

**“Start a Line and Get Me a Consent Waiver, STAT!”
Autonomy, Community Consultation, and Informed Consent in
Emergency Research**

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Let’s say that it’s a few years before the turn of the millennium—sometime in the mid-1990s—and you and your spouse are traveling to Houston to visit friends. There is a terrible car accident—this is when I knock on wood and say *I hope this never really happens to you*—and both of you are injured badly. Your heads are thrashed about identically. You are both identically wounded and identically unconscious. After a brief ambulance ride you are wheeled into the ER. You cannot see it, but nurses and doctors begin attending to you immediately. One of the doctors disappears behind a curtain; and if you were awake you would be able to make out his silhouette—a shadow surrounded by bustling bodies, flipping a coin, twice. When he emerges, he is carrying with him cooling blankets. He packs them around your spouse’s head and body in an attempt to induce hypothermia. Your spouse’s body temperature drops nearly eight degrees. There are no blankets for you. You will receive the standard treatment, for perhaps lowering the body temperature of a severe head trauma patient can reduce “both morbidity and mortality,” or perhaps it will only complicate matters. Nobody knows. That’s why the doctors are experimenting on you and your spouse.¹

Let’s say that I tell you this—tell you that this is perfectly legal and not out of the ordinary, tell you that you and your loved ones can be experimented on in emergency rooms across the country and there is nothing that you, individually, can do about it—I tell you this, and in shock and disbelief you clutch your chest and (knock, knock again) suffer a heart attack on the spot. Depending on where you live, when the paramedics arrive they might begin CPR—standard manual CPR—or they might try some new device on you, maybe a pneumatically inflated vest or some type of plunger that pumps your heart as if it’s a clogged

toilet. Of course, no one knows how well such technologies work. Or don't work. That's why the doctors are experimenting on you.²

Where We Are and How We Got There

In 1947, we—the victors of World War II—put to death seven Nazi doctors for what Nuremberg chief prosecutor Telford Taylor called “murders, tortures, and other atrocities committed in the name of medical science.”³ Essentially, the doctors had been experimenting on people without their consent.

The trial of the Nazi doctors had been unplanned. Goering, Hess, and other surviving Third Reich leaders were being tried in Nuremberg on “political” and “military” grounds; but as information regarding the medical experiments that took place in the concentration camps came to light, the prosecutors decided to pursue the matter separately, and the international tribunal agreed that the case could be prosecuted as a *war crime*.

The phrase itself says much about us—says much about our feeling that war itself is not a crime, that we are able to note hierarchies of misbehavior and levels of evil, that we long for rules—expect rules—even in hell. By the end of Hitler's reign, nearly half of the doctors in Germany had joined the Nazi party. At Nuremberg, though, attention was focused on only the top twenty-three who had power and access to the concentration camp inmates for their experiments. And what they did surely amounted to a moral crime, in and out of war.

In an effort to aid fighter pilots who crashed or parachuted into the cold North Sea, for instance, the Nazi doctors froze prisoners and systematically tested thawing techniques, searching for the one that would lead to the lowest rate of morbidity and mortality. Other prisoners were subjected to atmospheric pressure tests, forced to drink only sea water, or used in experiments involving new drugs and surgical techniques. From a utilitarian standpoint, it made sense—a few suffer so that many in the future survive—and although it is estimated that 100,000 concentration camp prisoners died as subjects of medical experiments during the war,

even such a large number could be outweighed by greater health and happiness for others in the future.

Perhaps it was this sort of reasoning that especially frightened the prosecutors at Nuremberg. How could any of this ever be called *right*? And so they searched to put into words exactly what the moral crime had been, and this is where the trouble first began.

Ironically, British-based ethics was little help. Bentham and Mill and the radical utilitarian might find a way to justify what was done. But a German-based ethic—one informed by a Kantian deontology, with its respect for persons and its commitment never to treat another individual as a means but rather as an end in-and-of him- or herself—could form the basis of a moral condemnation of the medical experiments. And so, the allied powers at Nuremberg cast the crime in terms of the lack of respect for the individual, the way in which the subject's autonomy had been overridden, and the basic non-consensual nature of the procedures.

But here was the difficulty: “the prosecutors soon discovered that the case raised issues that were more problematic than they had realized—among them the lack of internationally recognized codes of medical ethics by which the behavior of the Nazi doctors could be judged.”⁴ The lack of international rules has always been a concern for those looking at the legality of actions. Of course, what the Nazi doctors had been doing in Germany was not a crime in Nazi Germany—this is why we are forced to call their actions “crimes against humanity” or “war crimes.” Yet, the word “crime” strains here: no codified law has been broken. (This is one of the reasons we tend to talk so much about Nazis in undergraduate introductory ethics classes—it helps show the uninitiated that there must be some division between legality and morality.) We should have been clear, then. This was not a court of law; it was a “court” of morality. Granted, and accepted. But the more pragmatic problem remained: given the way that the court described the “crimes,” nearly every country was guilty to some degree of the same behavior. Before the Second World War, this was how most research took place—doctors would try out new techniques on their patients, and it never much occurred to the doctors to ask for their patients' consent. Autonomy was for all intents and purposes surrendered at the door to the doctor's office or the hospital. The doctor-patient relationship

was one based on paternalism—a specialist with guarded, expert knowledge who is assumed to know best was given great latitude. During World War II, in fact, large-scale research was being conducted on human beings in the United States without consent of the subjects. Prisoners, patients in mental institutions, soldiers, and even conscientious objectors were subjects of experiments without their consent and often without their knowledge. Consequently, we—the good guys—were just as guilty.

The three judges who handled down the sentences at Nuremberg that sent seven doctors to death and eight others to prison wished to provide the argument for their decision in a form that might become accepted as a universal standard for medical research. Thus was born the Nuremberg Code, which reads from the start: “The voluntary consent of the human subject is absolutely essential.”

At first, doctors around the world did not think that the code was relevant to their research. Characterizing their work as falling within the confines of a doctor-patient relationship and the Nazi doctors’ work as being better explained by a jailer-prisoner relationship, doctors in America dismissed the Nuremberg proposal as “a good ethics code for barbarians.”⁵ What they failed to see was that their relationship with their patients had necessarily changed once they began experimenting on them. Perhaps there was still a doctor-patient relationship at work in which the sole goal was improving the health of the patient. But as soon as experimentation began, there developed a researcher-subject relationship, the goal of which was to accumulate data and hopefully benefit others in the future, possibly at the expense of the patient on the exam table right now. At times, then, these roles can be at cross purposes, even in the most humane and well-intentioned doctor.

And it is also the case that there have been countless incidents of less-than-well-intentioned doctors in the U.S. who have adopted *only* a researcher-subject relationship with their “patients.” In the 1960s, researchers enrolled patients at the Brooklyn Jewish (!) Chronic Disease Hospital without their consent or knowledge, injecting them with live cancer cells in order to study how the immune system fails to eradicate cancer. In the same decade, orphans in Ohio were infected with dysentery and mentally retarded children infected with hepatitis.

Throughout its history, the U.S. has especially targeted its African American population for secret experimentation, and the list of abuses sounds strikingly Nazi-like: research on slaves was performed in order to find a cure for urine leakage into the vagina; various vaccines (including smallpox) have been tested on slave and black populations; radiation experiments have been performed on poor, black women; and the modern cesarean section that is used today was perfected by performing it on black women when it wasn't necessary.⁶ The most famous atrocity, however, is probably the Tuskegee syphilis study which took place from the early 1930s to the 1970s. In the study, Public Health Service doctors saw and studied more than four hundred African American men in Alabama, each of whom had syphilis. The doctors never told the men that they had the disease, and they were never offered treatment. After an investigative journalist discovered the story and made it national news, a seven year project to investigate the study was commissioned. In 1978 the findings were released, and the general ethos of the country soon changed such that voluntary informed consent was seen as a moral imperative in all human experimentation.

Earlier, in 1966, the surgeon general had in fact created a policy to protect human subjects. Institutions with Public Health Services grants would be required to form an institutional review board (IRB) that would be in charge of watching over experiments using human subjects and making sure that informed consent had been obtained. In the late 1970s and early 1980s, then, IRBs finally began to be taken seriously.

With all of this commitment to achieving informed consent, however, certain classes of patients were still overlooked. Consider experiments involving children—crucial, if cures for childhood diseases are to be found. Adolescents, after all, cannot give autonomous consent; infants cannot ponder whether or not to enroll in a clinical trial. And further, consider the case of the mentally ill. Using them for experiments to benefit the rest of society is surely wrong, but what about experiments that are necessary to cure their own various mental illnesses?

The solution to such cases had already been suggested in 1962 in the Declaration of Helsinki, and the same thinking would soon be adopted in U.S. law. In a reworking of the Nuremberg Code, the framers of the Declaration of Helsinki declared that consent of human

subjects was essential—but not *always* essential: “Where physical or mental incapacity makes it impossible to obtain informed consent, permission from the responsible relative replaces that of the subject. . . .”⁷ Surrogate consent was thus the answer, with the autonomy of an appropriated representative—typically a parent or family member—standing in for the autonomy of the subject. Hard-line supporters of the Nuremberg Code declared that autonomy and informed consent had been abandoned, that we were once again on a path toward abuse. But surrogate consent became a reality, balancing—or attempting to balance—the values of the individual and the society.

Though this is admittedly a brief sketch of a complicated history, it brings us to the 1990s and the latest major crisis. Though the concept of surrogate consent solved most cases in which the subject was incapacitated or otherwise incapable of understanding and communicating his or her wishes, there was still a class of patients and a type of experimental research that was being overlooked. When patients come into an emergency room unconscious and uncommunicative, their condition is often so pressing that there is often not enough time to track down an appropriate surrogate, explain the situation, and get informed consent. For treatment purposes—that is, for non-research therapies—the Emergency Exception was thus created. The Exception allows, for example, the compassionate use of drugs for advanced heart failure, or for a doctor to set a young child’s leg in a cast if the child is in a skateboard accident and is brought in by a stranger. The idea is that a reasonable person would want to receive such care and should not be denied it simply because he or she cannot give informed consent and no surrogate is readily available.

The problem arises, however, when the emergency procedure is not standard care, but experimental care. What if the doctor wants to try a new procedure on a stroke victim, a gunshot wound patient, or a person who is unconscious after being poisoned? What if the doctor has reason to believe that reducing the body temperature of a severe head trauma patient can reduce both morbidity and mortality, or substituting a pneumatically inflated vest or plunger device for standard CPR might save lives? Sometimes the only possible subjects for such

research are incapable of consenting, and the research is necessary to save countless lives in the future.

One of the reasons standard CPR is so ineffective—of those who initially survive and are admitted to a hospital, less than 25% recover and live—is that CPR was a theoretical construct, an idea that made sense and was accepted as standard care without controlled studies that could indicate its efficacy and refine the technique.⁸ In a certain sense, isn't standard CPR thus "experimental"? Not experimental in the sense that data is being collected in an on-going trial, but experimental in the sense that it is untested and unsure and has received the mantle "Standard Therapy" merely by default? Since the majority of the more than 350,000 people who have unexpected heart-attacks each year in the U.S. die, wouldn't it be wise for everyone, including the patient-subject, to support such research? Nearly everyone agrees, but the problem is consent.

For a while, many researchers promoted the idea of "deferred consent": enroll the patient in the experimental trial, and try to reach a surrogate later or wait until the patient is conscious and communicative again. Then, ask him or her (or ask the surrogate) if it's all right to continue with the experimental treatment. Consent would still be given under this model, it is argued, only it would be deferred.

The difficulty here is that deferred consent is not consent at all. There is an important—necessary, even—temporal element to consent. It must come *before* the procedure. Suppose that at the end of a date a man has sex with a woman without her consent (perhaps she is inebriated or even passed out). The next morning, upon learning of the unwitting coupling, she might indicate that she wishes to continue a relation with the man because she was planning on having sex with him anyway. Or she might (rightfully, hopefully, and more likely) phone the police. In the latter case, the woman is right to have the man arrested for it was clearly an act of rape. We would all recognize it as such. But in the former case it was rape as well, for what determines whether the act was one of rape or lovemaking is not how the parties feel about it afterwards, but rather whether or not there was consent before. In the unlikely event that the woman forgives the man and continues to be with him, let us not—as Scarlett O'Hara and so

many Soap Opera heroines have done before—gloss over this fact: the man is a rapist. So, too, with deferred consent in medical research. No amount of later agreement can change the fact that the initial experiment was done without consent.

So in 1992 the federal government banned the use of deferred consent. The ban came on the heels of the government's admission that it had knowingly funded experiments during the 1950s in which "unsuspecting patients received non-therapeutic radiation."⁹ Imagining asking those subjects for their retroactive consent now—as if that could make anything better—was, perhaps, the final straw for some. Regardless, deferred consent was no longer a possibility, and all emergency medical research came to a halt.

At a joint meeting of the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) in 1995, the American Heart Association teamed up with the Society for Academic Emergency Medicine and various independent critical care and acute resuscitation researchers to draft recommendations for ethically sound emergency research and to draw attention to the need for such research.¹⁰ A year later came the response. On October 2, 1996 the Secretary for Health and Human Services (HHS) announced, under Section 46.101 (I), a waiver for obtaining informed consent for some forms of emergency research. Essentially, the law states that an emergency research waiver can be obtained if an IRB finds that nine conditions hold: (1) the subject is in a life-threatening situation; (2) available treatments are unproven or unsatisfactory; (3) the procurement of informed consent from the subject or a surrogate is not possible in the time before the start of treatment is required; (4) there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research; (5) participation in the research holds the prospect of direct benefit to the subjects; (6) the research could not practically be carried out without the waiver; (7) researchers will continue to attempt to contact authorized and even non-legally authorized representative surrogates for each subject in order to obtain their retroactive and continued consent; (8) consultation with representatives of the communities in which the research will be conducted and from which the subjects will be drawn has taken place; and (9) an independent data monitoring committee has been established to exercise oversight of the research.

This is where we stand today. This is how you and your spouse might unwillingly become enrolled in the hypothermia head trauma study or the multicenter Vest CPR trial. Interestingly, there has been little public debate on the new waiver—for one reason or another, it has not become a hot issue in the media. But ethicists and those in the medical professions have strong opinions on the new regulations. In what follows, I will look at the arguments for and against the emergency waiver and even touch on why the public at large seems uninterested. Along the way, I wish to draw attention to the use of placebos, the nature of autonomy, and the challenges of community consultation as the most interesting and relevant ethical issues, suggesting—in the end—that emergency research might be ethically allowable, though not typically for the reasons it is championed today or in the manner it is currently conducted.

Seven Arguments for the Elimination of the Emergency Waiver

Let me first try to make as strong of a case as I can against the emergency waiver. Other than the general and perhaps valid worries that we might thus become those barbarians in need of an ethics code such as the Nuremberg, it seems to me that there are seven arguments that can be offered for the ethical elimination of the waiver.

(1) The Hippocratic Oath Violation

Sometime during the fifth century B.C.E., Hippocrates conceived of an oath to be taken by physicians for the purposes of protecting patients' rights. The oath has changed over the centuries—Christianized a millennium ago when all of the references to pagan deities were excised, for instance—but its spirit has remained the foundation for ethical medical conduct in the West. And Hippocrates' oath precludes the possibility of using a patient to gain knowledge that will later benefit others.¹¹ “First, do no harm” is the physician's primary guideline. But the researcher has no such commitment. The researcher is focused on the future, on other benefits to other people. When a doctor enrolls a patient in a clinical trial—especially when that

enrollment is done without the patient's consent—the doctor has decided to become a researcher as well, and the Hippocratic Oath has been necessarily set aside.

Dominique Sprumont argues that “therapeutic research” is an oxymoron and that there is a necessary dissonance between the doctor's role as healer and researcher.¹²

[T]here are two basic distinctions between practice and research. Firstly, the sole goal of practice is to enhance the health and/or the well-being of an individual patient. By contrast, the investigator's goals include those of the research itself. He or she is somehow a double agent whose two masters are research and practice. Even where one does not behave contrary to the interests of one's subjects, the investigator does not act exclusively in their interests. Secondly, the doctor-patient relationship is highly personal in the sense that all the activities of the practitioner are based exclusively on the specific needs and interests of the patient. By contrast, an investigator must strictly follow the procedures fixed in the research protocol....In fact, some research protocols mention severe side effects or adverse reactions as criteria to exclude a subject from on-going research. It is therefore admitted in principle that the subjects involved may have to suffer mild adverse reactions, even though this might not be necessary if treated as patients.

All of these matters are complicated when it is emergency research that is being considered, for often in emergency situations the possible adverse reactions to a treatment are not mild—they can be deadly. And while it is true that all forms of research change the doctor-patient relationship, this is especially troubling when the change takes place without the knowledge or consent of the patient. The ill—in this society—are taken to doctors for treatment and not scientists for study.

Jay Kutz argues further that the emergency waiver “blurs the lines” between research and therapy. Kutz writes:

[O]ne of my most fundamental objections to the regulation [creating the emergency waiver] is this: that in its emphasis on therapeutic benefits, the FDA obscures the fact that some of the permissible research activities either hold out no promise for therapeutic benefit or are so vaguely defined that potential therapeutic benefit can be inferred when research is the predominant intent. Research is not treatment, and whenever clear distinctions are not made between the two, the waiver of informed consent becomes problematic because some human subjects are being recruited to serve the ends of others.¹³

Researchers do not take the Hippocratic Oath swearing to do no harm and to place the patient's health as their top priority. But doctors do. When, unbeknownst to the patient, a doctor becomes a researcher, he or she has violated that oath and done wrong.

(2) *The Patient Has a Right to Standard Care*

It has been a “longstanding tenet of modern medical ethics that each patient has the right to the accepted standard of care for his or her condition. Yet, the new regulations let some patients unknowingly receive experimental treatments that are nonstandard for their condition.”¹⁴ That the *expectation* of receiving standard care has been violated is part of the moral problem here. It is not just that the patient has a right to standard care, but a right to expect standard care when attended to by a physician. The emergency exception undermines this expectation and thus the entire system of health care and the doctor-patient relation.

(3) *Methods and Risks Associated with Waiver are Inappropriate*

Before the new regulations, the HHS permitted a waiver of informed consent only when the research involved “no more than minimal risk to the subjects.” This reasonable rule has now been abandoned. Not only can emergency research lead to deadly risks, the risks in fact are not really known at all—this is why the treatments are experimental.

Part of what adds to the risk—i.e., what constitutes an even greater risk once all of the physical, emotional, psychological, etc. risks associated with the new drug or treatment are assessed—are the methods that are employed in standard clinical trials. These include the randomization of patients and the use of placebos. Both aspects of research have been attacked in general, but when they are used in conjunction with a consent waiver the worries multiply.

Randomization is one of the hallmarks of a well-designed scientific study. It assures that the investigator's bias does not sneak into the experiment, tainting the pool of subjects. Typically, a potential subject is told that agreeing to participate in the study does not necessarily mean that he or she will receive the experimental therapy. Once consent is obtained, it is often the case that an investigator will then flip a coin (often literally) to determine whether the subject

will be receiving the new therapy or will be placed in a control group (typically receiving the standard therapy). Sometimes the laws of statistics place the subject in the control group, and at this point the researcher must explain to the subject that he or she will not receive the experimental therapy but is still an important part of the study (since his or her data will be collected and will be used to compare with the data obtained from the group receiving the experimental therapy). Other times it is important that the subject not know which group he or she is in, thereby reducing the psychosomatic influences that may result in either getting better simply because one is hopeful about the new procedure or not getting better because one feels doomed to the less “innovative” treatment. In order not to let the subject know to which group he or she has been assigned, a placebo is often given to the control group such that there is no apparent distinction from the point of view of the subjects between the control group and the experimental group. They are *blinded* to their assignment. When the researcher, too, does not know into which group any given subject has been placed (because the randomization has been done by a neutral third party), the experiment is said to be *double-blinded*.

In non-emergency studies without blinding or placebos, troubles often arise when the researcher must explain to the subject that—after having gone through all of the explanations and the possibly nail-biting decision-makings to consent—it turns out that he or she has been randomized to the standard treatment. The subjects often feel “cheated.” According to one pediatric oncologist, it is especially difficult when dealing with parents who have decided to enroll their child in a trial: “It is very difficult to explain that a new treatment is unproved but potentially valuable, gain consent for entry into a trial, and then explain that the patient has been randomized to standard therapy, while still maintaining parents’ trust...”¹⁵ Because of this, various methods have been proposed to alleviate stress on behalf of the subject (and surrogates).

The Zelen 1 method of pre-randomization suggests that in emergency situations, newborn babies should be randomized into two groups *before* asking for parental consent. Then, only the parents of the babies randomized into the experimental-treatment arm of the study would be asked if they want to consent.¹⁶ Peter Allmark, for instance, maintains that this

will reduce stress on the parents who often find it difficult to understand the need for randomization in the first place. It will also prevent doctors from having to admit (as often) that they don't know which treatment is better (a fact that frequently ruins a parent's faith and trust in the doctor). And finally, since most parents prefer the unproven experimental treatment, it is argued that it seems cruel to offer them only a 50-50 shot at getting it. With the Zelen method, all patients offered the chance to participate in the trial would get the experimental treatment for their child if they choose to consent.¹⁷

Notice here that the arguments all assume a certain paternalism. Supposedly, the Zelen method is meant to make things easier on the parents, but the end result is to make things easier for the researchers: they no longer have to try to explain randomization; they no longer have to admit the truth (that they *don't* know what treatment is best). If the real goal is to build trust and faith in the doctor, how can this be generated by suppressing the truth? Also, as Raanan Gillon suggests, "once it becomes known that such methods are in use...[there is a] question whether there is in fact much reduction of parental distress...."¹⁸ Ultimately, the larger philosophical problem is in thinking that the Zelen method somehow magically transforms the nature of the experimental trial such that one is not participating until *after* the coin flip. It must be made clear that the clinical trial begins with the identification of a potential subject, with the randomization itself. When the doctor is secretly randomizing patients, they have already become subjects and are part of the trial. This is both commonsensically true (looking at the protocol—the actual document describing the research—the randomization is part of the process) and "metaphysically" true (when we ask ourselves where research begins it must begin with the randomization—after all, a coin flip is not part of the treatment, not part of standard therapy, and thus once it takes place it has obviously ushered in something new). Consequently, this method of randomization is actually a form of research without informed consent.

Gillon's proposed solution is an "Advance Directive" in which pregnant women are given information early in their pregnancy about possible clinical trials in which they might enroll their baby should the situation ever arise. The women could then have plenty of time to

think it over and indicate their willingness or unwillingness to participate in the future. This Advance Directive—a cousin to a Living Will—would be the basis for a physician making the decision to enroll the baby in a trial once it was born and the appropriate circumstance arose. One might then be tempted to transfer this solution to the general problem of the emergency research consent waiver. The burden would be on the researchers to identify potential subjects and obtain their advance directive. This is certainly better than assuming their willingness to participate. And while it is difficult for the researchers to single out and consult with the candidates, it is more ethical than placing the burden on the public to find out about the research that is being done and then request not to be included should they ever find themselves in that particular emergency situation. Some have championed this latter idea as a solution, but why should the public have to be concerned with stating that they don't wish to be experimented on? (To return to the rape metaphor, all women would be fair game, under this rule, unless they previously had contacted the authorities and put their name on a list of women who don't wish to be raped.) Norman Fost, a professor of pediatrics, has gone so far as to suggest that, for example, we make “available a mechanism for individuals to identify themselves as not eligible for the study...[such as] the use of bracelets....”¹⁹ The idea of necklaces, dog tags, and bracelets indicating unwillingness to consent to experimental research would be laughable if it were not so shockingly frequently proposed. The logistics alone would seem enough to dismiss the idea—should one be unlucky enough to live near an ER engaged in many trials one might be draped in so many “unwilling to participate” jewelry notices that it would bring to mind Mr. T circa 1980. (“I pity the fool who experiments on me without consent!). But surely the ethics are convincing: the burden of enrollment should be the researcher's, not the citizen's. Someone is going to have to work hard here, and it should be the one who has the greater odds of gaining—namely, the drug companies and researchers who back such experimental trials in hopes of achieving riches and advancement...along with saving lives.

Still, we might argue that however enrollment is done, randomization itself is always disrespectful to the human subjects involved. Simon Verdun-Jones and David Weisstub maintain that “it has been contended that, ‘ideally,’ randomization should not be resorted to

unless there is a real division of opinion concerning the relative merits of the therapies that are to be evaluated....”²⁰ While such situations should not exist—there should be a state of equipoise in which the arms of the study seem equally potentially beneficial and risky—the authors rightly note that this is seldom the case: “physicians will almost certainly have a treatment preference of one kind or another, frequently based on anecdotal rather than scientific grounds.”²¹ Placing a subject randomly in one arm or another thus often results in the subject receiving a treatment not considered to be the best by his or her physician. This is not only medically dangerous and unethical, it is disrespectful. As Sprumont concurs: “from the beginning of the research, the subject is not considered as an individual patient, normally entitled to receive the best known therapy for his personal condition. Instead, he is administered a randomly chosen treatment.”²²

If we look at the other possible type of study—one in which there is use of a placebo and thus the subject will not be told what kind of therapy he or she is receiving—the problems are even greater. The emergency waiver regulation does allow for certain types of trials that use placebos even though a placebo is a form of non-treatment. With the subject usually unconscious, even, there is little hope of a “placebo effect” managing to improve his or her condition.

The least objectionable use of placebos would be when they are in conjunction with standard therapy. The FDA has mandated that in “virtually all cases, when a placebo is used, standard care, if any, would be given to all subjects, with subjects randomized to receive, in addition, the test treatment or a placebo.”²³ It is this word “virtually” that is so troubling. The implication is that some patients in an emergency room may end up receiving no care at all! For this reason, Jay Katz and Sandra Carnahan have strongly criticized the emergency waiver, recommending that no waiver be granted in a study involving the use of placebos.²⁴ The only defense that might be given of an emergency placebo trial is when the standard care is itself virtually ineffective. Under ideal conditions, this should always be the case if a study includes a placebo-only arm, for if there is to be true equipoise then the researcher must sincerely believe that both arms of the study offer the same potential risks and benefits. Since a placebo has no

real potential effect, to include a placebo-only arm in the study is to claim that the standard treatment is just like the placebo—it has virtually no potential effect. Something seems disingenuous here, though, because if the placebo has no potential benefit and the standard care has no potential benefit then a third arm—the arm including the experimental drug or procedure—*must* have more *potential* benefit than the other two (otherwise, why be testing it at this point?). Consequently, there is no equipoise and thus there is no need for a placebo—the patients should all be getting the experimental treatment. The argument against this position is that the benefits of the new treatment may be greater than the placebo and the standard treatment, but the risks might be greater as well and thus the treatment needs to be closely monitored and studied. This works well for cases such as a new cold remedy. There is no standard treatment, a placebo is ineffective, and thus the new remedy has greater potential benefit than either of the other arms. But the new remedy also has greater risks than the other arms (since the risks of the non-existent standard treatment and of the placebo are simply that the cold will continue). It is often the case in emergency research, however, that the stakes are so high that the risks of the arms are equal. Standard methods for doing CPR have a great risk—a high mortality rate. A well-designed new therapy would likely have greater possible benefit but the same risk (how could it pose a greater risk than a high mortality rate?).

Sometimes it is argued that since the placebo arm of a trial is necessary for good science, giving a patient a 50% shot at receiving a new treatment is better than having no shot at all, and thus a reasonable person would want the 50-50 chance. Invoking the ideal of what a reasonable person would want (as in the general Emergency Exception), such an argument attempts to by-pass the need for an emergency waiver at all. To be a part of the research would be what a reasonable person would wish for if he or she could express those wishes. In this spirit, Fost suggests that the following speech could be given and then repeated to any late-arriving relative or late-awakening patient who wonders why he or she was entered into a clinical trial without consent and then merely given a placebo.²⁵ Soliloquy-like, the doctor says (to the unconscious patient):

I am reasonably certain the standard treatment will not help. I don't know if the experimental treatment will help, but I think it is reasonable to try. If you were able to consent, I would offer it to you, and my best guess is that you would be interested in and willing to try it. However, my conscience tells me that it would not be responsible to give it to you in an uncontrolled way, because neither you, nor I, nor future patients would ever know whether it helped or hurt. As part of a controlled trial, therefore, I am administering your treatment in precisely the same way that I would if you were awake, or if your relatives were here. I am basing this on a presumption...that a reasonable person would more than likely consent to such treatment, and I therefore also presume you would consent to a 50% chance of receiving such treatment. If you tell me you would insist on receiving the experimental treatment, without being part of a well-designed study, then I regret to inform you that I cannot accommodate that request. I believe it is irresponsible to give potentially dangerous treatments, of unknown benefit, without appropriate review, oversight and efforts to learn from the experience, so that lethal mistakes will not be repeated.

Note first that this speech will only work for cases in which the standard treatment is virtually ineffective and the risks of the experimental treatment are greater than the standard treatment. This already limits the number of cases. If, for instance, there is a standard treatment that has some hope of working, a placebo would not be justified. Even if a reasonable person might consent to a 50% chance at getting a new treatment when all other options (standard treatment and placebo) are virtually ineffective, it is not clear that a person would give up the assurance of a *somewhat effective* standard treatment knowing that there is then a 50% chance of receiving the new treatment but an equal 50% chance of receiving no treatment at all, i.e., a placebo.²⁶ Apart from this, there are two other concerns raised by Dr. Fost's speech.

First, there is clear shift in tone and role when a doctor gives such a speech. Phenomenologically, a new worldview is adopted, a new lifeworld inhabited by both doctor and patient. This is not the speech of a concerned caretaker. Regardless of the calm demeanor and the apologetic words toward the end, this is a speech given by one who is in power and knows it. I hesitate to say that it approaches the cold apologetics of a Nazi physician inquisitor. Instead we might liken it to a more fanciful situation. Imagine a game show in which terminal patients without insurance compete for a chance at a life-saving operation by answering a series of increasing difficult and banal multiple-choice questions. The music plays, the lights spin and focus on center stage, and an impish looking little fellow dressed in a dark suit, shirt, and tie chats with the woman seated across from him:

Welcome, Kathy Lee. Now, as you know, our staff physicians are reasonably certain that standard means toward achieving your health are not an option for you. Who knows if you can win our game, but I think it is reasonable to try. I'm sure we'll all be pulling for you, pulling for you to win that prize of a bone marrow transplant. I wish I could just give you the transplant right now but my conscience—which is to say my sponsors—tell me it's not responsible. [Audience laughter.] Now we all know that left alone you would be dead in a few weeks, and thus you would really like that BMT. And we understand that with no insurance, a reasonable person such as yourself would jump at the opportunity to play our game and thus have a chance at the operation that could save your life. What's that? You insist on receiving the operation just for agreeing to play the game? Oh, I'm sorry. We can't, of course, do that. It's the game, the risk, the chance that makes this show a success and thus makes it profitable. That's how we make the money to be able to afford to pay for the operations for the winners. So I regret to inform you that I cannot accommodate that request—it would be irresponsible to all of our future contestants. But I'm pulling for you to win, as are all of our viewers, OK? Now, you know how the game works, right? You know about your lifelines? All right, let's play.... Who wants to Be a Leukemia Survivor!

Given a libertarian worldview, this might be a reasonable future; but even libertarians would have to admit that there is a difference between a game show and an emergency room. The justification that I am doing good for you by giving you an equal chance at a cure and at an ineffective placebo because, after all, this is the only way you can possibly get the cure does not work when I myself am the one who set the rules of the game, set the rule that this is the only way possibly to get the cure.

Some would claim that it is the government that has set the rules—that because the FDA seldom licenses a new drug without a placebo trial, the doctor is doing his or her best when giving the patient a 50% shot at the new treatment.²⁷ But participating in the system is a way of strengthening the system. May doctors choose to fight the assumption that both the placebo trial gold standard of medical science must *always* be used for *every* treatment,²⁸ and that placebo trials are really even effective. Verdun-Jones and Weisstub cite evidence that “the use of placebos in [randomized clinical trials] is not only scientifically unnecessary, but may yield deceiving results by providing an inflated measure of the strength of the association which is subject to considerable statistical error.”²⁹

Finally, even in cases in which the placebo is an addition to standard therapy, the placebo is often unnecessary in emergency situations (since the subject is often unconscious

and thus could not manifest a placebo effect) and inherently disrespectful. Those outside of the medical professions tend to picture a sugar pill whenever they think of a placebo, but the truth is that pills are only one form of therapy tested in clinical trials with placebo arms. A placebo might require the use of an inhaler, shots, intubation, or other special equipment that is both uncomfortable and resource-consuming. Indeed, if the trial requires some sort of surgery, the placebo arm might even require that the researcher cut into the body of the subject randomized into the placebo arm, doing nothing but immediately sewing the incision back up. In order for the subject to be blinded in the study, he or she may have to risk anesthetic, minor surgery, infection, and a permanent scar.

(4) *Minorities Bear the Burden of Research*

In 1974 the National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research issued its Belmont Report which served as a guideline for federal regulations concerning medical research. The Belmont Report lists three basic ethical considerations that must be followed in all research: Respect for Persons, Beneficence, and Justice. The third principle includes the manner in which research subjects are chosen. The idea was that, given the United States' disgraceful history of mistreatment of minorities (especially African Americans), future researchers must make sure that the benefits and burdens of research are fairly distributed throughout the population.

The emergency waiver results in a disproportionate number of individuals from minority populations being enrolled in clinical trials and thus us unjust. Annette Dula explains:

African Americans, Hispanics, and poor people will be disproportionately the subjects of experimentation without informed consent. Because of the location of trauma centers and because of the disproportionately high rate of certain kinds of trauma, poor people and people of color will probably bear a great deal of the burdens of research. . . . Emergency research will most likely take place in poor communities because that's where the hospitals with sophisticated and well run trauma centers are located. A disproportionately large numbers of research subjects will likely be Hispanic and African Americans [as well] because of the large number of firearm-related injuries and deaths in minority communities.³⁰

The emergency waiver thus violates the justice provision of the Belmont Report and comes dangerously close to sanctioning and institutionalizing the kind of unethical experimentation on minority populations that took place routinely before the 1980s.

(5) *Big Business, Not Patients, Benefit Most*

The real winners in the waiver of informed consent for emergency research are large corporations. Before the waiver, emergency research took place but it was slow. Enrollment only occurred when a subject was communicative or had a surrogate who was easily contacted. Waiving consent merely speeds up enrollment, with the end result being that patients become subjects without knowing it and thus serve as guinea pigs for Big Business to test new drugs and devices. Make no mistake: no medical corporation cares about improving a patient's health. The corporations exist to generate profit for shareholders and thus would be in violation of their charter if they were sacrificing profit in order to act beneficently. As Jay Katz has argued, "[a]s currently drafted, they [i.e., the new regulations] represent a triumph of the interests of the pharmaceutical industry, medical device companies, and the research community—to advance not only scientific knowledge, but also their own self-serving agendas—over the therapeutic interests of patient-subjects as well as society's interests in limiting the authority of the state and investigators to conscript subjects for research without their consent."³¹ From a public policy standpoint, the goal is better health for all through ethically sound means, but—as Nancy King reminds us, it “is also a big money matter, with large grants, great potential for income from new drugs and devices, and the need, therefore, to enroll substantial numbers of subjects.”³²

(6) *Problems with Community Consultation*

The new regulations try to bypass consent of the subject with consent of the community. Although these particular words are not used, it is clear that asking for a consultation with the community from which the subjects will be drawn is a way of asking for communal consent. All of this is played fast and loose. During this consultation, what percentage of the community

would have to have problems with the research in order for it to be assumed that they do not give their consent as a whole? And what form is this consultation to take? Furthermore, how does one go about defining “community”?

These are such difficult questions; we will need to explore them in more depth below. Before this, though, consider briefly the ethical argument that regardless of the conceptual and logistical problems of consulting a community, it is wrong to put a community’s wishes before those of an individual’s.

According to Jeffrey Blustein, an individual has more to lose than a community should something go wrong in the medical experiment, and thus the community’s wishes should never override or even stand-in for the individual’s. Also, given the fact that it is “not necessary for community that there be complete identity of all ends and unanimity on all matters of value or the good, ... [i]ndividual rights are needed because a significant degree of diversity may exist even in a group united by a common conception of the good.” These rights, argues Blustein, “protect patient autonomy....”³³

(7) *Autonomy is Sacrificed*

Blustein’s ultimate conclusion is one of the strongest and most common arguments against the waiver: the waiver destroys patient autonomy. The first principle outlined in the Belmont Report, “Respect for Persons,” is typically interpreted as the preservation of patient autonomy. Respecting the patient means allowing the patient to make choices determining the direction of his or her treatment. When we waive the need for consent, we disrespect the patients and make choices for them. At the root, this is what the Nazis did to the prisoners on whom they experimented. Autonomy is necessary for the dignity of life; it is the one underlying value that supports the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, and most of all modern bioethics. Once it is removed, we are on the slippery slope to utilitarianism, paternalism, and all-out totalitarianism.

Rebuttal to the Arguments Against the Waiver

Such is the case for the elimination of the emergency research consent waiver. While I find some of the arguments more convincing than others, there are brief rebuttals to be offered in each case.

(1) Even if the emergency waiver violates the Hippocratic Oath, the Oath is not an end in itself, some golden standard that is good without need for justification. One might as well think that the abortion debate is forever solved because the *Roe v. Wade* decision says it is legal. The Oath is based on the idea of curing patients of their ailments, and research must be done in order to know how best to cure. Research is thus not always and necessarily at odds with treatment, but rather is a needed element of responsible treatment. The key is to make sure that the research is done ethically.

(2) While it is true that patients have a right to expect standard care, it is appropriate to ask how that care became standard. Typically, it is due to the goodwill and sacrifice of countless others who helped doctors determine which treatments were most effective. We are a society of rights—we use them to keep each other at bay and keep our unattached selves on course through an ocean of uncertainty and hostile Others. What is often overlooked is that we owe our sense of self to these Others—our own subjectivity is founded on a necessary intersubjectivity—and the world that appears is the world-for-us-all. Having a shared sense of self and shared Goods as well, we can admit that rights are not primary. They are merely ways of cashing out and recognizing the myriad ways in which our Goods are interconnected.³⁴ If rights are ways of negotiating the ethical nexus that binds us together, then responsibilities are the flip-side of these rights. As a society, we have come to focus on the former and nearly dismiss the latter. But responsibilities are the unavoidable other side of the coin, the needed second pillar that, along with rights, helps codify our being-together and thus makes civil society possible. Why think that I have a right to the best society has to offer if I do not also have a responsibility to aid my society in making this possible for others? As with the above criticism of the Hippocratic Oath, I do not wish to argue that this means that non-consensual emergency research is thus automatically allowable. I only suggest that appeals to the Oath and

to some (innate? Natural? non-obligatory?) right to standard care are not sufficient to condemn the waiver. The sort of communitarianism to which I am appealing would not be a utilitarian's utopia in which one person could be sacrificed for the many because it serves the common Good. Indeed, such a Good would not be a *common* Good at all. But it does suggest a much more complex society than that which is envisioned by those who assume a simple right to standard treatment that carries no responsibilities at all in turn.

(3) Concerning the question of the level of risk involved in emergency research, it seems inappropriate to demand that the risk be minimal. The simple fact that someone has ended up in the emergency room often means that life has taken a statistical turn and placed one in a situation where the stakes are suddenly raised. It is more reasonable to gauge the risk of the new treatment in terms of the risk *comparable* to the other possible treatments, rather than to the risks of daily life. As the regulation now stands, the risks must be reasonable “in relation to what is known about the medical condition of the potential class of subjects [and] the risks and benefits of standard therapy....”³⁵

These risks, however, should never include the risk of receiving a placebo without consent—especially when a trial is constructed so as to contain an arm with a *placebo only* (and thus no standard treatment). Federal regulations should be changed to rule out the use of the emergency waiver in trials using placebos, and philosophers of science should spend more energy critiquing the well-entrenched view of how science progresses and whether or not a “control” group is even theoretically possible.

(4) If it is true that the emergency waiver unduly burdens minority populations then there is little that can be said in its defense. This question needs further analysis, though. While it is true that a demand for Justice means that one sub-group of the population should not bear the brunt of supplying research subjects, it also includes the provision that one sub-group not be banned from participating. If emergency research were to use surrogate consent only, it has been suggested that the African American community would be *under*-represented. When the FDA first proposed the emergency waiver, it justified it in part by arguing that “it would likely increase enrollment of minority and low-income patients in critical care studies,

noting that surrogate consent was more easily obtained from white, middle, and upper class families than from poor minorities.”³⁶ Many interpreted this as a clear sign of racial bias in the FDA. Richard Saver thus wrote: “What the FDA does not discuss and rightly acknowledge...is that the problems in obtaining surrogate consent from minority and/or low-income family members suggests that certain patients have clear preferences about avoiding research participation.”³⁷ The emergency waiver would not only be a way to conscript minorities without their approval but in the face of knowledge that they do not wish to consent. The FDA quickly responded that its ruling had been misunderstood: “it meant that surrogate representatives of minority patients were often harder to locate, and that without the waiver, equitable numbers of minority patients may not have the opportunity to receive the potential benefits of the emergency research.”³⁸ Along the same lines it might be argued that while it is a lamentable fact that needs immediate social attention and correction that the majority of gunshot wound victims are minorities, this should not bring emergency research into gunshot wounds to an end. Statistically, minority populations will have equal participation in both the burdens as well as the benefits of the research. The statistical sampling is the most relevant fact when assessing the study from the vantage point of bioethics. If, say, 60% of the victims of gunshot wounds are minorities, then no more that 60% of the subjects used in the study should be minorities. (I will say more on assessing the study from an ethical vantage point beyond bioethics below).

(5) I have never been accused of being a friend to Big Business, and if it can be shown that emergency research is not benefiting the common citizen then it should be stopped. But the truth is that many doctors, drug companies, and medical equipment corporations hate the emergency waiver regulation, especially the requirement for community consultation. Following all of the new regulations takes time and valuable resources. The researchers behind the Vest CPR trial complain that “[t]he process was time-consuming, was relatively expensive, and required commitment and teamwork to complete [gasp!]”³⁹ Timothy R. Placek of Cardiologic System (another company with another CPR device) “estimated that it is about 5 times more expensive to do research with an exception than without.”⁴⁰ Baxter Healthcare

Corporation, a multinational pharmaceutical company, voiced its concern about the thousands of dollars it had to spend in Louisville to help researchers consult with the community about a blood-substitute study.⁴¹ The principal investigator in the Louisville study, Dr. Mary Nan Mallony, similarly worried that she had spent 40 hours talking to local representatives about the study. “That’s the time spent on one study out of 1,000,” she complained.⁴² And even IRBs are not beyond feeling sorry for themselves as their workload increases due to the new regulations. Bonnie Lee, a policy analyst for the FDA has computed that “70 staff hours per protocol of IRB members are needed to consider public disclosure steps.”⁴³ As will be seen, I am in favor of placing even greater resource-consuming requirements on corporations and IRBs in order to ensure that the emergency waiver is ethically applied.

Points (6) and (7) seem to me the most contentious and the most troubling arguments against the emergency waiver as it stands. For this reason I would like to discuss them in a bit more detail; but before doing so, it is important to first spell out and assess the arguments in favor of maintaining the waiver.

Seven Arguments in Favor of Having a Consent Waiver for Emergency Research

(1’) Better than the Alternatives

If we were to abandon the waiver, emergency research could only be done in the rare instances in which a surrogate would be readily available or the even rarer instance in which the trauma patient is conscious and communicative. In the latter case it is unlikely that the patient is going to be able to offer truly informed consent. Everything must happen so quickly that there is little time to explain the nature of the research, give the patient time to consider the option of participating, and then obtain the consent. Given that the patient is in a state of crisis (this is, after all, why he or she is in the ER rather than a doctor’s office), the time constraint is made doubly problematic by the patient’s state of mind: he or she is likely to be frightened and in a great deal of pain. It would be in the patient’s best interest to have another party—a reliable,

trustworthy party—make the decision with time and careful consideration given to the patient’s well-being. A community and an IRB could theoretically fulfill this role (though with important modifications to the existing process).

In the former case—leaving the decision up to an individual surrogate—there are fewer safeguards than could be put into place with an appropriate waiver. We tend to think that the surrogate is safer, that the surrogate—typically a close family member—knows the patient better and thus can authoritatively announce whether or not the patient would like to become a subject. We think that the surrogate will naturally care more about the well-being of the patient than an unrelated committee or community. But surrogates face many difficulties and have many pressures that tend to make their decisions less than reliable.

If the surrogate refrains from paternalism (i.e., basing the decision on what he or she thinks is in the patient’s best interest) and instead tries to mirror the wishes of the patient, it must be admitted that this goal is never going to be achieved. No one can mirror without distortion the wishes of another—every decision will be interpretation. Given this, however, there are even greater hermeneutic issues that arise for which a literal-minded surrogate may not be prepared.

Matters are hard enough when the surrogate’s job is to interpret a Living Will, let alone guess what the patient would want based on scattered past comments and generally “knowing” his or her personality. Living Wills notoriously contain such unhelpful phrases as “unplug me when an *appropriate* amount of time has passed and there is *little reasonable* hope that I will *recover*.” How is the surrogate to judge an appropriate wait or weigh when the hope is no longer reasonable or even compare the possible meanings of “recover” (recover fully? wake-up? be alive but unconscious without aid of life-support equipment? be severely disabled?)? Norvin Richards, expanding on the difficulties of interpreting a Living Will, suggests:

Suppose the patient wrote that he did not want a respirator to be used, under any circumstances. Suppose further that he had no idea respirators could be used during surgery, in ways which greatly increased the surgery’s prospects, then disconnected once the operation ended....The will was written in a context, and it may need the context for its meaning to be understood....⁴⁴

May need? Indeed, *will* need! And this is just one of the difficulties faced when we are lucky enough to have a Living Will. More often than not, an emergency room patient has no such document or the time-frame does not allow for it to be found and consulted. As a result, surrogates must take educated guesses. And stories show that they are often wrong, that statistically, surrogate and patient preferences do not achieve even “moderate strength of agreement.”⁴⁵

Even if a surrogate can accurately testify as to what the patient’s wishes would have been, everything changes once one is injured or ill. Identity is not stable; the self is not fixed. The person who had little concern for medical research suddenly becomes its strongest advocate; the trauma patient sees a new world with new eyes. Guessing how these changes would effect his or her decision to participate in a clinical trial is at best a guess. Only when we assume that a person is not affected by his or her life circumstances, let alone constituted by them, and is, instead, a rational, consistent, thinking machine—only when we adopt such a faulty phenomenological description of human being—can we assume that the patient’s wishes are unchanging and can be reflected purely by a surrogate. It is interesting to note, in fact, that in a survey of people with varying educational backgrounds on the topic of waiving informed consent, the higher the educational level of the respondents, the less likely they were to want a family member to make a surrogate decision on their behalf. Indeed, more college educated respondents preferred to waive consent if the research posed minimal risk rather than have the researcher contact a family surrogate! And the opposite is true of respondents with only a grade school education (who would always prefer a family member act as a surrogate).⁴⁶

All of this furthermore assumes a caring, compassionate surrogate from a loving family, but this is not always the case. Often, the surrogate’s best interests and the patient’s best interests are at odds (e.g., the prospect of inheritance, or the possibility of a long and costly rehabilitation or virtual incapacitation can cloud matters). Even if we do not assume a Machiavelian family, some family members are innate utilitarians and cannot be trusted to protect the well-being of their charge when the stakes are high. In a particularly troubling study conducted by the University of Maryland School of Medicine it was found that “one-third of

the family members who believed that their hospitalized mentally incompetent elderly relatives would not have wanted to participate in an experiment on the adverse effects of urinary catheters nevertheless gave their permission,...[citing] that *others* would ‘possibly benefit’ from the experiment.”⁴⁷

Finally there is the concern that if the waiver is revoked and we return to *surrogate* consent, certain cases will come up somewhere down the slippery slope in which physicians will abuse the spirit of the surrogate requirement. Surrogates tend to agree to research more often than patients, and doctors may end up limiting their attempt to enroll “troublesome” patients, waiting instead for the arrival of a surrogate. “Physicians,” for example, “may make less of an effort to discuss [the trial and consent procedure]...with...patients in early stages of Alzheimers’, if they know that a surrogate who may be ‘easier’ to talk to will be appointed [later]...”⁴⁸

(2’) *Lives are Saved Compared to Experimental Therapy*

As it is, physicians base some of their practices on poorly founded research— anecdotal evidence, really, arrived at by means of their experiences using innovative therapy. In a routine care setting (i.e., non-emergency setting), innovative therapy is often used with the understanding that there is *presumed* consent on behalf of the patient—continuing to go to the doctor, filling the prescription given, etc. all constitute evidence of presumed consent. The physician does not have to receive approval of an IRB or pursue formal consent as long as the patient’s treatment is not made part of a larger study in any way. Consequently, innovative therapies are often tried willy-nilly, with the same mistakes being made by different doctors in different geographic areas and occasional successes unreported and unstudied.

Everyone stands to benefit when experimental research replaces experimental (innovative) therapy. Future generations can benefit from the knowledge that is gained and current patients have greater protection for two reasons. First, the IRB clearance, community consultation rule, etc. protects the emergency subject to a greater degree than the patient who merely receives innovative therapy in the ER (which is a likely possibility⁴⁹). Second, the

creation of independent data monitoring committees saves lives because the committee, watching for trends in response to treatment, have the whole set of data before them and can thus stop deadly research long before any doctor would know to stop deadly therapy on his or her individual patient.⁵⁰

(3') *Reasonable Person Would Consent*

As long as the IRB is doing its job (and the placebo trial is rejected), the patient has much to gain and little to lose consenting to emergency research, and thus a waiver of consent reflects the fact that most would agree if they could. If the standard treatment is not trustworthy then agreeing to join a trial is not a sacrifice. If the arms of the trial have equipoise in terms of risk and the innovative treatment shows potential for success, then the trial is a good bet. Though the doctor may have a hunch which treatment is best, an independent data monitoring committee can protect the subject much better than an individual doctor's hunch. Though it is always a tricky endeavor saying what a *reasonable* person would wish, it is possible to set the rules and regulations such that the subject has more to gain than to lose.

(4') *Unjust to Exclude Trauma Patients*

Much is made of the way in which trauma patients are to be used as a group to forward emergency research. But perhaps the Belmont Report's call for justice requires that we not *exclude* this group unfairly from the possible benefits of research treatment. As Richard Saver argues, "[c]ategorically excluding critical care patients from participation in clinical trials because of informed consent difficulties conflicts with the justice principle...[by] directly withhold[ing] the potential benefits that may arise from research directed toward alleviating the conditions causing their diminished capacity."⁵¹ It is, after all, not their fault that they are incapacitated and unable to consent. Excluding them from research on the basis of this accidental quality would be unjust.

(5') *Patients Do Prefer to Be Enrolled*

Perhaps the most telling argument is that surveys indicate that the majority of individuals (and their surrogates) do wish to be enrolled in emergency research when they are not capable of consenting. Consider the following facts: (a) when using the ACD CPR plunger device without consent, researchers report that “no family member or bystander objected to the use of the...device in any patient”;⁵² (b) a 1990 brain resuscitation trial of calcium channel blockers given to comatose heart attack survivors without consent found that “the overwhelming majority of families were in agreement with what was done”;⁵³ (c) “in a study of post-resuscitation coma which employed the deferred consent process, no family member, once informed about the experiment, removed a patient from trials in progress except when further treatment was regarded as altogether futile”;⁵⁴ and (d) generally, 73% of people surveyed indicated that they would like to be enrolled in emergency research if they could not consent and the risks were minimal, and 50% wanted to be enrolled if the risks were greater than minimal but “comparatively appropriate.”⁵⁵ If we were to abandon the emergency waiver we would actually be going against the wishes of the majority in most instances.

(6') *Consent and Autonomy Are Fictions*

In his defense of the emergency waiver, Baruch Brody argues that even “if consent is obtained from subjects or surrogates, the pressures of time, of fears, and of anxieties raise serious questions about the meaningfulness of that consent as truly informed or truly voluntary.”⁵⁶ In fact, Jan Helge Solbakk has “established the fact that subjects are often unaware that they are even participating in experimentation despite well-worked legal requirements.”⁵⁷ That is, even after having the trial explained and after reading and signing the consent form, subjects often do not realize that they are being experimented on by their doctors. For this reason, Robert Veatch calls informed consent a myth of liberalism, based as it is on the belief that individuals are naturally and properly autonomous.⁵⁸ And Christian Mormont argues that informed consent is built on an illusion of knowledge and self-determination, when in reality

consent is based more on ignorance than knowledge,...[on] an illusion harking back to benevolent paternalism now expressed at the level of “honest-information” and no longer that of the benevolent decision. Honesty of

information in no way guarantees the justice of a decision...[but merely] brings the doctor the peace of a clear conscience....⁵⁹

Truly uncoerced informed consent is a myth. The presence of the doctor—that white lab coat, that stethoscope draped around the neck in a nearly ritualistic way—provides an air of authority to whatever takes place in the ER, hospital, or medical office setting. Doctors, after all, are the experts. They should know best. And here they are offering me a chance to enroll in a clinical trial. It is only natural to assume that this must be my best course of treatment (never mind our cultural proclivity to associate “new,” “innovative,” and “high-tech” with all that is good in the world). Patients in general also realize that if they say no to the study—a study in which their doctor obviously wants them to participate, otherwise why would he or she be asking?—it might upset the doctor, this doctor in whose hands their lives depend. No amount of disclaimers, no number of friendly reassurances that the choice is theirs, can do away with such worries for the patient. How, then, can consent be uncoerced?

And the task of making the documents—the consent form and trial description—easily understandable so that consent can be truly *informed* is equally challenging and often nearly impossible. An IRB on which I served once discovered that “randomized” was a word and a concept not being fully understood by many of the subjects involved in the trials. “Flipping a coin will decide which group you are placed into” was the suggested substitution on the consent forms, but surely the *concept* of randomization—its scientific merit and necessity—was being lost on the subjects as well. And every IRB member has probably faced the same problem concerning how to explain genetic testing to patients. Most people have at best a pop-culture understanding of DNA, imagining the animated strands of dinosaur DNA being taken out of amber and manipulated in some way reminiscent of that little cartoon guests are shown in the first “Jurassic Park” movie. Informed consent in these instances is at best a regulative ideal, but it is seldom achieved.

Even when it is achieved, why should it be only the patient who gets to consent? Presumably because his or her choice is an expression of autonomy. But autonomy, too, is a comfortable fiction, based on the idea of a person as an isolated, rational, thinking machine. The

spirit of the idea is good—autonomy keeps the Nazis at bay. But we should not delude ourselves into thinking that autonomy is ever truly achieved. As fundamentally a member of a community, my thinking patterns, my decisions, my Goods are always enmeshed with Others’.

Given this, it seems inappropriate to lament the loss of autonomy and informed consent as the reason for rejecting the emergency waiver. Such states don’t really exist when there is no waiver. And there are other means of keeping the Nazi’s away.

(7’) *Communitarian Concerns*

In this same spirit, we should not ignore the fact that individuals are constituted by their roles and relationships. Intertwined as we are in a nexus of community relations, it is not *clearly* the case that we should make public policy decisions based on maintaining the autonomy of the individual and promoting the good of the individual before (and as separate from) the Good of the community. John Hardwig expresses such a communitarian concern when he writes:

Our present individualistic medical ethics is isolating and destructive. For by implicitly suggesting that patients make “their own” treatment decisions on a self-regarding basis and supporting those who do so, such an ethics encourages each of us to see our lives as simply our own. We may yet turn ourselves into beings who are ultimately alone.⁶⁰

This does not mean that individuals are to be sacrificed for the community.⁶¹ Rather, we should see individual rights always in conjunction with responsibilities and this set of rights and responsibilities as just one possible way of cashing out our being-together. Communities in our culture are seen as suspect metaphysical entities and are not afforded rights of their own. Even the misguided and disingenuous move to multiculturalism in our recent past could only speak of celebrating diversity at the level of the practicing individual: it is not really cultures that are being given recognition, but individuals with different cultures.

But of course communities do not have rights; they are the source of all rights. What communities do have—in reality—is primary ontological status, and thus it makes sense to consult them, which is to say to consult the members who comprise them, when one of their members cannot be consulted on a matter important to him or her. The federal government’s

provision for community consultation when an emergency waiver is given is thus a bold step in the right direction, and is one of the aspects of the new regulation that most serves to legitimate it and keep it from degenerating into sanctioned abuse.

Rebuttal to the Arguments in Favor of the Waiver

Although in general I find the arguments in favor of the waiver more convincing, some of them are terrible and should be dismissed. Indeed, my support for the waiver might be better said to lie in a combination of what I take to be good arguments for it and the lack of good arguments against it.

(1') That a policy is the lesser of two evils does not make it a good policy. The argument alone that surrogate consent does not reflect a patient's wishes should not convince us that consent should be waived, but rather that no emergency research should be done at all. Furthermore, the argument that doctors may abuse the use of a surrogate (as in the Alzheimer case) offers little support for the waiver; it merely indicates that doctors' behavior must be even more closely monitored. What saves this argument is its extension into argument (6'). When the whole process of informed consent (whether by patient or by surrogate) is questionable, room is made to argue that we are not sacrificing inalienable Goods when a waiver is issued under specific controlled conditions.

(2') Similarly, the argument that experimental research is better than experimental therapy does not prove that we should choose experimental research. Perhaps there should be *neither* because again we would be choosing the lesser of two evils. The practice of using independent data monitoring committees, however, does seem the best safeguard given that simply stopping emergency research would be condemning so many people to pain and death. Such a committee helps to alleviate partially the tension when a physician must act both as a doctor and a researcher. The big question is always when to stop the experiment—when do the data show significant trends such that future patients should clearly be placed on one arm?

The first bioethics case ever presented to me in a professional capacity involved a device meant to reduce disfigurements in newborns needing a particular form of treatment.⁶² A woman had twins who were going to be enrolled in the study, and the dreaded randomization bestowed the new device on one of the twins and put the other twin in the control group without the new device. The mother understandably panicked, imagining the horror of possibly having to explain to her grown children why a coin flip left one of them with a deformity and the other without. The case proved a crash-course for me in many of the most contentious issues involved in informed consent. How would the integrity of the data be affected by adding and then having to remove the twins from the study, since the mother had indeed agreed to let her children be part of the study, so their information was included, but now she wanted them out because she didn't like the results of the coin flips? How was the well-being of the two babies that were there in that building with me at that very moment to be weighed against the importance of the study and the well-being of future babies (after all, getting twins in two different arms of a study is a researcher's dream come true since so many genetic variables are thus controlled)? The mother, at this point, was demanding not that her babies be moved to standard therapy (which meant no therapy), but that they should both receive the new device. Could the experimental device ethically be given to the twins outside of the confines of the study? Did the mother realize that this was, after all, experimental and untested, that it was not clear that there might not be negative side effects of the device and thus her request to have both children given the new tech could be a request to condemn both children rather than save them? One thing was clear: she had not understood the nature of the trial—and of experimentation in general—if she complained about the results of the randomization. But was the randomization treating her children fairly? Finally, was there enough evidence and data collected so far as to make an educated guess about the safety and efficacy of the device? If the answer was “no” then could the device be ethically given to the twins as “treatment”? If the answer was “yes” then why weren't *all* such babies receiving the device by now?

I later learned that I had ended up concurring with the majority of other ethicists and committee members consulted: give the device to both twins. It seemed the best way to respect

the mother and the children; and the data, I was told, “was looking promising” but was still statistically inconclusive. With the benefit of some years of further thought and experience, I still hope that this was the correct decision. I can, at least, trace back to this moment my commitment to vigilant data monitoring committees and my growing suspicion of the cold face of randomization—and perhaps research in general.

(3’) That a reasonable person would consent to the research is only a good argument if the conditions for allowing a trial are strict and well-enforced. What should be a worry for us here, however, are the various reasons one might have for refusing to the specific procedures used in the research more than refusing to the research. Some religions, for instance, do not sanction the drawing of blood. In a standard care situation, the patient would make it known to his or her doctor that this procedure is unacceptable. In an emergency situation, however, the researcher would not know. Perhaps this can be solved with the community consultation clause, but there will always be concerns (see below).

(4’) The argument that it is unjust to exclude unconscious/uncommunicative patients from research does not seem a good one. The quality in question that excludes these individuals from research may be “accidental” but it is relevant. One might as well complain that it is not fair not to have sex with incapacitated women who are unable to give consent: “just because she passed out is no reason to deprive her of the possible good benefits of having sex with me,” says the potential rapist. The goal is not to keep emergency patients from benefits but to protect them from harms. Sometimes in order to treat two groups of people *equally* (i.e., fairly), they must be treated *differently*.

(5’) Of all the arguments in favor of the waiver, however, the least convincing is that most people would prefer to have it. We should be especially wary of studies purporting to deduce the waiver is ethical from the fact that no families later complained. First, it is clear that in this culture we are conditioned to accept the authority of medical professionals. The fact that no bystanders objected to the ACD CPR plunger being used does not mean that its use was ethical or that consent was silently given. In a crisis, bystanders are anxious and afraid. When someone calls 911, he or she is inviting strangers to come save a life. From the start, great faith

is put in these strangers and their knowledge and judgment. When family members are contacted later and asked as surrogates whether or not the subject should continue an experimental therapy, it is not surprising that so few say “no.” Up until that point, the surrogate knows that doctors and nurses and other health care professionals have been making decisions to save the life of the patient. They made the decision to enroll the patient in the study as well—how hard it is to separate this decision from all of the others, to realize that this was a decision made by a researcher, not a doctor.

Emergency research seldom involves minimal risk, so the statistic that 73% of the population would like to be enrolled in minimal risk research without consent is irrelevant. More to the point is the statistic that only half of the population would agree to a comparatively minimal risk study. Basing the decision on pleasing the majority is thus impossible because half of the subjects will be enrolled when there is reason to believe they would not have chosen to enroll. Regardless of any statistical data, though, it is wrong to make an ethical decision using such a strict utilitarian calculus. Even if 95% of the people preferred to be enrolled, the cost of this is that 5% would be enrolled against their will. Preventing such abuse is why we have a *constitutional* democracy: the majority can do whatever they want, but there are limits (spelled out especially, e.g., in the Bill of Rights). Even if 95% of the people in the country want to enslave 5% or deny 5% the right to practice their chosen religion or to imprison 5% without due process, this would be wrong (and illegal). The protection of the minority is key to a constitutional democracy, as it is to a communitarian society.

Which brings us to points (6') and (7')—and points (6) and (7) against the waiver, because all of these points are related. Autonomy is not a fixed quality we all get stapled to our soul or our Platonic Form as human beings. Autonomy is a communally embedded and endowed quality like most others, and it ebbs and flows depending on our life circumstances and position.

In some way autonomy is always thought to be tied to rationality. The autonomous agent is not only uncoerced in the sense that another person is not forcing the decision, but is said to be uncoerced by irrational tendencies as well. Unfortunately, slipping “rationality” into

the discussion does little to clear up matters. In her call for research policies that “attend to the situatedness of groups and their members...[and] that recognize persons as physiologically unique and socially situated (relational, informed in their knowledge and moral commitments by group membership...[etc.]),” Lisa Eckenwiler reminds us that there are “misogynist and racist constructions of reason” that would claim that “certain groups in particular (women, cultural minorities, those affected by an illness or condition) are lacking in rationality.”⁶³ It is true that until recently, women and persons of color would not have been thought capable of informed consent but—like children—would have required the surrogate consent of a white male (or worse yet, would have been experimented on without consent since they didn’t matter anyway—as we do in our twisted, barbaric, immoral way to animals today).

Eckenwiler’s comments, though, raise an additional important point in that they confuse two strategies for attacking the notion of autonomous rational consent. The first method is to attack the concept as culturally subjective, to suggest that autonomy and rationality refer to nothing real but rather are constructs shaped and perpetuated by those in power who have hope of maintaining that power. I have sympathies for this approach and have argued elsewhere for both a similar feminist and a continental-phenomenological understanding of the social-construct: “rationality.”⁶⁴ The second method is to attack the conception of rationality not as being subjectively constructed but as failing to exist in *any* subject, even a white, middle class male. Along these lines we might ask how a person can be said to be autonomous if he or she is in pain, is anxious or afraid, or is distracted in any way.

The relation of pain to autonomy and informed consent is especially important in cases of emergency research where the patient is conscious. The issue is complicated. Can a person in pain truly make an autonomous decision? Discussing the use of pain medication for the acute abdomen and the problems it raises for informed consent, Mark Graber et al. argue that “pain can in itself cloud a patient’s judgment, understanding, and ability to concentrate, undermining the patient’s autonomy. Consider trying to take a test while simultaneously experiencing the pain of a kidney stone and the argument stands on its own a priori.”⁶⁵ As a kidney stone repeat customer, I buy this argument wholeheartedly. In general, I am not one

who tends to give in much to pain (though even this turn of phrase says much about the ways in which we mistakenly dualistically separate the realm of the body and the mind). But during my first and worst bout with a kidney stone I acted differently than I ever have in my life, begging for relief. I later half-jokingly told my wife that I fear had I ever been tortured similarly during war time, I might have given up the fleet for a few drops of morphine. The question is whether our true character (and autonomy) is exposed or overridden in such instances. Most champions of autonomy choose the latter, suggesting that the person in extreme pain is not fully responsible for his actions. Such false dilemmas are based on bad metaphysics—as if there is a true and real character we all have, as if we are not always and necessarily constructing ourselves and playing parts in narratives over which we only have partial authorial control—but the problem grows more complicated, though, with the use of a narcotic analgesic. “Do narcotics invalidate a patient’s ability to sign an informed consent because of a loss of judgment and competence due to mental clouding?”⁶⁶ Again, my first kidney stone was also my first (and hopefully last) experience with morphine. My wife reports that I rambled incoherently after receiving the drug (something about leprechauns, she tells me). I recall only a bit of it—it is indeed a haze that I hope never to experience again under any circumstance. I think that I would have consented at the time to let the leprechauns experiment on me. Both the pain and the cure for the pain, then, supposedly took away my autonomy.

Graber et al. suggest that it is not uncommon for ER doctors to withhold pain medication because it will make later consent impossible.⁶⁷ While we would not wish to think that any doctor would knowingly leave his or her patient to suffer when relief was possible, it should also be noted that such actions further invalidate consent because the patient is not only under great distress and pain, but is most likely viewing consent as a mechanism for pain relief—i.e., the faster I agree to this study, the sooner the doctor will shut up, stop explaining this stupid experiment, and give me some pain medication. As Gregg Bloche argues, there are many types of coercion, and by “itself, the ideal of patient autonomy tells us little, perhaps nothing at all, about the legitimacy of a claim that someone has consented to serve as a research subject.”⁶⁸

Even in non-emergency situations, autonomy has been so stripped of its communal roots it has lost its meaning as a principle to found medical ethics. This does not mean we should strive for non-autonomous decision making in which patients are never consulted and their goods are never considered. Rather, we must set communal responsibilities alongside communal rights and come to see *responsible* decision making as the ideal—or, if we insist on the language of autonomy, at least realize, as John Hardwig does, that

we have come to interpret “autonomy” in a sense very different from [Immanuel] Kant’s original use of the term. It has come to mean simply the patient’s freedom or right to choose the treatment he believes is best for himself. But as Kant knew well, there are many situations in which people can achieve autonomy and moral well-being only by sacrificing other important dimensions of their well-being, including health, happiness, even life itself. For autonomy is the *responsible* use of freedom and is therefore diminished whenever one ignores, evades, or slights responsibilities.⁶⁹

It is not my intention here to give a comprehensive analysis of the debate surrounding the concept of autonomy. But I do want to hint at the reasons that autonomy is not necessarily understood appropriately today, stripped as it is of its communal roots and mirror responsibilities. If this is the case, then an emergency waiver need not violate our ethical principles and we might fairly turn to the community as well as the individual for consultation on such matters.

How to Understand “Community Consultation”?

But the problem so far has been that no one has done a very good job of consulting the community. And the new regulations are not specific in defining just what counts for community consultation, though this lack of specificity was intentional according to government officials. The hope is that local IRBs will be free to interpret the regulation in multiple ways and a general consensus will eventually result. For now, the FDA is taking an approach similar to the Supreme Court’s “I-know-it-when-I-see-it” position on pornography: they’re not sure what community consultation is, but they know what it isn’t when they see it. According to

Mary Pendergast, a legal advisor to the FDA: “We have been disturbed by some of the methods of consultation presented....We can’t help wondering if the ...[parties involved] are taking the rule seriously when the only evidence we see of community consultation is an advertisement in the newspaper.”⁷⁰

The newspaper ad seems to be a favored plan by researchers, but there are other poor attempts at community consultation as well. A study at the University of Washington went forward after consulting with the community by phoning people randomly from the phone book.⁷¹ And possibly the most notorious example was the multicenter Vest CPR trial, the first emergency research clinical trial to be undertaken after the new regulations were put in place. In a metropolitan area of 1,464,000 people, the researchers placed a 5 x 7 ad over two weekends in a local paper with a circulation of 239,304. The ad included a phone number to call for registration for a public forum to be held on the proposed research. Twelve calls were received and twenty-five people eventually attended the forum. Out of the twenty-five attendees, fifteen worked in healthcare. At the forum the research was explained and the Vest CPR system was demonstrated. When the floor was opened up for questioning, the majority of questions focused on the Vest itself—how it worked, the technology behind it, etc. An attending IRB member became concerned and reminded everyone that the purpose of the forum was to talk about conducting the research without consent—to talk about ethics. No one seemed to have any interest in this, however, and preferred to learn more about the new miracle technology that had come to town. A vote was taken in which there was unanimous support for the trial.⁷²

Researchers admitted that it is hard to see the low turnout as constituting communal representation and thus consultation. (The forum attendees constituted .002% of the local population.) Still, they argued that “lack of participation may be viewed as implied consent for this type of project...[since] persons with strongly held viewpoints could have made efforts to attend.”⁷³

In fact, nothing could be further from the truth. First, the overwhelming majority of possibly affected citizens were not given the opportunity to participate. The newspaper ad at best reached only 16% of the population, and this is a population that is necessarily literate and

able to buy the paper on the weekends. The placement of the ad was no doubt important as well. If buried in the classifieds, this would greatly limit the number of readers. But what is most troubling is the manner in which the public forum was conducted. At such a forum it is not surprising that the public was more interested in the flashy James Bond-ness of the gadget more than the ethical issues. This is not to put down the average citizen but rather is a recognition of our culture's preoccupation with technology. The Next Thing is consistently touted as The Next *Best* Thing for us, and a lifetime of enculturation will not be suppressed when Q wheels out the life saving vest and asks us to pay attention as he demonstrates. What needs to take place is *education*. Not just information about the new drug or device, but education about the ethical issues involved. The public can understand why this is important from an ethical standpoint, but often they first must come to see it *as a moral issue*.

Phenomenologically, the issue must stand out in relief as ethically striking—and if at first glance it does not do this, then it is the job of the researchers and the IRB members to make sure that it does. Some background on the history of informed consent, the rise of the Nuremberg Code, the controversy surrounding the emergency waiver is necessary.

“Ordinary” citizens can understand this—just as they can understand the procedures explained on a consent form when an IRB is doing its job and writing those forms appropriately—and it is the job of the researchers and the IRB members to see that there is understanding before any sort of vote is taken.

As for initially getting the attention of the public, we need to focus on more inclusive means of communication. After their failed attempt at reaching the masses through a newspaper ad, it is tragically comical that one of the recommendations the Vest CPR researchers came up with for future “refinements” to the process is “proctored Internet ‘chat rooms’ and bulletin boards.”⁷⁴ This would only result in a more narrowly defined public—more white, more up-scale, more techno-friendly and thus more willing to adopt blindly the latest innovation. And the level of discourse would only plummet—as it always does in e-mail, in chat rooms, on the Internet in general.⁷⁵

The Texas hypothermia head trauma study has done a somewhat better job of inclusion. The mayor of Houston agreed to declare a Head Injury Day during which various programs took place to increase public awareness of the study. The investigators also tapped into a variety of other outreach programs: “civic organizations, churches, minority health centers, education centers, senior citizen groups, chambers of commerce, the local chapter of Mothers Against Drunk Driving, radio programs, and school [programs]” all participated.⁷⁶ Here, at least, there seems to be a genuine attempt made to cast a wider net. A complication, though, is that the net must be wide but also thrown in the right direction. In order to reach the community most likely to be affected, appropriate consultation procedures must be adopted. Michelle Biros, the research director at Hennepin County Medical Center of Minneapolis, Minnesota, has argued for innovative consultation techniques for use at her institution—a medical center conducting a trial involving cocaine addicts. Rather than TV or newspaper ads, Biros has championed contacting parole officers and former drug addicts to spread the word on the streets and in crack-houses.⁷⁷

Special concerns are raised, however, when research is being undertaken at an institution typically serving a public that does not have a geographical identity. A hospital undertaking “head injury research [that] receives most of its admissions from highway accidents” involving out-of-state motorists is a particular problem.⁷⁸ Here we must understand “community” in the sense of a group of people with similar habits (using the highway to reach their yearly vacation spot) or proclivities (non-seat-belt users); and the concept of “community” indeed suffers. But the challenge can be met by interested researchers to reach out to the potential pool of trial candidates—even if it takes a great deal of time and money and ingenuity.

In fact, it may be important to consult the community in general as well as the community from which the subjects will likely be drawn. If we are true to our communitarian ethic, we must admit that the results and repercussions of the research will be felt by everyone, not just the subjects and those in the subject pool. There may be good reasons for focusing on men as the target group if a new prostate protocol arises; and there are surely good reasons not to ask *only* women about such a study. But there are no good reasons to deny women

participation in the consultation—women whose fathers and sons and brothers and husbands and friends and neighbors may be called upon to join the research. We are, in the end, all in this together.

Recommendations for the Short Term

Such communitarian ideals serve best a truly communitarian society. And we are not such a society. But the terrible Catch-22 of it all is that if we thus abandon such ideals and adopt a more individualistic approach, we merely perpetuate the system and “may yet turn ourselves into beings who are ultimately alone.” We make our institutions, but our institutions make us in return. As we strive to move away from this individualistic future, though, there are steps that can be taken in the interim. Apart from outlawing waivers in trials with placebo arms, increasing our general commitment to moral education, finding ways to abandon the cold-hearted system of randomization, and increasing the power and presence of independent data monitoring committees, I offer here two specific proposals.

Years ago, Otto Guttentag proposed the appointment of a “physician-friend” for every patient turned subject in a clinical trial. Gregg Bloche has recently come out in favor of the approach as well. And it is a good idea.⁷⁹ The reason that there is such danger in emergency waiver cases is that the subject is incapacitated, cannot protect his or her own well-being, and is at the mercy of a physician-researcher who necessarily has more than the subject’s well-being in mind. If it were the case that every candidate for research were to be looked at by and assigned to both a researcher and a clinical caretaker, then the conflict of interests would be minimized. The doctor, the clinical caretaker, would have one goal only: the patient’s well-being. In consultation with the researcher, he or she would help make the decision whether or not to enroll the patient in the trial, and would continue to monitor the patient throughout the trial (as another safety net alongside the data monitoring committee) in order to ensure that the patient’s good was not being suppressed and/or ignored.

Secondly, and similarly, we need to establish dual IRBs—one composed of health care experts and another composed of community lay-persons—in order to protect further the public interest.

As they stand, IRBs need have only five members, one of which “whose primary concerns are in nonscientific areas.”⁸⁰ As an IRB filled with doctors and other health care professionals is more likely to approve research, many ethicists have argued for the need to increase lay-membership. Denmark law, in fact, requires an equal number of doctors and lay people on IRBs. And Rep. Ron Wyden (D-OR) has requested that “IRBs include more non-medical members, so that they won’t outnumber and be swayed by physician majorities.”⁸¹

The thinking is straightforward. Physicians are not only more likely to support medical research because it is their livelihood, but because they are affecting their colleagues in a negative way by voting “no.” This creates an inherent conflict of interests as most IRB member physicians know that they will someday face the board and hope to have their own research approved. When the worst happens, people die—as was the case in New Zealand where an IRB whose members were all doctors and all peers of the researcher approved poorly reviewed protocols which eventually led to several women needlessly dying from cervical cancer. It is such a case—where the chair of the IRB was eventually guilty of “unprofessional and disgraceful conduct,” partially for his role in approving the trial and partially for failing to monitor the trial and stop it when “it became obvious that the trial was ethically unsound”—that causes Paul McNeill to characterize an IRB stacked with doctors as “putting Dracula in charge of the blood bank.”⁸²

We need not be so cynical. We need only admit that doctors—even well-intentioned doctors—are unable to navigate the difficult conflicts of interests that they have as members of an IRB. And we need to admit further that doctors have a cultural air of authority such that their opinions—as “expert opinions”—are often given great weight by laypersons, even those on the same IRB as the doctors. For this reason, adding more laypersons to IRBs accomplishes nothing (a fact that is borne out by studies conducted in Australia and the U.S.⁸³). Community

lay members still tend to defer to the medical “experts” on the committees and thus their expert opinions prevail.

For these reasons I suggest a dual IRB system in which an institutional review board (an IRB: composed of members of the medical institution—doctors, nurses, technicians, lawyers, administrators, etc.) and a community review board (a CRB: composed of at least one ethicist and other non-health care related members of the community) would meet separately to review all research. Unless both boards approve of the research, it would not go forward. Both boards would be free to call on members of the other board to explain their reasoning or offer background information, testimony, etc., but the deliberations and voting would be done privately. Neither board would focus specifically on one aspect of the trial—i.e., the IRB should not focus merely on the possible benefits, for instance, assuming that the CRB will be watching out for the interests of the individual subjects—but rather both boards would attempt to keep a view of the whole and assess the research *on ethical grounds*.

It is hoped that the CRB will be a way to make community voices heard in earnest. I would propose that there be at least nine members, with the chair being chosen by majority vote. The professional ethicist(s) should make it his or her priority to help instruct the members in matters of philosophical, ethical import, though not in a paternalistic way. Mandatory service—as in jury duty—would be one way to enlist membership for a set time, though I suggest that voluntary participation might be the better model. As with community consultation in general, a wide net should be cast in an attempt to inform the public of the importance of the CRB and of their participation. Unlike specific research trials, however, public funds could properly be used to bring this about.

Diversity of membership should be pursued. In multiple personal communications, IRB chairs from around Chicago and Northern Illinois have responded to my query about their interpretation of the “community consultation” regulation by lamenting how frustrating the concept is when living in a culturally diverse area. These good people have legitimate concerns, but diversity need not be seen as an impediment to ethical consensus.⁸⁴ If we abandon the analytic, scientific, limiting definitions of autonomy, rationality, and objectivity as concepts

relating to a radically individual, disinterested thinker and adopt instead a more communal understanding of the terms, we discover that some degree of diversity is necessary for truth. The Greek conception of *logos*, championed by such philosophers as Edmund Husserl and Hannah Arendt, was based on such an ideal. Objective truth was to be discovered by admitting that we live in an intersubjective world, a common world on which we all have a different perspective. Objectivity is then a matter of making the rounds—going to each perspective, seeing what the world looks like from there, and trying to forge an agreed upon description that does justice to them all. This is something that could not be done in a lab or an office by an isolated thinker. Objectivity is essentially the culmination of our combined subjectivity. The process of arriving at a specifically good, true, objective decision, then, involves a need for a diversity of viewpoints. Such is the underlying ethical justification for our trial by jury system. The more diverse the members of the jury, the greater the chance that their verdict is true: after all, if the prosecutor's story fits and the defendant seems guilty to a single mother, a retired engineer, an Asian American businesswoman, a Republican, a Democrat, a Muslim, a Christian, etc., then it must not be the case that the defendant only seems to be guilty because of one's particular social, religious, sexual, racial, etc. perspective. This doesn't always work—other perspectives are always necessarily available—but truth is a project, and as a community we do the best we can. The CRB, then, would be called upon to do the best it could.

Recommendations for the Long Term

But what is really needed is radical change. Diversity is good, but practically speaking, once the members of a community no longer share a common vision of the Good, they have ceased to be the kind of community that can sustain healthy, productive citizens. Size is an important concern. As Aristotle knew well, a *polis* has an upper limit, just as there is a limit to the number of real friends one can have at any given time. This does not mean that non-friends are enemies or that those outside one's community are to be oppressed or even ignored; but it does mean

that sharing a life requires our getting to know each other, time to get to know you and the way the world—and the Good—looks from your perspective.

Ultimately, the safest solution to medical research is having a doctor and a researcher who knows the patient-subject and is related to him or her in multiple ways (e.g., you are not just my doctor, you are my bridge partner, or your spouse runs the daycare where I take my kids, or my parents operate the bakery where your neighbors buy their bread, etc.). The more ways we are related, the clearer our ethical entanglement will be. Robert Veatch has suggested pairing doctors and patients in terms of their “deep value orientation”—something that feminist health centers, Catholic hospitals, and holistic health clinics try to do.⁸⁵ This is a step in the right direction, but unless we forge real communities in which these values grow together naturally, we will at most be conducting a huge medical computer dating service where desperately lonely and isolated doctors and patients are placed together because they both happen to check “I take ginseng supplements” on a questionnaire. True community grows from a shared life; it cannot be forced.

Rather than pining for the loss of community (if, in fact, it ever fully existed in this country) we should be taking the steps necessary to build it at a grassroots level. Perhaps, then, it is the general ethos of the culture that needs to change—and the general ethos of the medical profession.

Doctors do not typically treat people as people. I do not say this to disparage doctors in any way (allow me to invoke a cliché that happens to be true: “some of my best friends are doctors!”), but I wish to remind us of this—of the fact that doctors’ training and their institutions force them to be this way. So much fuss is made over whether I should be treated as a patient or a subject; how sad that we are beyond the possibility of my hoping to be treated as Peter. A patient is only one thing that I am—one narrative in which I am participating. Doctors must be taught to think bigger, as must we all.

John Hardwig argues that “[g]enerals need to consider more than military consequences, businessmen more than economic consequences, teachers more than educational consequences, lawyers more than legal consequences”—with the presumed addition that

doctors need to consider more than medical consequences.⁸⁶ This is, in part, what it means to treat people as people. It is, in part, what Annette Dula cites as a possible concern in African American communities told that they might be the subject of trauma research. “Community members,” she notes, “seeing a tension between research needs and community interests, may require researchers to justify emergency research. They may want to know why trauma research is being conducted when they perceive the real problem as the easy access to firearms in minority communities.”⁸⁷ In the past, the doctors’ retort mirrored musician Tom Lehrer’s tragic-comic version of the famous Nazi rocket and missile scientist who was recruited by America after the war: “‘Once the rockets go up who knows where they come down. That’s not my department,’ says Werner von Braun.” It is a legitimate question to ask—why spend so much money and experiment on unconsenting “volunteers” to study gunshot wounds instead of spending the resources on stopping the shootings before they happen? But the medical researcher is dumbfounded. Partially because he or she cannot imagine being connected to that community in any way other than “doctor,” partially because until they become *patients* (and then *subjects*) these kids who are shooting each other don’t appear as part of the doctor’s lifeworld—they aren’t seen at all.

Frank Huyler, in a collection of stories drawn from his experiences as an emergency room physician, writes with the candor of a doctor remembering he is much more. His admissions of anger at patients who refuse to die, guilty arousal when called on to attend to a beautiful young girl, and feelings of godhood when manipulating the bodies of the dying—pulling them back into the world by sheer force of his talent and will—need to be acknowledged and attended to.

One night a woman is shot in the head and her swollen brain compresses her brainstem. Nothing, finally, can save her. Dr. Huyler writes:

She was dead now, though you wouldn’t have known it to look at her....[N]ow it was her organs we were taking care of. She was the best of donors, young, strong, undamaged in every other way, with decades left in her heart and lungs and kidneys, in her eyes and liver....She lay there like a person, she looked and smelled alive. That morning there were pictures in her room. A family portrait. A child on the grass. A girl in a white dress, smiling in the kitchen. She looked happy, excited. I’ve often seen these photographs. It’s the nurses who do it.

They tell the family, bring pictures, it will help us see her for what she is. Something that doesn't occur to us, the doctors, very often. Gestures, a curative power—this is why we are here, this is what we are working for. And I recognize the man in the photograph after all. He stood behind the girl, his hair still dark. Her father, whom I had spoken with in the consultation room.⁸⁸

Conclusion: Between Life and Death

Days before the turn of the millennium, the *New England Journal of Medicine* published a report admitting that a certain class of experiments takes place in emergency rooms around the country with some regularity and without consent.

It is a difficult skill, threading a tube into the femoral vein in the groin. But it is an important skill that can save lives in an ER when a patient needs fluids quickly or requires an emergency transfusion, and thus every doctor must learn it. But it is hard to learn unless one has a live patient complete with throbbing blood vessels to indicate the appropriate place of insertion. This is why many young doctors-in-training practice the procedure on dying patients who don't need it.

The “practice sessions usually take place when resuscitation efforts have failed for twenty minutes, doctors are about to give up and the patient is just minutes from being pronounced dead.”⁸⁹ Neither the patient nor the family are ever asked for permission, nor are family members told of the procedure later. In some cases, residents and interns also experiment on the recently dead, practicing inserting breathing tubes into their silent but still warm throats.

I don't much care what happens to me after I die, or even in the few seconds during which death is immanent. But that is not—and can never be—the point. When we train generations of physicians to sneak around and perform secret experiments for practice on our friends, on family, on strangers, we are shaping their worldview such that when they finally become doctors they will never be able to see more than a thing in their waiting rooms, exam tables, and gurneys. In their streets and their neighborhoods. In *our* world.

In the end, *this* is why we must condemn the Nazi physicians who gave rise to the need for the Nuremberg Code. Not because they didn't obtain informed consent. But because they reduced their mostly Jewish subjects to "vermin." Because they attempted to suppress the publicity of the world and our common Good. Because they refused to see who stood before them and who they themselves had become. Because, ultimately, they had grown evil.

Endnotes

¹See Charles R. Mc Carthy, “To Be or Not to Be: Waiving Informed Consent in Emergency Research,” in *Kennedy Institute of Ethics Journal* (v. 5, n. 2) 1995, pp. 155-162.

²See, e.g., Mark Stuart Kremers, et al., “Initial Experience Using the Food and Drug Administration Guidelines for Emergency Research Without Consent” in *Annals of Emergency Medicine* (v. 33) Feb. 1999, pp. 224-229; and Keith G. Lurie, et al., “Evaluation of Active Compression-Decompression CPR in Victims of Out-of-Hospital Cardiac Arrest,” in *JAMA* (v. 271, n. 18) May 11, 1994, pp. 1405-1411.

³Taylor as quoted by Jonathan D. Moreno, “The Dilemmas of Experimenting on People,” in *MIT’s Technology Review* (v. 100, n. 5) July 1997, p. 32.

⁴Moreno (1997), p. 33.

⁵Moreno (1997), p. 33.

⁶One might see, for more on these atrocities, Annette Dula, “Bearing the Brunt of the New Regulations: Minority Populations,” in *The Hastings Center Report* (v. 27, n. 1) Jan./Feb. 1997, pp. 11-12.

⁷*The Declaration of Helsinki*, quoted in Sandra J. Carnahan, “Promoting Medical Research without Sacrificing Patient Autonomy: Legal and Ethical Issues Raised by the Waiver of Informed Consent for Emergency Research,” in *Oklahoma Law Review* (v.52, n. 4) winter 1999, p. 570.

⁸See Richard S. Saver, “Critical Care Research and Informed Consent,” in *North Carolina Law Review* (v. 75) 1996, p. 207.

⁹Editorial, “Emergency Informed Consent,” in *Anesthesiology* (v. 89, n. 5) Nov. 1998, p. 1048.

¹⁰See Charles Marwick, “Informed Consent Waiver for Emergency Research,” in *JAMA* (v. 274, n. 15) Oct. 1995, p. 1184.

¹¹“Clinical experimentation is contrary to the basic ethic of the Hippocratic Oath,” argues Carnahan. Cf. Carnahan (1999), p. 570.

¹²Dominique Sprumont, “Resolving the Inherent Dissonance Between the Doctor’s Roles as Healer and Researcher: A Proposal,” in *Research on Human Subjects*, ed. David N. Weisstob (Oxford, UK: Pergamon, 1998), p. 549-550.

¹³Jay Kutz, “Blurring the Lines: Research, Therapy, and IRBs,” in *The Hastings Center Report* (v. 27, n. 1) Jan./Feb. 1997, p. 10

¹⁴Paul Root Wolpe, et al., “Hospital ERs on Front Line in Informed-Consent Debate,” in *Forum for Applied Research and Public Policy* (v. 12, n. 3) fall 1997, p. 130.

¹⁵Quoted in Rosalind Smyth, et al., “Research in Children: Ethical and Scientific Aspects,” in *The Lancet* (v. 354) Sept. 1999, p. 2 (page reference to on-line version of article).

¹⁶One assumes that this makes the statistical number crunching more complex, but not impossible. Also, the parents of the babies randomized to standard therapy can later be asked to take part in the study by means of data collection using their child’s records.

¹⁷See Peter Allmark, “Should Zelen Pre-Randomized Consent Designs Be Used in Some Neonatal Trials?,” in *Journal of Medical Ethics* (v. 25, n. 4) Aug. 1999, pp. 325-329.

¹⁸Raanan Gillon, “Research into Emergency Treatments—Could the Offer of ‘Advance Directives’ Help?,” in *Journal of Medical Ethics* (v. 25, n. 4) Aug. 1999, p. 291.

¹⁹Norman Fost, “Waived Consent for Emergency Research,” in *American Journal of Law & Medicine* (v. XXIV, n. 2&3), 1998, p. 182. One imagines here a bracelet saying “I am a diabetic” dangling alongside the “I don’t wish to be raped” bracelet.

²⁰Simon N. Verdun-Jones and David N. Weisstob, “Drawing the Distinction Between Therapeutic Research and Non-Therapeutic Experimentation: Clearing a Way Through the Definitional Ticket,” in *Research in Human Subjects*, ed. David Weisstob, p. 105.

²¹Simon N. Verdun-Jones and David N. Weisstub, "Drawing the Distinction Between Therapeutic Research and Non-Therapeutic Experimentation: Clearing a Way Through the Definitional Ticket," in *Research in Human Subjects*, ed. David Weisstub, p. 105.

²²Sprumont (1998), p. 550.

²³See 61 Fed. Reg. 51, 509 (1996).

²⁴See Carnahan (1999), p. 577 & 587.

²⁵Fost (1998), pp. 179-180.

²⁶Cf. Carnahan (1999), p. 578 for more on this.

²⁷For more on this FDA regulation, see Trevor Smith, *Ethics in Medical Research* (Cambridge: The Press Syndicate of the University of Cambridge, 1999), p. 161.

²⁸See Carnahan (1999). pp. 577-578.

²⁹Verdun-Jones & Weisstub (1998), p. 106.

³⁰Annette Dula, "Bearing the Brunt of the New Regulations: Minority Populations," *The Hastings Center Report* (v. 27, n. 1) Jan./Feb. 1997, pp. 11-12.

³¹Katz (1997), p. 11.

³²Nancy M. P. King, "Medical Research: Using a New Paradigm Where the Old Might Do," in *Beyond Regulations: Ethics in Human Subjects Research*, ed. Nancy M. P. King, Gail E. Henderson, and Jane Stein (Chapel Hill: The University of North Carolina Press, 1999), p. 209.

³³Jeffrey Blustein, "The Family in Medical Decisionmaking," in *Taking Sides: Clashing Views on Controversial Bioethical Issues*, 7th edition, ed. Carol Levine (NY: McGraw Hill, 1997), pp. 38-39.

³⁴I pursue these matters in much greater detail in my *Founding Community: A Phenomenological-Ethical Inquiry* (Dordrecht: Kluwer, 1998).

³⁵Cf. *OPRR Reports*, Number 97-01, revised, 31 Oct. 1996, p. 3.

³⁶Carnahan (1999), p. 579.

³⁷Saver (1996), p. 253.

³⁸Carnahan, (1999), pp. 579-580.

³⁹Kreners et al. (1999), p. 228.

⁴⁰Cf. Charles Marwick, "Assessment of Exception to Informed Consent," in *JAMA* (v. 278, n. 17) Nov. 5, 1997, p. 1393.

⁴¹Cf. Paulette Walker Campbell, et al., "Debate Swirls Around New Rules for Informed Consent in Trauma Research," in *The Chronicle of Higher Education* (v. 44, n. 9) 24 Oct. 1997, p. 3 (page number refers to on-line version).

⁴²Cf. Paulette Walker Campbell, et al., "Debate Swirls Around New Rules for Informed Consent in Trauma Research," in *The Chronicle of Higher Education* (v. 44, n. 9) 24 Oct. 1997, p. 3 (page number refers to on-line version).

⁴³Cf. Marwick (1997), p. 1393.

⁴⁴Norvin Richards, "Surrogate Consent," in *Public Affairs Quarterly* (v.6, n.2) April 1992, p. 230.

⁴⁵Cf. Allison Seckler, et al., "Substituted Judgment: How Accurate Are Proxy Predictions?," in *Annals of Internal Medicine* (v. 115, n. 92), 1991, pp. 94-5; and Saver (1996), p. 266.

⁴⁶Cf. Howard A. Smithline & Michael L. Gerstle, "Waiver of Informed Consent: A Survey of Emergency Medicine Patients," in *The American Journal of Emergency Medicine* (v. 16, n. 1) Jan. 1998, pp. 90-91.

⁴⁷Cf. Daniel A. Dombrowski, *Babies and Beasts: The Argument from Marginal Cases* (Urbana & Chicago: University of Illinois Press, 1997), p. 149.

⁴⁸Saver (1996), p. 260.

⁴⁹Cf. Carnahan (1999), p. 576.

⁵⁰See, e.g., Fost (1998), p. 177.

⁵¹Saver (1996), p. 237. See also p. 251.

⁵²Lurie et al. (1994), p. 1407.

⁵³Fost (1998), p. 178; and Carnahan (1999), pp. 576-577.

⁵⁴Saver (1996), p. 246.

⁵⁵Cf. Smithline & Gerstle (1998), p. 91.

⁵⁶Baruch Brody, "In Case of Emergency: No Need for Consent," in *The Hasting's Center Report* (v. 27, n. 1) Jan./Feb. 1997, p. 7.

⁵⁷Jan Helge Solbakk, "The Concept of Goodness in Medical Research: An Action-Theoretic Approach," in *Research on Human Subjects*, p. 69.

⁵⁸See both Solbakk (1998), p. 71 and Robert M. Veatch, "Abandoning Informed Consent," in *Taking Sides*, pp. 12-18.

⁵⁹Christian Mormont, "Ethical Questions Pertaining to the Use of Placebos," in *Research on Human Subjects*, p. 542.

⁶⁰John Hardwig, "What About the Family?," in *Taking Sides*, p. 26.

⁶¹Though this is the spirit behind conscription in times of war. The rights afforded a citizen are attached to the responsibility to fight when called upon to do so. I do not like this analogy, though, since the community I envision is pacifist. To discuss this further, however, would require an analysis of just-war theory, the ethics of non-violence, etc., and would take us ways from our primary concern.

⁶²I am, of course, keeping the details of the situation purposefully obscure and somewhat altered in an attempt to maintain the anonymity of the parties involved.

⁶³Lisa A. Eckenwiler, "Pursuing Reform in Clinical Research: Lessons Learned from Women's Experiences," in *The Journal of Law, Medicine, and Ethics* (v. 27, n. 2) summer 1999, pp. 7 & 6 (pages refer to on-line version).

⁶⁴See, e.g., my *Founding Community* as well as "She Knows What You Did Last Summer: Feminist Epistemology, the Scientific Ideal, and a Phenomenologically Founded Interpretation," in *Labyrinth* vol.2, winter 2000 (Kaltenleutgeben, Austria); on-line publication in February 2001; see <<http://www.labyrinth.iaf.or.at/2000/steeves.html>>.

⁶⁵Mark A. Graber et al., "Informed Consent and General Surgeons' Attitudes Toward the Use of Pain Medication in the Acute Abdomen," in *American Journal of Emergency Medicine* (v. 17, n. 2) March 1999, p. 115.

⁶⁶Graber et al. (1999), p. 115.

⁶⁷Graber et al. (1999), pp. 113-115.

⁶⁸M. Gregg Bloche, "Beyond Consent," in *Research on Human Subjects* (1998), p. 52.

⁶⁹Hardwig (1997), p. 28.

⁷⁰Pendergast, quoted in Carnahan (1999), pp. 581-582.

⁷¹Cf. Campbell (1997), p. 3.

⁷²For more on this story see Kremers et al. (1999).

⁷³Kremers et al. (1999), p. 228.

⁷⁴Kremers et al. (1999), p. 229.

⁷⁵A colleague of mine recently added an on-line discussion group to his undergraduate class on twentieth century art. Images of paintings were displayed, and students enrolled in the course could view them and post comments. The most typical exchange? “I think this one’s cool.” “Yeah, it rocks.” Such is the nature of the medium.

⁷⁶Marwick (1997), p. 1393.

⁷⁷Marwick (1997), p. 1393.

⁷⁸See King (1999), p. 24.

⁷⁹For more on Guttentag’s proposal, see Bloche (1998), pp. 53-54.

⁸⁰Fed. Reg. 56, Sec. 107 a & c.

⁸¹Cf. Jim Montague, “Balancing Caution and Courage,” in *Hospitals and Health Networks* (v. 68, n. 18) 20 September 1994, p. 51.

⁸²Paul McNeill, “International Trends in Research Regulation: Science as Negotiation,” in *Research on Human Subjects* (1998), p. 245.

⁸³See, e.g., McNeill (1998), pp. 246-247.

⁸⁴Of course, though, the diversity cannot be too deep either. There must be a shared local good and a common commitment in order to make progress on a specific social good. The same is true of friends. The balance between commonalities and diversity is always part of friendship. The point is that this need not be a Liberal sort of commitment to diversity that leads to such morally bankrupt notions as cosmopolitan ethics and commitment to multiculturalism for multiculturalism’s sake. Indeed, without some sense of shared culture, we cannot be a community in a truly meaningful sense.

⁸⁵Cf. Veatch (1997), esp. pp. 16-18.

⁸⁶Hardwig (1997), p. 25.

⁸⁷Dula (1997), p. 12.

⁸⁸Frank Huyler, *The Blood of Strangers: Stories from Emergency Medicine* (Berkeley: University of California Press, 1999), pp. 57-58.

⁸⁹Denise Grady, “Medical Training Procedure Criticized,” in *The Denver Post* 30 December 1999, p. A-02.