

Ivy Journal of Ethics

A Publication of the Bioethics Society of Cornell

In this Issue:

**The Evolution of the Biomedical
Lab Rat**

**International Bioethics:
AIDS Prevention in
Developing Nations**

Vol. 5 Issue. 1
Fall 2005



Théodore Géricault,
The Raft of the Medusa, 1819



From the Editor:



Eugene Licht
Editor-in-Chief
Ivy Journal of Ethics

Nepotism. Imprudence. Anguish. Théodore Géricault's masterpiece, *The Raft of the Medusa*, breathtakingly encapsulates all three as it depicts the tragedy of the men aboard the doomed vessel. For those unfamiliar with the tale, a brief lesson in history.

After the restoration of the French monarchy in 1816, a man by the name of Hugues de Chaumareys capitalized on his royalist background and was granted command of a French fleet sailing to Senegal on the west African coast. Having never piloted a ship, much less a fleet, de Chaumareys came under the influence of the equally foolhardy Governor of Senegal, Julien Désiré Schmaltz. Favoring a quicker, yet far more dangerous direct route, the two men distanced the *Medusa* from the remainder of the fleet and predictably grounded the ship in shallow water.

Instead of methodically ferrying passengers to shore, de Chaumareys allowed them to chaotically plunge into the lifeboats, which could only accommodate 250 of the ship's 400 voyagers. Those of lower socioeconomic status, mostly soldiers and sailors, were left with a hastily fashioned and crude raft, unsuitable for the load it would have to bear. At first the lifeboats tugged the makeshift vessel along, but progress was slow. Fearing an attack from the raft's occupants, de Chaumareys ordered the lines cut, leaving the men to their presumed demise. Inevitably, the situation deteriorated into madness, factionalism, starvation, murder, suicide, cannibalism, and human suffering of the worst kind. When another ship stumbled upon the raft, only fifteen out of one hundred and fifty men had survived.

The tragic story of the *Medusa* may appear strangely out of place in a bioethics journal. The link, however, is far from tenuous. While the dismissal of ethical objections to scientific research as impediments to progress is a simple proposition, we must continue to remain wary of any such efforts. Empowered decision makers must come to terms with the notion that the quickest route is often not the most judicious. More importantly, the repercussions of any such actions have historically been borne by the economically and socially disadvantaged. As a result, we must continue to promote the kind of ethical discourse that this journal fosters so that we may ensure that those most in need of sturdy lifeboats are not left on sinking rafts.

Sincerely,

Eugene Licht '05

* * * * *

Special thanks to Jessica, Nick, and Matt for all of their hard work. This journal could never have been published without their incredible support.

PUBLISHED BY:

Bioethics Society of Cornell

IVY JOURNAL OF ETHICS

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* * *

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This journal is published twice a year and is distributed free of charge. If you are interested in either a personal or institutional copy, please send your request to the address below.

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The Evolution of the Biomedical Lab

Rat: The History of Human Subject Research



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The use of humans as research subjects has been a controversial topic in the field of biomedical and behavioral research. With the history of scientific advancement marked by several unethical forms of human subject research, the primary goal of modern ethical organizations, such as the Institutional Review Board (IRB), has been to elucidate what it really means to simultaneously obtain informed consent, ensure the safety of the subject, and foster the advancement of society. At the basic level, the horrors of the Second World War demonstrated the very importance of gaining consent. The men and women that were held captive in Nazi concentration camps suffered many tragedies including those at the hands of Dr. Joseph Mengele and his fellow scientists. These physicians used prisoners to pursue “scientific research” that included drowning individuals in ice cold water to determine resistance to death by hypothermia, performing unwarranted bone marrow surgery without the necessary anesthesia, and injecting malaria into patients to observe clinical symptoms.

All of these horrific studies were

implemented in the name of science, to promote the understanding of the human body and its afflictions; however, they were designed and carried out under morally unsound justifications. Today, the United States Holocaust Memorial Museum displays many testimonies that were given during the indictment of sixteen doctors during the 140 days of the Nuremberg Trials. While each unique story presents a personal atrocity, all of the testimonies enforce each other to show how unchecked ethical conduct can expand to unprecedented and disastrous levels. One survivor, Father Leo Miechalowski, described his specific case, one which he “was not asked for [his] consent”:

I was given malaria in such a manner that there were little cages with infected mosquitoes and I had to put my hand on one of the little cages and a mosquito stung me...Somewhat later...I had my first malaria attack. Such attacks recurred frequently and ... I was given nine injections ... one every hour and that every second day through the seventh injection. All of a sudden my heart felt like it was going to be torn out. I became insane. I completely lost my language — my ability to speak. This lasted until evening....Several days later... I had also to wear a long pair of boots with cat's fur and one aviator's combination. And afterwards a tube was put around my neck and was filled with air... and then I was thrown into the water. All of a sudden I became very cold, and I began to tremble...I was conscious for one hour and a half...During this time the temperature

was lowered very slowly in the beginning and afterwards more rapidly...as low as 30, but then I already became somewhat unconscious and every fifteen minutes some blood was taken from my ear...I felt as if I was just about to die, and then I was still asking them to pull me out because I could not stand this much longer.¹

From testimonies such as these, it is inexcusable that such forms of research were justified by scientific progress. In retrospect, significant advancements were made through the Nazi studies, but the costs of the immoral and degrading experiments greatly debilitate the concept of bettering humanity and stimulating progress that are the ultimate goals of research.

The outcome of the Nuremberg Trials was a codification of guidelines that included the necessity to gain “voluntary consent” from those who have “legal capacity to give consent...without...constraint or coercion.” The researchers, themselves, are required to inform the subject thoroughly about the goal, format, and time period of the study, in addition to the corresponding benefits and risks associated with the implemented method. Ideally, human subject research should be based on prior successful, animal research that predicts a beneficial outcome for society. The risk “should never exceed that determined by the humanitarian importance of the problem solved by the experiment” and the “scientifically qualified” researcher must always be prepared to end the study since the general well-being of the subject is of the utmost importance.²

Even with this institution, the twentieth century nevertheless experienced countless situations where human subject was unwittingly manipulated in the name of science, which in turn was sustained by poor federal regulation and enforcement. In the 1950s, the prescription of the drug, Thalidomide, which was given to pregnant women to treat nausea and insomnia, embodied a specific case of un-informed consent. This drug had neither obtained FDA approval nor received consent from the subjects, the American public, who were all relatively uninformed of the drug’s origin and effects. The unfortunate



consequence of the drug was the birth of over twelve thousand deformed babies.³ In response to the resultant public outrage, the Senate established the Kefauver Amendments to the Food, Drug and Cosmetic Act “to ensure drug efficacy and greater drug safety.”⁴

A few years later in 1964, the World Medical Association Conference for the “Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects” began its proceedings with the key belief that the main priority of human research is to safeguard the well-being of the patient above everything else. With this basis, physicians should then seek to “improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.” The basic principles that physicians and researchers should follow include several that build upon the Nuremberg Code as well as guidelines that explicitly state clauses concerning risk vs. benefit analysis, accurate publication of findings, privacy of the subject, and the necessity of an official relationship between the scientist and subject. In addition, there are many clinical situations that present ideal environments for both research and practice. Such clinical trials should only be performed if they assuage personal suffering or realistically aim to save a life. All participants

of the study must be “assured of the best proven diagnostic and therapeutic method” and be allowed to end treatment at any given time. Interestingly, there is a clause that allows exemption from obtaining informed consent, where the physician’s reasons must be brought upon review by an independent committee.⁵

Ironically, even with the passage of new guidelines for ethical human research, a horrific study was concurrently being conducted in the United States from 1932 to 1972. Based in Alabama, the Tuskegee Syphilis Study recruited 600 low-income, African Americans to “volunteer” for a clinical trial that aimed to delineate the natural progression of the syphilis disease. Of the 600 subjects, 399

were diagnosed with syphilis, and exhibited additional symptoms characteristic to anemia and fatigue. Sadly, the volunteers of the study were only given free medical exams, meals, and burial insurance in return for their cooperation. In addition, the

study considerably exceeded the projected six-month duration by continuing for 40 years. The study however blatantly breached ethical guidelines in 1947, when the physicians intentionally abstained from prescribing the newly determined cure for syphilis, penicillin, in order to continue the study.⁶ The corresponding physical and mental damage inflicted upon the subjects and their families sparked a national controversy, which fueled the need for stricter guidelines of ethical conduct for human research studies.

During the decades of the Cold War, researchers and the federal government followed a joint effort to stimulate the United States’ scientific advancement in order to better protect the domestic affairs of

American citizens. Through the controversial Manhattan Project, researcher-physicians conducted many biomedical experiments including the Human Radiation Experiments from 1944 to 1974. Most of the experiments used concentrations of radioactive tracers in minimal amounts that would be acceptable in contemporary American research studies. However, according to the Advisory Committee on Human Radiation Experiments, there was “little evidence of rules or practices of consent” with many subjects, and some cases clearly depicted a violation of ethical conduct. The unscrupulous conduct of these researchers became public knowledge only recently, in the 1990s. The release of confidential documents revealed appalling



experiments, which included studying the “Biological Half-Life of Cesium-137 in Children Determined by Urinary Assay,” “Morbidity and Mortality of Children Irradiated in Fetal Life,” “Aminoaciduria Associated with Mental Retardation in Puerto Rican

Children,” “Strontium 85 for Evaluation of Therapy in Chronic Rheumatoid Arthritis,” and “Fetal Effects of Radioactive Iodine Therapy in a Pregnant Woman with Thyroid Cancer.”^{7,8} Most Americans today are not aware that such practices were allowed, much less administered by the government and certified scientists in the name of humanity, science, and progress. However, public outcry during the seventies, mostly due to the more publicized Tuskegee Study, sparked the passage of new legislature.

In 1974, the National Research Act was ratified, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was “charged to identify the basic

ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.”⁹ In April of 1979, the National Commission created the Belmont Report. The document is one of today’s most extensive manuscripts detailing ethical guidelines and regulations for conductance of human subject research. Specifically, it sets the boundaries between practice and research, as well as calls for the need for the explicit explanation of “experimental research” to the participants. In addition, it establishes the three essential ethical principles for human subject research of “respect for persons,” “beneficence,” and “justice.” Together, these standards protect informed consent, aim to better society overall, and requires the equal distribution of research burdens and benefits. In addition, the Belmont Report explains the process by which to assess risks and benefits, as well as the premise by which to select subjects.¹⁰

In retrospect, it may seem that there has been substantial progress in the codification of human subject research to ensure the general welfare of the modern citizen. However, albeit a cliché, history does have a tendency to repeat itself, and consequently there are always exceptions to ethical progress. From the general consensus that sick individuals who volunteer for medical studies are overly optimistic about their results, to the manipulation of phrasing and explanations to recruit volunteers and attain “informed consent,” America still needs to vigorously sustain ethical codes for research. Yet legislature such as the Title 45 Code of Federal Regulations, which came into effect in December of 2001, cannot alone enforce principled conduct during research studies.¹¹ More specifically, the cyclical recurrence of ethical infringement insinuates that there is also more of a necessity to educate the public on their rights as human subjects. The guidelines are in place, but the researchers and physicians are not always checked for unethical conduct because the final arbitrator is usually a relatively uninformed citizen.

However, there should not be federal attempts to hinder biomedical research and consequently scientific

advancement by instituting absolute impediments. Notable progress has been made through human research, which has experienced tremendous growth especially since February of 2001, when the Human Genome Project consortium and Celera published their respective drafts of the human genome.¹² With the rapid growth of the biomedical, bioengineering, and bioinformatics industries, as well as progress in cloning and stem cell technology, there has been a revival of public interest in human subject research. Moreover, advancements in understanding specific cases of gene regulation, signal transduction pathways, and organic biosynthesis have fostered improved techniques in disease diagnosis and treatment. For these studies, the ultimate goal is usually a clinical trial that can apply the results to human subjects and therefore provide a basis for therapy for the public at large. And once approved for public use, there should also be guidelines set in place that guard the welfare of society. In order to facilitate this process, the editor-in-chief of Science Magazine wrote an expose on recent clinical trials in 2004 and called for the establishment of a proactive governmental drug regulation agency:

The United States has lacked a system than can detect things that go wrong with an already-marketed drug. Physicians are asked to make voluntary reports and manufacturers are required to tell the FDA when they spot a problem, but there’s little incentive for either. Moreover, there is no centralized way of knowing how much of a given drug is being used, so there is no denominator and no adverse reaction rate can be calculated... The absence of an effective national adverse event reporting and analysis capacity is an embarrassment. Instead of complaining about the FDA, Congress should fund it to



support an effective Office of Drug Safety, with the authority needed to encourage physician reporting and a way to audit prescriptions.¹³

Human subject research is a vital component for biomedical progress. In no possible way can this element be removed from the scientific process of elucidating potential therapies. However, the route by which the clinical trials are performed is of utmost importance: forfeiting ethics and thereby sacrificing the means to achieve a Machiavellian end in the name of scientific progress is unacceptable.

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Featured Article

International Bioethics: AIDS Prevention in Developing Nations



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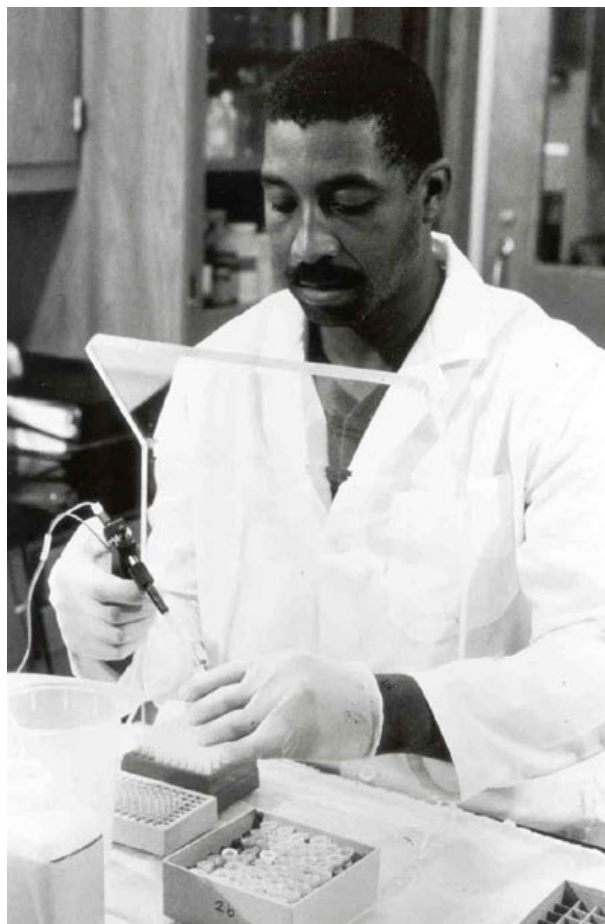
In an era when the financial and regulatory burdens of research continue to escalate in wealthy, industrialized nations, researchers from universities and drug companies in such countries have increasingly begun to conduct experimental AIDS prevention trials in developing nations. Although some developing countries are ideal locations for testing potential AIDS vaccines due to the existence of high HIV seroconversion rates, which permit desirable trials

with smaller sample sizes and/or trials with expeditious periods of duration, many researchers have been notorious for taking advantage of the poor and vulnerable populations of these AIDS prevention trials.¹

One area of contention is the use of placebos in AIDS prevention trials when effective prevention techniques exist and would be otherwise used in developed countries like the United States. The evidence that will be presented in this report will substantiate the claim that AIDS prevention trials that require the administration of placebos to control groups when effective prophylactic techniques exist are highly unethical and, therefore, should not be funded by any U.S. government agencies.

First and foremost, this claim is embodied in the Declaration of Helsinki of the World Health Organization, an internationally recognized document that furnishes the principles that guide all research involving human subjects. This document states the following: “In any medical study, every patient---including those of the control group, if any---should be assured of the best proven diagnostic and therapeutic method.”² The Declaration of Helsinki also sets forth the principle that the well-being of human subjects should always take precedence over the interests of science and society.³ This principle reiterates the Kantian notion that humans are not a means to an end. Therefore, such statements imply that placebos may only be used in clinical trials when no effective treatment or prevention technique currently exists. A similar conclusion was also reached by the panel appointed by the Department of Health, Education, and Welfare (HEW) in 1972 to investigate the Tuskegee Syphilis Study--- a study in

which researchers attempted to “determine the natural course of untreated, latent syphilis in black males.”⁴ Although no effective treatment existed when the study was initiated in 1932, researchers refused to treat the men with penicillin when it became the preferred method of treatment for syphilis in the 1950s. As a result, the HEW investigatory panel concluded that the study was “ethically unjustified” because the subjects of the study were refused the standard, widely accepted syphilitic treatment of penicillin.⁵



This conclusion reached by the HEW investigatory panel raises another intriguing issue: If an effective technique or treatment becomes available during the course of an experimental trial, it must be administered to the control group if they are receiving a placebo treatment. This is especially applicable to research subjects in placebo-controlled groups of therapeutic AIDS vaccine trials in developing countries. However, a similar logic can be applied to research subjects who become infected with AIDS during a prophylactic AIDS vaccine trial: infected subjects must be offered therapeutic treatment by the researchers. This conclusion was also

reached by members of an ad hoc advisory group to the United Nations’ AIDS program who attended a meeting in Geneva, Switzerland in 1998. Although the majority of participants agreed that treatment should be bestowed upon these AIDS-infected research subjects, they concluded that the treatment offered should be the “‘highest attainable’ treatment in their locale that can be sustained after the trial ends.”⁶

Such a statement, once again, opens Pandora’s Box.

It raises the question of whether control groups in developing countries should be given the best current treatment available, or if they should be provided with the local standard of care. Some researchers argue that control groups should only be provided with cost-effective treatment that can be sustained in the environment in which the subjects live.⁷ However, Sidney Wolfe and Peter Lurie, physicians who head the Health Research Group of the Public Citizen, believe that researchers have an

“ethical responsibility to provide treatment that conforms to the standard of care in the sponsoring countries, when possible.”⁸ They believe that the only exceptions to this rule would occur if achieving this standard of care would incur extravagant expenses to the researchers. Further support for their view is found in the Declaration of Helsinki, which requires “control groups to receive the ‘best’ current treatment, not the local one,” in the Department of Health and Human Services regulations in regard to U.S.-sponsored research in foreign

countries, and in the joint guidelines for research in the Third World issued by WHO and the Council for International Organizations of Medical Sciences. The joint guidelines issued by the latter two groups require that “human subjects receive protection at least equivalent to that in the sponsoring country.”⁹

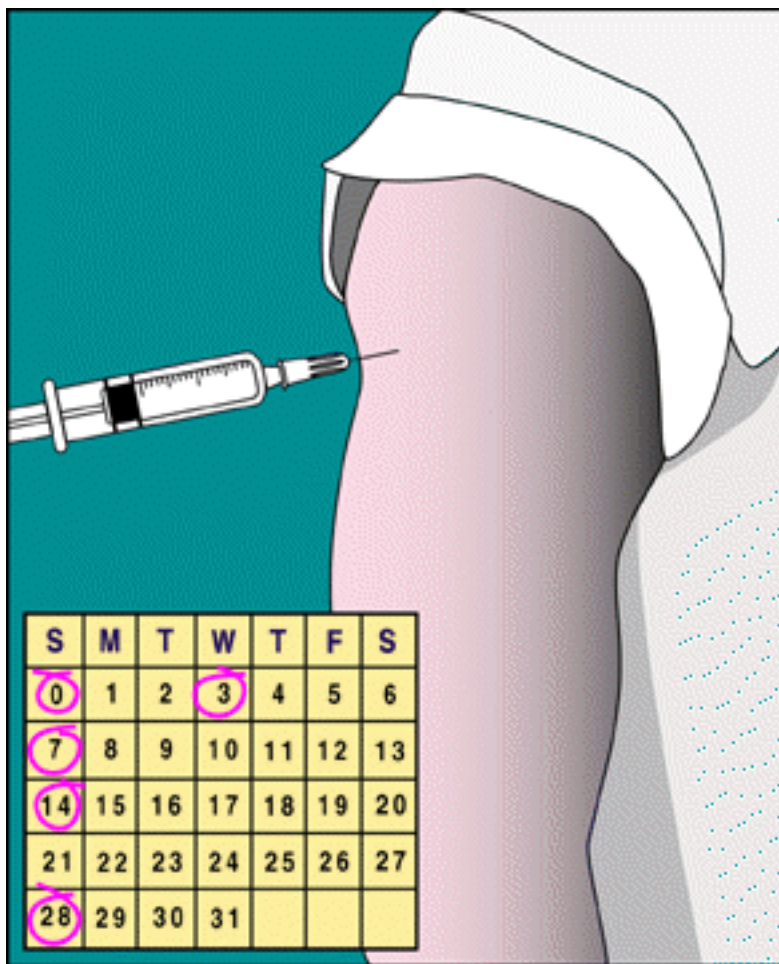
Although a substantial amount of evidence has been provided to validate the claim that placebos may only be used in trials when effective treatments/techniques

do not exist, many researchers argue that placebo-controlled trials are necessary even when viable treatments/techniques are present. Such researchers believe that placebo-controlled trials provide the only means to swiftly and accurately probe the merits and efficacy of a treatment or technique. One such defender of this proverbial gold standard of experimentation has said, “Without the science of clinical trials in general, and without double-blind, placebo-controlled trials in

particular, physicians were left with nothing but anecdotes and hunches.”¹⁰ However, controlled experiments can still be conducted without the use of placebos through the method of historical controls, in which data obtained from treatment groups is compared with data contained in medical records of matched cohorts who had not been treated for AIDS. It is also possible to compare data from the treatment group against data contained in the medical records of those being treated prior to the commencement of the trial. Such methods are

successfully utilized in research with cancer drugs.¹¹ Therefore, it is clear that researchers have other options available to them to investigate the efficacy of certain treatments in AIDS prevention trials.

In conclusion, I recommend that U.S. government agencies discontinue their funding of AIDS prevention trials in developing countries in which placebos are used when effective prevention techniques exist and would be used in the United States. Furthermore, if



an effective prevention technique becomes available while a placebo-approved study is being conducted, all members of the placebo-controlled group must be given access to this technique by the researchers. Lastly, the control group in any AIDS prevention trial being conducted in a developing country must be afforded treatment at least equivalent to that in the United States.

It should further be noted that behavioral interventions should be provided to both the placebo and treatment arms of a study to encourage and maintain behavioral change that can substantially reduce and possibly eradicate the risk of becoming infected with AIDS. Some such interventions include, at a minimum, clinic visits, counseling, education, distribution of free condoms along with demonstrations on how to use them, and methods to disinfect syringes or how to obtain sterile syringes.¹²

Upon the completion of a vaccine trial, U.S. researchers should freely distribute the effective vaccine to the placebo/control group of the study. They should then compensate the host country for their cooperation by providing the vaccine free of charge, or at an extremely reduced rate, to the citizens of that country.¹³ By doing so, the United States would be fulfilling the ethical principle of justice set out by the Belmont Report, which is a statement of basic ethical principles that should be used to guide the resolution of ethical problems regarding research on human subjects.¹⁴ The principle of justice states that those who bear the risks and the burdens of a trial should also partake in a commensurable share of any benefits produced by the trial.¹⁵ If U.S. government agencies follow this recommended course of action, they will be upholding the rights of human beings while providing them with treatments and techniques that would otherwise be

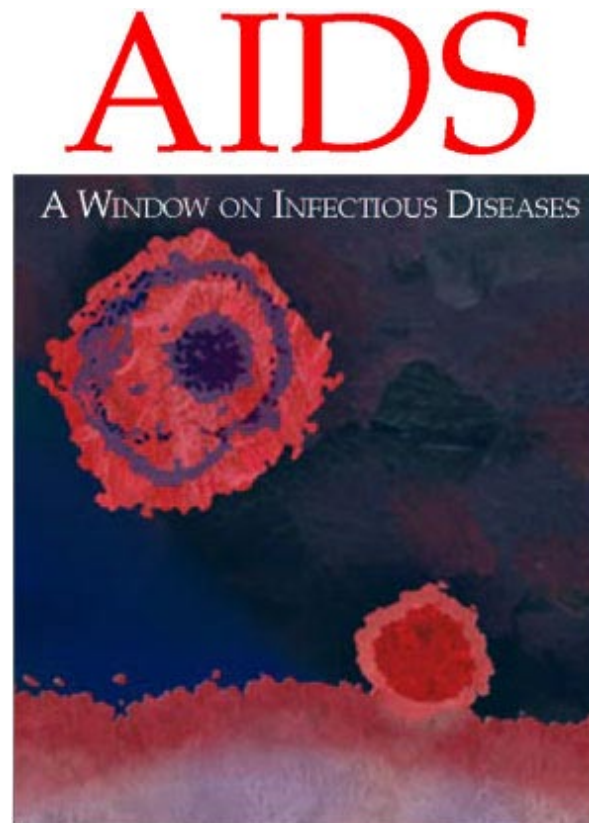
unavailable to them. Humans would no longer be treated as means to an end, but as ends in and of themselves.

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Nutrition in the Developing World: How Do You Orient Your Moral Compass?

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Waking up after too little sleep to a buzzing alarm, drudgingly hauling oneself to class, running errands all afternoon, and then frantically finishing papers and preparing dinner at night – this is the haste of everyday living for students in the industrialized world. Somehow in this haste, it is tragically simple to carry about one’s business while completely ignoring the nutritional problems in developing nations - problems that leave a significant percentage of the world’s population at an almost sub-human standard of living.

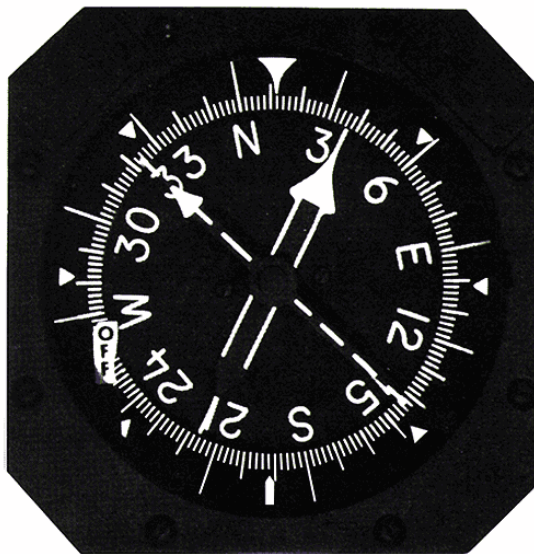
Dr. Rebecca Stoltzfus, an associate professor and expert in international nutrition in the Division of Nutritional Sciences at Cornell University, estimates that 10 million children die every year around the world. Put another way, by the time you finish reading this article, approximately 60 children around the world will have died.

According to Dr. Jean-Pierre Habicht, a professor in the Division of Nutritional Sciences, 55% of all child mortalities occur because children are underweight and/or undernourished, which makes them highly susceptible to rampant diseases and illnesses such as malaria, diarrhea and pneumonia.¹ The underlying causes of childhood malnutrition are insufficient access to food, inadequate maternal and child-care practices, and poor water sanitation methods coupled

with insufficient healthcare.² Fortunately for those in the developing world, it is often possible to mitigate or even eradicate causes of childhood malnutrition through vaccines against common childhood diseases, construction of irrigation systems, and establishment of health clinics.

Some in the developed world may feel terribly ashamed to live comparatively comfortable lives, taking access to healthcare and high living standards for granted while others in the world will live their entire lives without seeing a doctor. Some may feel that the developed world has a moral obligation to bring indigent citizens closer to the standard of living that those in industrialized countries enjoy. Overall, citizens of the developed world are faced with a moral quandary. Should people feel ethically obligated to donate money to organizations such as UNICEF and OXFAM?

If so, how much would be appropriate? According to Peter Unger, a philosopher at New York University, it costs an average of \$200 to help a sick 2-year-old in a developing nation grow into a healthy 6-year-old. Does this mean that all people economically capable of donating \$200 should be morally obligated to do so? While ethical beliefs and moral values are socially constructed, I believe each individual is entitled to his/her own moral framework.



There are many explanations for the secondary role of charitable donation in the consciousness of American people. A major problem with the very design of monetary donation is its inherent social diffusion of responsibility. Common responses that keep people from donating to charitable organizations include “Why should I donate \$200 when my donation will barely have an impact on the world hunger crises” and “I don’t need to donate money, other people will donate enough to help the problem at hand.” Other positions against donating money focus on a nationalistic approach. This view holds that because there are so many disadvantaged people in industrialized nations, these individuals merit society’s assistance before helping people in developing countries can be a priority. According to UNICEF, 13 million children in the United States have a difficult time getting all the food they need.³ Nationalistic philanthropists would prefer to eradicate the immediately visible hunger in their home country before facing challenges abroad. International images of poverty and starvation register in the minds of such citizens, but there is a prevailing sentiment that these problems do not affect them directly; the immediacy and urgency of the international crisis is not as compelling a motivator as the situation at home. In cases of foreign donation, people are often uncertain whether the entirety of their foreign donation will actually go towards helping those in need. Nationalism may attenuate insecurities about whether donated money will be used to fund causes other than the desired humanitarian efforts. Regardless of individuals’ reasons for not contributing financially to persistent world problems such as hunger and malnutrition, this inactivity has caused devastating transnational consequences.

While enormous international tragedies, such as the December 2004 Asian tsunami disaster, may receive widespread media coverage, billions of dollars in donations, and the sympathy and support of much of the international community, less dramatic crises often elude the world’s attention. Today in Cambodia there is an urgent nutritional crisis that has escaped much of the United States public’s notice. After 20 years of civil war, 52% of Cambodian children aged 6 months to 5-

years are underweight.⁴ Chronic underweight makes children more susceptible to other diseases, such as diarrhea, measles and malaria. Underweight children are likely to be ill for a longer period of time and a greater level of severity than well-nourished children. In fact, it is estimated that malnutrition causes 55% of all child deaths in the world because poor nutrition acts synergistically with disease agents to amplify the negative effects of an illness.⁵ According to the Boston Globe, the healthcare concerns in Cambodia include a lack of transportation to hospitals, absence of treatments for curable diseases, and outright lack of any medical care whatsoever in several areas.⁶ These conditions are simply unimaginable to most people in industrialized nations. Diseases like tuberculosis and typhoid fever are rampant killers of children in Cambodia, while advancements in industrialized countries have practically eliminated these diseases. Perhaps because world hunger is a chronic problem and tragic scenes of hunger are not often displayed prominently on television, in magazines or in newspapers, the Cambodia crisis and others like it have slipped past the consciousness and awareness of the average American.

Morality is relative, socially constructed, and often cannot provide direct right or wrong answers. Morality is also not something one person can impose on another. For some people, it is an easy moral decision to donate money to solving the hunger crisis in the developing world. For others, it is easy to do nothing, and get swept into the perpetual motion of everyday life without ever looking back. No one should donate money or time because they feel guilty or pressured. Rather, a commitment to addressing the issue of world hunger should come about as a result of moral introspection and a detailed analysis of personal motives.

It is important to develop a moral compass - an individualized guidance system that helps one develop



and internalize a system of beliefs. As Socrates said, “the unexamined life is not worth living.” In addition to leading a life filled with the mundane pressures of school, work, friends, and family, it is vital to reflect on one’s actions and inactions. It is crucial to develop and accept a personal moral framework because as of right now, another 60 children around the world are dead.

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In the News

“Do No Harm”: Why the Goals of Medicine Should Be Reoriented

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Primum non nocere. “First, do no harm.” This principle has been the paramount guideline for medical practitioners since the time of Hippocrates and remains fundamental to the role of medicine practiced around the world today.



philosophers have appealed to the obligation of medical caregivers to do no harm in attempts to resolve ethical dilemmas from abortion to euthanasia. However, there have been countless controversial medical cases in which two parties concerned about a patient in a single situation both appeal to the principle to “do no harm,” yet each party reaches a starkly different conclusion about the medical action that would (or would not) be ethically appropriate to implement the situation. At the heart of most bioethical controversies, there lies a fundamental disagreement about the meaning of do no harm in the context of contemporary medical practice.

In the contemporary medical context, doctors and This disagreement can be illustrated by an example of

an end of life scenario. Imagine: A 75 year-old patient is dying of a terminal illness; he refuses medical treatment and requests physician-assisted suicide to relieve the incessant, excruciating pain that plagues him during every waking moment of his life. The conventional understanding of *primum non nocere* requires that his doctors do what is within their power to sustain his life and deny his request for physician-assisted suicide. As president of the American Medical Association, Lonnie Bristow claimed, “The AMA believes that physician-assisted suicide is unethical and fundamentally inconsistent with the pledge physicians make to devote themselves to healing and life”.¹ Nevertheless, many members of today’s medical community believe that it would actually be more harmful to this patient to keep him alive in his miserable condition—after all, what is the value of a life lived in constant, unbearable pain? Members of the latter camp believe it is morally reprehensible and ultimately harmful to force a patient with a terminal illness, who will inevitably be in relentless pain for the remaining duration of his life to continue living against his will. In order to evaluate these oppositional ethical standpoints, we must be able to assert whether doctors should always try to sustain a patient in the interest of doing no harm to his body, or whether they should allow their patient to exercise his own autonomy in the interest of doing no harm to his person.

This difficulty illuminates the problem that underlies most bioethical controversies: there is confusion about the definition of harm, which arises simply because the way harm is understood in a purely physical context (namely, that which is detrimental to bodily integrity) is different from the way harm is understood in a larger context of human values (namely, that which is detrimental to the ultimate goal of human life—be it happiness, dignity, or some other end). For instance,

in the case above, it could be considered harmful to help the patient commit suicide because that would be detrimental to his bodily integrity; however, it could alternatively be considered harmful to sustain the patient’s life because that would be detrimental to his personal end (i.e. happiness or dignity). With a positive understanding of this distinction, we can ask about the ends to which it is applied in contemporary medical practice. More specifically, we are now in a position to ask whether the practice of medicine should be teleological insofar as the ends of human life are contained in biological life and health, or whether we should recognize that at least some ends of human life are external to the practice of medicine, and that medicine should thus be instrumental to those ends.



I am inclined to believe that the value of life transcends biological integrity and thus lies outside the context of medicine. For example, I do not acknowledge any value in the life of a person who lays unconscious in a permanent vegetative state; is reliant on a respirator to breathe, an IV to obtain nutrients, and a catheter to

excrete wastes; and is incapable of communicating or interacting with other human beings. The exact end of human life is an open question for philosophers; I simply maintain that mere biological integrity is not sufficient for achieving any such end. This assertion is at the root of my philosophical argument, so a person who believes that there is in fact value in a “life” like the one mentioned above will inevitably disagree with my sentiments throughout the remainder of the paper. If, however, we concede that the value of human life involves any end beyond sheer biological functioning, then practicing medicine—like every other practice in which humans partake—should simply be a tool that we can use to help ourselves achieve that end. In other words, medicine should be instrumental to achieving a greater goal in life.

Bristow's assertion is accurate insofar as the Hippocratic Oath obligates doctors to use all of their technological and medical resources to promote life, but this conception of life is purely objective and purely biological, suggesting that the practice of medicine is more about mere quantity of life than its actual quality. However, if it is in fact the case that the ultimate end of human life lies beyond the realm of biology itself, and we concede that the value of human life is actually dependent on quality, which is implicit in achieving some higher end, then medicine should be simply a tool for helping us achieve a life of sufficient quality that we are able to promote our end.

At this point we must ask ourselves whether doctors should try to prolong life even when it will render a patient physically or emotionally miserable, or whether doctors should be exhorted to withhold treatment if the former option proves to be somehow detrimental to the personal end of the patient. In light of what has been established, the answer seems obvious: If doctors should only employ their knowledge and skills instrumentally to help us achieve our ultimate end (e.g., happiness or some other end), which is necessarily contingent upon a sufficient quality of life, it follows that they should abstain from implementing medical treatment if it would be detrimental to this end. Under circumstances that seem to render life itself detrimental to its own end (a notion that is elaborated upon below), doctors should be in no position to try to sustain it against a patient's will. The pledge physicians make to prolong life to the best of their ability under any circumstances should be reoriented toward a new understanding of life that is framed outside the context of medicine such that its value comes from something superior to mere bodily health.

Although I am in no position to determine the ultimate goal of life, it seems that the intense and

enduring desire to die is an outward manifestation of a profound obstacle a person is confronting in her attempt to achieve that goal. (The definitions of intense and enduring are, again, matters to be determined elsewhere.) In this case, the obstacle (be it physical or psychological pain) the person is facing in her attempt to achieve her personal end may be more detrimental to her ends than death itself; indeed, if her desire to die outweighs her desire to live, it seems likely that some component of her life is in fact more detrimental to her end than death would be. That being said, it is self-defeating to sustain the life of a rationally competent patient who truly finds death more desirable than any life she could attain through the most effective medical intervention. Thus, she should be able to use medicine as a tool to help her die, whereby she would be closer to achieving her desired end than she would be if she were forced to continue living.



I have thus far attempted to extrapolate that a person and a person's body are not identical, and that as such, a person can be harmed even when her body is healthy. In the context of conventionally understood medical objectives, doctors do in fact perform certain acts of

medicine that harm persons at the expense of promoting their bodily health. Medical actions that require a distinction between types of harm arise whenever a competent patient refuses treatment and her request is not respected, and also whenever a person desires a certain treatment that she is subsequently refused. I maintain that the doctrine to do no harm should be applied to both persons and their bodies; however, as the end or purpose of life lies outside the context of biology, the creed should be applied to persons over their bodies when there is a conflict implicated in promoting both. Ultimately, since the ends or purposes that give life value are properties of persons, and not merely properties of healthy bodies, medicine should be instrumental to our achievement of the

ends of persons instead of simply the ends of bodies.

Although some might object that having bodily health is in fact a necessary condition for satisfying personal ends, I contend that the former is not necessary for the latter to be achieved. Without making a positive claim about what the ends of life are, it is challenging to illustrate a particular circumstance in which bodily integrity is compromised but personal ends are achieved; nonetheless, it seems altogether intuitive that there are people who suffer bodily ailments but are still able to achieve personal goals such that their lives contain intrinsic value (even in the absence of biological health). That is not to say that any possible end could be achieved by anyone with any bodily ailment (i.e. that fame or fortune can always be achieved by someone who lacks the ability to both see and hear); it is just to say that complete bodily integrity is not always necessary for achieving the ends that instill value in human life. The objection is intended to demonstrate that the role of medicine should be to promote biological health under all circumstances, but it is insufficient for doing so because it is indeed the case that sometimes our ends can be achieved even when our bodily health is compromised. Moreover, when we consider cases in which the interests of someone's person and the interests of her body conflict, we have already implicitly acknowledged that she will be more likely to achieve one at the expense of the other—thus, if the interests of her person are more likely to be achieved at the expense of her bodily health, it must formerly be understood that in this circumstance she can in fact achieve her personal ends even if her bodily integrity is to some extent sacrificed.

The Schiavo Case

This distinction is of particular importance in light of the current legislative decision-making that is being prompted by the Terri Schiavo case in Florida. Schiavo, now 41, collapsed in 1990 in her home and suffered from heart failure that led ultimately to severe brain damage. For the past 15 years, she has been in what doctors term “a persistent vegetative state,” and her brain has continued to deteriorate as years have passed.

According to Terri's doctors, her entire cerebral cortex—the area of the brain that is responsible for thought, imagination, emotion, and other higher-level functions—has been virtually destroyed. Although she appears conscious



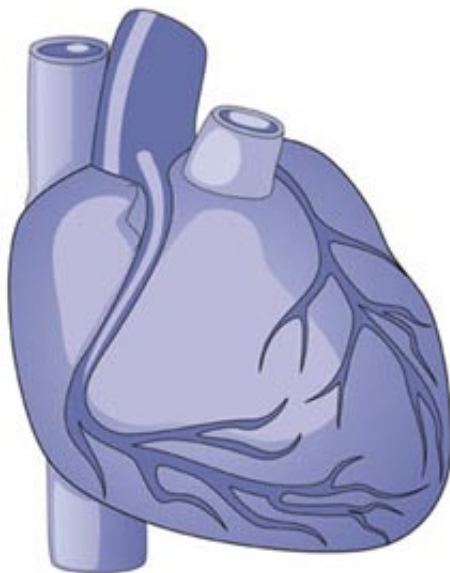
and her eyes are open, her deceptively lifelike features are simply a result of minimal activity in her brain stem—the area that is responsible for involuntary functions and reflexes. Terri has been rendered utterly thoughtless, and is she completely incapable of interacting on any level with the people around her. She obtains nutrients from a feeding tube and is assisted in breathing by a respirator. The overwhelming majority of doctors involved in her case concede that the damage to her brain is irreversible, and that Terri will live out the remaining duration of her existence as a lifeless body whose biological functions are being sustained by medical technology.

Since 1998, Terri's husband has been fighting furiously against her parents and the courts to have her feeding tube removed so that his wife can die—he claims that, were Terri capable of making a rational choice for herself, she would not want to continue to exist lifelessly; rather, she would prefer to die with dignity and be remembered as the person she was before her brain ceased to function. Her parents, however, believe that removing their daughter's feeding tube would be killing her, and they maintain that she should be kept alive by medical intervention indefinitely. Terri's mental and bodily deterioration has been overshadowed by a battle involving not just her family, but the entire country; the Schiavo case has received national attention because it is emblematic of the ongoing moral clash concerning “the right to die.” Although the war seems to be waged between the democratic and republican parties, political affiliations do not necessitate one

particular viewpoint or another. Essentially, the battle is over how to delineate the value of human life.

Terri's parents must believe that the value of their daughter's life is ultimately a function of her continued biological existence. If her parents and other right-to-lifers did not in fact believe that the value of Terri's life is wholly entailed in her biological integrity, then they would have no qualms about removing her feeding tube. This statement holds because it is objectively true that biological functioning is all that Terri is capable of attaining with the assistance of current medical technology. Thus, Terri's parents and others believe that removing Terri's feeding tube would be stripping her of a life of some value to which she has the right to preserve.

In stark contrast with those who argue that the life of Terri Schiavo should be maintained, her husband believes that Terri's life is no longer of any value to her. Despite the fact that her parents are able to find comfort in knowing that they can see their daughter in veritable physical form every day (which may be of some value to them), he asserts that Terri's life as such is something that she would never want for herself. His assertion essentially rests on the belief that the value of life is entailed in something beyond sheer biological integrity. As she is incapable of thinking or interacting, she will never be able to achieve any of her personal ends; Terri's husband contends that if she were in a coherent state, she would recognize her life as meaningless and would prefer to die peacefully instead of being sustained in a permanent



comatose state. Terri's husband—like all those who are fighting to have Terri's feeding tube removed—is not condoning murder; rather, he believes that biological functioning, in and of itself, does not entail the components of human life that make it valuable and that Terri would concur with that sentiment. Whether the value of life comes from the ability to think, remember, communicate, understand, or anything else, it seems that a person must have some form of higher-level brain functioning in order for her life to be meaningful. Perhaps the end of human life is happiness, perhaps it is dignity, perhaps it is fulfillment. Regardless of what exactly this end is, though, it cannot be achieved simply through bodily integrity. In this framework, the “life” of Terri Schiavo does not have any value, and as a consequence, sustaining it at such a great expense is self-defeating. She has no hope of satisfying her goals or ends by being kept alive, and the pain, loss of dignity, etc she must endure from medical intervention seems more detrimental to her ends than death would be.

It simply appears that those who maintain that Terri should be kept alive at all costs have a more narrow conception of human life wherein its value is entailed in biological integrity, while those who believe her feeding tube should be removed recognize that the value of human life lies outside the context of biology. Clearly, in the national clash over the Schiavo case, I fall into the latter faction of Americans. I have already explained that the value of life comes from achieving some purpose or end that lies in a realm beyond the context of biology, and that as such, medicine should only be instrumental to our achievement of that end. Terri Schiavo's life has no intrinsic value because she is entirely incapable of achieving any end whatsoever that lies outside the realm of biological functioning. Thus, if her husband is accurate in suggesting that Terri would recognize the truth of this sentiment, then enabling her to die with dignity seems to coincide more closely with her ends than being kept alive in a persistent vegetative state. Unfortunately, today's political (and religious) circumstances are such that Terri's life will most likely be sustained at an

astronomical expense for years to come; nonetheless, since her life in fact has no intrinsic value, it would be morally preferable to remove her feeding tube so that she could die in a peaceful and dignified manner.

Conclusion

Arguments for mercy, patient autonomy, or self-determination that have been put forth in favor of physician-assisted suicide or the moral legitimacy of withholding patient treatment have been unconvincing to those who believe in the validity of the conventional pledge physicians make not to harm. These arguments have failed because the philosophers who have promoted them have not clearly delineated the multiple ways in which harm can be understood, and have not further insisted that the role of medicine should be to do no harm in the broader context of human values. While I actually do believe that mercy, patient autonomy, and self-determination are sufficient justifications for granting patients' requests to have their treatment withheld or be assisted in their own suicides, those who do not will surely have to concede that these actions would be justified in the event that taking the alternative actions (or abstaining from acting at all) would be detrimental to the ultimate end of human life. If medicine should in fact be an instrument that we use to promote an overarching goal of human life, then either withholding a patient's treatment or assisting a patient in her own suicide could be a morally commendable action if it is committed as a means to help her satisfy her goals and ends.

In light of the fact that the value of human life comes from something that is found outside the context of biological functioning and corporeal health, the established goals of medicine should be amended; doctors should be exhorted to use medicine as a tool to help people achieve the end in which the value of human life is entailed (i.e. happiness), not simply to promote bodily integrity under any and all circumstances. As I am in no position to claim what exactly the end of human life is, I am similarly in no position to provide guidelines within which doctors should implement their medical skills to pursue that end. I am merely suggesting that medicine should be an instrument that we use to achieve an all-encompassing end of human existence, not a teleological practice wherein biological life is of paramount importance. This new framework of medical practice should allow for the moral permissibility of withholding patient treatment or assisting in patient suicide under circumstances in which keeping a patient alive is detrimental to the ends of human life.

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In the News

A Healthcare Revolution: Arguments for Embryonic Stem Cell Research

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Shortly after the 1973 *Roe v. Wade* decision, the United States government prohibited the use of federal funding for human embryonic research.

Today, with the exception of 60 stem cell lines made available by President Bush, this is still true.¹ There is much enthusiasm over the potential use of stem cells

for treating a variety of diseases and injuries, including Parkinson's, Alzheimer's, Crohn's, Lou Gehrig, certain cancers, stroke, arthritis, and spinal cord injuries.² With the number of individuals in the US suffering from these ailments and injuries exceeding 30 million, the benefits of stem cell therapy could be immense.³ Despite the advantages stem cells may hold for medicine, there are staunch opponents of this research who claim that it is unethical and should be discontinued.⁴ I argue that embryonic stem cell research is ethical and that the restrictions on using federal funding for this research should be significantly attenuated.

Human embryonic stem cells (HESCs) are pluripotent, meaning that they can give rise to all the differentiated cell types in a human.⁵ Researchers hope to induce HESCs to differentiate into specific cell types and then use these cells to replace defective or deficient human cell populations. For example, researchers believe that transplanting HESC-derived Beta cells into patients with type I diabetes may lead to the amelioration of insulin regulation in these individuals.⁶ While the medical applications of HESCs are promising, there is significant controversy surrounding the derivation of HESCs. The three sources of HESCs are surplus embryos created through IVF procedures, primordial germ cells isolated from aborted or miscarried fetus, and therapeutic cloning.⁷ Thus, obtaining embryonic stem cells requires



the irrevocable use of either an embryo or a fetus. The strongest argument that can be made for human embryonic stem cell research (HESCR) is the potential

it has to reduce human suffering. The recent death of actor Christopher Reeves has brought considerable attention to this pursuit. Reeves was rendered a quadriplegic after a horse riding accident and died from a systemic infection related to his paralysis. Following his accident, Reeves championed stem cell research and vowed to walk again.⁸ Reeves admitted to contemplating suicide after his accident, which reveals the emotional impact a spinal cord injury can have on an individual.⁹ While it is too late for Reeves, embryonic stem cell research offers hope for those with spinal cord injuries. Studies in rats have demonstrated that embryonic stem cell transplants can colonize damaged spinal cord and lead to improved function. While it remains too early to know the long-term application of this research, some have speculated that it may lead to a breakthrough in neuro-regeneration within the next twenty years.¹⁰ With approximately 200,000 individuals in the US with spinal cord injuries that preclude them from carrying out normal functions, such as walking, breathing without assistance, and controlling bowel movements, we must expedite this research.¹¹

In addition to the potential benefits for individuals with spinal cord injuries, stem cells could in theory be used to cure degenerative diseases, such as Parkinson's. Parkinson's is the second most common neural degenerative disorder and results in the destruction of dopamine producing dopaminergic neurons. The disease is typified by tremors, bradykinesia, muscle rigidity, and postural instability; it affects 1% of individuals over the age of 50, including TV celebrity Michael J. Fox.¹² Parkinson's sufferers like Fox undergo dopamine replacement therapies, which can reverse many of their symptoms initially, but after 5-10 years treatment become less effective. At this point many patients elect to have deep brain stimulators implanted into their brains, which can reduce their symptoms by up to 60%.¹³ While these treatments can help Parkinson's sufferers lead a more normal life, they are not cures. It is hoped that HESC's can be induced to form dopaminergic neurons, which would then be used to restore the depleted cells population in Parkinson's patients.¹⁴ This treatment may have

more permanent results than current treatment options and offer individuals like Fox a new lease on life.

HESCR also has promising implications for understanding early human development. There are many unknown developmental abnormalities that result in spontaneous abortions. The use of HESCs to model early development may allow researchers to explain and to prevent these occurrences.¹⁵ HESCs can

also be used to better assess the impact pharmaceuticals will have on the human system. New drugs are put through a series of preclinical trials before they are tested in humans including tests examining the impact of a drug on cultures of human cells. The human cells used in these tests are generally maintained in vitro for a long time, and consequently they develop properties that are different from in vivo cells. It is believed that embryonic stem cells can better mimic in vivo cells, and therefore can provide a better assessment of a drug's safety.¹⁶

Although embryonic stem cells have promising implications for the future of medicine, religious fundamentalists object to HESCR on ethical grounds. They claim that using human embryos for research results in the destruction of potential persons.¹⁷ However, the main source of HESC is surplus embryos and aborted fetuses, which does not involve additional destruction of potential persons. To obtain eggs from a woman for IVF, a minor surgical procedure must be performed in which the woman is induced to super ovulate through hormonal injections in order to maximize the number of oocytes that are recovered in the operation. Because implantations are often unsuccessful and individuals

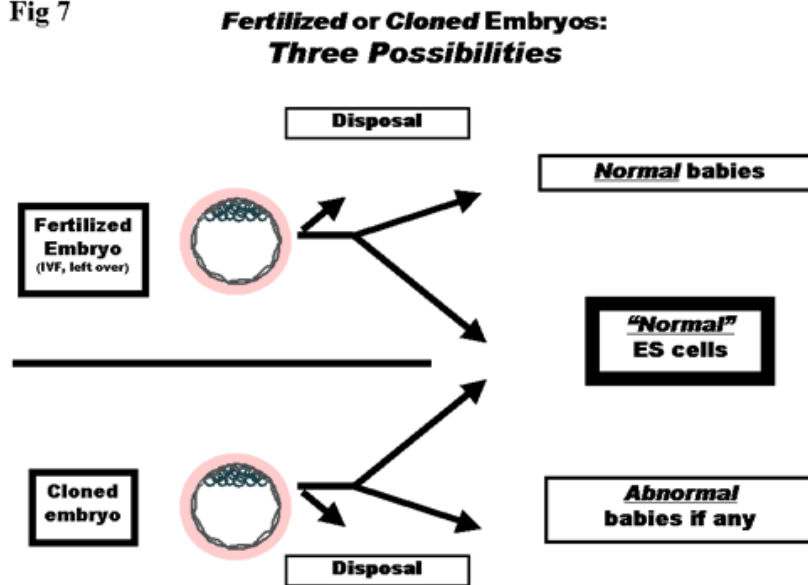
sometimes choose to have additional children at later times, clinicians recommend cryogenically freezing any viable embryos that are not implanted in order to avoid future surgeries.¹⁸ Frequently, surplus embryos are never used and if these surplus embryos are not donated to other couples, then they are discarded.¹⁹ Thus, using these excess embryos for research will not contribute to the loss of potential persons. A similar argument can be made for aborted fetuses. There are

approximately 30 abortions per 100 live births, which results in over 1 million aborted fetuses per year.²⁰ These aborted fetuses have already been deprived of the opportunity to live, so extracting stem cells from them will also not contribute to the loss of potential persons any more than

medical studies on cadavers contribute to deaths in the population.

The late Pope John Paul II stated that an embryo should be treated as a human from the point of fertilization, which precludes the use of embryos for research, regardless of the source.²¹ If we follow this line of reasoning then an embryo morally represents a person, and in a modernistic sense this implies that an embryo is afforded certain rights, namely the right not to be killed.²² Undoubtedly, an embryo represents human life at some level, but there is substantial evidence against the notion of an embryo as a unique person. First of all, the argument that an oocyte becomes a person upon fertilization is contingent on this process being instantaneous. However, fertilization takes between 12-24 hours to complete, and then an additional 24 hours is required for the chromosomes of both gametes

Fig 7



to organize and form the zygote.²³ I am also living evidence that an embryo is not a unique person. I am a monozygotic twin and if an embryo represents a unique person, then my brother and I would have to be the same individuals. Clearly my brother and I, though similar as we may be, are different people.

If an oocyte does not become a unique person at fertilization, then it must become one at some subsequent point. The twinning argument indicates that an embryo is not a unique person until at least after the point that it can no longer separate into twins. Twinning generally takes place before the primitive streak forms, which occurs around the fourteenth day of development. Embryonic stem cells are typically obtained from the inner cell mass of the blastocyst around five to six days after fertilization, which is well before any conceivable point that an embryo can be deemed a unique person.²⁴ If surplus embryos are not unique persons then we need not afford them the same rights as human beings. Furthermore, the ruling in *Roe v. Wade* set the precedent that embryos do not have the same rights as living persons. Thus, while some may believe that an embryo is a person, this viewpoint is not in line with legal precedent; therefore embryos should be made more available for research purposes.

Another common argument against extracting HESCs from embryos is that such a practice will lead to the creation of embryos solely for purpose of harvesting stem cells as the demand for embryos required for research outstrips the number that can be obtained from IVF donors and aborted fetuses.^{25,26} But the potential to alleviate human suffering justifies this practice. Furthermore, since embryos are not unique persons and are not afforded the same legal rights as persons then creating extra embryos solely for research would not represent an ethical or legal dilemma.

Opponents also object to stem cell research on account of the potential dangers. For instance, there is a risk of transmitting infectious and genetic diseases from donors to recipients via embryonic stem cells transplantations. For example, it would

not be advisable to transplant heart tissue from a donor with a family history of cardiovascular disease into a patient who suffered a myocardial infarction. However, careful screening for infectious and genetic diseases can avert this potential problem.²⁷ Another problem is that embryonic stem cells could produce teratomas- benign tumors composed of multiple cell types when injected into humans.²⁸ This is certainly a risk that needs to be assessed, but it should not on its own impede the research process. There is also danger that HESCs could be rejected when transplanted into patients. Researchers hope to avoid this problem by genetically engineering these cells to express the major histocompatibility complexes of their recipients. Utilizing somatic nuclear transplant, in which the nucleus of an adult cell is transplanted into an oocyte, may also prevent rejection.²⁹



Stem cell research may conceivably lead to a revolution in healthcare, surpassing even the discovery of antibiotics by Alexander Fleming in 1928. It seems that America is ready for these new therapies, as a recent poll found that 72% of respondents supported research on embryos donated with parental consent.³⁰ For these advances to occur, however, changes need to be made in stem cell policy. The moratorium on federal funding for this research, with the exception of lines created before 9 August 2001, is slowing down progress. While the private sector is not restricted from conducting this research, any discoveries they make will be less accessible to the public. They will also patent any techniques they develop, which will drive up the cost for stem cell therapies.³¹ There is an additional danger that researchers may migrate to other countries, such as Britain, Australia, and

China, where there are less stringent HESCR laws. This will lead to a loss of talented researchers and consequently a decline in the number of U.S. scientific discoveries. The restrictions on HESCR may also lead to economic losses, by forfeiting technological advances to other countries.³² These issues are secondary to ensuring that we adhere to strict ethical guidelines, but clearly HESCR is morally justified.

HESCR is ethical and has the potential to alleviate human suffering. We need to accelerate this research in order to create viable therapies in the near future and to ensure that the U.S. remains a leader in the scientific community. California's recent commitment of \$3 billion dollars over the next 10 years to fund HESCR, represents a step forward.³³ But the federal moratorium should be lifted so that federal funding is available for scientists working in this field. Nonetheless, we should ensure that HESC efforts are carried out with the utmost respect for embryos, and also that the safety of any developed techniques is adequately analyzed.

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Blessing or Curse?: The Case of DNA Fingerprinting

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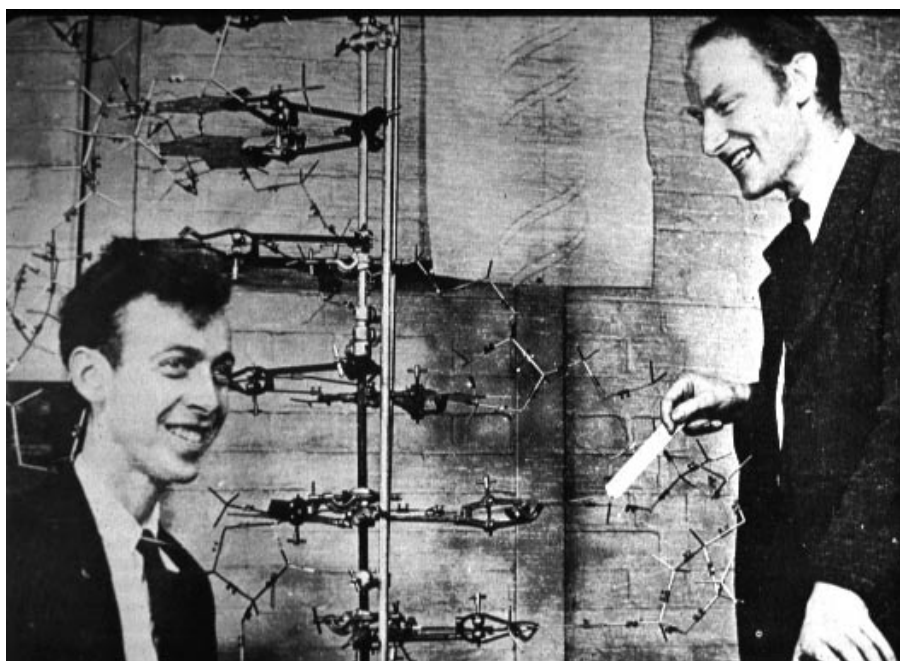
The problems associated with identification are much more vociferous than one would originally be led to believe. Difficulties arise even under the most ideal conditions, prompted by the falsely secure relationship between perception and reality. What one senses (sees) and consequently integrates (via neural tissue) is not necessarily that which really occurred. In sum, the mind plays tricks. This becomes a deafening problem in the arena of forensic criminal investigations, where proper identification can determine, entirely, the fate of another being. The phenomenon of falsehood becomes even more troubling when applied to cases involving capital punishment.

The perils of recognition are not a modern affair; in fact, intellectuals have spent the last century attempting to crack this perplexing dilemma. The official history of forensic science begins with an individual named Alphonse Beritillon, a 19th century Paris Prefecture of Police who developed a classification system based on signalleic cards and standardized mug shots. Such a scheme, though helpful, was imaginably far from accurate and scientists as well as law enforcement agencies continued

the search for more refined techniques. The next trend to hit forensic science – fingerprinting – is still in use today. In its heyday, the procedure was considered a ‘gold standard’, even prompting a brief spark of hope in proponents of eugenics analysis (i.e.: Sir Francis Galton), who believed that it could provide an index of genetic type. In more recent times, fingerprinting has been eclipsed by a far more powerful procedure entitled genetic typing, prompting Marine Jacot of UNESCO to

report that “police and judges in Western countries all agree that the arrival of genetic testing in their daily lives is a far more revolutionary development than the introduction of fingerprinting at the end of the 19th century.”

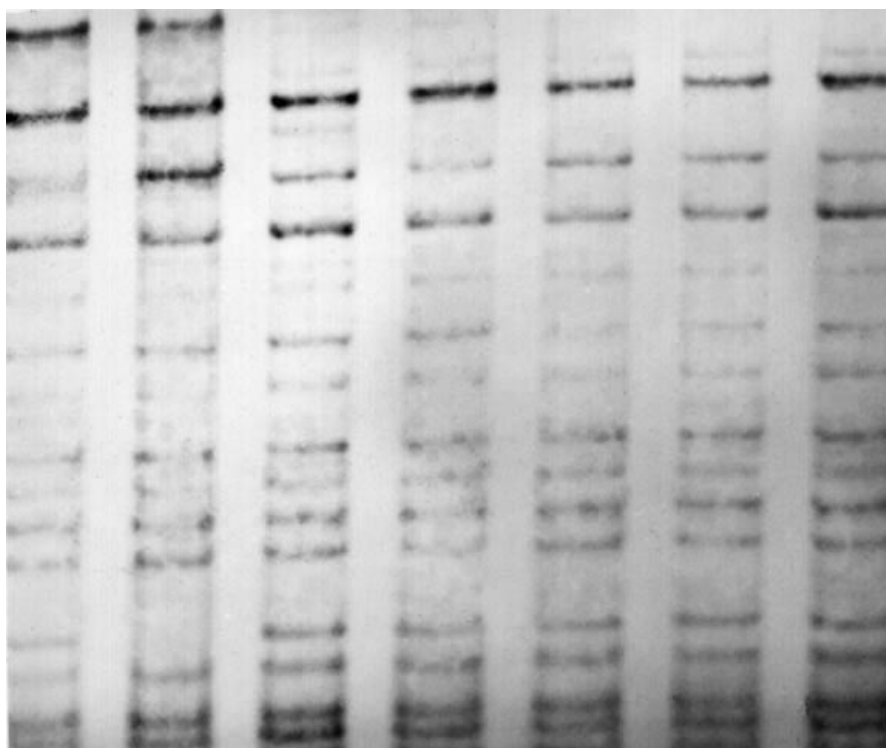
D N A
fingerprinting
explained



The use of micro-sized elements of the human person as a means of identification has extended as far back as 1900, when the first useful markers, the ABO blood groups were discovered. Since then and continuing on a timeline to 1985, scientists have consecutively made use of MN groups, blood group systems, serum proteins, enzymes and protein polymorphisms. The date of 1985 is set apart because it was during this year that Sir Alec Jeffreys, a

researcher at the University of Leicester announced the discovery of DNA typing in Nature. The technique is defined in several steps by Carrol Ezzel of Science News; firstly, a laboratory technician uses enzymes to cut DNA (a cell's genetic material) into several pieces, which are run on a gel. The gel is then promptly washed with a solution containing four types of radioactively labeled DNA probes. These probes form a pattern on photographic film, permitting analysis.

More specifically, the technique defined by Jeffreys involved DNA fragments called VNTRs (Variable Number of Tandem Repeats), which are sections of "junk DNA" in our chromosomes. These pieces do not code for functioning proteins and can therefore accumulate multiple mutations without any negative effects on the individual who carries them. VNTRs, according to the Department of Justice, are usually 8-35 bases in length and are repeated 100 or more times. Human



DNA contains multitudes of VNTR regions, many of which are available for analysis and comparison. More recently, labs have begun using STRs (Short Tandem Repeats) instead of VNTRs as the newer technology permits for the amplification (via PCR) of even the tiniest fragments of recovered DNA. In addition, STR analysis is preferred due to its rapid and unambiguous nature.

Recent Developments and Applications

All of this science only becomes relevant upon application – in the criminal justice system. Since its

development, tandem repeat analysis has been used for multiple identification purposes, the most prominent of which involves suspect recognition in violent crimes. A suspect's DNA fingerprinting results can be compared with analysis of fragments found at the crime scene. If these match-up, there is a strong probability that the suspect is, in fact, the perpetrator.

DNA fingerprinting is a relatively new development, and as such, its future path is still flexible. In fact, according to the National Academy of Sciences, "this new technology burst on the scene so rapidly that there

are essentially no standards and no regulations." Many groups, including the FBI, desire to influence the route that typing will eventually take. To promote this aim, as well as that of consistency, the Bureau has identified 13 STR core chromosome loci for testing in convicted felons. Further expansion of points is a possibility, but these will remain the resolutely most

influential. Furthermore, the FBI is currently in the process of data compilation and database development. This database is called the Combined DNA Index System and, according to the DOJ, was already equipped with 300,000 STR profiles by the end of 2000. In addition, all fifty states have enacted legislation providing for database creation on a more local level. All state databanks are connected to CODIS which, according to the Center for Strategic and International Studies, allows for identification of criminals across state lines.

If one were to glance at it first-hand, DNA fingerprinting and the consequent development of databases of convicted felon DNA are all very worthy, beneficial, and risk-free procedures. Society benefits in innumerable ways, with a seemingly fool-proof system for the segregation of innocence and guilt. The ascension of “cold hits” (the identification of a suspect based on nothing but a match-up with the database) as well as the exoneration of those the courts have found guilty offer heartening proof that fingerprinting works. As expressed by Barry C. Scheck, a professor at Cardozo School of Law, who stated that, “DNA testing is a public safety imperative, because each time an innocent person is arrested, indicted and executed the guilty person is out there free to commit more crimes.” In fact, Scheck and a colleague (Peter Neufeld) are now involved in the “so-called” Innocence Project, which works to uncover, declassify, and utilize DNA evidence to prove the innocence of those who have already been convicted. Currently, the tally of post-conviction exonerations via the analysis of DNA evidence stands at 85, a prominent number considering some of the accused were on death row. (CSIS)

Post-conviction exoneration, however, points us to the first of many blots on the otherwise rosy outlook for DNA typing. This mar concerns the effect that DNA testing after-the-fact has on the statute of limitations and the principal of finality in criminal law. Because the technique is so relatively new, such kinks have yet to be evened out, and eventually accumulate to produce a mound of evidence negating some of the overt

optimism inherent in the system.

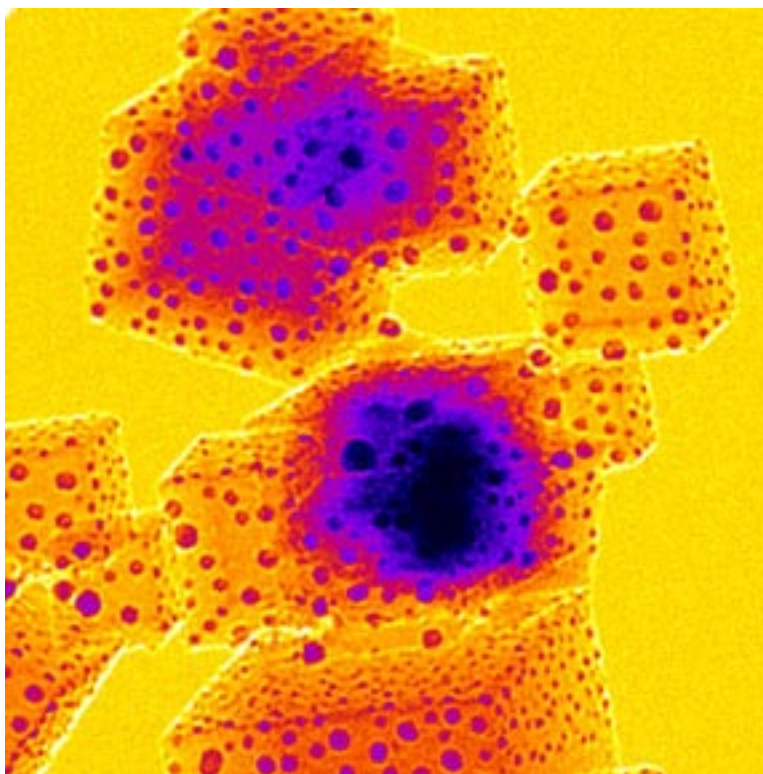
An Examination of Difficulties

DNA fingerprinting lends itself to three types of fallacies – the technical, the statistical, and the theoretically Orwellian. The first of these deals with the probability of error due to the mishandling, contamination and misinterpretation of evidence itself. In fact, Richard Dawkins (Arresting Evidence), a proponent of DNA fingerprinting, grudgingly admits to the difficulties associated with the above three factors when he lists their probable results: “A guilty suspect

may not be recognized, and thus escape – a false negative. Or an innocent suspect may be convicted because he happens, by ill luck, to resemble the genuine guilty party – a false positive.” Laboratory error is a serious concern and can occur pre-analytically or during scientific analysis, involuntarily or via conscious tampering. All of these provide for avenues of distress and fallacy. The nationwide backlog of DNA samples only contributes to the haste

and sloppiness of the private labs where analysis is frequently performed.

The second type of fallacy noted is of the statistical nature and involves the touted astronomically small possibilities of a mismatch. In fact, the oft-quoted figures of one in hundreds of thousands, millions, billions, and so on are based on simplistic assumptions of the sample population and may, in fact, be quite higher. Such an erroneous result is possible due to the following analysis: a person’s genetic material, even those regions classified as “junk”, are closely related



to and exhibit many of the characteristics of the same loci in their surrounding populations, involving family, geography, and ethnic group. Those individuals whose origins lie in identical or even similar “sub-ethnic” groups (as Rabinow classifies them in Galton’s Regret) have DNA whose similarity to one another is closer than to the general population. Therefore several of their STR loci could be sufficiently alike to merit a false positive and an unfair conviction. Carol Ezzel explains the phenomenon in Science News: “Because people tend to marry within their race, ethnic group or hometown, defense attorneys have argued that the frequency of a random match might be higher if an innocent suspect and the criminal were of the same race or came from the same city.” To alleviate the possibility of such an occurrence, the DOJ suggests several analysis approaches including conditional match probability, likelihood ratios, corrective factors and the Sib method.

Recent developments in regulation, the most prominent of which was the passage of the Innocence Protection Act, alleviate some of the burdens associated with the above two fallacies. Mainly, the legislation seeks to define the statute of limitations as well as to impose mandatory standards of DNA testing. Improvements have been so impressive that bold statements such as this one made by Dawkins – “Provided enough genetic loci are examined, the

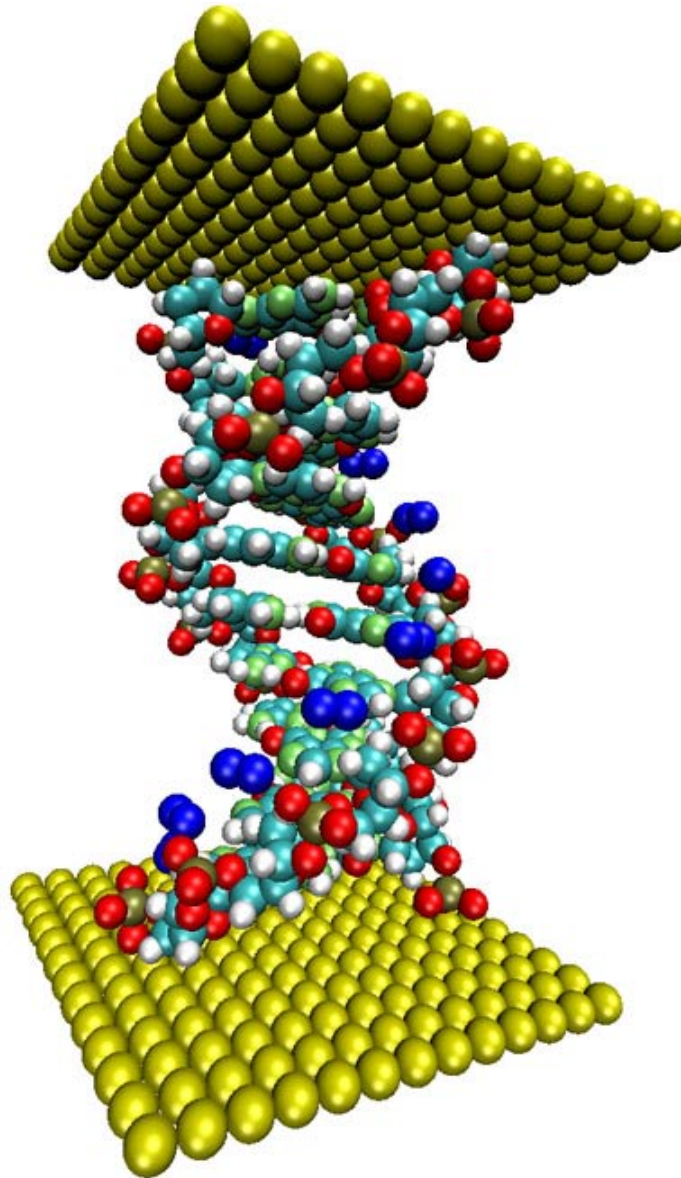
chances of a misidentification, even among members of minority groups, even among family members are much smaller than they are with any other method of identification” – are warranted.

If the list of dilemmas associated with the technique was to end there, DNA fingerprinting would remain above

reproach. Unfortunately, we have yet to explore the most worrisome aspect of DNA fingerprinting – mainly, the social costs involved in such a system. Most of the questions raised touch upon a wholly novel human right, that being the right to “DNA privacy”. If we make the assumption that such a privilege exists, several imperative questions instantly raise for answering:

- S h o u l d the government be allowed to take DNA from someone without their express permission? Civil libertarians worry that such a development could prompt the Big Brother activities on the part of the administration.
- W h o owns the DNA

used to establish a persons genetic ID – the individual, the laboratory, or the police? The existence of a government database presupposes the administration’s regard of the material as its own. However, both the firms and actual individuals involved may



have prior claim to the sensitive bases. According to Rabinow, “Enforcing a common standard will not be easy in a field in which private companies are doing the bulk of the analysis and want to retain proprietary right over their techniques.” Additionally, Ballve notes that many tested individuals would be uncomfortable with the idea that strangers could retain a piece of canvas spelling out their “most intimate information”.

- Who will have access to the database? Perhaps most importantly, an authority (presumably the government again) must define the entities who would be able to utilize databases for non-criminal analysis. In relation to this very point, Rabinow buries a very astute point into an otherwise bland paragraph of Galton’s Regret, stating that “risk profile analysis might well be hard to resist.” Prominently, many experts worry that insurance companies would become obsolete if they were able to analyze the information that the databases contain. Genomic material can spell out a cause, as well as a relative timeline, for death. Under such conditions, insurance would only be applicable for accidental termination of life. Additionally, employers might bias against hiring certain individuals based on an analysis of their genetic make-up. As hard as such a situation is to fathom, the FBI has already carried out a number of such operations in relation to its own employment practices.

Concluding Remarks

The history and, more significantly, modern development of DNA fingerprinting point to two phenomena scientists of all fields are experiencing. The first is the loss of public naivety about the absolute nature of science. Merton’s scientific norms, as well as Bourdieu’s insistence on the separateness of the scientific community, are being put aside with a greater recognition of the fallibility of this discipline. This is reflected in the squabbling of expert witnesses on what constitutes correct practice and certainty in DNA

matching. As such, the second phenomenon – that being a greater need for, and realization of, government presence in the sciences – is gaining momentum. The appointment of authority is necessary to thwart the disarray that could result from the incorrect application of this highly prized technology. In this case, efficiency (and thus the garnering of all possible benefits) can be achieved only through directives from the top. The recognition of the necessity of such action is reflected in the central role that the FBI and Congressional legislation is playing in further developments. Most importantly, the case of DNA fingerprinting prominently exhibits the many points of interface between the “disciplined sciences” and society. Only when a perfectly balanced relationship is achieved will all profits of technology accrue.

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Images:

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Electronic Health Records: Patients' Rights to their Health Information

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Determining the appropriate access scheme to govern access to a patient's electronic health record (EHR) is often couched in philosophical terminology, e.g. the patient has the right to restrict access, or it is unethical to afford such-and-such organization with access. However, less attention has been paid to justifying the assumption that ethical considerations – as well as the ethical principles – should underlie our use of EHRs. Are we justified in suggesting ethical principles and suggested guidelines to govern medical informatics, and if so, what form will these principles and guidelines take? These questions can be answered by an analysis of the nature of the patient record, both independently, as well as within its socially embedded framework.



The argument here is relatively straightforward. It focuses on the logical requirements for something to function as a model or analogue of something else. Put in a nutshell, it argues that electronic patient records stand in such a close relationship to the subjects of the records that any non-ethical treatment would have immediate ethically relevant repercussions on the subjects themselves (Kluge, 41).

Because the non-ethical treatment of the patient's information would produce ethical problems in the actual patient, Kluge convincingly argues that we are justified in assigning an ethical status to EHRs. This epistemic analogue exists because the patient and the record are embedded in a framework of other relationally interconnected users. (Kluge, 43).

The Analogue Role of the EHR

The patient health record can be viewed as a functional entity that can hold and disseminate pertinent information regarding specific patients. Patient records can hold a vast amount of information, making the record a window into the life and health of the individual. Therefore the record becomes – for all intents and purposes – a reflection of the patient. In E.W. Kluge's book *The Ethics of Electronic Patient Records*, Kluge furthers this idea by contending that the health record is an 'epistemic analogue' of the patient, and that the analogous ontological nature of the record provides justification for ascribing ethical principles and guidelines to EHRs:

The Socially Embedded Framework of EHRs

Kluge proceeds to point out that the logical form of an entity is a function not only of itself (i.e. what the record is, the patient) but of the logical nature of the framework in which these entities are embedded (Kluge, 44). Determining the logical nature of the healthcare framework is complex, particularly because there are numerous entities in addition to the patient and their EHR analogue. However determining this framework is imperative – thus it is worthwhile to focus on the different entities that are functionally related to the patient.

Many individuals in the United States have more than one



healthcare provider – in fact many have numerous providers. The number of physicians that have some sort of relationship to the patient has dramatically

increased as specialization in our country has itself increased. Furthermore, the number of entities has risen as a result of the different ways that patient's can pay for their health care. Instead of the patient paying for a physician's or hospital's services out of their pocket, payors such as HMOs and insurers have become common place. Legitimately, insurers and HMOs require documentation to warrant submitted claims. Many times this corresponds to information about a patient's diagnoses and procedures, usually taking the form of a standard vocabulary such as the International Classification of Disease (ICD9 and ICD10) for diseases as well as the Current Procedural Terminology (CPT) for procedures. Therefore these organizations justifiably require a unique relationship to the patient's medical information – in turn forging a relationship with the patient in addition to the relationship the patient has to their physicians. In addition to insurers and HMOs, by simply being a citizen of the United States, all patient's have a relationship with certain public health organizations whose goal it is to increase the health of the overall population. To accomplish this task, public health organizations routinely need access to large amounts of patient information in order to conduct epidemiological studies and the like.

Some of the other entities that are functionally related to the patient and their EHR analogue are entities that are themselves functionally related to the above entities. These include secretaries, clerks, pharmacists, healthcare clearing houses, as well as a host of others. Each of these entities has a unique stake in accessing the patient's information. For example secretaries and clerks require some kind of access to the patient's EHR for scheduling and billing purposes – two facets of patient care that will likely be incorporated into the EHR.¹

Thus, the analogue is connected to other entities because the record serves the analogue function of the patient

(i.e. as a source of information necessary to make accurate decisions). In other words, the record provides users with information that would otherwise only be available if the patient was physically present. Paper-based charts are available to physicians but are bulky and often incorrect. EHRs, on the other hand, represent a patient analogue that may be increasingly accessible to the other entities qua nodes of the healthcare network. The transition to electronic records complicates this framework in that – unlike paper based records – EHRs allow new entities to easily join the network. Therefore the entities within the healthcare framework quickly can grow depending on the health of the patient. Because some users will desire write-access, the information stored within the record will also grow at exponential rates, placing the issue of data integrity at the forefront of write-access considerations. Moreover, as EHRs come to represent cradle-to-grave charts of a patient's health history, the amount of highly sensitive information will be an important consideration in protecting the patient's rights.

Unique Patient-Entity Relationships (UPER)

It should be clear that there is a plethora of entities that are part of the health care framework. These entities form relationships with the patient, their analogue, and at times both the patient and their analogue. Each of these entities has a unique role because each of these entities desires unique information for distinct purposes. Though these relationships are unique, their purpose is the same: to positively affect the patient's health. Therefore, it is helpful to discuss and investigate the unique patient-entity relationships (UPER) to determine how EHR access should be distributed. These unique relationships will be the basis for the different access schemes that can be implemented.

The Patient and the UPER – Co-ownership of Data

The way in which the patient relates to their analogue will have a significant affect on the UPERs. It is not sufficient to say that patient's should be involved in making decisions regarding their health information. Rather, the position of active patient involvement must be justified before we can draft design suggestions and guidelines that incorporate the patient. Batami Sadan, of the Hadassah Medical Organization in Jerusalem explains the idea of co-ownership of data by providing a scenario from banking. Imagine if banks sold personal

account information to insurers and to travel agents, estate brokers and other third parties with the justification that the consumers will benefit from the sharing of such information. Sadan rightfully holds that this is ‘ludicrous’ – describing how the accepted model is that bank information is owned by the client and only disseminated by the bank if given personal authorization (Sadan, 11). Likewise, Sadan argues that:

This is the model we advocate for the ownership and custodianship of medical data. The patients will be the owners of their medical data, but these data will be managed by the treating institutions and physicians. This will accomplish two major goals: the preservation of data confidentiality, because data will not leak out of a treating institution without the owner’s permission and the maintaining of a high standard of information, because individuals can control and thus continuously monitor the correctness of the information in precisely the same way they do their bank accounts (Sadan, 4).

Sadan’s example from banking is quite helpful in understanding the problems surrounding the sharing of medical information. For years banks have had complex computerized systems that stored sensitive information about their consumers. As banks and credit companies started to embrace the digital storage of information, federal legislation followed to protect privacy.² Parallels definitely exist between information storage and dissemination in the banking arena and in the health care arena. Likewise, there is no reason that patient’s should not be afforded rights to their health information in somewhat the same way that they are afforded rights to their financial information. Sadan frames the idea of patient rights as patient ownership which is helpful for our discussion. As Sadan points out, patient ownership will help ensure the preservation of data confidentiality as well as data integrity in that the patient will inspect the information to ensure its accuracy. Kluge also frames the issue of patient rights in terms of ownership. As Kluge points out, institutions, physicians as well as any other health care professionals are paid for their services. This payment creates a contractual relationship with the



institution, or in our terms, the entity. Therefore any entity that desires a relationship with a patient will enter into some kind of contractual relationship through the payment of services. The patient has a right to these services, and the medical record is one aspect of these services that the patient should have ownership over (Kluge, 125). Kluge rightly points out that there are limitations to the patient ownership of medical data – many records incorporate proprietary information or results from proprietary clinical decision support systems that the patient does not have ownership of. Nevertheless, patients must have some form of ownership rights over certain aspects of their medical record.

But how does the fact that patients have ownership over their health information connect to the different UPERs that will arise? Well, it seems as though the patient’s right to ownership will provide the patient with some degree of autonomous decision making authority over what information entities can and cannot access. Discussion of the details of access privileges is outside the scope of this paper, however it is important to keep in mind that patients are justified in owning their medical information and that the autonomous decisions that arise from ownership may influence the interaction between the entities and the patient’s EHR.

Footnotes:

¹ Scheduling is something that many have discussed as being incorporated into the EHR. If certain schedules of the patient could be entered, efficiency could be dramatically increased. This could include reminders for clinical visits, for medication refills, or to simply remind patients to take their medication.

² For instance one of the sections of the Financial Modernization Act of 1999, also known as the “Gramm-Leach-Bliley Act” is the Financial Privacy Rule that establishes strict guidelines to protect the privacy of consumer’s financial information. Medical information is often as sensitive as financial information, and can be used for a wide variety of discriminatory purposes.

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