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The Tuskegee Syphilis Experiment, Social Change, and the Future of Bioethics

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I. THE TUSKEGEE SYPHILIS EXPERIMENT AS A CONSEQUENCE OF SOCIAL CHANGE AND ILLUSTRATION OF REPEATED, LONG-TERM ETHICAL FAILURE

This article presupposes some familiarity with the notorious Tuskegee Syphilis Experiment. In brief, the United States Public Health Service (PHS), from 1932 to 1972, conducted a study of the effects of untreated syphilis on impoverished, rural, African-American males.[1] It is fascinating – and a cautionary tale – to perceive the experiment itself as an unintended consequence of positive social change and of the work of some reputable "change agents." First, the experiment presumably would never have happened, if not for the work of the Julius Rosenwald Fund in regard to "health care for African-Americans in the rural South."[2] Julius Rosenwald was a "Jewish philanthropist" who can be characterized as a positive change agent through his foundation's assistance for both schools and health care. The Rosenwald Fund assisted the Tuskegee Institute, financed construction for schools for African-Americans – the first of which was built in Macon county, Alabama – and helped to construct hospitals and clinics. The Fund sought to improve race relations and promoted the hiring and training of African-American medical professionals and public health workers. The Rosenwald Fund successfully created an alliance with the PHS.[3] It is noteworthy that the federal and state governments, as well as the Rosenwald Fund, were all active in trying to

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[1] *See* FRED D. GRAY, THE TUSKEGEE SYPHILIS STUDY (1998); TUSKEGEE'S TRUTHS: RETHINKING THE TUSKEGEE SYPHILIS STUDY (ed. Susan M. Reverby, 2000)[hereinafter *Reverby*].

[2] GRAY, *supra* note 1, at 39.

[3] *See id*. at 39; *see also* STEPHANIE DEUTSCH, YOU NEED A SCHOOLHOUSE: BOOKER T. WASHINGTON, JULIUS ROSENWALD, AND THE BUILDING OF SCHOOLS FOR THE SEGREGATED SOUTH (2011).

provide treatment for syphilis and sexually-transmitted disease in the period prior to the Tuskegee experiment. The joint work of the PHS and the Fund in 1930-31 demonstrated very high infection rates and very low treatment rates, in six specified locations in the South, with the highest infection rates in Macon County, Alabama. Just as this significant, unmet need for treatment was revealed, however, the Great Depression limited both governmental and private funding for treatment. The Rosenwald Fund, with its funds diminished by lowered stock values, ended its support of syphilis treatment in 1932, and thus was not involved in the notorious Tuskegee experiment itself.[4] However, one can certainly view the experiments as an unintended consequence of the positive work of the Rosenwald Fund, as the Fund's work and partnering with the PHS opened up a pathway of concern and information about syphilis in the local area. The PHS in launching the experiment was able to build upon the good will and local contacts created by the Fund's work in Macon County.[5]

In its context, the initial decision of the U.S. Federal Health Service to launch the Tuskegee study, while clearly unethical, is more understandable. First, the initial launch was intended as a short study of six to eight months.[6] Second, there was a genuine debate at the time as to whether the forms of treatment than those available, which used heavy metals including arsenic, were more harmful than helpful to patients. Penicillin was not yet available.[7] Third, due to the insistence of Alabama State Health Officer Dr. Baker, treatment was to be provided during the term of the study. While this would provide too short of a course of treatment to be deemed full treatment at the time, it was presumed to be significantly more than the complete lack of treatment that would occur apart from the study.[8] Fourth, initially the study was *not* designed to examine the ongoing effects of untreated syphilis going forward in time. Instead, the initial intent was to study the effects from untreated syphilis that had already occurred on a population that had suffered high rates of untreated and undiagnosed syphilis prior

[4] GRAY, *supra* note 1, at 39-42.
[5] *See id*. at 44-45.
[6] *Id*. at 43.
[7] *Id*. at 40-42; GREGORY C. PENCE, MEDICAL ETHICS: ACCOUNTS OF GROUND BREAKING CASES, 181-82 (6th ed. 2011).
[8] GRAY, *supra* note 1, at 45.

to the study.[9] Fifth, the study was a result of several intentions: to draw attention to a neglected public health and medical problem in society, by documenting the extent of the harm it produced, and settling issues as to whether there are disparate effects in different racial groups, as prior studies had been done on white Norwegians. In the context of the time, where public health officials believed they were documenting a very significant public health problem, and where funds for treatment were otherwise unavailable, the initial study plan probably seemed like a way to keep their efforts going and hopefully make a case for future attention and prioritization of the problem of untreated syphilis.[10]

Of course, a fundamental ethical problem at the outset was the decision to mislead the treatment subjects and wider community.[11] However, at the time, such medical paternalism, involving not informing or misleading patients or research subjects, was common in both medicine and research.[12] To note this historical fact is not intended as a support of ethical relativism; such misleading of the research subjects was unethical at the time, despite being a common practice.[13] However, if the Tuskegee study had ended after that first year, it would not have been a historically significant event, but merely one of innumerable examples of a broader trend in which physicians and researchers misinformed patients and research subjects.

There are at least three more critical moments of decision that made the Tuskegee experiments into such an infamous example of unethical human experimentation. The first occurred in 1933, when PHS officials decided to extend the study as one of untreated syphilis going forward in time. Thus was born the most infamous aspect of the study: the decision to deliberately watch the effects over time of untreated syphilis. At the time, this was conceived as lasting five to ten years, a much shorter time than the eventual term of forty years, but nonetheless a substantial amount of time. Coupled with the continuing decision to mislead the patients and community, this led to the bait-and-switch pattern in

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[9] *Id*. at 42-47.

[10] *See id*. at 39-47.

[11] *See id*. at 44-45.

[12] *See, e.g*., John C. Fletcher, *A Case Study in Historical Relativism: The Tuskegee (Public Health Service) Syphilis Study*, in *Reverby*, *supra* note 1, at 276, 280-87.

[13] *Cf*. *id*. at 276 – 298.

which the research subjects were led to believe that they were receiving medical treatment, when in fact the major point of the intervention was to see that they did not receive treatment for their syphilis. Of course their diagnosis was also withheld from them, and a control group of those without syphilis was added to the study.[14] Although the study took on its characteristic form at that time, and was extremely unethical, there were several mitigating factors. Again, the side-effects of the available treatments were thought by some to be worse than the effects of the disease, at least for a significant proportion of patients.[15] Second, the PHS presumably thought that absent their intervention, the patients would not receive any treatment, due to a lack of funding and the general lack of access of the subject population to health care services. Thus, it was possible to envision the study against the backdrop of a baseline or norm of no treatment. From this perspective the only thing the study added was observation, plus some things that were actually of benefit to the research subjects, such as burial insurance and some medical attention. This problem of the baseline (the experience of human research subjects pre-experiment or apart from the experiment) is something that haunts both ethics and bioethics, and has caused severe problems in other settings.

Of course the study continued far beyond the five to ten years envisioned. Even as many relevant contexts in medicine and society changed, the study continued as though on some kind of ethical autopilot. Shortly after World War II, methods for mass production of penicillin were successfully established, and penicillin became the normative and successful method of treatment for syphilis. One would have thought that these changes would have induced an abandonment of the "no treatment" model at least by 1950, as the creation of a clearly effective treatment modality made the experiment far more unethical and far less medically significant. Indeed, the study took systematic and individualized actions to block the men from being treated with penicillin, thus obliterating the argument that the study itself had no impact on whether the men received treatment. Instead of merely observing what would anyway occur (the men not receiving treatment), deliberate actions were taken to prevent the men from receiving ap-

[14] *See* GRAY, *supra* note 1, at 53-58.
[15] *Id.*

propriate medical treatment of their conditions.[16] One would have thought that such actions would have been deemed indefensible, even at the time, making it initially difficult to explain the determination to continue the non-treatment model post-penicillin.

Information that has come to light relatively recently provides some context for the dubious research ethics practiced by the Federal Government during this period immediately after World War II. Between 1946 and 1948, the U.S. Public Health Service and the National Institutes of Health, in collaboration with various Guatemalan governmental agencies, carried out research in which 1308 human subjects were, without consent, deliberately exposed to bacteria causing sexually transmitted diseases (syphilis, gonorrhea, and chancroid). The subjects included female commercial sex workers (CSWs), prisoners, patients in psychiatric facilities, and soldiers. Exposure was accomplished by sexual exposure to CSWs who themselves had been experimentally exposed, as well as direct inoculation. Some of the test subjects were treated with penicillin, but some also apparently received an incomplete course of treatment, and the records indicate that a significant number were never treated. The Guatemala experiments were directed by Dr. John C. Cutler, who in the 1950s and 1960s would help direct the continuing Tuskegee syphilis experiment for the PHS.[17]

An examination of the career of Dr. Culter illustrates the mainstream nature of those involved in the Tuskegee syphilis experiment, and the tendency of those who viewed themselves as "change agents" to be involved. His 2003 obituary portrays him as a humanitarian and trailblazer in the field of reproductive health. Labeling him a "pioneer in preventing sexual diseases," the obituary credits him in 1944 as a part of a group that determined ways that "penicillin could be used to treat syphilis."[18] On issues of reproductive issue for poor women, he appears as a progressive: he "worked tirelessly to find better ways to provide affordable repro-

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[16] *See id*., at 55-65; Pence, *supra* note 7, at 182-90.

[17] *See* Presidential Commission for the Study of Bioethical Issues, *Ethically Impossible: STD Research in Guatemala from 1946 to 1948* (Sept. 2011), *available at* http://bioethics.gov/cms/sites/default/files/Ethically-Impossible_PCSBI.pdf (last accessed May 23, 2012).

[18] *See* Jan Ackerman, Obiturary: John Charles Cutler/Pioneer in preventing sexual diseases, Pittsburgh Post-Gazette, Feb. 12, 2003, *available at* http://www.post-gazette.com/obituaries/20030212cutler0212p3.asp.

ductive health-care services to women who need them" as early as 1971, believing that access to such care should be available without regard to income.[19] Dr. Cutler was portrayed as embodying a progressive public health mindset, looking at health from a "holistic" perspective in relation to "social, political, economic, and cultural customs."[20] He was also described as a pioneer through his experiences with "living and working in the Third World."[21] In relationship to AIDS, he commented in 1988 that "the AIDS problem was a replay of venereal disease scenarios of bygone years."[22] "The control of AIDS will come only when there's a shift from a preachy, moral approach to a medical viewpoint," maintained Cutler.[23] He thus advocated an approach similar to that which was used during WWII, involving a combination of education and the provision of condoms. In 1949, Dr. Cutler headed a venereal disease project in India for the World Health Organization. After working for the U.S. Public Health Service, rising eventually to the rank of Assistant Surgeon General, he moved to academia, obtaining a professorship in international health at the School of Public Health at the University of Pittsburgh, beginning in 1967.[24]

Dr. Cutler's apparent defense of the Tuskegee study after it came into public view, and his apparent lack of publicly expressed regret for his roles in human-subjects experimentation, provides a context for the decisions of the U.S. Public Health Service to continue the Tuskegee experiment until public disclosure forced its end in 1972. In particular, there are records of meetings held in 1965 and 1969. Of course by these points in time, the civil rights movement was quite prominent, and the federal government was officially opposed to racial segregation and discrimination. One might have thought that these very significant social changes would have led to a cessation of the study. Indeed, at least by the 1969 meeting, questions were being raised, and it was apparent to

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[19] *See id*.

[20] *Id*.

[21] *Id*.

[22] *Id*.; see also John C. Cutler & R.C. Arnold, *Venereal Disease Control by Health Departments in the Past: Lessons for the Present*, 78 AM. J. PUB. HEALTH (1988), at 372-76, *reprinted in* Reverby, supra note 1, at 495, and *available at* http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.78.4.372.

[23] *See* Ackerman, *supra* note 18; see also Cutler & Arnold, *supra* note 22, at 372-276.

[24] *See* Ackerman, *supra* note 18.

the group that the experiment could prove embarrassing if disclosed, in terms of both racial issues and the withholding of treatment.[25] Indeed, the premise of the meeting was that "[t]his type of study would never be repeated."[26] Yet, remarkably, the decision was made to continue the study of untreated syphilis. One can see in these decisions, and in Dr. Cutler, not only the typical human defensiveness in regard to criticism, but more significantly, a mindset in which medicine and science, as positive, progressive forces for improving human life, are given a kind of ethical free-ride as presumptively acceptable. Dr. Cutler and the early generations of those investigating and combating sexually-transmitted diseases seem to perceive themselves (in modern parlance) as change agents in an epic struggle against ignorance, disease, and the forces of backward social conservatism that would hinder their rational, scientific, progressive work. When later the forces opposing them included concerns with race and the rights of human research subjects, some – including apparently Dr. Cutler – continued to adhere to their sense of themselves as representing the good and right forces of scientific and medical progress.

Significantly, the Tuskegee study was conducted through a wide variety of Presidential administrations, liberal and conservative, Democratic and Republican. The ultimate problem is neither left wing nor right wing politics, but a sense of ethical entitlement for science and medicine. Certainly the Tuskegee syphilis experiment is about race and racism, but in fact, until relatively recently it was open season on any population that a physician or researcher were able to get their hands on. Of course, it is easier to exploit powerless, vulnerable populations, including racial minorities, the poor, mental patients, children in orphanages, soldiers, prisoners, the dying, and the desperately poor and sick in developing nations. So racism and the powerlessness of the Macon County, Alabama African-Americans was an extremely significant factor. However, it is significant that the study was continued even through Presidential administrations that otherwise acted positively to combat racial discrimination and segregation. It is also significant that there is a clearly documented record of similarly unethical human

[25] *See* Gray, *supra* note 1, at 55-73; Reverby, supra note 1, at 463-72 (reprinting *Summary of Ad Hoc Committee to Consider the Tuskegee Study*, February 6, 1969).
[26] *See* Reverby, supra note 1, at 465.

experimentation on other vulnerable populations. Thus, in broader perspective it is important to include the Tuskegee experiments not only as another sad chapter in the history of racial discrimination in the United States, but also as another chapter in the history of exploitation of vulnerable populations of various kinds in human subjects research.

A key lesson from Tuskegee is the propensity of some change agents to believe that their laudatory end justifies any means they choose to employ. This has allowed, unfortunately, some "change agents" to do horrific things with a seemingly clear conscience. In the case of those involved in scientific and medical research, this danger is manifested as a belief in the ethical autonomy of those critically important human enterprises, freeing them from the shackles of what are viewed as arbitrary religious or moral scruples.

This point was made strikingly by the famous 1966 paper by Dr. Henry Beecher, published in the New England Journal of Medicine, which played such an important role in opening up to public view the problem of unethical human subjects experimentation.[27] Dr. Beecher had found fifty published medical journal articles reporting on research involving human subjects, which he believed had employed "unethical or questionably ethical procedures."[28] The research was unethical due to a lack of informed consent, and due to the degree of harm to which the research subjects were subjected. Dr. Beecher's article noted:

"There is a belief prevalent in some sophisticated circles that attention to these matters would "block progress." But, according to Pope Pius XII, ' . . . science is not the highest value to which all other orders of values . . . should be subordinated.'"[29]

Beecher's article helps provide a context for understanding how seemingly responsible parties could decide to continue the Tuskegee study after the discovery of penicillin, and even as late as the 1960's. Dr. Beecher's article also helps explain how the Tuskegee experiment could be presented in medical journals or discussed in medical contexts while only rarely evoking any ethi-

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[27] *See* Henry Beecher, *Ethics and Clinical Research*, 274 N.ENG. J. MED. 1354 (1966).

[28] *See id*. at 1355.

[29] *Id*. at 1354 (quoting Pope Pius XII's address presented at the First International Congress on the Histopathology of the Nervous System, Rome, Italy, September 14, 1952.).

cal objections. While presumably not all human subjects research was conducted without informed consent or with risk of significant, unwarranted harm, such practices were apparently so common as to have been de facto accepted in the medical and research communities.

Beecher's article discussed, but did not provide identifying information for, the specific experiments he critiqued. However, he informed the mainstream press of his article in advance, allowing the press to identify and publicize some of the experiments. Thus, publication of Beecher's article in a medical journal became the occasion of a much broader debate. Several of the studies are worthy of discussion here, for they underscore again that the Tuskegee study was representative of a much broader problem.[30]

First, in a notorious 1963 experiment funded by the PHS and the NIH, investigators, "led by a physician at the Sloan-Kettering Cancer Research Institute, injected live cancer cells into twenty-two indigent, chronically ill, and debilitated elderly patients at the Brooklyn Jewish Chronic Disease Hospital (JCDH) in New York."[31] There was no informed consent, and the experiment was unrelated to any therapeutic program on behalf of the patients.[32] Second, between 1956 and 1971, at Willowbrook State School, a New York state institution for mentally retarded persons, children were intentionally infected with hepatitis, either through being "fed extracts of stools from infected children" or through injection.[33] In the latter case, the same kinds of baseline arguments were used as those invoked to justify the Tuskegee study: it was argued that because hepatitis infection was prevalent at the institution, children benefitted from being infected in a controlled way and from receiving expert attention.[34] Apparently, the authors of the study did not feel responsible for alleviating the inhumane conditions at the institution, which Senator Robert F. Kennedy in 1965 described as "less comfortable and cheerful than the cages in which we put animals in a zoo."[35] Others described conditions in which "the over-

[30] *See* CARL H. COLEMAN, ET AL, THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 37-41 (2005).
[31] *Id*. at 39.
[32] *Id*. at 39-40.
[33] *Id*. at 39.
[34] *Id*. at 39-40.
[35] *Id*. at 41.

crowded hallways of Willowbrook were filled with beds jammed together and with unattended children, some of whom were naked, covered in their own feces, and lying on the floors."[36] Thus, the researchers essentially used the inhumane conditions under which the children were kept, and in which disease was prevalent, to justify an experiment in which they intentionally infected the children with hepatitis.

Few enterprises have done as much good for humankind as medical progress; before the modern era of medical progress, large pluralities of infants died before their first birthday, average life spans were around forty, and many spent much of their lives in sickness and pain. Thus, few enterprises are greater "change agents" than medical research, with most of the changes wrought constituting advances in human life. Medical research occurs in the broader context of scientific and technological advances in other fields, including agriculture, transportation, energy, and information and communications technologies. Viewed more broadly, technological progress is an overwhelming force for the improvement and transformation of human life. In this context, the temptation of hubris in these fields is enormous, as the ends seem to justify the means, and ancient religious and moral teachings can appear as little more than irrelevant superstitions.

Of course, from the point of view of civil rights law, the Tuskegee experiment looks like the same old racial discrimination. Viewed through the lens of the Nuremberg Tribunal, the inhumane acts of the Nazi doctors looked like just another example of racist and brutal Nazi ideology in action, and in significant part as a rebirth of the ancient prejudice of anti-Semitism. From the point of view of human rights activists and those fighting for the human dignity of vulnerable populations, the studies revealed by Dr. Beecher's famous 1966 article look like just another instance of the age-old story of the powerful exploiting the vulnerable. When one set of "change agents" meets another, each defines the other as old, superstitious, and outmoded, while perceiving themselves as representing the wave and direction of the future.

Thus, the concept of "change agent" ultimately needs to be anchored in a broader set of values or realities, for "change" and "change agent" are amoral concepts. Change can be good or bad

[36] COLEMAN, *supra* note 30, at 41.

and must be measured against some larger scale of the good and the right. In addition, one difficulty with "change agents" is that they tend to work in a one-dimensional way, with their focus on a narrow band of perspectives and issues. Thus, they may not be attuned to other values; they may not acknowledge proper limits on means toward what they view as an overriding end; they may not care to account for the problem of unintended consequences. Change agents tend to push in a single direction irrespective of these difficulties; the energy and drive required to change a status quo reality or practice does not lend itself easily to nuance or even acknowledgement of complexity.

By contrast, society and the law need to balance competing interests and competing values, for society, life, and the law are always multi-dimensional and so complex as to render "social engineering" an oxymoron. Thus, in the area of human subjects research, the simplest solution to the problem would be to prohibit any kind of experimentation on human beings. This would certainly satisfy the basic dictum that human beings should not be reduced to being "guinea pigs." The law of the United States, however, goes in a rather different direction, with the Food and Drug Administration (FDA) requiring three levels of human clinical trials prior to the approval of new pharmaceuticals and medical devises. The law is based on the viewpoint that the advancement of medical science requires empirically-based human subjects research, with protection against clinical or research bias and the placebo effect through methodologies involving control groups and double-blind studies.[37] The question then becomes how to conduct and regulate such research to ensure that it is compatible with values related to human dignity and equality.

The positive legacy of the infamous Tuskegee experiment is a rigorous attempt to define this balance between society's need for human subjects research in order to promote medical progress, and protecting the human dignity and equality of human research subjects. According to the typical narrative, the public revelation of the Tuskegee study in 1972, along with other disclosures, such

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[37] *See,* e.g., David M. Smolin, *Nontherapeutic Research with Children: The Virtues and Vices of Legal Uncertainty*, 33 CUMB. L. REV. 621, 627-31 (2003); *see also* Nat'l Inst. of Health, *Understanding Clinical Trials*, *available at* CLINICALTRIALS.GOV, http://clinicaltrials.gov/ct2/info/understand. (last updated Sept. 20, 2007).

as those contained in the 1966 Beecher article, led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the 1974 National Research Act. The Commission in 1979 released the famous Belmont Report on the Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The Belmont Report identified "respect for persons," "beneficence," and "justice" as applicable ethical principles, with "respect for persons" described as respecting the autonomy of the competent and protecting those with diminished autonomy. Beneficence embodies both the "do no harm" principle and also the mandate to "maximize possible benefits and minimize possible harms."[38] For the field of bioethics, the Belmont Report brings into prominence the so-called principlism method, which has become one of the most significant approaches to bioethics. Another positive legacy is an emphasis on institutionalizing protections for human research subjects; hence, the 1974 National Research Act strengthened policies begun in the 1960s providing for systematic review of human subjects research. Legally, these norms are reflected today in the system of Institutional Review Boards (IRBs) and related rules provided through administrative regulations promulgated by the Department of Health and Human Services (DHHS) and the FDA. While these regulations do not cover all human subjects research conducted in the United States, their scope is considerable and the regulations provide a norm of institutional review of human subjects research.[39]

A fundamental part of the positive response to the Tuskegee experiment is a program of re-balancing the power imbalance between researchers and their research subjects, and more broadly between physicians and patients. The old paternalism is replaced by institutionalized processes, which at least attempt to empower research subjects and patients as the vulnerable parties in these relationships. In this way, the IRB approach bears some similarity

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[38] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 44 Fed. Reg. 23, 192, 194 (Apr. 18, 1979). *available at* http://ohsr.od.nih.gov/guidelines/belmont.html; *see also* COLEMAN, *supra* note 30, at 52.

[39] *See* COLEMAN, *supra* note 30, at 52; *see generally* COLEMAN, *supra* note 30, at 105-205.

to the approach of the United States Supreme Court in *Miranda v. Arizona*, which created the famous Miranda warnings, with their prototypal concern being the vulnerability of the detained individual subject to police interrogation.[40] The Miranda warnings are in many ways analogous to the center-piece of the IRB process, the informed consent statement, with both containing ritualized statements of the rights of the individual, who is in a position that seems powerless. Obviously, in both situations, the more powerful party remains the same after the procedural, institutionalized routines mandated by law are implemented: the prisoner is still a prisoner, the patient is still a patient, the research subject is still a research subject. In a world of conflicting needs, interests, and values, both *Miranda* and the IRB system represent significant successes in addressing systematic abuses in relationships with inherent inequalities, vulnerabilities, and risks of exploitation, without undermining the purposes that those relationships serve.

II. TUSKEGEE REBORN?: THE CONTINUING PROBLEMS WITH BASELINES

Despite the significant progress made in relationship to human-subjects research since the Tuskegee experiment, continuing and serious difficulties remain in sustaining an appropriate balance between the rights and equality of human research subjects and society's needs for continuing medical and scientific research. The federal regulatory role in human subjects research and the IRB system have not solved all difficulties nor stopped all abuses. The continuing problems are illustrated by the famous 2001 case of *Grimes v. Kennedy Krieger Institute*, which involved human subjects research on children subject to lead paint as an environmental hazard in low-cost housing, and also by continuing issues with human subjects research conducted in developing nations.[41] Some of this research is unfortunately reminiscent of the Tuskegee syphilis experiment.[42] Researchers continue to find it attractive to use the deprivations suffered by vulnerable populations as an opportunity to conduct research that generally could not be conducted on

[40] 384 U.S. 436 (1966).

[41] 782 A.2d 807 (Md. 2001); *see also* PENCE, *supra* note 7, at 190-94.

[42] PENCE, *supra* note 7, at 190-94.

those not suffering those deprivations, based on the theory that the study is not causing the deprivation. Governments and other actors generally regarded as responsible and socially-conscious continue to make such decisions. The inability of researchers to fully take responsibility for the well-being of their research subjects, and the tendency of researchers to take advantage of the vulnerability of research subjects, thus, continues to haunt the field. An examination of the *Grimes* case illustrates these difficulties.

A. Grimes v. Kennedy Krieger Institute: Another Tuskegee Study?[43]

Grimes v. Kennedy Krieger Institute illustrates how even the new IRB system could fail to prevent a study that bore an uncomfortable resemblance to the Tuskegee syphilis experiment. The research program evaluated in *Grimes* arose out of the significant public health concerns associated with children and lead paint. The goal of the study was to determine the lowest cost method of effective lead abatement in low-cost housing. The public health context for the study included two factors: (1) older low-cost residential housing stock, including rental property, frequently subjects residents, including children, to hazardous levels of lead; and (2) traditional full-scale lead abatement is frequently not economically feasible, particularly in low-cost housing, leading to the abandonment of the property by landlord-owners. Inexpensive lead abatement methods, if proven successful, could provide significant public health benefits for society. Given this context, it is not surprising that the study involved a significant federal-state-city partnership. The federal Environmental Protection Agency (EPA) and the Maryland Department of Housing and Community Development (DHCD) co-sponsored the study, with collaboration from the Maryland Department of the Environment and the Baltimore City Health Department. The EPA funded the study with a $200,000 contract with the Kennedy Krieger Institute (KKI), a research institute associated with Johns Hopkins University.[44]

The study involved three different kinds of properties: (1) older properties that had undergone full-scale lead abatement, pur-

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[43] The description of the *Grimes* case in this section is adapted from SMOLIN, *supra* note 37, at 634-44.

[44] *Grimes*, 782 A.2d at 819.

portedly leading to full abatement; (2) newer properties which had never been subject to hazardous lead levels; and (3) older properties in need of lead abatement. The third class of older properties, unabated older properties, was divided into three different levels of abatement: (a) Level I ("minimal" repair and maintenance costing $1,650); (b) Level II ("greater" repair and maintenance costing $3,500); and (c) Level III ("even greater" repair and maintenance costing $6,000 - $7,000). Given these three subgroups, the study ultimately involved five types of properties. The first two kinds of properties (older fully abated, and newer properties) served as control groups for the three different levels of abatement to be conducted under the auspices of the study. One hundred twenty five (125) houses were supposed to be included in the study (twenty-five houses in each of the five groups), although only 108 houses were actually included.[45]

The study was designed to examine both: (1) lead load levels in each house, using dust, soil, and drinking water samples; and (2) lead levels in the blood of the children residing in each house. Significantly, the study was designed to last for two years. KKI thus sought to enroll tenant families with healthy young children, including at least one child between five and forty-eight months, where the family had no immediate plans to move elsewhere.[46]

The *Grimes* litigation arose out of complaints filed by research subjects against KKI (and other defendants) for negligently failing to warn, or abate, lead-paint hazards. The trial court dismissed the claims on summary judgment, accepting KKI's argument that it had no legal duty to the research subjects.[47] The Maryland Court of Appeals, that state's highest court, reversed these judgments and reinstated the lawsuits.[48] The reversal was not surprising, given the questionable holding that research institutions have no legal duty to research subjects. Indeed, Johns Hopkins experienced substantial embarrassment by the public exposure of its legal argument that it had no legal duty to research subjects. Johns Hopkins publicly disowned the argument on its website,

[45] *See id*. at 823 & n.20.
[46] *See id*. at 812, 822 & 823.
[47] *Id*. at 818.
[48] *Id*. at 818, 858.

characterizing it as a technical argument used by its insurance lawyers.[49] Of course, it is disingenuous for an institution to simultaneously recruit large numbers of human research subjects through promises of careful concern and proper treatment, and then as soon as it faces litigation seek to evade any responsibility by arguing that it lacks any legal duty to its research subjects.

Although the blanket argument that research institutions owe no legal duty to research subjects appears highly implausible as a legal doctrine, its use in the *Grimes* case underscores the ethical similarities between the KKI lead paint study and the Tuskegee syphilis study. The concept of "no legal duty" could stem from the concept that researchers, observing a harm that does and would occur absent the study, have no legal or ethical duty to alleviate the harm they observe. From this point of view, the act of observing a harm as a part of a research protocol does not create any ethical duty to alleviate that harm, even if means of alleviation exist. Of course, this kind of ethical viewpoint echoes that found in the Tuskegee study. Thus, in the KKI lead paint study there seems to have been a presumption that, absent the study, the families and children involved anyway would be living in unabated, high-lead environments, without any form of environmental or pediatric lead-level testing. From this perspective, the baseline condition of the research participants is that of living in an untested, hazardous environment. Hence, any testing and abatement provided is a gratuitous benefit, and any failure to test or abate does not violate any ethical or legal duty. Of course, from this point of view, it is much easier to justify a study upon the poor and other vulnerable populations, as their relative deprivations provide opportunities to observe and study human beings subject to various medical conditions or dangerous circumstances.

Of course, the contrasting ethical viewpoint, which had been presumed to have been established by the overwhelming repudiation of the Tuskegee syphilis experiment, would be that researching or studying human beings suffering such deprivations requires alleviations of such deprivations, at least where such alleviation is reasonably feasible. Thus, where a proven technology exists to alleviate the deprivation, and it is economically reasona-

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[49] *See* Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows Their Interpretation*, 30 J.L. MED. & ETHICS 38, 47 (2002).

bly feasible in the context of the study to alleviate it, it is unethical to simply study the deprivation without intervening to alleviate it. Thus, the presumed lesson from the Tuskegee syphilis experiment is both that informed consent is necessary and also that, where effective treatment is available, it must be provided to research subjects.

The KKI study was also similar to the Tuskegee syphilis experiment in illustrating the factual and ethical ambiguity often present in the distinction between passively observing and actively facilitating harms to subjects of human research. Thus, as programs to provide penicillin to syphilis patients began to reach the Tuskegee research subjects, government actors instigated active efforts to prevent the research subjects from receiving such treatments. In those instances, the study went beyond merely observing a lack of treatment to actively preventing treatment.[50] This change illustrates the momentum that can occur in a research protocol of the untreated, which over time becomes invested in ensuring a lack of treatment in order to sustain the research protocol and continue the stream of data. The line became similarly blurred in the KKI study. The study protocol in KKI required that very young children live in housing that was only partially abated. While the theory of the study was that low-income families would inevitably, apart from the study, live in low-cost housing with lead paint exposure, the study encouraged, and in one instance required, the landlords of the partially abated apartments to rent to families with young children. The study protocol envisioned that the children would remain in the partially abated units for the two year study period. Thus, the Maryland Court of Appeals found that the services provided by the study and the overall functioning of the study were designed to ensure that the parents chose to rent and remain in dangerous environments for their children.[51] Lead paint is of course most dangerous for the very young children targeted by the study. The Maryland Court of Appeals not only compared the KKI study to the Tuskegee syphilis experiment, but also to infamous studies of "research subjects being intentionally exposed to infectious or poisonous substances in the name of scientific re-

[50] See supra note 16 and accompanying text.

[51] *See Grimes*, 782 A.2d at 816-17, 823-24.

search."[52] The court included in this category the Jewish Hospital study noted above, involving patients who were infected with cancer cells without consent, Buchenwald concentration camp studies of prisoners who were deliberately infected with typhus, and the infamous LSD experiments conducted on soldiers and carried out by the CIA and Army in the 1950s and 1960s.[53]

B. Explaining the Failures: From Nuremberg to Tuskegee to KKI and Beyond

Despite the gains that have been made in the field of human subject research, the recurrent scandals indicate continuing difficulties. Beyond bemoaning them, it is important to seek some explanation in order to better design appropriate responses.

The obvious question is why the same behaviors keep recurring, even after such scandals? This article suggests several explanations:

(1) Researchers, physicians, research institutions, and government ministries with responsibilities for public health, scientific advancement, and similar areas, generally perceive themselves as positive actors engaged in important work for the betterment of humankind. They also perceive themselves as fundamentally different from those in the past whose research has been subject to public criticism. Thus, the revelations of horrific medical experiments by Nazi physicians seem to have taught researchers and physicians in the United States very little; American researchers and physicians envisioned themselves as so unlike the Nazi doctors as to make the lessons seemingly inapplicable.[54] Apparently much the same thing happened after the revelation of the Tuskegee syphilis experiments: researchers and physicians presumed that the study arose in a different era characterized by an extremity of racial discrimination not relevant to the present. Hence, the presumption was perhaps that such things would not happen today. It seems to be difficult for contemporary researchers and scientists to understand that, for example, the Tuskegee researchers were, by and large, people like themselves, with an identity as change agents addressing very real public health and social problems.

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[52] *Id*. at 816.
[53] *Id*. at 816-17.
[54] *See* Fletcher, supra note 12, at 289.

(2) Economic and professional incentives for ongoing research continue to create ethical difficulties. These incentives are enormous, given the legal requirements for human subject research to bring new pharmaceutical products to market, the large amount of government funding for research involving human subjects, the enormous value of intellectual property rights at stake, and the professional necessity for researchers and academics to design and carry out human subjects research in order to sustain and advance their careers. Hence, there are enormous economic incentives and pressures to engage in new forms of human subjects research.[55]

(3) In ways that are perhaps still not fully appreciated, the field of bioethics has yet to work out the tensions between the perceived need for specific kinds of human subjects research and the ethical limitations on such research found in the relevant legal and ethical guidelines. The ethical approaches outlined by the Belmont Report and the principlism method of bioethics can obscure rather than illuminate the ways in which these tensions remain. Multiple and ambiguous ethical principles, when applied to difficult problems, fail to deliver clear ethical answers, even when the larger society presumes a clear and definite answer exists. The federal regulatory approach similarly buries difficult problems in a combination of bureaucratic processes (the IRB system) or vague ethical precepts.[56] The net impact is that the field moves from scandal to scandal with research moving from one vulnerable population to the next.

(4) One difficulty is the increasing tendency to conduct human subjects research in developing or transition nations.[57] These research venues present an opportunity to justify studies that seem ethically similar to the Tuskegee and KKI studies because they rely on the deprivations suffered by the subject population to justify research that otherwise could not be conducted on more privileged populations. One prominent example was the contro-

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[55] *See generally* Pence, *supra* note 7, at 195-96; Coleman, *supra* note 30, at 8-9, 63-103.

[56] *See Smolin*, *supra* note 37.

[57] See Talea Miller, *"Explosive" Growth in Foreign Drug Testing Rasies Ethical Questions*, (Aug. 23, 2011), *available at* http://www.pbs.org/newshour/rundown/2011/08/sending-us-drug-research-overseas.html; Seth W. Glickman, et al., *Ethical and Scientific Implications of the Globalization of Clinical Research*, 360 NEW ENG. J. MED. 816 (Feb. 19, 2009), *available at* http://www.nejm.org/doi/full/10.1056/NEJMsb0803929.

versy over perinatal HIV transmission studies involving placebo control groups. In a context where there was a proven, but expensive regimen used in the United States, subjecting HIV-positive pregnant women to placebo treatment would be totally unacceptable inside the United States. Yet, many in the research and bioethics community supported not only use of an untested, less expensive regimen, but also the necessity of a control group that would receive no treatment – mere placebos – at least until initial results indicated the efficacy of the new treatment regimen. This study combined the unattractive features of the KKI study – some subjects receiving a less expensive regimen rather than a proven one in the interests of developing a less expensive regimen – as well as the equivalent of Tuskegee's "no treatment" approach for the placebo group. Further, such an approach was justified with research on poor pregnant women, and their unborn children/fetuses. Not only did the research employ extremely vulnerable populations; the researchers also used the fetus/infant obviously incapable of informed consent in research posing extreme danger to the very survival of the child.[58]

Perhaps the fundamental lesson of the Tuskegee syphilis experiment is that we have not yet adequately described the lessons we claim to have learned from the study. Instead, there is an incoherent tendency to condemn the Tuskegee study while simultaneously supporting or acquiescing in studies that, to the lay person, look ethically indistinguishable. The studies seem to move from one deprived population to the next – from the segregation era, poor, African-American men of Macon Country, Alabama, suffering from untreated syphilis; to poor children in Baltimore, Maryland, subject to unsafe lead paint in low-cost housing; to poor, pregnant women in developing nations suffering from untreated HIV infections and their unborn children/fetuses and newborn babies at risk for the transmission of HIV infection.

As ethically sensitive human-subject research continues to migrate overseas where it can be conducted with less expense and where protocols which would be unacceptable in the United States can potentially be carried out, there will be new necessities to relearn the lessons of the Tuskegee syphilis experiment. Although

[58] See Pence, supra note 7, at 190-92; David Resnik, *The Ethics of HIV Research in Developing Nations*, 12 BIOETHICS 286 (1998).

the Tuskegee experiments have become a kind of touchstone and icon, there are lessons we have not yet learned and issues we have not yet resolved.

Indeed, it is an irony of the regulatory response to the Tuskegee experiments that we now require bureaucratic procedures for mere survey research conducted by undergraduate students on their classmates, where there is virtually no risk of harm, while simultaneously having failed to create clear standards that would prevent research protocols that pose serious risks of harm and threaten to replicate the Tuskegee experiments. In casting a broad net we have become entangled needlessly in endless examination of research projects posing no reasonable risk of harm, wasting time and inhibiting potentially productive work, while failing to address the fundamental harms we purportedly were seeking to avert.

This year marks forty years since the end of the Tuskegee syphilis experiment and eighty years since the infamous study commenced. This would be a good time, in light of the disclosure of the Guatemalan syphilis experiments, and the dangers posed by the large scale movement of human subject research overseas, to more fully assess lessons that can be learned and applied.

III. CONCLUSION: THE FUTURE OF BIOETHICS

The Tuskegee syphilis experiment was a critical turning point in the creation of modern bioethics. The disclosure of the study led to the Belmont Report and the embracing of the principlism method of bioethics. This method was apparently intended as a unifying secular approach that could incorporate and accommodate differing philosophical and religious perspectives. The Report, principlism method, and accompanying regulatory scheme have helped protect and empower research subjects. They have served as a partial corrective against the opportunities for abuse in the researcher-subject relationship, addressing the sharp power differentials in the relationship through insertion of certain ethical norms and bureaucratic processes.

This progress has left at least two tasks unfinished. First, it has become clearer over time that the principlism method of bioethics is an incomplete method unable to resolve a large proportion of bioethical dilemmas. The method was originally created in response to human subject research, and the attempt to construct

from it a method that could resolve all or most bioethical dilemmas in all fields, from clinical ethics to reproductive issues to those involving death and dying, has been unsuccessful. The method has been most useful in the analogous task of strengthening patient autonomy and reversing the historic tendency toward physician paternalism, since redressing vulnerabilities in the physician-patient relationship is analogous to doing so in the researcher-human subject relationship.

Second, and more germane to this essay, the responses to the Tuskegee experiment in the area of human subject research, while for the most part helpful and appropriate, have also proven incomplete and inadequate. The recurrence of Tuskegee-like incidents, for example in the KKI lead paint study, and in various research protocols conducted in developing nations, and the arguments put forward that such protocols were ethically defensible, indicate that fundamental dilemmas in human subject research remain unresolved. Condemnation of the Tuskegee syphilis experiment is necessary but not sufficient. Such condemnation has not yet been translated into clear analysis that explains how the principles derived from that condemnation can be reconciled with the felt need for human subjects research. In a context where the entire world has become a field for human-subjects research, it is now necessary to address yet another set of ethical dilemmas: How can the rights of poor people in developing and transition economies, who often lack access to adequate medical care, whose political systems are sometimes more authoritarian than democratic, and who live in societies where corruption is endemic, be protected in the vulnerable role of research subjects? There is an overwhelming power imbalance between poor research subjects in developing and transition economies and the multi-national corporations and researchers from the United States and other wealthy nations who often fund such studies. In addition, political contexts where the rule of law is not fully established can make it extraordinarily difficult to implement effective protections even when they are a theoretical part of research protocols.

The future of bioethics thus requires sustained new efforts; one can only hope that we will be up to the task.