennessee by conducting the study of family unites and information on the family unit study.**

Neither the rationale nor the details of the "family unit study" in Tennessee are provided in the Report, but there is an indication that persons with congenital syphilis received treatment. It is also not clear that this determination was deemed a deviation. The Report appears to frame this determination as one made at the outset of the study and, perhaps was within the discretion of the respective states based on factors existing within their jurisdiction (e.g., geography, access to care, community makeup) (p. 21) .

**3. Please provide the details, and where available the results, of any investigation, judicial or other inquiries carried out in relation to the Rosenwald Fund Study in general, including as they may concern members of the Noel family. If such information does not exist, please provide details on any planned investigation in relation to the Rosenwald Fund Study.**

The United States government is not aware of any investigations, judicial or other inquiries carried out in relation to the Rosenwald Fund Study or the Noel family. However, as noted above, Ms. Noel did receive responses to the inquiries she sent in 2012 and 2014. Specifically, in response to Ms. Noel's outreach in 2012, the CDC responded by attempting to explain the study and the lack of evidence that mercury toxicity could be passed between generations. We are not aware of any planned investigation in relation to the Rosenwald Fund Study at this time.

- 4. Please provide information on the measures taken by the Government in response to any of the above inquiries made by Ms. Helen Noel since 2011 and in response to any other inquiries or requests for information made by subjects of the Rosenwald Fund Study and other individuals affected by the Rosenwald Fund Study.**

As noted above, we are aware that the United States government responded to Ms. Noel's emails in 2012 and 2014. However, at this time, we are not aware of any other "measures" taken by the United States government in response to her or other (to the extent they exist) inquiries or requests for information.

- 5. Please provide information on the efforts made by the Government to identify the subjects and the descendants of subjects of the Rosenwald Fund Study and any efforts by the Government in relations to the identified subjects including:
  - a. efforts made by the Government to provide information to the subjects of the Study and the descendants of subjects on the potential adverse impact of participation in the Study; and**
  - b. efforts made by the Government to research and study the impact on descendants of the original victims exposed to mercury, particularly those known to exhibit adverse effects linked to the earlier exposure.****

We are not aware of efforts to identify subjects and descendants. As such, there are no current efforts to provide information to subjects or descendants of the study or to research and study impact on the descendants of the original study participants' exposure to mercury. Again, to the best of its knowledge, the United States government is not aware of any documented instances of adverse effects of mercury being passed between generations.

- 6. Please provide information on the steps taken by the Government to provide effective remedy to the members of the Noel family and other subjects of the Rosenwald Fund Study, including reparation and measures taken to prevent adverse effects of mercury poisoning in future generations of Rosenwald Fund Study subjects.**

The United States government is not aware of any legal claims or requests for remedy made in relation to the Rosenwald Fund Study or the Noel family. We are not aware of any steps taken by the United States government to provide remedy to members of the Noel family or other study subjects.

**7. Please provide information on the background and explanation to the Presidential apology issued on 16 May 1997 to the subjects of “the Tuskegee syphilis experiment”. Please also explain the reason why a similar investigation and apology have not been extended to the subjects of the Rosenwald Fund Study.**

As noted above, the Rosenwald Fund Study, started around 1929-1930, was a project to demonstrate the feasibility of controlling syphilis in the rural South using standard methods of treatment. As such, it had the goal of developing model programs for the treatment of syphilis in the rural South. Participants were treated with neoarsphenamine and mercury, as was the standard of care at the time. The study was terminated between 1931 and 1932, because of a lack of local resources.

In contrast, the Tuskegee Study, which began in 1932, had the goal of examining the natural history of “untreated syphilis in the Negro male.” Treatment was intentionally withheld from participants at the time of enrollment and continued to be withheld, even when the benefits of penicillin for syphilis treatment were established in the 1940s. The study continued until 1972.

In his apology for the Tuskegee Study, President Clinton stated that, “The United States government did something that was wrong – deeply, profoundly, morally wrong,” and that “I apologize and I am sorry that this apology has been so long in coming” (<http://www.cdc.gov/tuskegee/clintonp.htm>). It is important to appreciate that the Rosenwald Fund treatment studies were separate and distinct projects from the Tuskegee Study. They had significantly different purposes and were carried out under very different contexts, including standards of care for treatment and ethical standards for research subjects at the time. The apology provided in response to the Tuskegee Study was intended uniquely for those particular participants and their families.

**8. Please provide details and, where available, the results of any health policies or regulations related to the Rosenwald Fund Study or similar studies with the view of providing preventive measure that the Government has taken to ensure non-recurrence.**

As noted in response to 2.c above, the concept of “informed consent” is now a vital and integral aspect of research conducted today.

Over the decades, there have been a host of measures undertaken by the United States government, and the international community, to address human subject protections ([http://history.nih.gov/about/timelines\\_laws\\_human.html](http://history.nih.gov/about/timelines_laws_human.html)). Basic regulations governing the protection of human subjects in research supported or conducted by HHS (then the Department of Health, Education and Welfare) were first published in 1974. In 1974, the



United States enacted the 1974 National Research Act (Public Law 93-348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the National Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to assure that such research is conducted in accordance with those principles. In 1978, the Commission published "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as the Belmont Report, named after the Belmont Conference Center where the Commission met when drafting the report. The Belmont Report identifies three fundamental ethical principles for all human subjects research -- respect for persons, beneficence, and justice. Based on the Belmont Report and other work of the National Commission, HHS revised and expanded its regulations for the protection of human subjects in the late 1970s and early 1980s. These HHS regulations are codified at 45 CFR part 46, subparts A through D. The statutory authority for these HHS regulations derives from 5 U.S.C. § 301; 42 U.S.C. § 300v-1(b); and 42 U.S.C. § 289.

The regulations found at 45 CFR part 46 are based in large part on the Belmont Report and were written to offer basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS. In 1991, 14 other Federal departments and agencies joined HHS in adopting a uniform set of rules for the protection of human subjects, identical to subpart A of 45 CFR part 46 of the HHS regulations. This uniform set of regulations comprises the Federal Policy for the Protection of Human Subjects, informally known as the "Common Rule." The United States government is committed to ensuring compliance with these regulations and the principles behind them.