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Quote to note

When you set up a guardian for a fetus, you're creating a situation with the mother and fetus having competing legal rights.

—Howard Simon, American Civil Liberties Union of Florida
The New York Times
Jan. 11, 2004

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The total artificial heart: Is paying for it immoral and stopping it murder?

By Robert M. Veatch, PhD
Professor of Medical Ethics
The Kennedy Institute of Ethics
Georgetown University, Washington, DC

Slowly, but surely, we are developing the ultimate replacement part for the human body. The idea of a totally artificial heart (TAH) has been with us for decades.[1]

A range of devices to totally replace the heart are in clinical trials. Some are envisioned as a bridge to transplant while others are seen as permanent replacements for the human's biological pump.[2–9] As long as these devices are used as temporary support while a patient awaits transplant, most of the moral issues raised by them will not be too novel or too challenging. The issues of consent,[10] government approval[11] and the use of humans as subjects[12, 13] have arisen with the artificial heart from the beginning and will continue.

Murder vs. forgoing treatment

The development of a permanent replacement device, especially the TAH, will, by contrast, create some truly new problems. One of these involves terminal care ethics. Over the past two or three decades a mainstream consensus has emerged that relies on some conceptual distinctions: between actions and omissions, as well as between directly intended killing and death that results as a side effect of actions that are in themselves good.[14] It is now commonplace to accept the forgoing of life-support even though active interventions to kill are illegal and many consider them unethical. Patients may withhold or withdraw consent, as long as doing so does not intentionally, directly cause their death. The death is thought of as a side effect of forgoing a burdensome or useless intervention.

The TAH may change all of that. How should we think about patients who demand that their TAHs be stopped? When dealing with life-supporting technologies not directly related to the heart, many concluded that we could forgo a technology that was maintaining life even if the end result was that death could proceed unabated. We accepted, for example, a patient's decision to forgo hemodialysis even though everyone knew that the patient would die without it. The common wisdom was that the purpose of forgoing the treatment was to remove an intervention that failed to offer more benefit than harm. As long as the death of the patient was merely a foreseen, but unintended outcome and it was the consequence rather than part of the patient's action, even traditional Roman Catholics opposed to all euthanasia have found the forgoing of life-supporting technologies morally acceptable.

Now, however, we anticipate the case in which the life-supporting technology does not merely make continued life possible, but whose functioning actually is the basis for saying that life continues. In

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the old world of 20th century medical ethics, clinicians could choose to believe that, when the patient refused dialysis or a ventilator and the physician removed the technology deemed disproportionately burdensome, the physician didn't cause the patient's death; some intervening disease process did.

Some have always found this distinction between direct and indirect killing problematic. The new TAH technology, however, presents a new twist. If one stops a TAH or removes the machine, one does not merely permit the dying process to continue. The very act of stopping the machine is the event that, by traditional cardiac-based definition of death standards, we call "death." A person dies, according to that definition, when cardiac function ceases irreversibly. Turning off the TAH is the direct and immediate cause of death just as certainly as injecting potassium into the ventricle.

We have some options: One would appeal to "liberals" who never accepted the doctrine of double effect. They have tended to be consequentialists. They have long believed that it makes no difference whether one forgoes life support or actively, intentionally kills a patient. According to them, it is not the action/omission distinction or the direct/indirect distinction that is critical; it is whether the patient is better off dead. For them, even if turning off the TAH is an act of direct killing it may be morally justified.

Another option might appeal more to conservatives. They might insist that stopping the TAH is somehow different from stopping any other technology necessary for life and insist it is both unethical and illegal.

There is a third option, however. The conclusion that stopping the TAH is a direct killing rests on the use of the traditional cardiac definition of death. One dies according to current law when *either* the heart or the brain function ceases irreversibly. A patient is legally dead when the heart stops permanently (even if, hypothetically, the brain continued to function).

Some of us are now convinced that can't really be correct. If we believe in brain death, it is because we accept the notion that the essence of a living human being has something to do with the functioning of the brain. Imagine the hypothetical case of someone whose cardiac function had irreversibly stopped, but whose brain continued to function—who continued to think, feel, reason and emote. Surely, that person is not dead just because the cardiac function is gone.

If so, then stopping the TAH is no more the immediate cause of death than stopping a ventilator or a dialysis machine. The patient would continue to live for the few seconds or minutes when the heart was not beating, but the brain was still alive and functioning. Stopping the TAH would turn out to be no different from stopping any other life-supporting treatment.

It could turn out that the TAH will force us to fix our now naive and implausible two-pronged definition of death that permits death to be pronounced when either heart or brain function is lost and replace it with one relying only on brain function loss. We could, of course, continue to use loss of heart function as a sign that the brain function is irreversibly gone just as we always have, but it would now be merely an indicator of brain function. Moreover, the first few minutes of heart function loss would not imply brain death; only loss long enough to conclude that brain cells could not survive would signal death.

The TAH will raise an additional problem. Until now, we have generally assumed that the right to refuse treatment implies the duty of the clinician to stop whatever life-support is currently functioning. The removal of treatment has generally been noninvasive or only minimally so. But removing a TAH would involve significant surgery. It may be we will have to develop an entirely new set of moral standards for the duty of clinicians in such cases. It may be, for example, that the clinician would have a duty to turn the TAH off, but not a duty to remove it. Some clinicians may object to stopping the TAH, which they perceive as direct killing, but they plausibly would nevertheless have such an obligation.

We may also have to contemplate the reverse case: the one in which the clinician sees no point in continuing, but the patient insists that the TAH be maintained. The clinician may come to see the TAH as "futile" in the case of someone whose life cannot otherwise be maintained. Some commentators have claimed that physicians should not be forced to provide support for a TAH once they conclude it is serving no purpose,[15] but they usually don't address the interesting case of when the patient still sees value in the treatment. One thing seems clear: when the physician and patient disagree about the value of a treatment that could continue to maintain life, there is no reason to assume that the physician's view must prevail.

The ultimate resource allocation problem

The transplant of human hearts is one of the most expensive medical technologies. It currently comes, however, with a natural constraint. In the United States, fewer than 2,500 human hearts are available in a given year. Because of that limit, the cost of heart transplants in the United States is in the range of $350–700 million a year.[16]

If that natural limit were overcome through the use of artificial organs, present heart transplant costs would dwarf in comparison. Estimates are that as many as 100,000 patients a year could be candidates for these devices. For the first implantable heart attempts, the devices alone would cost $75,000. Although they expect costs could be reduced to about a third with mass production, that would amount to $2.5 billion a year—just for the pump. Evans estimates that the total direct annual costs for cardiac assistance and replacement would be in the range of $5–24 billion.[16]

When the technical problems are solved, the scarcity of transplantable hearts will be replaced by financial scarcity. Providing them for all Americans would tax the system significantly. The TAH may be the device that pushes the inevitability of rationing into the open. If the TAH arrives before universal health insurance, money will determine which patients are covered for the TAH. Otherwise the society will have to decide which factors justifiably limit access—medical hopelessness, low expected benefit, patient age, or an element of voluntary lifestyle risk that was the cause of the cardiac disease. They would all be better than ability to pay or judging the social usefulness of the recipients.

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Ask the ethicist:

Should a clinical trial coordinator blow the whistle?

Question: A 34-year-old pharmacist entered a multi-institutional, blinded, placebo controlled clinical trial for amyotrophic lateral sclerosis (ALS) in which a drug available by prescription was the active agent. At no time was the patient explicitly told that an attempt to ascertain the contents of the pills that she was taking could be considered a violation of the integrity of the study. During one study visit, she confided to a study technician that she had given one of the pills to a friend to be analyzed. That friend had in turn placed the results of the analysis in a sealed envelope and given it to the patient who stated that she had not opened the envelope. With ambivalence, the study technician informed the principal investigator, torn between respecting the perceived confidence that the patient shared, and the apparent violation of the integrity of the study. How should the principal investigator respond?

Response: Failure to maintain blinded conditions is a common flaw in randomized clinical trials, and a serious criticism of a great many such trials is that the investigators fail to determine how well the blinding is preserved. In many cases, the experimental drug has common, minor side effects, and unless the comparison drug mimics those side effects, it is relatively easy for subjects to guess if they are getting the experimental or the control drug. Indeed some critics have claimed that the entire case for the efficacy of antidepressants rests on this failure to maintain blinded conditions; if one looks only at studies where the investigators documented that double-blind conditions were scrupulously maintained, then antidepressants cannot be shown to be much better than placebo.[1] I mention this merely to show that one does not have to analyze one's own pills, for the problem of breaking the blind to arise.

Breaking the blind does indeed challenge the integrity of the research study. Fortunately it does so only for this one subject. Therefore, if at the end of the trial, data have to be discarded, they would involve only this one person and one hopes that would not threaten the successful completion of the trial. But that assumes that the blind has been broken, and according to the facts as stated, this has not yet occurred.

If the subject has not yet actually found out what medicine she is receiving, the blind has been preserved. But she must be told that if she wishes to remain in the trial, she must not "open the envelope," and if she does, she is obligated to inform the study team.

I see no reason why the study technician should feel "torn" in this case when one analyzes the ethical duties of all parties. She presumably has no relationship with this person except for her role in the study. She has appeared at this person's doorstep, as it were, solely in her role as a member of the study team. She has no right to any "private" confidences with this woman where matters that impact upon the study integrity are concerned.

The reason the study technician might inappropriately *feel a sense* of being "torn" points out a common ethical misperception about randomized controlled trials of innovative medications. This misperception has been fueled by a schism within the bioethics literature itself. A portion of that literature takes the view that the clinical practice of medicine and the conduct of clinical research trials are two distinct types of activities, and therefore the ethical principles governing them are also distinct. Another portion of the literature takes the view that all of medicine ought to be governed by the ethical principles of therapeutic practice, and that clinical research is really a subset of practice and so should fall under those same principles.

My position is that the first view is correct.[2] The investigator-subject relationship in a research trial is a fundamentally different ethical relationship from the physician-patient relationship in a therapeutic context. The goal of the research enterprise is fundamentally that of discovering new knowledge that will help future patients. The goal of the therapeutic enterprise is fundamentally that of helping each individual patient with the best available remedies.

This example highlights why these goals and relationships are ethically distinct. We presume today that it is virtually never in the best interests of a patient to be denied the knowledge of what medicine she is receiving. The withholding of that information serves the goal of research, not any reasonable goal of therapy. But a person in a clinical trial is not being treated as a patient at all; she is being treated as a research subject. This role is quite appropriate assuming that the conditions of the study, including voluntary informed consent, are not exploitive.

The study technician might assume that she had a therapeutic relationship with this patient and that therefore there was a duty of confidentiality. But no such relationship exists and the technician can report her concerns to the principal investigator with a clear conscience.

It sometimes happens that real-world circumstances cause a blurring of the roles that I have described here as ethically distinct. A neurologist, for instance, may be both the patient's attending physician, and the principal investigator of a study in which the patient is enrolled. I would argue that it is usually desirable to avoid this role conflict, but for various reasons avoidance is not always possible or desirable. When the same physician (and perhaps the office staff) are forced to cross role boundaries, I would argue that it is still highly desirable to think about each encounter with the patient as falling within one role or the other. That is, the technician should remind herself that in this situation the "patient" is really a research subject and not truly a patient, even though in another setting this same individual might be a patient. Some difficulties and gray areas will inevitably arise, but trying to maintain role clarity in one's mind will go a good way toward resolving many ethical problems.[3]

Howard Brody, MD, PhD
Professor, Family Practice
Professor, Center for Ethics & Humanities in the Life Sciences
Michigan State University, East Lansing, MI

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The legal column:

Keeping genetic secrets

By Leonard H. Glantz, JD
Professor of Health Law
Boston University School of Public Health

On September 16, 2003 the *New York Times* ran a story in its science section entitled "When a Doctor Stumbles on a Family Secret." The article was about what to do when it is determined that the apparent father of a child is not the child's biological parent. Should one tell the child? The mother? The "father?" Indeed, unlike the title of this article, this was not a family "secret;" it could well be that no one knew the truth until the biological testing was done.

In the coming era of widespread genetic testing and counseling, many people will discover information about themselves that might have importance for others. Unlike other medical tests, genetic testing provides possible information about families, as well as about the individual. For example, a woman who finds out that she has the BRCA1 gene and therefore is at higher risk for breast cancer than the general population also has information that might be useful to her sister—particularly her identical twin. The question then becomes, is there some obligation to share that information with the untested, but possibly at-risk, sister?

Like other good ethical and legal quandaries there are strong arguments on both sides. The two principles involved are the obligation of physicians to keep private patient information secret, and the desire to aid another person to avoid harm. It is also a question that presents the issue of weighing positive long-term social goals against positive short-term benefits. The reason both law and ethics safeguard patient privacy is because it is felt that in order for patients to disclose their most personal and embarrassing health concerns, patients have to feel secure that what their doctor knows about them will remain secret. Both individuals and the general society benefit from this doctrine, as patients will not be discouraged from getting treatment by the fear of gossip. On the other side of the argument is the desire to make disclosures to protect others from possible harm.

Generally the law does not require one person to act for the benefit of another unless there is some relationship between the people that requires such action. It should be obvious that a doctor is obligated to act to attempt to save the life of a patient who has had a sudden heart attack. But a stranger who sees the person having a heart attack is under no legal obligation to perform CPR even if the stranger is well trained to do so. In the law we would say that the doctor has a duty to the patient as a result of the doctor-patient relationship but strangers have no duty to other strangers. How does this pertain to the genetic testing and counseling scenario? If it is determined, for example, that a woman has the BRCA1 gene, is she or the doctor required to inform her sister? In general the legal answer is "no." Neither the tested sister nor the doctor has a legal duty to protect the health or safety of the untested sister. The doctor has no relationship with the untested sister at all, so how could he have such a duty? The untested sister is a "stranger."

Difficult questions generally embody some twists and turns in deriving an answer and this one is no exception. In 1976 the California Supreme Court decided a case entitled *Tarasoff v. The Regents of the University of California*,[1] in which the parents of a college student who had been murdered sued the murderer's therapists and the school that employed them for the therapists' failure to protect their daughter from harm. The murderer had disclosed his intent to kill the young woman, Tatiana Tarasoff, to the school psychologist in the course of treatment, and the psychologist and his psychiatrist colleagues took a few ineffective steps to begin commitment procedures. They asked the campus police to detain their predicted violent patient, and when the campus police released him, the psychiatrists did nothing further to protect the potential victim. At his first opportunity, the patient killed Tarasoff.

The victim's parents sued the psychiatrists arguing they did not do enough to protect their daughter, which might include warning Tarasoff of their patient's murderous intent. The psychiatrists argued that they had no duty to the victim since she was a stranger to them. The Supreme Court of California ruled that, while as a general rule individuals do not have a duty to control the actions of another to protect strangers, there are times when a "special relationship" exists that does create such a duty to strangers. While the court did not say what made the psychiatrist-patient relationship a "special" one, in general one only has a "special relationship" in circumstances where one is in a position to control another person's actions. In this case we can only guess that the California court decided the therapist-patient relationship is a "special relationship" because of the therapist's authority to commit the patient. Indeed, in the Tarasoff case the therapists began the process of exercising this authority.

This can be compared to a case following Tarasoff in which a teenage girl put her newborn child up for adoption. The adoption agency later learned from the adoptive parents that the child was afflicted with and died from severe combined immunodeficiency disease (SCID), a genetically-transmitted X-linked disease. A few years later the biological mother of the deceased child married and bore a child who died from this same disorder. She sued the adoption agency arguing it should have warned her of her risk of transmitting this genetic disease to her future children. The same court that decided the Tarasoff case found that the adoption agency had no duty to disclose this fact to the plaintiff because it had no "special relationship" with her.[2] In other words, the fact that the information might have been very important to the woman was not

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The misuse of antibiotics

This is an edited and updated transcript of a forum presented by the Harvard Medical School, Division of Medical Ethics in February 2003. It was moderated by Joel Roselin, Director of Public Programs, Division of Medical Ethics, Harvard Medical School. The Alliance for the Prudent Use of Antibiotics co-hosted the forum.

A recent report published in the *Journal of the American Medical Association* indicated that from 1994 to 2000 the effectiveness of ciprofloxacin, a fluoroquinalone antibiotic, in intensive care settings decreased significantly, with an additional 10 percent of gram-negative bacteria becoming resistant to ciprofloxacin.[1] Bacteria previously destroyed by ciprofloxacin now survive exposure to this agent. While fluoroquinolones comprise only one segment of the physician's antimicrobial armamentarium, drug resistance poses an increasingly general threat to the treatment of infectious disease. The causes of antibiotic resistance are manifold. Antibiotics are over-prescribed, being given for conditions that they do not treat, and broad spectrum antibiotics are used when those with a narrower spectrum that are less likely to cause resistance would be just as effective. Physicians contribute to the problem of antibiotic resistance by prescribing in cases of diagnostic uncertainty, or by succumbing to patient requests. The pharmaceutical industry also shares responsibility in light of their aggressive marketing campaigns.

Stuart B. Levy, MD*, Professor of Medicine and of Molecular Biology and Microbiology, Tufts University School of Medicine, Director of the Center for Adaptation Genetics and Drug Resistance at Tufts University School of Medicine and the President of the Alliance for the Prudent Use of Antibiotics (APUA)*

There are many facets to the drug resistance problem, with the most contributing factors being the antibiotic, which selects, and the resistance genes, which are being selected. Bacteria, in many instances, are just the innocent bystanders of antibiotic onslaught who have to (and will) survive. If you were a bacterium, you would have a very hard time finding a place to hide in the face of antibiotics, antibiotic soaps and disinfectants, all of which are trying to destroy you. There are approximately 115 available antimicrobial agents, falling into roughly 15 large classes. Yet, antibiotic use, whether it is in salmon fisheries, animal husbandry, spraying fruit trees, hospital care or in homes, brings broad ecological consequences. As a result, we face multi-drug resistance among many types of bacteria in our hospitals and our communities. Some of these strains have become untreatable. In the United States, an estimated 35 million pounds of antibiotics are produced and used, with roughly half consumed by humans and the other half by animals. Another 300,000 pounds are sprayed onto fruit trees as a prophylaxis against bacterial disease. These widespread applications, often applied in subtherapeutic doses, produce innumerable Darwinian"survivors," microbes that linger and propagate through both genetic and non-genetic mechanisms.

Regarding the overuse of antibiotics, it is a recognized fact that patients can insist on them, if not outright demand them. FOX-Television, upon reading the first edition of my book, *The Antibiotic Paradox*,[2] sent a 26-year-old associate director into four Denver doctors' offices. Four out of four times, in less than 10 minutes, she had a prescription for a different antibiotic. Of course, there is the widely known example at an area hospital where a woman came into the emergency room and wanted to be seen for a case of acne. The astute, well-trained physician said, "Change your diet. There is no need for an antibiotic." She got irate and demanded, "Look here, I want tetracycline." He stood his ground, replying, "I am not going to give it for this." To which, she said as she was escorted out, "All right, I will call my lawyer and I will see you in court."

The APUA has been working to correct these patient expectations and physician prescribing practices since 1981.[3] There have been, however, a few prominent challenges to our efforts. Number one is the miracle feature of antibiotics. Over the past 50 years, a large portion of the population has embraced the excitement over penicillin and tetracycline, and what these drugs accomplished in the fight against infectious disease. Admittedly, many factors contributed to the reduction in mortality, but much of the public attributed it all to antibiotics. There exists this myth that antibiotics are something utterly fantastic, and no consumer should be denied. In the early days you could get antibiotics over the counter, even in face creams. Finally, the FDA designated antibiotics as prescription drugs. Even so, they were not thinking about resistance at the time, but rather the side effects, the allergic reaction to penicillin and such. The FDA's actions did little to diminish that mystique of the antibiotic.

The second challenge is something that Alexander Fleming, the discoverer of penicillin, foreshadowed. When penicillin becomes an oral antibiotic, Fleming warned, one could expect resistance to emerge. Today, many antibiotics can be acquired easily and kept in the home. The "miracle-ness" of penicillin suggested that it should not do any harm. Antibiotics are made not to be toxic. (I always wonder if they had a little toxicity whether people would take them so readily.) People keep them in their medicine chest and they take them a little bit at a time for whatever ailment. When I speak to kids at area schools, they tell me their parents sometimes say, "When I was your age, my mom gave me an antibiotic and that is what you are going to get." This is an assumption that we need to correct, and it is this education gap that is being partially met by APUA's outreach programs.

The third challenge derives from the fact that no other drug therapy resembles antibiotics. Antibiotics are social drugs. You can improperly take a neuroleptic or a cardiac medication, and it is basically your problem. When you misuse an antibiotic, however, you present a problem to the rest of society. For example, there were studies done in England that examined homes where patients were chronically taking antibiotics for acne. When they surveyed the skin flora of family members, they found astounding differences from the flora present in homes without antibiotic use. There were thousand-fold differences in the antibiotic resistance of the staphylococci

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on the skin. While resistant microbes on the skin might not pose, at first glance, a societal problem, we know that bacteria have the ability to amplify that resistance and transfer it to other bacteria. Such simple abuses jeopardize treatments in more urgent areas.

***Larry Star**, Chief Executive Officer, Harrison and Star Healthcare Communication, a healthcare marketing and communications company in New York City that has launched more than two dozen commercial drugs from many leading pharmaceutical firms*

What I would like to do in the next few minutes is to provide an introduction to some of the commercial interests involving antibiotics. Among U.S. residents in the year 2000, there were approximately 83 million bacterial infections, with the vast majority (97 percent) acquired and treated outside hospitals. For a marketer, that is important data because it tells him that the prescriptions for these antibiotics are written by community-based physicians. In fact, primary care physicians wrote more than 60 percent of all of the antibiotic prescriptions in the United States. Additionally, the market itself is highly fragmented, with no single antibiotic holding even 25 percent share. The largest single antibiotic, amoxicillin, has 17 percent of the market with over 200 million prescriptions annually. However, amoxicillin itself represents many brands, as it is available generically. In contrast, Zithromax (azithromycin) is the largest patented brand, with 13 percent of the pie. Of the many other antibiotics, none represents more than 1 percent of the marketplace. While the market is highly fragmented, it is still worth a heck of a lot, nearly $6 billion a year, excluding animal use.

These market percentages do not tell the entire story. For example, amoxicillin comprises 17 percent of the total prescriptions written, but only 2 percent of the actual sales dollars. That is because it is a generic drug. In contrast, Zithromax's 13 percent of the market accounts for 60 percent of the total dollars. The remaining groups of antibiotics, in comparison, represent only 38 percent of the sales income. The market, as a result, is both very fragmented and very competitive. The pharmaceutical industry invests a lot of money in selling antibiotics, conducting almost six million sales calls on physicians and delivering more than 55 different types of sample packages last year. Now, why are they doing that? Well, coupled with this $6 billion market and heavy competition, is the fact that pharmaceutical firms have a relatively short period to optimize their sales before their patents expire. Within the pharmaceutical sector there is a rule of thumb indicating that when a drug loses its patent, you can expect sales to decrease by 60 percent to 70 percent within 12 to 18 months. The rule suggests an urgency to make money while one can.

Why is all of this important? The simple answer is that lots of antibiotics are soon to lose their patents, including some very large ones (*e.g.*, Augmentin, Cipro, Zithromax); this is a change that will alter the marketplace dramatically. Given the large sums of money at stake, the limited window of opportunity, and the number of manufacturers competing for the same market share, we might correctly wonder if the "appropriate use of antibiotics" is in the best interest of the pharmaceutical industry? I believe the answer is actually "yes," precisely because of these market conditions. Appropriate use protects the research investments of pharmaceutical firms. If they develop a compound that then is rendered ineffective because of resistance, that investment goes down the drain. Appropriate use aligns the industry with the interests of their customers, both physicians and patients. Promoting appropriate use can avoid legal restrictions by federal and state governments. We may already be moving in that direction. If the industry learns how to police itself, it would certainly foster good will. Yet, there is plenty of evidence suggesting that the industry has not promoted appropriate use. For example, a wire release from January, 2003 announced that: "Pfizer, Inc. has agreed to resolve a multi-state investigation into allegations that it employed deceptive advertising to market its blockbuster drug, Zithromax, and has promised to pay for an education campaign aimed at clearing up misconceptions. Under terms of the agreement, Pfizer said it will add certain disclosure statements to future advertisements for Zithromax and will reimburse the states a total of $4 million for legal costs, as well as fund a $2 million public education campaign on the appropriate use of antibiotics. The company did not admit to any legal wrongdoing." We might remember that $6 million accounts for less than one-half of 1 percent of Zithromax's sales, so it is not terribly painful punishment.

***Eric D. Kupferberg, PhD**, Lecturer, Program in Science, Technology and Society, MIT, and Assistant Director of Public Programs, Division of Medical Ethics, Harvard Medical School*

Dr. Levy and Mr. Star have outlined several aspects to the problem of antibiotic resistance, and before I offer my remarks, I would like to repeat four of them. First, the problem of antibiotic resistance is growing and will likely pose a significant threat to public health in the coming decades. Second, physicians overprescribe newer broad-spectrum antibiotics, both in general instances where antibiotics are not likely to have therapeutic value and in cases where older narrow-spectrum antibiotics would work as well. Third, patients demand antibiotics from their physicians for ailments better suited to non-antibiotic treatments, often requesting the antibiotic by trade name. Fourth, the antibiotic market is highly fragmented, competitive and lucrative, presenting pharmaceutical firms with strong incentives to aggressively promote new broad-spectrum antibiotics before their profits are undercut by patent expiration and generic competition. At this point in our consideration, we might want to reflect on the relationship between this final factor and the prior three. In particular, we might wonder how much blame should be placed on the pharmaceutical giants for the problem of antibiotic resistance.

Unfortunately, I will not be able to offer a quantitative reply to this question. Instead, I hope to broadly depict the nature of this connection by closely examining one particular firm, Pfizer, and one antibiotic, Zithromax. My remarks could apply equally well to other firms and other drugs, but I believe that my choice of examples is particularly illustrative. By all measures, Pfizer represents one of the giants among the big pharmaceutical firms, steadily increasing its market share year after year. Beyond its well-publicized mergers and acquisitions, Pfizer relies heavily on advertising to sustain its revenues and profits. In 1997, for example, Pfizer allocated $370 million to promoting its sundry products, $13.8 million of which it devoted to Zithromax. Pfizer netted $12.5 billion from its prescription drugs that year. By 1998, Pfizer stood as the 44th largest domestic purchaser of media advertising,

promoting such blockbusters as Lipitor, Viagra, Zoloft and Zyrtec.[4] Pharmaceutical industry analysts have repeatedly praised Pfizer for its relentless marketing. *Business Week*, for example, named Karen Katen, President of Pfizer's U.S. Pharmaceuticals division, as one of its top 25 executives of 1998, in part because she beefed-up the domestic sales force by adding 750 additional drug reps, raising Pfizer's U.S. sales force to above 10,000 persons. In gushing terms, *Fortune* depicted Pfizer as a promotional juggernaut and a "marketing machine," noting that its reps logged an average of 459 doctor visits over a single six-month period (representing some 4,606 minutes of persuasion per rep).[5]

Pfizer introduced the antibiotic Zithromax to the U.S. market in 1992, but did not bring the full force of its promotional might until some years later. In 1997, the company recruited the Minneapolis firm Campbell Mithun Esty to launch Zithromax's print campaign, the first ever direct-to-consumer effort for an antibiotic in the United States. Pfizer's initial "advertorials" appeared in such magazines as *McCall's, Ladies Home Journal*, and *Newsweek*, and offered a photograph of a baby gawking at 10 spoonfuls of medicine. The tagline highlighted Zithromax's lower dosage of five spoonfuls, reminding anxious parents that "Five days and you're done." In the fall of 1999, Pfizer transferred its estimated $15 million Zithromax direct-to-consumer account to the New York firm of Cline, Davis & Mann. Similar to the print ads of Campbell, Cline's campaigns targeted parents, and stressed Zithromax's shorter treatment regimen. Nevertheless, it was Pfizer's other promotional efforts, particularly those featuring Max the Zebra mascot, that drew attention. Almost immediately, Pfizer sales representatives began delivering plastic replicas of Max by the thousands, encouraging pediatricians to hang them from their stethoscopes and clip them to their hospital coats. For those pediatricians facing anxious youngsters, Pfizer reps supplied stuffed zebras as fuzzy comfort. At Children's Hospital in Boston, Max became so ubiquitous that several families assumed that the zebra was the hospital's mascot. The *American Academy of Pediatric News*, among other journals, were soon mailed with wrap-around advertisements featuring zebra stripes. Pfizer even donated a living zebra named Max to the San Francisco Zoo. Like R.J. Reynold's Joe Camel, Max the Zebra sauntered across many media formats.[6] The PBS's show *Sesame Street* announced, in 1999 and 2000, that its daily show was made possible by Pfizer, which "brings parents the letter Z, as in Zithromax." The spot featured a zebra and several children at play and a colorful tumbling wooden block with a Z on its sides.

According to a global bench-marking study conducted by Innovara between 2001 and 2003, Pfizer's marketing of Zithromax set an enviable standard. Pfizer established "one of the most aggressive direct-to-consumer media campaigns that reinforced the brand through the use of the Zebra" image. Moreover, it "created pills with a large print brand name on them that require very little effort to pop out of their blister packs." Less than a year after the launch of the campaign, "not only were customers aware of the product and requesting it but doctors were prescribing it by simply writing 'Z Pak.'" The report also cited the clever strategy of copyrighting the package, creating a non-substitutable product to help sustain brand loyalty after the patent expired.[7]

Max certainly helped sales. Measured by the number of written prescriptions in 2003, Zithromax outpaced every other Pfizer product, with the exception of Lipitor. Yes, Pfizer sold more Zithromax than it did Norvasc, Zoloft, Viagra and Zyrtec. Zithromax represented the fifth most prescribed medicine in the country, netting Pfizer almost $1.5 billion in revenue. Moreover, by 2003, doctors wrote more prescriptions for Zithromax (39 million) than amoxicillin (37.7 million). And, its share of the market continues to rise. One year prior, Zithromax represented the 14th most commonly prescribed drug, while amoxicillin held the 12th spot.[8] As a recent synopsis in *Advertising Age* quipped, "No doubt that if you've been sick enough to head to the doctor, you've heard your physician talk about Pfizer's Z-Pack."

We can return to my guiding question: does brand identification lead to antibiotic misuse? As many of you are aware, the subtleties and effectiveness of the large pharmaceutical firms' marketing efforts are well-documented. Physicians and American Medical Association officials have increasingly acknowledged the level of influence exercised by the glut of free pens, food, samples, flashlights, educational seminars, travel junkets and canvas bags.[9,10] Combined with direct-to-consumer-fueled patient expectations, this brand awareness might partially explain why nearly one-fifth of all prescriptions for broad-spectrum antibiotics were written for viral conditions (*e.g.*, the common cold) where there is little clinical rationale for their use. With respect to Zithromax, the inappropriate use can actually be measured against Pfizer's promotional efforts. The print copy for many of its 1999 direct-to-consumer ads read: "Your son has another bacterial ear infection. He may need an antibiotic, and remember, he has to take all of it." As with its earlier promotions, the copy stressed the five-day, once-a-day, dose. Yet, this campaign directly contradicted the recommendations of the Centers for Disease Control and Prevention (CDC). Pfizer marketed Zithromax for pediatric otitis media, despite its having no established therapeutic superiority over the generic amoxicillin. In fact, the CDC, backed by a panel of national pediatric experts, chose not to list Zithromax as the second-, or even the third-line, antibiotic. Furthermore, the guidelines warned that its use for otitis might encourage the development of resistant strains, as azithromycin often failed to kill the bacteria contributing to ear infections. Of course, Zithromax is highly effective against many types of adult pneumonia, as well as against other respiratory-tract infections, but from a marketing perspective, pediatric otitis proffered pay dirt. Ear infections constitute the most common reason that parents bring their child to a physician, prompting some 25 million office visits per year.

Pfizer's pecuniary motives came under public scrutiny in the summer of 1999, when Dr. Sidney M. Wolfe, Director of the Public Citizen's Health Research Group, obtained an internal Pfizer company document. The memo specified that the new campaign's focus was "to counter the CDC guidelines," and convince doctors, via paid teleconferencing, to forego the inexpensive amoxicillin ($19 per full course) in favor of the more costly Zithromax ($35). In response, Wolfe and Joshua Sharfstein, then a Fellow in General Pediatrics at Boston Medical Center, sent an open letter to Donna Shalala, Secretary of Health and Human Services, decrying Pfizer's efforts.[11] Within months, Oregon and 18 other states initiated investigations and legal action, alleging that the adver-

***Antibiotics** continued on page 8*

Antibiotics continued from page 7

tisements misrepresented the efficacy of Zithromax in comparison to other antibiotics in treating pediatric otitis. Specifically, the state attorneys general argued that Pfizer's direct-to-consumer ads failed to mention that physicians need to consider other factors besides dosing convenience, including antibiotic resistence, when prescribing antibiotics to treat ear infections.

As Mr. Star mentioned, Pfizer reached a $6 million settlement with the 19 states. As part of that settlement, Pfizer agreed to fund "a $2 million public service announcement campaign during the next three years about the appropriate use of the medicine." These announcements will appear during the cold season, and will stress to parents that all antibiotics are ineffective against viral infection and that "only your doctor can decide what type of infection your child has and the best way to treat it." Still, Pfizer admitted no wrongdoing, and offered no apologies for its promotion of Zithromax for cases of childhood ear infections. Given this mild retreat, we might wonder what effect this $667,000 per cold-season public service campaign will have in the face of the $13.8 million that Pfizer spends promoting the drug. And, if we conclude that big pharmaceutical firms have an overriding incentive to promote new broad-spectrum antibiotics despite the long-term consequences, I wonder who might take the needed action to curb the counterproductive abuse of these vital drug therapies.

Stuart B. Levy: I quite honestly believe that the responsibility lies with the prescriber and with the consumer. We are failing in our medical schools in that we do not teach our physicians to evaluate the data and deal with marketing. What disturbs me about the industry is their direct advertising to the consumer, which leads not only to patient demands, but also to consumer stockpiling of antibiotics. If I gave a more expanded lecture, I would have certainly mentioned pharmaceutical marketing. But if I am to highlight just two important features of antibiotic resistance, industry advertising is not going to be one of them.

Larry Star: I think that there is common ground between the needs of the pharmaceutical industry and the needs of the medical profession. I also believe that pharmaceutical dollars could be spent on public education, without the pharmaceutical companies directing the content of these educational campaigns. We might think of the advertising campaigns developed to increase awareness of blood cholesterol. These ads informed Americans on the importance of knowing one's cholesterol level, and suggested means to reduce one's cholesterol. Those same marketing and communications techniques could be brought to bear on this issue as well.

Joel Roselin, (Moderator)*, Director, Public Programs, Division of Medical Ethics, Harvard Medical School*

I am interested in pushing this issue of industry advertising just a bit further. Advertising, as we know, approaches the physician not just in a rational way, but also targets his or her motivations, psychological states and emotional frames. In essence, ads can target the nonrational aspects of prescribing. I am wondering if Larry Star might say a little on how the industry looks at physician motivation, and how the ad copy and images target those nonrational components.

Larry Star: Physicians are consumers like all consumers. In the interviews with many, many thousands of physicians that I have conducted over my career in market research, I have found that if you ask them rational questions, they will give you rational answers. If you ask them different kinds of questions, however, you will get emotional responses. Pharmaceutical marketers, like all product marketers, look to manipulate those emotional connections in order to get physicians to prefer and choose certain products and particular brands. It is a common practice. We might look at some of the issues that came up today, such as the threat of legal liability. That is a huge concern hanging over the heads of many physicians. An ad for effective antibiotics might refer to an emergency room at 12 midnight, with a doctor examining a patient who might not get the right follow-up. The copy and image might begin with the thought: "If you can't be 100 percent sure, you can get some more peace of mind by just writing for an antibiotic." In market research, we try to understand those emotional triggers that would lead a physician to make the decision to prescribe a brand.

Audience Member: When I hear Mr. Star and Dr. Levy refusing to assign any responsibility to the pharmaceutical industry on the grounds that, after all, the doctor is the prescriber, I think of the ethics of the bribe. Who is more culpable, the briber or the bribee? Doctors are in effect bribed to prescribe and pharmaceutical companies clearly bribe them to prescribe. My answer is that the responsibility rests with both sides; I don't excuse the medical profession, and I don't excuse the pharmaceutical industry either.

Stuart Levy: I will still say that the professional groups bear the responsibility and we as physicians, should stand up and decide when the industry behaves in an unethical manner. Certainly the industry will not make these changes on its own. □

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Ethics and the humanities:

Long for This World

By Michael Byers
Houghton Mifflin Company (Boston-New York), 2003

Review by Tony Miksanek, MD
McKinley Health Center
University of Illinois at Urbana-Champaign
Department of English
John A. Logan College, Carterville, IL

Henry Moss, a 51-year-old physician living in Seattle, is the world's foremost authority on Hickman syndrome, an extremely rare genetic disorder. Hickman syndrome is a fictional disease modeled after Hutchinson-Gilford syndrome (progeria). Children with progeria age approximately seven times faster than the normal rate and reach senility before puberty. By the time these patients are ten years old, they are dwarfish, wrinkled, balding and feeble. They are doomed to die of "old age" while still teenagers.

Although Moss has identified the gene responsible for Hickman syndrome, there is no cure for the disease. He feels pity for all his patients afflicted by this form of premature senescence but becomes especially attached to William Durbin, an intelligent and sensitive boy. The physician showers him with as much affection as he devotes to his own son. Although Henry Moss is a good man and a good doctor, his sense of professional helplessness spills over into his personal life.

Actually the entire Moss family is in a state of flux. Henry's wife, Ilse, is also a physician suffering from a midlife crisis. Their daughter, Sandra, is an outstanding high school student-athlete struggling with the transition from teenager to young adult. Fourteen-year-old Darren is unable to match the accomplishments of his successful sister and has many questions that no one can seem to answer. Darren, a boy full of life, forges a secret friendship with his father's favorite patient, William, a youngster very close to death.

The lives of all these characters change dramatically when Moss meets Thomas Benhamouda, the 17-year-old brother of a patient with Hickman syndrome. Thomas has a perfect body despite the fact that the teenager genetically has Hickman syndrome. Moss recognizes the genetic anomaly that not only corrects the disease in Thomas but seemingly confers exceptional health as well. Moss isolates and then replicates a protein that he believes might not only retard and even reverse the progression of Hickman syndrome but also might possibly prolong life in normal individuals.

But wait—everything has a price and even a serendipitous discovery carries a cost. If Moss is going to save the dying William, then the physician must act quickly and boldly. The synthesized enzyme appears safe based on limited testing in laboratory animals but Moss has no time to waste on lengthy research protocols. He self-experiments by injecting himself with the enzyme. After obtaining permission from William and his parents, Moss administers the experimental drug to the boy at doses and intervals that Moss can only guess at. He struggles with his decision to violate medical ethics: "It's the worst thing I could do as a doctor. Human experimentation without an experimental protocol." William understands that this treatment is risky but represents his only chance of survival. His medical condition briefly improves but one day his parents discover their son dead in his bedroom surrounded by empty vials of the enzyme.

Long for This World poses many profound questions. When is it appropriate to break the rules? What are the causes of failure? How do we achieve balance in our lives? The solutions to many of the dilemmas presented in this tender and thought-provoking novel often invoke the depth of our compassion, the power of love, and our ability to adapt. The book offers a fascinating view of growth —physical, emotional, intellectual, spiritual, professional, familial and marital— by contrasting it with degeneration. Hickman syndrome functions as an apt metaphor for the rapid transformations that threaten and alter every aspect of modern life. Change is inevitable but Moss realizes that we can be instruments of change as well. "So we're doomed to deteriorate," he acknowledges early in the novel but later adds, "there were repair mechanisms too … so it wasn't all downhill."

Multiple conflicts beyond the collision of regeneration and deterioration fuel this story. These additional antagonisms include chance versus fate, risk versus reward, faith versus hope, duty versus irresponsibility and discovery versus secrets. Mistakes of all kinds—genetic, professional and personal—figure prominently in the plot. The pursuit of ambition and the chase for rewards exact a high toll. Readers are cautioned about the attractiveness of evil and the lure of money. Apparently one can never have enough! Work changes us long before we are ever aware of the metamorphosis. Physicians are admonished that attachment to patients can wear doctors down and even waste them. Boundary issues are effectively presented. Being too close to patients sometimes skews medical judgment. Breaking bad news is frequently as hard on the doctor as it is for the patient.

One of the great strengths of the book is its wonderfully constructed cast of characters. No other novel so poignantly captures not only the awkwardness of adolescence but also the miscues of middle age. Family means everything. Fittingly the Moss family is depicted as fragile yet cohesive, evolving but somehow still permanent. Patients, neighbors, colleagues and friends comprise an extended family where human affection counts for as much as human biology. As one teenager in the story astutely points out, we are after all unlikely byproducts of random events.

The physicians and scientists in *Long for This World* are realists. We are unlikely to discover the secret of immortality. We cannot avoid death. Yet there is no escape from living either. How we spend each moment, how much we love, and how we value life are what matter most. Compassion ultimately trumps the laws of nature. □

Dialogue:

Who does the ethics consultation serve?

An ethics consultation service is supposed to do just that—to provide a service. When I receive a request for an ethics consultation, whether from a member of the health care team (most commonly), or from a family member or directly from a patient, my first question to the requestor is, "How can I be of help?" The conversation that ensues is intended to help me articulate "the ethics question" that will appear prominently at the beginning of the typed ethics consultation report, part of the patient's permanent record. This is often the most difficult part of the entire consultation process because the person making the request commonly perceives some distress, or discomfort or conflict, but may not be able to articulate a classically understood ethical dilemma.

Notice that I did not open the consultation by asking, "How can I help you?" but "How can I be of help?" There is a subtle difference. The former would imply that the ethics consultation is expected to, or even intended to, serve the requestor. While that is often the case, sometimes the service the ethics consultant provides is for another of the three entities mentioned (team, family, patient), or even for "ethics" per se.

David Ozar has clearly articulated six potential values of an ethics consultation ("The value of an ethics consultation," *Lahey Clinic Medical Ethics*, Fall 2003, www.lahey.org/ethics/). This expansion on James Rest's components of morality[1] is useful in understanding the process of consultation and is also affirming for the ethics consultant. In his essay, however, Ozar says something that some professionals and some patients or families may find quite surprising: "Ethics consultations are done for the sake of decision-makers, to help them in their desire to make the best ethical decisions they can, not for some more abstract purpose." The ethics consultant must occasionally point out that the course of action proposed or chosen by the decision-makers is outside the bounds of accepted ethical standards. They may not be thrilled that "the best ethical decision" is not the decision they would make, and thus they might construe that the consultation was not done for their sake, but for the sake of some abstract purpose.

While I agree with Ozar that the ethics consultant must not be perceived to be either the ethics police or the ethics judge, proclaiming "Thou shalt …" or "Thou shalt not …" there are occasions when the ethics consultant must articulate standards and must try to ensure that these standards are met. For example, if the parents of a newborn girl with duodenal atresia refuse consent for standard life-saving surgery because the infant also has Down's Syndrome, and they request an ethics consultation to support their claim of parental discretion, the consultant is obligated to support the professionals and serve the infant by protecting her from this unethical request.

Some ethicists believe the ethics consultant should always maintain a neutral stance, acting only as a mediator in resolving conflict. In contrast, and more correctly in my estimation, Marsha Fowler has said the ethicist should "… analyze the case, explore acceptable alternatives and exclude wrong options."[2] The ethicist is sometimes obligated to establish some boundaries, such as that options A and B are ethically permissible, but option C is outside the bounds of accepted practice.

Dennis deLeon and I have argued elsewhere that the role of the ethics consultant varies in conflict resolution, serving in the three different roles understood in alternative dispute resolution, or sometimes serving a role not clearly representing any of these.[3] Sometimes the consultant does act as a mediator—facilitating the discussion, reframing the question, helping the parties develop creative alternatives. At other times he or she acts as a negotiator, actually "taking sides" after thoroughly evaluating a dispute and determining that one perspective is morally obligatory, then trying to persuade the other party to understand and relent. In other situations, the consultant is called in as an arbitrator to give guidance about the substance of the dilemma. Sometimes the ethics consultant changes roles as new information comes to light. And sometimes the ethics consultant "serves" without clearly fitting into any of these three roles.

The roles—mediator, negotiator, arbitrator—vary in at least two different ways. They vary first in the issue of partiality. The mediator enters the discussion as an impartial third party and remains neutral as he or she guides the process. The negotiator enters the discussion at the behest of one party to act as his or her advocate, and is thus partial from the outset. The arbitrator, on the other hand, is invited in by both parties to be an impartial analyst of the situation, ultimately giving an opinion as to the merits of both parties, and often "taking sides" at the conclusion.

The roles vary also in terms of standards. The mediator applies standards of process, insisting that both parties have a fair hearing, encouraging each to present his or her argument as clearly as possible, searching for common ground or helping create a new solution, etc. The negotiator applies personal or professional standards in deciding whether to accept the request to advocate for one side, but once he or she accepts that role, pursues that goal with dedication. The arbitrator is expected to apply external standards of substance—standards that may come from medicine, ethics or law.

While I believe Ozar's statement that ethics consultations are done for the sake of the decision-makers is most often correct, there are situations where the consultant (or committee) may be called upon to advocate for the patient who no longer has capacity to participate in the decision at hand. At other times, the consultation may articulate standards of ethics that may run counter to the wishes of one or more of the decision-makers.

Measuring the value of ethics consultation

When researchers are trying to measure the value of a particular intervention, they must choose an objective end-point, most often mortality, morbidity, quality of life or cost. Assessing the value of ethics consultations is not so easy or precise. The end-point most often chosen in such research is satisfaction—satisfaction of the professionals or satisfaction of the patient or surrogate. It is an interesting curiosity that health care professionals have generally found ethics consultations more helpful (71–90% of the time) than have patients or surrogates (57%).[4] In our earlier study, one family member

queried about the usefulness of an ethics consultation done a few weeks earlier said, "The doctors and nurses may have found it helpful, but we didn't see the need for it."

Recently a multi-center study expanded the research to include cost and resource utilization. In a randomized comparison, Schneiderman, et al found that ethics consultations were associated with reductions in hospital days, and in the use of life-sustaining treatment without affecting mortality.[5] Their study again found that 90% of professionals and 80% of families found the consultations helpful.

The disvalue of ethics consultation

After providing bedside ethics consultations for about 15 years, I have a nagging concern about a potential problem with this whole endeavor. Mark Siegler, director of the fellowship program where I learned how to do ethics consultation, said at the end of our training, "You should work yourselves out of a job. Teach clinicians how to properly struggle with these ethical dilemmas so they will not need to request future consultations." I think that does actually happen in some settings and with some clinicians.

My fear, however, is that just the opposite happens in other situations. Some clinicians encounter a difficult situation and immediately request an ethics consult without taking the time or effort to dive into the dilemma themselves. The complexity of modern medicine, compounded by the pressure from payers to be efficient in providing health care, encourages some clinicians to "let the ethicist worry about it." Such a knee-jerk response to these profoundly important issues in medicine can further erode the vitally important patient-professional relationship.

Clinicians should continue to strive to provide whole-person care. Rather than becoming merely medical technicians, they should seek to identify and resolve the physical, psychological, social, spiritual and ethical needs of their patients. This sounds overwhelming in our current health care delivery system. Consultations are available in each of these domains and are clearly "of value." However, the availability of consultants does not relieve the clinician from the responsibility of addressing ethical dilemmas. □

Robert D. Orr, MD,CM
Director of Ethics
Fletcher Allen Health Care
University of Vermont College of Medicine
Burlington, VT

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The legal column *continued from page 4*

enough to say that the adoption agency was required to inform her. This is much more analogous to the case of a doctor aware of a genetic risk to a sibling of a patient than the Tarasoff case. Furthermore, unlike the Tarasoff case, the adoption agency did not "cause" the genetic injury, which is the result of biology, not the inactions of a physician. If there is an obligation to disclose genetic information to a family member, it comes from societal norms and the moral obligation of family members to care for each other. A family member who has knowledge of genetic risks to other members can, and should, in ordinary circumstances, inform relevant family members that they may be at risk and may wish to be counseled and tested themselves. But the failure of a family member to take such action does not transform that obligation into the physician's obligation.

What flows from this for physicians and others who conduct genetic testing and counseling is the obligation to inform the tested person of the risks to other family members, and to suggest ways to make this information available to them so that the tested person has the opportunity and ability to make this knowledge available to others. Failure to adequately disclose this information to a patient makes it impossible for tested persons to understand or act on their natural desire to help family members. Indeed, there is one case in which a court explicitly adopts this as a doctor's legal obligation.[3]

The second obligation rests on those physicians and counselors who feel they have a responsibility to make these disclosures about genetic risks to family members if the patient does not do so. They must inform the person to be tested that the results will not remain private. Unlike the Tarasoff situation, which presents a relatively rare circumstance, genetic tests will routinely reveal information that is often important to others. If there are professionals who feel a need to regularly disclose this information without patient consent, they must inform patients that the ordinary rules of confidentiality and privacy will not apply. This is not only the fair thing to do, it will give a potential patient a chance to go elsewhere.

Secrecy in medicine is an ancient and socially beneficial doctrine. The sensitive secrets of patients that will be learned in the new genomic era will present the opportunity and need to apply venerable rules to novel situations. □

[1] 17 Cal. 3d 425; 551 P.2d 334(1976).

[2] Olson v. Children's Home Society of California, 252 Cal. Rptr. 11, 13 (Cal. App 2 Dist. 1988).

[3] Pate v. Thelkel, 661 So.2d 278 (Fla 1995).

Ask the ethicist *continued from page 3*

Outcome: The technician and the principal investigator explained their dilemma to the patient. She stated that she had not opened the envelope, and she was allowed to continue in the study with the caveat that she would be dropped if there was an additional violation. The patient remains enrolled in the trial. □

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Heart *continued from page 2*

They would probably all be better than blindly attempting to pay for all artificial organs and leaving other important projects underfunded. When the TAH arrives, we should be ready to figure out whether giving the machine to everyone who could benefit will break the bank as well as ready to figure out whether stopping it would be murder or merely forgoing disproportionally burdensome treatment. □

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Medical Ethics

Lahey Clinic Medical Ethics **encourages reader participation. We welcome comments for our "Dialogue" column and invite submission of ethical dilemmas for "Ask the ethicist." Send correspondence and requests for complimentary subscriptions to David Steinberg, MD.**

David Steinberg, MD, Editor
Lahey Clinic Medical Center
41 Mall Road, Burlington, MA 01805
david.steinberg@lahey.org

James L. Bernat, MD, Assoc. Editor
Dartmouth-Hitchcock Medical Center
One Medical Center Drive, Lebanon, NH 03756
bernat@dartmouth.edu

Eric D. Kupferberg, PhD, Editor
Medical Ethics Forums
Harvard Medical School
611 Huntington Avenue, Boston, MA 02115

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