of ethical review, including not only the participation of the public health and scientific communities in the developing countries where the trials are being performed but also the application of the U.S. rules for the protection of human research subjects by relevant institutional review boards in the United States and in the developing countries. Support from local governments has been obtained, and each active study has been and will continue to be reviewed by an independent data and safety monitoring board.

To restate our main points: these studies address an urgent need in the countries in which they are being conducted and have been developed with extensive in-country participation. The studies are being conducted according to widely accepted principles and guidelines in bioethics. And our decisions to support these trials rest heavily on local support and approval. In a letter to the NIH dated May 8, 1997, Edward K. Mbidde, chairman of the AIDS Research Committee of the Uganda Cancer Institute, wrote:

> These are Ugandan studies conducted by Ugandan investigators on Ugandans. Due to lack of resources we have been sponsored by organizations like yours. We are grateful that you have been able to do so. . . . There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

The scientific and ethical issues concerning studies in developing countries are complex. It is a healthy sign that we are debating these issues so that we can continue to advance our knowledge and our practice. However, it is essential that the debate take place with a full understanding of the nature of the science, the interventions in question, and the local factors that impede or support research and its benefits.

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THE USES AND ABUSES OF TUSKEGEE

AMY L. FAIRCHILD & RONALD BAYER

The Tuskegee Syphilis Study has come to symbolize the most egregious abuse of authority on the part of medical researchers. Tuskegee has also come to serve as a point of reference for African Americans distrustful of those with power, emblematic of the history of a people enslaved and then subject to social, legal, and political oppression after the end of formal servitude. When Tuskegee as a symbol of research abuse and Tuskegee as an emblem of racial oppression are merged, a potent device is at hand for uncovering profound social injustice. When, however, the legacy of Tuskegee is incautiously invoked—when its legacy is abused—it can serve to make a careful consideration of complex matters involving research with socially vulnerable people all but impossible.

To understand both the uses and abuses of Tuskegee requires that we understand the oft-told—and sometimes mistold—story of what happened between 1932 and 1972. The seminal study by James Jones, *Bad Blood*, provides the indispensable reference.[1]

As part of its study of the long-term effects of syphilis begun in 1932, the U.S. Public Health Service (PHS) denied treatment to 399 African American men suffering from the tertiary effects of the disease. The PHS launched its 40-year study using a group of patients originally identified in Macon County, Alabama, as part of a demonstration project that recommended mass testing and treatment of syphilis in the South. When money for testing and treatment dried up in the midst of the depression, PHS officers saw an opportunity to prove that syphilis among African Americans was "almost a different disease from syphilis in the white."[2]

Researchers and physicians involved in Tuskegee chose not to inform the study's participants that they were infected with syphilis or educate them regarding its treatment or prevention. During the study's recruitment period, PHS officers knowingly provided inadequate treatment for syphilis as a means of securing the support of the state department of health. Although subjects were not told that they had syphilis or were receiving modified treatment for it, the act of offering any kind of treatment helped in luring subjects to the study and gaining their trust.

Amy L. Fairchild is assistant professor of public health and Ronald Bayer is professor of public health in the Program in the History of Public Health and Medicine, Joseph L. Mailman School of Public Health, Columbia University.

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Once the study was under way, scientists deliberately misled the men, telling them that they were receiving treatment for "bad blood"—a generic term that referred to a variety of ailments—rather than syphilis.

Receiving broad cooperation from state and local health officers, local medical practitioners, the military, and the Tuskegee Institute, the PHS successfully thwarted all efforts the men made to receive treatment from other sources. The PHS gave only a placebo to those expecting a full course of treatment. The intent of this study of untreated syphilis—albeit one clearly undermined by the therapy the PHS administered during the enrollment period—was to observe the untreated men until death: "Everyone is agreed that the proper procedure is the continuance of the observation of the Negro men used in the study with the idea of eventually bringing them to autopsy."[3] In 1950, one of the study's originators triumphantly declared, "We now know, where we could only surmise before, that we have contributed to their ailments and shortened their lives."[4]

Penicillin dramatically altered the treatment of syphilis. The PHS's Division of Venereal Diseases—the driving force behind the Tuskegee study—began using penicillin in several of its clinics across the nation in the early 1940s.[5] Despite the promise of the new treatment, Tuskegee directors withheld penicillin from its subjects. Not only did the PHS remain committed to seeing the study through to its end, but also used penicillin as a rationale for continuing the study. Never again would the PHS find such a group of untreated individuals.[6]

Even after the study was exposed in 1972, the PHS officials involved with Tuskegee refused to admit wrongdoing. They justified the study on the grounds that they had simply observed a group of men who would not have received treatment anyway and for whom treatment—even penicillin—would not have provided benefit. In any case, argued PHS officers, the men—who believed they were receiving treatment, who were thwarted at each juncture at which they sought outside treatment, and who were threatened with losing free medical care and death benefits if they left the study—had been "free" to leave the study and receive treatment at any time.

Although Tuskegee was a study that the PHS adapted to changing circumstances, from this account it is possible to derive three critical features that characterize the nature of the consistent research abuses that occurred over the course of forty years. The study involved, first, deceptions regarding the very existence and nature of the inquiry into which individuals were lured. As such, it deprived those seeking care of the right to choose whether or not to serve as research subjects. Second, it entailed an exploitation of social vulnerability to recruit and retain research subjects. Finally, Tuskegee researchers made a willful effort to deprive subjects of access to appropriate and available medical care, which changed over time, as a way of furthering the study's goals.

Thus viewed, Tuskegee touched on issues central to research ethics and can

serve as a standard against which to judge contemporary examples of research abuse.[7] But, as a historical event involving the exploitation of African Americans that entailed the examination of a racist thesis, the legacy of Tuskegee and the outrage it has spawned are suffused with race. When the story broke in 1972, there was intense but brief discussion in the medical and public-health press. Some of the problems raised by Tuskegee were, in some limited sense, resolved with the passage of the National Research Act of 1974. The act created institutional review boards (IRBs) and charged them with approving all federally funded human research. But while Tuskegee lay dormant in the popular press for the next decade, it served a critical function in the African American press, becoming a metaphor for genocide.

Within weeks of the first news reports of Tuskegee, the African American press and African American political leaders characterized the forty-year experiment as "outright genocide."[8] *Jet* magazine, for instance, created a new news section on "Genocide." Along with the rest of the African American press, it began to view a host of issues—the lack of health services; birth control, abortion, and involuntary sterilization; adoption; overexposure to X rays; research among prisoners and infants; prison riots; the U.S. Census—through the lens of Tuskegee.[9] "Tuskegee" crystallized a history of medical neglect and abuse that was a consequence of social and political disempowerment.[10]

It is not surprising, then, that Tuskegee has found potent invocations in the context of the AIDS epidemic, which has so disproportionately affected African Americans. Particularly when falsely remembered, as a tale of how poor African American men were deliberately infected with syphilis,[11] the story of Tuskegee rang true, for it resonated with suspicions of an epidemic manufactured to annihilate a people.[12] James Small, a black studies professor at City College of New York, summed up the views of many when he concluded, "Our whole relationship to whites has been that of their practicing genocidal conspiratorial behavior on us—from the whole slave encounter to the Tuskegee Study."[13]

In this paper we examine the uses and abuses of Tuskegee in three highly visible AIDS-related debates, which spanned the past decade: the clash over the provision of sterile injection equipment to intravenous drug users, the conflict over unidentified anonymous HIV seroprevalence studies, and the debate over the investigation of interventions to reduce the rate of HIV transmission from pregnant women to their offspring in Third World countries.

Needle Exchange

The provision of sterile injection equipment to intravenous drug users has been proposed as a way of interrupting the spread of HIV infection since the mid-

1980s.[14] The debate over needle exchange within the African American community unfolded against a backdrop of suspicions that the failure to provide adequate treatment to drug users represented a form of genocidal neglect—most potently captured in the legacy of Tuskegee.[15]

Needle exchange compounded a community's sense of outrage over a failure to provide effective drug treatment. Drawing on this community outrage, Congregational minister Graylan Ellis-Hagler succeeded in his forceful campaign to shut down a Boston needle-exchange program in 1986 by extending the genocide analogy: "First the white establishment push drugs in the community. They cripple the community politically and economically with drugs. They send males to jail. Then someone hands out needles to maintain the dependency."[16]

Wherever needle-exchange proposals emerged, black leadership gave voice to their dismay and fury. In New York City the dual specters of genocide and Tuskegee explicitly helped to shape the debate surrounding the nation's first controlled clinical trial of the intervention.[17] Because of political opposition to needle exchange from both law-enforcement proponents and the African American community, the city's health commissioner was compelled to present his 1988 needle-exchange effort as a small experiment designed to determine whether such a radical innovation could reduce the incidence of infection among drug users without encouraging drug use. Ironically, the very political cover that the experiment was designed to provide set the stage for the charge of "Tuskegee." As the *Amsterdam News* noted, "Given [the commissioner of health's] knowledge of the Tuskegee experiment—it would seem to us that he would want everything that he is doing to be above suspicion."[18]

Benjamin Ward, the city's African American police commissioner, alluded to the Tuskegee syphilis trials when he explained that his community felt "a particular sensitivity to doctors conducting experiments, and they too frequently seem to be conducted against blacks."[19] Hilton B. Davis, a Harlem City Council member, more pointedly characterized the program as a "genocidal campaign."[20] Rev. Reginald Williams echoed his sentiments, combing the imagery of Tuskegee and genocide: "Why," he demanded, "must we again be the guinea pigs in this genocidal mentality?"[21]

When David Dinkins, long opposed to needle exchange, assumed the office of mayor in 1990, thus becoming the city's first African American chief executive, he almost immediately ended the trial. Dinkins felt that "we need to go at fighting drugs in the first instance and I don't want to give people the paraphernalia to continue using drugs."[22] Ironically, when the city moved even further by withdrawing funds from a community program that provided bleach to drug users for needle cleansing, Dr. Mathilde Krim, the well-known head of the American Foundation for AIDS Research, drew a comparison to Tuskegee and concluded, "It will be genocide, pure and simple."[23]

By the mid-1990s, the intense African American opposition to needle exchange had all but vanished—eroded by the apparent effectiveness of such efforts and by the fragmentation of opinion among African American leaders. Nevertheless, opposition remains, and when it finds expression, Tuskegee continues to serve as a touchstone for criticism. Thus in 1997, Harlem Hospital psychiatrist and drug-treatment expert Dr. James Curtis denounced such programs, stating that they amounted to "reckless experimentation on human beings" akin to "a replay of the infamous Tuskegee experiment."[24]

Yet as Tuskegee ceased to serve as a tool for critics of needle exchange, it increasingly became a symbol for the advocates of such efforts, who denounced the failure of federal officials to fund such programs. It was in this context that a furious debate emerged when the NIH funded a clinical trial in Anchorage, Alaska, to answer the question of whether over-the-counter sale of injection equipment—a practice permitted in Alaska but prohibited in many jurisdictions with serious drug problems—was more effective than formal needle-exchange programs. In October 1996, Peter Lurie and Sidney Wolfe, physicians at Ralph Nader's Public Citizen's Health Research Group, sharply attacked the $2.4 million study. In a series of letters, they charged that the study was "deceptive" in failing to inform participants of the relative benefits of the needle exchange and that it " 'actively prevented' [those assigned to the pharmacy arm] from obtaining access to clean needles through the needle exchange."[25] Equally troubling, they noted one of the study's measures of efficacy—the incidence of hepatitis B infection—was utterly preventable through the provision of a vaccine. Lurie and Wolfe concluded, "The parallels here to the Tuskegee Syphilis Study . . . are clear. . . . [In] the Tuskegee study known effective treatment for a life-threatening disease was withheld, in this human experiment, two known effective means of prevention—hepatitis B vaccine and the provision at no cost of sterile needles and syringes—are being withheld."[26]

In an unprecedented move, Harold Varmus, head of the NIH, suspended the study pending review by an outside committee headed by Yale physician and expert on research ethics Robert Levine. The panel included James Childress, a senior figure in the field of medical ethics. Levine's panel reported back to Varmus in December, concluding that the study was no Tuskegee, primarily because the drug users in the study would, in fact, have ready access to clean syringes. Indeed, the study protocol stipulated that those assigned to the study's pharmacy arm would be instructed on how and where to buy clean needles over the counter. The panel described the critique of the study as "misunderstanding, mischaracterization, or both."[27] Significantly, the panel also endorsed the study's protocol regarding hepatitis B infection, asserting that it was not a typical service of needle-exchange programs and that study participants had easy access to it already.

With the study set to move forward, Arthur Caplan and George Annas, two prominent bioethicists, argued that neither the need to determine the efficacy of

over-the-counter syringe sales nor the addition of NIH funds to offer hepatitis vaccines to those requesting them altered the basic ethics of the study. Caplan and Annas maintained that the study amounted to allowing researchers to "stand by and observe as their subjects develop devastating diseases that could be prevented." "This," they continued, "is the lesson learned in the notorious Tuskegee syphilis study. . . . It is not ethically acceptable to learn from the misery of the vulnerable without protecting them from known risks of serious harm." Concluded the two, "There is no excuse for not pursuing every reasonable avenue, including both drugstore sales and needle exchange programs, to get sterile needles into the hands of these people."[28]

Both iterations of the needle-exchange debate revolved around pressing questions of fairness in dealing with vulnerable populations. Both focused on the question of whether withholding (or providing) an innovative intervention could be justified given the risks and burdens of prevailing conditions in the HIV epidemic. Both challenged public-health priorities. But the charge of the Tuskegee-like abuse of research subjects was inappropriate in each instance. The failure to provide adequate treatment options for drug addiction, central to the complaint of African American opponents of needle exchange, most certainly represents tragic neglect on the part of the health-care system and an example of gross inequity. But while Tuskegee may serve as a powerful means of bringing serious, difficult questions to light, not all injustices are the equivalent of those represented by Tuskegee. Needle-exchange efforts do not represent a substitute for drug treatment. They simply attempt to prevent the acquisition of a lethal infection. Whereas in Tuskegee the PHS used the social circumstances of poor African American men to manipulate them into a study that would deprive them of treatment, proposals to provide sterile injection equipment seek to address the vulnerable situation of those exposed to HIV by offering a potentially life-saving intervention. The emphasis on the provision of clean needles rather than on treatment may, arguably, reflect a mistaken ordering of social priorities. Indeed, it may well reflect the extent to which the needs of the most vulnerable receive inadequate attention. But it does not demonstrate a disregard for the basic principles of research ethics.

Strong as is the evidence for the relative efficacy of needle exchange, the failure to establish such programs also does not constitute Tuskegee-like abuse. Every social policy failure, every demonstration of neglect, every injustice is not the equivalent of what happened in Macon County, although they may share common racist underpinnings. Even the challenged Alaska study was not comparable to Tuskegee. However one evaluates the evidence, it is clear that those who were to be enrolled would not suffer the kind of covert manipulation designed to deprive individuals of access to potentially effective care experienced by the men studied in Tuskegee. Only insofar as the original study failed to offer hepatitis B vaccination to participants did it arguably involve an ethical lapse—a lapse addressed by the

NIH despite the recommendations of its ethical review panel. But that lapse, in and of itself, did not constitute the kind of abuse represented by Tuskegee.

Blinded Seroprevalence Studies

The conflict over blinded seroprevalence studies involved charges that, as in Tuskegee, vulnerable individuals were unwitting subjects of surveillance. Further, critics charged that those responsible for the studies withheld critical information bearing on diagnosis and the need for treatment.

Beginning in 1988, health departments across the nation, with the support from the federal Centers for Disease Control and Prevention, conducted studies of HIV infection in the population by testing blood samples, stripped of all personal identifiers, that were drawn from hospital, clinic, and emergency-room patients. When subject to ethical review in the 1980s, experts deemed such screening unproblematic.[29] It involved samples of blood, not identifiable individuals. The privacy of no one could be violated. Informed consent was hence unnecessary.[30] But what made the studies—based on unconsented testing—ethically acceptable also precluded notification of infected individuals. Since there was little that could be done for people with asymptomatic HIV infection in the late 1980s, there was widespread consensus that the blinded surveys were ethically permissible and served a critical public-health need.

As early clinical intervention became the standard of care for both adults and infants with HIV, these studies came under legislative, clinical, and ethical attack. Notably, it was only those studies involving women and infants—arguably vulnerable by definition or history—that drew the critical challenge. Nettie Mayersohn, a democratic representative to the New York State Assembly who believed infected babies—most of whom were the children of poor, minority women—had a right to testing and treatment, explained that when she first learned of the CDC studies in May 1993, she was struck by the semblance to Tuskegee: "I was just so astounded. This was the Tuskegee experiment all over again."[31] Mayersohn accordingly introduced her "Baby AIDS Bill" to make newborn HIV testing and parental notification mandatory.

Mayersohn gained press attention for her cause by interesting *New York Newsday* columnist Jim Dwyer.[32] In the opening salvo of his Pulitzer Prize–winning series on newborn testing, he quoted Dr. Arthur Amman, a professor of pediatrics at the University of California and head of the Pediatric AIDS Research Foundation, who was among the first to argue the similarities between blinded surveillance and Tuskegee but who, unlike Mayersohn, opposed mandatory testing. "The maintenance of anonymous test results at a time when treatment and prevention are readily available," he observed, "will be recorded in history as analo-

gous to the Tuskegee 'experiment.' "[33] Amman was joined by Scott Isaacman, a lawyer and staff physician with the Cook County Department of Health, who in 1993 accused epidemiologists of "ignoring the difference between human subjects and laboratory animals" and of using the logic "used by the PHS to abrogate responsibility for the Tuskegee Syphilis studies."[34]

The analogy helped to sharpen the attack on blinded surveillance even as Mayersohn, though not all her allies, sought to promote mandatory newborn testing. As she pressed the legislature to adopt a policy requiring the state to test all newborn babies for HIV and notify parents or guardians of the results, Mayersohn played on themes of Tuskegee's deception.[35] Her most powerful rhetorical challenges, however, drew on Tuskegee's shameless exploitation of the most vulnerable. Mayersohn argued that blinded surveillance was "a policy that conspires to deny medical treatment and care . . . to the most vulnerable among us."[36] She claimed it "unconscionable for us to continue treating helpless babies as useful, but expendable, statistical tools."[37] In 1996, after her mandatory-testing bill passed the state legislature, she jubilantly declared, "We will no longer allow infants to be used as statistical tools in some scientific experiment."[38]

Congressional representative Gary Ackerman, whom Mayersohn had helped elect to the New York State Senate years earlier, took up the gauntlet at the national level. In May 1995 he unveiled legislation to unblind the CDC newborn seroprevalence study.[39] H.R.1289 instructed states requiring infant HIV surveillance testing promptly to disclose that information to a child's parent or guardian. For Ackerman, it was simply unacceptable that unconsented testing continue in a context precluding notification of those needing treatment. Women, he asserted, knew that if their child were infected with a disease like syphilis or hepatitis, doctors would notify them. They had every reason to believe that would also be the case with HIV. Hence, they were the objects of deception when the CDC tested their babies and failed to disclose critical clinical findings.[40] Ackerman's bill sought to unblind the CDC survey, and in so doing sought to achieve his second goal of mandatory newborn testing. It was that second goal that remained clouded to many.

Perhaps because of its ambiguity, Ackerman's "Newborn Infant HIV Notification Act" carried the bipartisan support of more than 220 House members. Most striking, whereas the Mayersohn bill for mandatory testing in New York State was opposed by virtually all African American and Latino activists, the Ackerman bill won the critical endorsement of 31 members of the Congressional Black Caucus, some of whom withdrew their names from the legislation as debate intensified, the question of mandatory testing came to dominate, and Ackerman's alignment with Mayersohn became clear.

So soaked in the rhetoric of Tuskegee was the blinded seroprevalence debate that Ackerman did not even need to name the Alabama atrocity when he made his final bid to unblind the CDC's study on 11 May. Speaking before the House Commerce Committee, Ackerman warned, "There was one point in our society, a very dark day when people were allowed to walk around after being tested with a dread disease just so the medical establishment could . . . see what happens. . . . Let's not fall back to that kind of an era."[41] In response to the broad support behind Ackerman's bill, the CDC—opposed to mandatory testing—preempted Ackerman's proposal and announced it would suspend the newborn serosurvey, effective 12 May 1995. Ackerman, ironically, angrily alleged that the CDC was driven by the simple desire to avoid the taint of Tuskegee.[42]

Despite the fact that local, national, and international reviews of the ethics of blinded seroprevalence studies provoked no objection when they were initially launched, changing therapeutic prospects appeared to alter radically the context within which such efforts were conducted. In this new context, were the charges of "Tuskegee" appropriately applied to the newborn serosurveys? Had not public-health officials chosen to take information from socially marginalized populations without informing individuals that they were the objects of study, without notifying them of their HIV infection, and without offering them potentially effective treatments? That so many political leaders identified with the interests of the most socially vulnerable evidenced deep concerns about the blinded seroprevalence studies suggests that the answer to each of these questions was complex. That those responsible for the conduct of blinded surveys could not give assurance that the communities they identified as being at greatest risk would, in fact, receive the resources needed for HIV care and prevention only exacerbated the situation.

Nevertheless, on several critical accounts, blinded seroprevalence failed to meet basic criteria that could arguably reflect the abuses of Tuskegee. Neither the CDC nor state public-health departments engaged in blinded testing made efforts to deprive individuals of the opportunity for voluntary testing through which they could discover if they were infected. Nor was there an effort to divert women who sought diagnostic testing from treatment for themselves or their infants. Indeed, the very purpose of the studies was to identify *populations* at increased risk for HIV so that efforts to identify *individuals* in need of care could be given the greatest priority. Unlike Tuskegee, which sought to withhold treatment from men with syphilis, officials hoped to use the blinded seroprevalence studies as a prod to enhance the prospects that therapeutic interventions would be directed to those most in need.

Maternal-Fetal HIV Transmission Prevention Trials in the Third World

In the case of Third World trials to prevent maternal-fetal HIV transmission, two core elements of Tuskegee were at issue: the exploitation of impoverished, vulnerable populations and the denial of access to effective treatment.

In February 1994, the Data Safety and Monitoring Board of the U.S. National Institute of Allergies and Infectious Diseases interrupted AIDS Clinical Trial Group (ACTG) Study 076.[43] The preliminary data revealed a statistically significant and dramatic difference in vertical HIV transmission rates from mothers to their newborns between women who received the active regimen and women in the placebo group. The rate for the former was 8.3 percent, for the latter, 25.5 percent.

The regimen quickly became the standard of care in industrialized nations. There is no question but that further placebo-control trials of efforts to reduce vertical transmission in the wake of clinical trial 076 would be considered unethical in the United States or any other advanced industrial nation. No trial that would deny access to the ACTG 076 regimen, or to an intervention thought to hold the promise of being at least as effective as, if not more effective than, the prevailing standard of care, would satisfy the requirements of ethical review.

In developing countries, however, where maternal-fetal transmission represents an epidemiological disaster, the costs of the 076 regimen ($800 for the drug alone) put zidovudine therapy out of reach. In Uganda, for example, the cost of the zidovudine component of the ACTG 076 regimen represented 400 times the yearly per-capita expenditure on health care. It was, therefore, a matter of some urgency that trials begin to determine whether radically cheaper alternatives to the ACTG 076 regimen could achieve some measure of reduced maternal-fetal HIV transmission. In all, 15 placebo-controlled trials—9 funded by the CDC or NIH, 5 by other governments including Denmark, France, and South Africa, and one funded by the United Nations Program on Acquired Immune Deficiency Syndrome (UNAIDS)—were launched in developing countries. All had been subject to careful ethical review.

Nevertheless, on 18 September 1997, Dr. Marcia Angell, executive editor of the *New England Journal of Medicine*, denounced the placebo-control trials in Africa, Asia, and the Caribbean. "Zidovudine," she wrote, "has already been clearly shown to cut the rate of vertical transmission greatly and is now recommended in the United States for all HIV-infected pregnant women."[44] Citing the Declaration of Helsinki for authority, she noted that control groups had to be provided with the best current therapy, not simply that which was available locally. Failure to observe this ethical mandate "could result in widespread exploitation of vulnerable Third World populations for research programs that could not be carried out in the sponsor country." She concluded, "The justifications are reminiscent of those for the Tuskegee study: Women in the Third World would not receive antiretroviral treatment anyway, so the investigators are simply observing what would happen to the subject's infants if there were no study."

Writing later in the *Wall Street Journal*, Angell asserted: "All the rationalizations boil down to asserting that the end justifies the means—which it no more does in

Africa than it did in Alabama. It is easy to see the findings of the Tuskegee study from a safe distance of 25 years. But those so offended by the comparison of the African research with Tuskegee have yet to show how these studies differ in their fundamental failure to protect the welfare of human subjects."[45] Peter Lurie and Sidney Wolfe, who had leveled the charge of Tuskegee in Anchorage, Alaska, provided the basis for Angell's editorial.[46] They stated: "Many people will hear in these experiments echoes of the notorious Tuskegee syphilis study. . . . This time, the people of color affected are babies from Africa, Asia, and the Caribbean, many hundreds of whom will die unnecessarily in the course of this unethical, exploitative research."[47]

Despite the allure of the Tuskegee analogy in studies that denied access to the standard of care in industrialized nations, the disanalogies are striking. However problem-ridden the efforts to obtain informed consent in the Third World settings, it is clear that, unlike Tuskegee, investigators made efforts to inform the enrolled women that they would be part of a study to reduce maternal transmission of HIV and that some would receive a placebo. Additionally, no effort was made to exploit the social vulnerability of the women involved. Indeed, it was the very poverty of *the nations within which these women lived* that served as the predicate for the challenged studies. Only to the extent that women living in poor Third World countries could be said to have a realizable claim on the care available to women in industrialized nations would the conduct of a placebo trial have mirrored the deprivations of Tuskegee. But then any trial to find a cheaper and potentially less effective regimen than that which was standard in the industrialized world—whether it relied on a placebo-control design or not—would have been unethical as well. To the extent that the search for a less costly and potentially less effective intervention could be justified by the desperate need to find affordable interventions, the analogy to Tuskegee was simply misleading.

Yet to the extent that women in poor countries have a moral—as contrasted with a realizable—claim on the care available to women in industrialized nations, critics helped to underscore the profound injustice that characterizes the world distribution of medical resources. Unfortunately, the invocation of Tuskegee launched a furious methodological debate that diverted attention from an analysis of the very poverty and inequality that necessitated the challenged studies.

Conclusion

When we understand Tuskegee as emblematic of a history of racism and the experience of social, economic, and political disempowerment, its legacy does much to explain the atmosphere of mistrust that surrounds research, especially

when the subjects of study are poor, vulnerable, and the potential targets of exploitation. That legacy is especially helpful in explaining the profound suspicions expressed by African Americans when the prospects of medical experimentation present themselves. Thus understood, Tuskegee heightens the importance of carefully and sensitively seeking to establish trust where it is absent or where historical experience has shattered it. As important, Tuskegee can draw our attention to the inevitable moral challenges that will emerge when research involves those who, for cultural, historical, political, or economic reasons, are socially vulnerable.

But for Tuskegee to serve as a useful analogy for illuminating research abuse, the challenged study must meet some reasonable, general criteria. It must involve deception regarding the nature and very existence of the research study; it must capitalize on social deprivation or vulnerability; and, not only must it fail to provide the best available effective therapy, but it must also contrive to keep individuals from receiving such therapy.

The past decade has demonstrated that the charge of "Tuskegee" is extremely effective in riveting public attention, but just as research demands of its practitioners that they adhere to standards of moral responsibility, challenges to research carry with them certain moral obligations. Those who would use Tuskegee to indict research efforts bear responsibility for how they deploy the legacy of that awful historical episode.

Not every disagreement about whether a particular study raises troubling ethical questions justifies the invocation of Tuskegee. Not every ethical lapse involving vulnerable populations is the equivalent of Tuskegee. Finally, not every injustice in the social context within which research occurs recreates the conditions that prevailed and were exploited in Alabama. The reckless invocation of the misdeeds of federal researchers between 1932 and 1972 risks derailing serious and sustained discussion of the unique dilemmas posed by contemporary research with vulnerable populations under conditions of social deprivation. Tuskegee is an unwieldy weapon in public discourse. It makes current research abuses, when subject to careful scrutiny, pale in comparison to the historic syphilis study, thus minimizing their gravity. Alternatively, in instances where contemporary problems in justice exceed the bounds of Tuskegee, its invocation ironically guarantees inadequate discussion. The ethical challenges raised by the problems of drug use, ensuring access to HIV testing and treatment resources for those in greatest need, and the world economic order should not require "Tuskegee" to merit our attention.

In the end, the abuse of Tuskegee has consequences not only for present discussion but also for the past. It threatens to rob Tuskegee of its unique value and meaning. It misuses the memory of the 399 African American men whose most basic rights were violated for 40 years. In so doing it diminishes the significance of their suffering.

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