The Cure at a Crossroads: The Intersection of Ethics and Ambition in AIDS Research

The Cure at a Crossroads: The Intersection of Ethics and Ambition in AIDS Research

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Abstract:

This paper explores the structure of the major code of ethics regarding human experimentation, the Nuremberg Code. The paper begins with an explanation of the modern ethical standards and how they were established. Following this background is an inquiry into the actual force the Nuremberg Code carries in American courts, and how cultural values are reflected in the courts' decisions. These ethical codes are then explored through the lens of the AIDS vaccine research being conducted currently in Africa and other third-world countries. This more philosophical part of the paper questions the strength of the Nuremberg Code, and highlights some of its weaknesses with regards to real-life crises. In conclusion, the paper exposes the many conflicting aspects of this ethical debate between human autonomy and medical emergency and reveals that while perhaps there is no "right" answer at this time, the debate itself is a valuable check on our ambitions.

I. Introduction

The progression of modern science has given the world the ability to control and conquer deadly diseases, and to understand how the human body functions. Babies born today in wealthy countries like the United States of America enjoy average life expectancies of 76.7 years[1]. The eradication of smallpox and polio are only two of the myriad triumphs that science has had over the cruelties of nature, and many in the scientific community continue to search for new and innovative ways to cure disease. Congress spends billions of dollars a year funding medical research in hopes that breakthroughs can be made that will save lives and further improve the quality of life and healthcare for Americans and citizens of the world. However, the money dispersed by Congress is not divided according to how many victims of each disease there are, but rather is a game of politics, with those groups possessing lobbying power and visibility receiving disproportionate amounts of funds.[2] This method of division reflects not only the power of lobbying, but also the different levels of urgency that surround different diseases. Whereas many methods currently exist for controlling and treating ailments like heart disease, viruses such as AIDS remain elusive killers, with no methods of prevention known, apart from education and behavioral practices.

The AIDS pandemic is under a certain level of control in the United States and in Europe, but recent years have shown that it has reached staggering, plague-like levels in sub-Saharan Africa, with cases in Asia on the rise as well. In sub-Saharan Africa it is estimated that nearly 30 million people are living with HIV/AIDS. In 2002 there were 3.5 million new infections and 2.4 million deaths. In India approximately 3.9 million people were living with HIV at the end of 2001, and current research shows this number is increasing rapidly.[3] AIDS

[1] G. Scott Thomas. "Life expectancy study: Lucky white females." Washington Business Journal. January 18, 2002.

[2] For every $10 spent per cancer death on cancer research, $110 is spent per AIDS death on AIDS research and $3 is spent per heart disease death on heart disease research. See CRS Report 97-917: Disease Funding and NIH Priority Setting

[3] All statistics from AIDS Epidemic Update. UNAIDS, December 2002.

is a modern-day plague. The U.S. is under increasing pressure to lead the world in contributing money and research to fight the spread of this disease, and there are political, economic, social, and humanitarian reasons why it should do so. The hunt for a vaccine has been in progress for nearly two decades, ever since the disease appeared on the scene, at first primarily in gay men and intravenous drug users. The course of this research reflects not only the practices and idiosyncrasies of the scientific method generally, but also raises difficult questions of ethics and morality.

Research has been conducted on human beings for most of recorded history, as Romans performed vivisection on slaves and gladiators and Hippocrates declared that true physicians must not do harm to their patients.[4] In the modern era, however, human rights groups such as Amnesty International pay careful consideration to experiments being done on human beings, even in the most hidden and secretive circumstances.[5] Most scholars on the subject of ethics relating to experimentation on human beings explain our modern standards as the result of an increasing awareness of worldwide practices, and the lingering influence of one of the most tragic episodes in the history of scientific research—the Nazi experiments during World War II. Today's standards set clear guidelines for human experimentation, with primary emphasis on the importance of informed consent. These strict rules, however, can be an impediment to important studies that may lead scientists to breakthroughs in the field of AIDS research. A closer examination of the history of these standards, and their actual use and importance, will reveal that much of the research being performed today crosses ethical lines into gray areas that must be explored. The United States, which presided over the Nuremberg trials themselves, must decide whether it is willing to compromise its purported values and ethics in the name of scientific progress. Does the end goal of a potential AIDS vaccine justify the breach of clearly mandated ethical standards? In the current race to find a cure, ethics may become just another

[4] "Primum non nocere." (First do no harm) from Hippocratic Oath, 5th century B.C.E.

[5] Amnesty International Health Professionals Network groups campaign on behalf of prisoners who have been subjected to violations of human rights that have a health-related perspective, such as deprivation of medical care and breaches of medical ethics. See www.amnesty.org

casualty.

II. Modern Standards Regarding Human Experimentation

The standards that exist today can only be clearly understood through the lens of history, by examining the events that inspired their adoption. There is a long history of human experimentation. An early example comes from 1796, when Edward Jenner injected a healthy eight-year-old with cowpox, and then smallpox, helping to discover the vaccine.[6] In 1906 Dr. Richard Strong, a professor of tropical medicine at Harvard, experimented with cholera and killed 13 prisoners.[7] But it was the horrors of the Nazi concentration experiments during World War II that propelled the world to consider the adoption of international standards of ethics for human research. The experiments performed by Nazi doctors demonstrated a reckless disregard for the value of all life considered "other" by the Aryan establishment.

The experiments themselves are so horrific as to be nearly unimaginable. Hitler enlisted doctors to help justify his racial policies with "scientific" proof, and also to run his death camps and experimental labs.[8] In one experiment performed at Dachau, inmates were placed in chambers that simulated altitudes as high as 68,000 feet, in order to see how German soldiers would react if they had to eject from their aircraft at high altitudes. Sigmund Rascher, who performed these experiments, was said to have dissected the victims' brains while they were still alive in order to show that tiny air bubbles in the brain caused the damage. Of the 200 people who were used in this experiment, 80 died immediately and 120 others were executed

[6] See "A Chronology of Human Research" by Vera Hassner Sharav. See www.researchprotection.org/history/chronology.html

[7] Id.

[8] Annas, George J., Grodin, Michael A. "Medical Ethics and Human Rights: Legacies of Nuremberg" Hofstra Law and Policy Symposium 1999 p.112

thereafter.[9]

In another infamous study, Dr. Josef Mengele studied pairs of twins in order to find a way to quickly increase the Aryan population. After collecting data from the twins, Mengele murdered them with chloroform shots to the heart, although amazingly 20% of the pairs managed to survive.[10] Clearly, people all over the world were shocked and horrified upon hearing of these atrocities. And though this spurred the Doctors' Trials at Nuremberg, and the adoption of the Nuremberg Code, American researchers continued to perform fundamentally unethical experiments with human subjects.

One of the darkest chapters in American scientific research history was the Tuskegee syphilis study. The study began in 1932, and for 40 years poor African-American men with syphilis were followed while doctors studied the natural course of the disease. The men were not informed of their condition, or the purpose of the study. Penicillin, a known cure, was never administered to these men.[11] In fact, the experiment was so horrendously unethical that President Clinton felt it was necessary to make an official apology to the survivors and the families of the victims. In his official statement he said: "The United States government did something that was wrong – deeply, profoundly, morally wrong. It was an outrage to our commitment to integrity and equality for all our citizens. To the survivors, to the wives and family members, the children and the grandchildren, I say what you know: No power on Earth can give you back the lives lost, the pain suffered, the years of internal torment and anguish. What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful, and I am sorry."[12]

The Nazi experiments and the Tuskegee study are only two examples of ethical violations that have occurred in the field of scientific research on humans. There are countless other examples, both known and unknown.

[9] http://www.pbs.org/wgbh/nova/holocaust/experiside.html
[10] Id.
[11] Jones, James H. Bad Blood: The Tuskegee Syphilis Experiment. New York : Maxwell McMillan International, c1993.
[12] The White House, Office of the Press Secretary. "Apology for Study Done in Tuskegee." May 16, 1997

But it was the high visibility and extremity of the Nazi doctors that helped to create an international discussion on ethical standards.

There are two codes that shape most modern approaches to human experimentation. The earlier document is the Nuremberg Code, created in 1947 following the Doctors' Trials at Nuremberg. The trial, which began in December of 1946, was under the order of the American Military Tribunal. Twenty-three German doctors were tried for crimes against humanity. Seven were eventually executed. In his opening statement, the prosecutor explained that "in some instances the true object of these experiments was not how to rescue or to cure, but how to destroy and kill. The sterilization experiments were clearly purely destructive in purpose. The prisoners at Buchenwald who were shot with poisoned bullets were not guinea pigs to test an antidote for the poison; their murderers really wanted to know how quickly the poison would kill."[13] The evidence introduced in this trial was obviously shocking and disturbing. The result of this outrage was the Nuremberg Code.

The Code emerged because two of the American doctors who had worked with the prosecution were worried because some of the defendants had argues that there existed no international code on the ethics of human experimentation. Dr. Alexander therefore submitted to the United States Counsel for War Crimes a memorandum containing six basic factors that defined legitimate human research. In the verdict of the trial these six points were expanded to ten, and these factors became known as the Nuremberg Code.[14] The main tenet of the Code is the value of informed consent, as embodied in principle one: "The voluntary consent of the human subject is absolutely essential." The judges went on to explain in detail what such consent entailed, and stressed that in weighing the competing interests of the individual's autonomy and freedom and the

[13]From the opening statement by Teleford Taylor [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O, 1949–1953.

[14]See The United States Holocaust Memorial Museum online, http://www.ushmm.org/research/doctors/code_expl.htm

advancement of science, the rights of the individual should always triumph.[15] The other nine principles are as follows:

> 2. The experiment should be such so as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
>
> 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
> 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
> 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
> 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
> 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
> 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
> 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
> 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.[16]

In the years following the Nuremberg Trials, many physicians felt as though the Code was deficient and inapplicable to basic research, having meaning only in the context of war crimes.[17] In response to this dissatisfaction, the World Medical Assembly adopted the Declaration of Helsinki in 1964. This document consists of recommendations to physicians by physicians, making it more relevant to the realities of research.[18] But the basic ideas of the Nuremberg Code are still held up as an example of basic standards of ethical

[15]Katz, Jay. "Human Sacrifice and Human Experimentation: Reflections at Nuremberg." Yale Journal of International Law. Summer 1997. p.413

[17]Roman, Joanne. "U.S. Medical Research in the Developing World: Ignoring Nuremberg." Cornell Journal of Law and Public Policy. Spring 2000 p.451.

[18]Id. at 452

research. The Code, however, has not been formally adopted as law. By examining the role the Code has played in American courts it becomes clear that, while the intentions of the judges who promulgated this Code were salutary, the courts in the United States since World War II have not used the Code directly as a measure of ethical behavior.

In one of the earliest American court cases discussing the role of consent in experimentation, the Supreme Court of Michigan stated that "if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure."[19] This attitude of encouragement for medical innovation has played an important role in shaping the way courts have handled these difficult ethical questions. Americans have always prided themselves as being on the cutting edge of scientific progress, forging the road into a future of cures and vaccines. Another pre-World War II case illustrates this appreciation for new techniques in the medical arena. In 1941 in New York, a physician had his license taken away after being accused of fraud and deceit when he treated a cancer patient with an experimental formula after informing the patient that it may or may not work, but would not be harmful. The patient consented to this line of treatment.[20] The court overturned the suspension and noted that "it is not fraud or deceit for one already skilled in the medical art, with the consent of the patient, to attempt new methods when all other known methods of treatment had proved futile and least of all when the patient's very life has been despaired of. Initiative and originality should not be thus effectively stifled, especially when undertaken with the patient's full knowledge and consent, and as a last resort."[21] This court reflected the American values of innovation and progress, and declared that as long as there was consent, such methods were ethically acceptable. Other pre-War cases espoused the same

[19] Fortner v. Koch, 272 Mich. 273, 282 (1935)
[20] Stammer v. Board of Regents, 262 A.D. 372 (N.Y. App. Div. 1941)
[21] Id. at 373-374

standards.[22]

As World War II drew to a close, America and the world began to learn about the hidden horrors of the Nazi regime. Stories of experiments and torture were revealed, some too horrible to even believe. As previously discussed, these experiments were tantamount to physical and psychological torture, performed under the auspices of "medical" research. In fact, the Jewish, Gypsy, and countless other "undesirable" victims were simply discarded as valueless under Nazi rule. The Nuremberg trials put these medical doctors and Nazi officials on trial for crimes against humanity, and the entire free world declared their intent to create a world in which this kind of tragedy could never occur again. In America, however, the newly created Nuremberg Code was not discussed in the courts until decades after the close of the trials. This is quite curious, considering that all the judges at the Doctors' Trial were American, as well as the prosecutors.[23] Before 1973, the only time the Nazi doctors were even alluded to was by a dissenting judge in a case that allowed the transplant of a kidney from an institutionalized individual for his brother. Judge Steinfeld stated that "because of [his] indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies [he] ha[s] been more troubled in reaching a decision in this case than in any other. [His] sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society."[24]

Utilitarianism seemed to be the American value most relied on at this time, as the Cold War loomed and the excitement over the polio vaccine justified its being tested on institutionalized mentally retarded children.[25]

[22]See Bonner v. Moran, 126 F.2d 121, 121 (D.C. Cir. 1941) (ordering a retrial and stating that a finding of parental consent would justify a surgery on a 15 year old boy)

[23]Annas, George J. "Mengele's Birthmark: The Nuremberg Code in United States Courts." Journal of Contemporary Health Law and Policy. Spring 1991 p.24

[24]Strunk v. Strunk, 445 SW2d 145, 149 (Ky. Ct. App. 1969)

[25]Annas at 24

One of the next cases to refer to the Nuremberg Code was not until 1980, in a New Jersey Supreme Court case involving a physician who was fired when she refused to continue developing and testing a drug because she believed one of the ingredients to be harmful and argued that the Hippocratic oath prohibited her from continuing the research.[26] The New Jersey Supreme Court declared that "Dr. Pierce espouses a doctrine that would lead to disorder in drug research. Under her theory, a professional employee could redetermine the propriety of a research project even if the research did not involve a violation of a clear mandate of public policy. Chaos would result if a single doctor engaged in research were allowed to determine, according to his or her individual conscience, whether a project should continue."[27] In dissent, Judge Pashman explained the societal value of ethical codes, and cited the Nuremberg Code as one of four examples of ethical constraints put on those in the medical profession.[28] The majority concluded that the ingredient was merely controversial and not declared unsafe, and hence the physician was not entitled to further employment simply because her sense of ethics was offended.[29] This court seems completely insensitive to fact that it was not simply her personal ethics that were challenged, but also her ethics *as a physician*. It seems only the sole dissenting judge recognized the importance of this distinction. As shown from this exploration, the American courts did not openly embrace the spirit and meaning of the Nuremberg Code, instead putting a high value on the benefits of innovation and experimentation. In fact, even a case which did cite the Nuremberg Code as the standard of ethics of nontherapuetic research found a doctor *not liable* for failing to warn of risks the could not be declared "reasonably foreseeable".[30]

The Supreme Court did not directly discuss the Nuremberg Code until 1987, in the context of the United States military.[31] In the Stanley case, the plaintiff, James Stanley, was given LSD without his knowledge

[26] Pierce v. Ortho Pharmaceutical Corp., 84 N.J. 58 (1980)
[27] Id. at 75
[28] Id. at 80
[29] Id. at 75
[30] See Whitlock v. Duke University, 637 F. Supp. 1463 (M. D. N. C. 1986)
[31] United States et. al. v. Stanley, 483 U. S. 669 (1987)

or consent, in order for the Army to test how soldiers performed under the influence of this hallucinogenic drug. Stanley's mental health was permanently damaged, resulting in his divorce. In fact, he was not even informed that he had been given LSD until 1975.[32] In Justice Scalia's opinion, he stated that an active serviceman could not sue the government for injuries sustained as a result of experimentation, even though this particular experiment clearly violated the Nuremberg Code's requirement of informed consent. Such a finding indicates that the Code was simply a guideline with no teeth. In his partial dissent, Justice Brennan explicitly emphasizes the importance of the Nuremberg Code and the historical era out of which that Code arose.[33] This is a difficult case to use as a measure of the role of the Nuremberg Code in the Supreme Court, however, because it is easy to distinguish the case based on its military context. The only other Supreme Court case to mention Nuremberg does so only in a footnote about informed consent.[34] This, however, was in the contexts of prisons, yet again a very particularized situation. In whole, the Supreme Court has given little indication as to the role of the Nuremberg Code in American cases. Perhaps America imagines itself as so distant from Nazi Germany that it does not clearly see the relation it should have to the Nuremberg Code. Overall, the case law in American courts shows an emphasis on innovation in science and technology, not a strong insistence on human rights. This general sensibility translates to the world outside of the courtroom as well, as modern crises put pressure on the scientific community.

III. Ethics in Practice

The modern day AIDS epidemic provides a clear illustration of the dilemmas that arise when scientific

[32] Annas at 38
[33] Stanley at 687
[34] Washington et al. v. Harper, 494 U.S. 210, 237 (1990)

research is constrained by ethical codes, and how American researches have responded to, and eluded, such constraints. The areas of the world most devastated by this disease are the least developed countries, particularly sub-Saharan Africa.[35] Since 1997 the Center for Disease Control (CDC) has been sponsoring research trials in Africa and other regions of the world in which researchers study the transmission of HIV from pregnant women to their babies. This study is an attempt to find a cheaper way to prevent this transmission, though a more expensive long-term AZT treatment already exists.[36] Despite the fact that this treatment already exists, the research done by the CDC uses a placebo group to compare results, a decision which will lead to the infection of more than 1,000 babies.[37]

The implications of using a placebo group when a known treatment exists are quite complex and raise many moral issues. Many critics believe that using a placebo when a known treatment exists is inherently unethical, especially when the disease in question is a fatal one.[38] Beyond the use of a placebo, some trials in developing countries are conducted in a manner such that the participants are not as informed of the details of the study and of their own health as they would be in America. For example, in one Ugandan community, an experiment was conducted to test the effects of increased viral loads on heterosexual transmission of HIV. A total of 415 couples were enrolled, one partner in each pair being HIV positive. The researchers visited the pairs four times over the course of 30 months and collected data and specimens. Ninety people became infected with the virus over this time period, during which the researchers never informed them that their partner was HIV positive, and did not offer anti-retroviral drug therapies.[39] The results showed that increased viral load did increase the likelihood of transmission of HIV through heterosexual sex and that anti-retroviral drugs could help reduce this spread. However, such drug therapies are too expensive to be

[35]Pitler, Lisa. "Ethics of AIDS Clinical Trial in Developing Countries: A Review." Food and Drug Law Journal, 2002. p.134
[36]Dyckman, Jay. "The Myth of Informed Consent: An Analysis of the Doctrine of Informed Consent and its (Mis)application in HIV Experiments on Pregnant Women in Developing Countries." Columbia Journal of Gender and Law, 1999. p. 92
[37]Id. at 93
[38]Pitler at 139
[39]Pitler at 145

available in countries like Uganda. This pricing dilemma is why trials are conducted that attempt to find cheaper alternative methods, thus leading to the use of placebo groups.

Beyond the obstacle of cost, many other barriers exist to providing affordable treatments in these underdeveloped countries. Issues of lack of education, access to both pre- and post-natal care, illiteracy, male sexual dominance, lack of alternatives to breastfeeding, and home delivery births all contribute to the difficulty of providing known treatments for AIDS patients in Africa.[40] Acknowledging that a crisis exists, and that if it is not stopped, millions of people will die, researchers are placed in an ethical dilemma: do they do whatever experiments will lead them to a cure or vaccine most rapidly, thus saving lives?; or do they adhere strictly to all ethical standards practiced in developed countries, thus stunting the progress of their work and losing countless patients to the disease?

One of the largest criticisms of these trials is that "the researchers and their sponsoring governments adopted an ethical 'double standard': the use of the placebo in such a clinical trial would never have been allowed in a developed country because of ethical principles."[41] All trials conducted in America are subject to the law of Title 45 of the Code of Federal Regulations, Part 46, which is promulgated by the Department of Health and Human Services. This statute applies to all experiments using human subjects conducted within the United States. In addition, section 46.101(h) notes that if the research is being done in a foreign country, that country's procedural requirements may be substituted *if they are equivalent to those provided by the statute*. This last point of the rule is often ignored by researchers in foreign countries, as they attempt to escape the more rigid regulations required by American laws. For instance, in the United States, offering a trial where the known AZT treatment was not offered and instead a placebo was used would be difficult to justify and would not pass ethical review because the AZT treatment is readily available.[42] By going

[40]Pitler at 147

[41]Fidler, David P. "'Geographic Mortality' Revisited: International Relations, International Law, and the Controversy Over Placebo-Controlled HIV Clinical Trials in Developing Countries." Harvard International Law Journal, Summer 2001 p. 303

[42]Pitler at 141

to third-world countries, however, researchers are able to escape these requirements because the alternative treatment in those locations is, quite sadly, nothing. Therefore, providing at least some of the research subjects with treatment is better than what they would otherwise receive.

The researchers' goals are noble, as they search for a way to alleviate this crisis while being constrained by the reality of the depressed economies of these African nations. For instance, in Malawi, the cost of the anti-retroviral treatment for an HIV-infected woman and her child (which is affordable in the United States) is greater than 600 times the yearly per capita expenditure for healthcare.[43] Faced with such dismal statistics, it is no wonder these physicians and scientists want to find a vaccine as soon as possible. The question that must be faced, however, is at what cost does this cure come? History has taught that people can be blinded by external forces such as war, or threat to national security, or fear of death. The Nazi doctors illustrated the lowest depths to which humanity can sink in its treatment of fellow human beings. But ethical violations do not have to be as extreme as they were in World War II to be rendered egregious or unacceptable. Many aspects of the work the researchers in Africa are performing cross boundaries into ethical gray areas, and a further exploration of the main areas of concern will help illuminate the dilemmas these researchers face.

The first difficult issue arises straight out of the Nuremberg Code itself, which stresses above all else the value of informed consent. Does such truly informed consent exist in the context of the AIDS trials in Africa and other third-world countries, or is it merely a fiction? Many critics believe it is impossible that the consent these research subjects give is as informed as the Code intended "informed" to mean. The judges who created the Nuremberg Code placed heavy emphasis on the concept of informed consent. They did not merely state that such consent is necessary, but went on to define it in terms of the research subjects' capacity and the type of information that must be provided.[44] The judges stated that a research subject should be informed

[43]Pitler at 142
[44]Katz at 413

of all possible risks and hazards to be expected, the nature and duration of the experiment, and should have sufficient comprehension of the topic to ensure that his or decision to truly informed. In addition, it is the researcher who is responsible for ascertaining the quality of the consent given.[45] These standards, rigorous on their own, become even more difficult to fulfill when viewed in light of the reality of the educational level of many of the subjects, and the feasibility of relating often complex scientific information.

One of the obstacles in obtaining informed consent in the context of these AIDS trials is the manner in which the subjects view the researchers. One advisory Committee found that patients-subjects "believed that 'an [experimental] intervention would not even be offered if it did not carry some promise of benefit [for them],' and that therefore the consent process was 'a formality' to which they need not give much thought."[46] In this type of setting, where the patient-subject equates research with therapy, it is difficult to believe that these subjects understand that the consent they are giving allows for the possibility that they may be receiving no help at all, but merely a pill made out of sugar. Examining the actual testimony of some African participants illustrates how what the researchers believed was informed consent was in fact not very well informed at all. One participant, a 23-year-old woman infected with HIV, was repeatedly asked about placebos and why they are used. The woman replied that she was given many different pills and that she believed that " 'if one of them didn't work against AIDS, then one of the other ones would."'[47] This woman, like many others in these trials, was illiterate, unemployed, and unmarried, and this trial was the only chance she had of obtaining any sort of treatment at all.

Even the more educated participants can be misled into consenting to clinical trials. One single mother who had her law degree explained that she was never told that there was a known AZT treatment that prevented transmission of HIV from a pregnant woman to her unborn child. When she was asked how she would feel if she knew she was given a placebo instead of this known treatment, her "tone changed

[45]Katz, footnote 50
[46]Katz at 417
[47]Dyckman at 98

abruptly. '[She] would say quite simply that is an injustice."'[48] In countries where healthcare is absolutely unaffordable for these patients, is consent truly consent? Is there really an option for these subjects? In a society where women are subjugated socially, economically, politically, and sexually, "it is deeply problematic to label their decision to volunteer a freely made choice."[49] Sometimes the governments of these third-world countries allow experiments to take place on their citizens that would violate standards in the modernized world, and thus citizens are put at risk as the result of foreign researchers taking advantage of lower standards of ethical treatment. One example of this took place in Haiti, where a study took place of couples in which one partner was HIV-positive and the other was not.[50] While in the United States there is an available drug (Zidovudine) that can help stop the spread of the virus from one partner to another, this treatment was being withheld from the Haitian participants. In addition, the Haitian doctor in charge of the trials (a professor at Cornell), told the HIV-positive participants to provide three "healthy" subjects to serve as the control group.[51] This type of behavior would never be permitted in the United States, but this study survived in Haiti nonetheless. This oversight can be attributed in large part to the limited resources of the Office for Protection from Research Risks (OPRR) in the Department of Health and Human Services. With thousands of projects to review, the truth is that the ones performed domestically receive greater attention.[52]

It is the most vulnerable populations, therefore, who receive the least amount of protection from ethical guidelines and restrictions. In the Nazi camps the people used against their will as subjects in research were deemed by Hitler's government to be of less value than Aryan citizens. Their bodies were thought to be disposable, merely tools for the Germans to use to advance their own agenda. By making the Jews, Gypsies, homosexuals, and countless other "undesirables" into "the other," the Nazis could justify their behavior to

[48]Id. at 99
[49]Id. at 100
[50]Daniels, John. "U.S. Funded AIDS Research in Haiti: Does Geography Dictate How Closely The United States Government Scrutinizes Human Research Testing?" Albany Law Journal of Science and Technology, 2000 p. 207
[51]Id. at 220
[52]Id. at 219

themselves. The thought of white doctors from rich countries entering poor Black countries to do medical experiments raises similar issues about subject as "the other" and invites further exploration into the fine ethical lines that can be crossed even with the best intentions. Despite the fact that these scientists want to help these people fight AIDS, not kill them like the Nazis did, the relative power positions of the subjects and the researchers means that the Nuremberg Code should be even more closely followed, not side-stepped in the name of convenience. Why are poor Black people being subjected to trials that American citizens would not tolerate? Americans must ask themselves if the fact that some help is better than none justifies using ethical standards on other populations that are substantially lower than those we expect in our country.

Beyond the differences in levels of regulation, another disparity that must be addressed is the possibility that those who are being subjected to these trials may not be the people who end up benefiting from the results. Given the economic distress in these countries, it is likely that, even if a vaccine or extremely effective drug treatment were discovered as a result of these trials, the countries in which the experiments took place would not be able to afford such therapies as soon as they became available.[53] The scientists and physicians involved in these studies are committed to using scientific progress and innovation to find the cure for AIDS, or perhaps just a vaccine. As discussed previously with regard to the case law on this matter, the American attitude embraces this focus on progress and technological advancement. American society encourages creativity and innovation, and thus the inherent and societal values of many of the researchers often blind the counter-weight of ethics and human rights. What emerges can be viewed as a benevolent paternalism, wherein the wealthy white countries are telling the poorer Black ones what is good for them in the long run. This is a difficult subject to ponder because the intentions of the researchers are good; but is that good enough to justify the kinds of experiments that have taken place? Many argue it is not.

Critics of these trials advocate for stricter adherence to the Nuremberg Code. But some people argue that

[53]Specter, Michael. "The Vaccine." The New Yorker. February 3, 2003 p. 57

data obtained through unethical means should not be used at all. This is an argument mostly used in the context of the Nazi experiments, where the atrocities were so devastating that use of the information gathered seems to some to defile the memories of the lives lost. Some advocates of non-use do so on the principle that the scientific practices used by the Nazi doctors were simply faulty. This argument claims that "first, drawn as they were from the death camps, experimentees were usually malnourished, emaciated, and severely weakened, and thus their physiological responses to the experiments would likely be different from those of normal, healthy people. Second, Nazi doctors had political aspirations and sought results that supported Nazi racial theories. Third, the data were never replicated and, in an ethical world, can never be replicated."[54] However, some experiments, like the hypothermia experiment, produced data that could potentially save lives and has been cited in medical literature.[55] This conundrum presents a difficult choice between disqualifying the data because of its faulty methods, or using the beneficial data that was obtained to help save future lives. But beyond this initial conundrum, an even more difficult issue arises: Is it moral to use the results of these experiments?

The moral issue of non-use as a memorial touches the deepest depths of ethical beliefs and human rights, and challenges people to see how far these doctrines should go. Museums, statues, and the preservation of concentration camp barracks have memorialized the Holocaust. Some advocates of non-use argue that sacrificing scientific data as a memorial is no different than sacrificing the potentially valuable real estate on which the preserved barracks stand.[56] Mostow argues that because non-use interrupts the normal flow of scientific research, it "can lift scientists out of their esoteric world and reconnect them with lifeworld symbols. Non-use can thus interject lifeworld values into the scientific enterprise. Specifically, it can convey the message that science must not become detached from human values."[57] The idea of non-use as memorialization is

[54] http://www.pbs.org/wgbh/nova/holocaust/experi02_yes.html

[55] Id.

[56] Mostow, Peter. "'Like Building On Top Of Aushwitz': On the Symbolic Meaning of Using Data from the Nazi Experiments, and on Mom-Use as a Form of Memorial." Journal of Law and Religion, 1993/1994 p. 405

[57] Id. at 416

countered by the notion that perhaps use of this data, if helpful, can be a way to make sure these victims did not die in vain. The debate between these two viewpoints can never be resolved, sadly, because the world will never know what the victims would have wanted.[58] This dilemma intersects with the discussion of the ADIS trials when Mostow admits that perhaps if some of the data that was obtained had the potential, through its use, to save millions of lives, then perhaps the benefits would out weigh the costs.[59] The difficult questions remains, however, because no one can say for certain whether or not these trials in third world countries will lead to the cure for AIDS. If they do, it is likely that the retrospective view would be that these experiments, even though perhaps not adhering strictly to the doctrine of informed consent, were worth it because an AIDS vaccine or cure exists and millions of lives would be saved. If, however, the trials are utter failures, many critics may argue that people were exploited and their dignity and autonomy violated simply because of researchers' obsession with conquering this viral enemy.

Non-use is an extreme form of memorialization and carries with it potentially far-reaching consequences. Upon considering the remembrance of these victims, Jay Katz, a leading scholar in the field of bio-medical ethics, is reminded of the passage in Deuteronomy, "Tzedek, tzedek, tirdof" (Justice, justice, shalt thou pursue). There has been much discussion of the meaning of saying justice twice, and Katz gives an example of one explanation, which stresses that justice cannot simply be a goal or an idea, but rather is reflected in the means employed to attain the goal.[60] By focusing on the means instead of simply the end goal of justice, one can see how perhaps non-use is an appropriate response. However, when faced with the reality of the AIDS virus, Mostow's own exception about cost/benefit analysis seems more appropriate. If the trials in Africa and Haiti lead to the cure, most people would be willing to accept the quality of informed consent that is generally obtained.

[58]Cohen, Baruch C. "The Ethics of Using Medical Data from Nazi Experiments." See http://www.jlaw.com/Articles/NaziMedEx.html

[59]Id. at 418

[60]Katz at 418

In defending their behavior, the American researchers often employ just that argument, stressing the dire consequences of inaction and the beneficial treatment many of these participants are receiving. Upon learning of the experiments using placebos, many health and human rights advocates became incensed with the CDC and called for such research be discontinued. In a letter to Donna Shalala, then-Secretary of the Department of Heath and Human Services, the director of the Public Citizen's Health Research Group, Sidney Wolfe, demanded that Shalala "immediately order the researchers to stop any arm of their studies in which women are denied access to antiretroviral drugs and to provide at least short-term AZT for all women now getting a placebo or other unproven treatments."[61] Wolfe discussed the problems with the informed consent being given and even compared the study to the infamous Tuskegee syphilis experiment. But the CDC defended its actions by saying that "a placebo control will provide the best scientifically valid and credible comparison to confirm the efficacy and safety of short course AZT under developing country conditions."[62] The CDC emphasized that these women were getting more care than they would under their own country's health care system and argues that experiments should be done in the communities most at risk.[63]

Beyond defending these experiments, the CDC also went on the offensive, turning a popular argument on its head when they declared that critics of these experiments were culturally insensitive in demanding that African countries employ the same standards as Western countries.[64] Most critics use that argument when accusing the United States of imposing their own values and standards, but here the CDC was being attacked for *not* imposing its own standards and values, but rather for adopting the standards of the countries in which the research was being performed. In bolstering its argument, the CDC claimed that the African countries employed a more communal approach to ethics and that imposing an American, individual-based

[61] Letter to Dept. of HHS (HRG Publication #1430). See www.citizen.org/publications/print_release.cfm?ID=6627

[62] Henderson, Charles W. "Ethics CDC Explains Its Stand on Controversial Third World AZT Study." AIDA Weekly Plus, Monday July 28, 1997.

[63] Id.

[64] Dyckman at 103

system would be inappropriate.[65] In addition, the CDC researchers emphasized the oft-repeated truth that these women, in the absence of these clinical trials, would be receiving absolutely no health care at all, thus indicating that, in a sense, "beggars can't be choosers." This justification is quite persuasive, but Dyckman makes a strong counterclaim by asserting that the researchers manipulated the situation to defend their behavior, explaining that in reality, the African communities are not choosing these standards at all; in fact, they have no choice. Either they accept the Western system of testing, or they cannot participate.[66]

These two different perspectives on cultural relativism provide one of the most interesting and thought-provoking aspects of this debate. If advocates of third-world cultural autonomy oppose imposition of Western values generally, why do they support the imposition of these same values in this particular area? This could be an example of hypocrisy at work, or perhaps it does in fact fit into the framework of a preservation of these individuals' autonomy. Whatever one's position is on that issue, it seems clear that the CDC sees the AIDS pandemic as an emergency, which must be addressed immediately and vigorously, and they are content with the level of ethical compliance in the clinical trials. On the other side of this debate, many human rights activists believe these trials are an example of Western exploitation of foreign bodies, motivated by an obsession with technological advancement and achievement. These activists argue that all aspects of the Nuremberg Code and Helsinki Document should be adhered to in all countries around the world, and that crisis is not an excuse for abandonment of these cherished principles.

IV. Conclusion

[65] Id. at 105
[66] Id. at 107

In weighing both sides of this intensely emotional and difficult debate, it is easy to see why no clear answer has emerged. No one would argue that the Nuremberg Code should not be followed, but rather the question arises as to how strictly the Code must be adhered to in all situations, including emergencies. The legacy of the Nuremberg Trials and the Code itself is a reminder of the horrors of the Nazi regime during World War II. Many believe that if the Code is not vigorously upheld, society risks history repeating itself.[67] While most people would like to believe that the horrors of World War II could never be repeated, history has shown man's capacity to do harm unto his fellow man in all societies around the world. It is easy to see what proper behavior is in extreme situations, like torture or forced experimentation. The difficulty arises in situations like the clinical AIDS trials in Africa and other third-world countries. In these environments the ethical questions are shrouded by the blurry effects of a researcher's best intentions and a participant's desperate need for care. Factors such as poverty, illiteracy, and cultural differences only complicate matters further.

The ultimate question that emerges is: What price is society willing to pay for a cure for AIDS? Will the world be happy if, upon looking back on the process, we realize that human lives were exploited and autonomy violated? These questions remain unanswerable because the process is still in motion. The beneficial effect of this ethical debate, however, is to constantly remind researchers of their ethical obligations and bring visibility to their actions so that the world can know the truth about these trials. This openness is what will ensure that international ethical standards will remain the guiding force behind these experiments. For this reason alone, this constant debate between physicians, human rights activists, government officials, and researchers is immensely important and should continue in the public arena. The Nuremberg Code, and subsequent documents regarding the ethics of human experimentation, are crucial reminders of how low humanity can sink in its chase for scientific advancement, and how society can ensure that such depths are

[67] Fogelson, Steven. "The Nuremberg Legacy: An Unfulfilled Promise." Southern California Law Review, March 1990 p. 905

never reached. These documents must be respected and upheld, but at the same time, must be able to adapt to particular circumstances and environments. It is only through this flexibility and debate that true progress, progress which society can be proud of, will be achieved.