

Rabbinic Comment: Risk-Benefit Ratios

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After that brilliant dissection of the ethical issues, nothing is left for the rabbi to add to what the hematologist has said, except possibly a discussion on the origins of the Kupfer cells in the liver; a recent *Science* issue reports they begin in the bone marrow. To answer the questions posed by Dr. Rosner, I could just say: Yes, No, Yes, No. However, I would like to approach the same topic from a slightly different vantage point, one which lays the foundation for a Yes or a No.

At issue in any high-risk procedure is, first and foremost, the concept of the physician-patient relationship, or more accurately, the definition of the words "physician" and "patient." A physician is not a physician any time he or she feels like being a physician, but only when he has a patient. Not every patient who lays down in bed is a patient. Some patients should be at home. They don't belong with a gastroenterologist; they are having trouble with their spouse, not their colon. Some should be in the chapel, not the hospital. Sometimes physicians are confused about their patient and, hence, present issues for solution that don't lend themselves to solution. Theologically, we are aware of the dilemma.

Medicine in the Realm of Natural Law

It would seem that the fundamentalists, such as the Christian Scientists, have with greater integrity analyzed the proper role of physician and patient. The patient is subject to God. The physician opposes God's will. Get rid of the physician, leave the patient to God. It is a simplistic approach and one that should be understood in the light of Jewish tradition. It is our Jewish understanding that God sent forth a world that runs by natural law, and by natural law humans get sick. God instilled in us human wisdom, including

the ability to cure and the ability to invent new and better cures as the years go on. God indebted us to be at the service of our fellows in need. In the language of the sages, if you are required to return a lost object, surely you must return lost health. If, indeed, it is forbidden to watch your fellow human drown from the shore when you could throw out a lifeline, surely you cannot watch another human in illness when you know how to cure it, and yet withhold such cure. In both ethical situations, the physician is compelled by ethical law to intercede by God's direct command.

Hence, Jews see no adversary relationship between physician and God. We merely have a question. God, why did you set up the world this way? Why did you leave for yourself certain theologic prerogatives while asking us to make believe that the world is run by natural law and that we are committed within natural law to function, indeed obligated to act? Obviously, there must come a time when the doctor or the patient seeks help or solace outside of natural law. Faddism, superstition, medical approaches that lack a rational underpinning fall out of the framework of natural law under which the physician services others. Neither physician nor patient can go outside natural law for fear that an adversary relationship with God is being set up. The physician can only function within natural law, which is rational and understood.

When a doctor says, "I don't know what to do but let's try something anyway," that physician is functioning outside the realm of the physician. He is not behaving as a physician. For this action, he has no patient. When the patient has been to twenty doctors and wants to go to a twenty-first not because doctor twenty-one is better, but because twenty-one is his lucky number, then he is acting outside the realm of a patient. He is seeking help outside natural law. Such help is not available to him. Such help was not intended for him.

What are the ethics when a doctor with integrity says, "I don't really know what to do because to know what to do means to offer help to the

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patient. I am not convinced this particular treatment will help, because it often doesn't. Sometimes it does, but I have no way of knowing whether this patient will respond with a benefit or a deficit, whether this patient is one of the 30% who I will cure or one of the 70% who I will kill with this treatment." The first question to be asked is: "Am I functioning within the boundaries of natural law? What is the winning number in the game that allows one treatment modality into the legitimate pharmacopoeia and keeps another out as faddism?" The winning number is really a composite number that has to do with many factors, including how much pain the patient has, his or her family relationships, social needs—the cost of treatment to society and whether society can afford to offer it to this patient. Put that all together in any one case, and it is possible to decide.

It is a daily occurrence for a rabbi to be consulted by a patient and a physician in cases like Dr. Rosner's. Dr. Rosner cited a 40% chance that the child will die of a graft-versus-host response, 60% chance Dr. Rosner would do some good, and 15% chance that he'd do a lot of good. What do you say, rabbi? Is this within natural law or outside natural law?—for that is the question. Analyzing the question to its fullest and deepest, what really is being asked is, When do you treat and when don't you treat? Are there patients that should not be treated? Most physicians, when it comes to nontreatment, subjugate ethical and medical considerations to legal concerns about abandoning a patient. The doctor may very well not want to treat this patient but is compelled to continue treatment long past the point of no return. The problem at this time has no solution.

But are there guidelines to determine which patient should not be subjected to treatment? I present four situations in which the possibility of nontreatment arises and then analyze the one in question, the risk-benefit factor in nontreatment. First, the patient who is neurologically dead. A decision has to be made: Is this patient dead and no longer subject to ministrations from the housestaff? It is clear to me that brain death, as defined by the Harvard criteria—total cessation of brain function—means the patient is not a patient and is not subject to any medical ministrations.

The second case is the patient with intractable pain, for whom the benefits to be achieved by treatment are only temporary prolongation of life or, as some ethicists would put it, postponement of death. Intractable pain without hope of cure is a reason for nontreatment even when treatment

is easily available within natural law, as a so-called tried and proven treatment. The benefits to be achieved are not worth the risk involved. The risk is not risk of death. The risk, or the price to be paid, is an unacceptably pain-filled life. If such situations still exist despite the advances of neurosurgery and pharmacology, there is adequate reason not to treat a patient who does not want treatment because of intractable pain. There are adequate biblical references for this conclusion.

In the third case the issue becomes most difficult. Postponing the patient's death will not mean intractable pain, but the treatment involves risk without hope of long-term survival; the ravages of the disease are such that the patient cannot survive for long. Here, the numbers game comes in—how long is "prolonged"? The definition that some physicians use for "terminal patient" is that, in medical opinion, the patient will not survive beyond four to six weeks. Such a patient can be treated and should be treated, if the treatment involves no significant risk. If there is risk to the patient, even a 25% risk of fatality from the treatment, and the benefit to be gained is only a prolongation of life of a month or so, the clear biblical evidence is that the treatment should not be given unless the patient demands it. Then the issue would be the psychological trauma of refusing treatment. For that reason alone, the treatment would have to be given. Treatment that will prolong life only at the cost of significant risk to the patient is not in the realm of natural law in which the physician can function—not because the treatment is outside natural law, but because the patient is no longer a patient. A patient is your patient to suffer risk when you are a physician who offers a cure. Again the numbers game arises. How much risk? Why 25%, how about 22%? I speak only from case law, from cases that have been so decided by authorities in the field.

The fourth case, triage, I keep hoping will never be necessary; but it exists. Is needing the treatment for somebody else adequate reason not to treat a patient? I hope no physician ever gets caught facing two people dragged off the West Side Highway on a Saturday night when all but one respirator is in use—two people need the one respirator that is available. Such are the soul-searing decisions that physicians have to make, day in and day out, when it comes to beds in intensive care units (ICU). I'm close enough to medical practice to know the magnificent work that's done in ICUs as compared to other hospital rooms. Clearly, someone in the ICU bed has a far

better chance of survival than anyplace else. There are not enough ICU beds to go around. In fact, you physicians are practicing triage.

Before the federal law providing free dialysis service to anyone who needed it, a law that Dr. Grier had much to do with, "God-squad" committees decided who did and who didn't get dialysis; I sat for a few weeks on such a committee. Five to six thousand patients died each year in America for want of a dialysis machine. Triage was the reason for withholding treatment. I hope that the guideline given in the Bible—that the greater scholar deserves more concern than the lesser scholar—will never have to be used. I would not want to decide on the basis of a person's scholarship who deserves the dialysis machine, or the ICU bed, or the respirator.

Medical students I have worked with say to me, "We are trained to help, to make a patient who isn't breathing breathe, a bleeding patient stop bleeding. We don't analyze the ethical issue of whether or not this patient should be treated. If we did, too many people would die. We need a Pavlovian response. If there's a person in need, I'm the one to help. It is only the rabbis who have time to sit around and study what to do in such a case." But a time will come when instantaneous reactions will not be possible because the treatment modalities won't be available for everyone.

Dr. Rosner's Case

In the case cited by Dr. Rosner, what are the ethical issues—those raised by Dr. Rosner, and a few more?

Who Should Decide? I think the first issue that we've been skirting is, who is the captain of the ship? Who makes the decisions? Some people solve their own problems. They call the rabbis, they are oriented to family tradition, a serious decision requires rabbinic intervention; they have no problems. But what should society do? Who should make decisions about which treatment should be offered or not offered? Who decides whether the risk is too great for the benefits, whether the benefits warrant the risk?

What has become one of the great landmark decisions in medical ethics is the Sakiewiez decision in the Massachusetts Supreme Court. The court decided that neither you nor I should decide, but that the court should decide. This issue is fundamental and impacts on the ethical roots of our society. Only society can decide, and society speaks by legislation. The courts speak the will of society by administering laws in accord with the will of society. It is a stand that cannot be

faulted, but God forbid decisions should work that way. Anytime you have a decision to make in the emergency room or the operating room, will you call the court? Then will you call your lawyer to file a brief?

The mechanism is lacking for *Sakiewiez* to work, although the theory is there. Some issues are of such ethical import that a doctor cannot be trusted to make the decision because even a doctor is only a person. The decision is fundamental to the survival of our society.

All of us involved in a case have to contribute to medical decision-making by throwing our data into the computer and seeing what comes out. Nevertheless, I must raise a practical issue that may come up for elucidation in discussion later. The role of the guardian has been, for me, one of the most troublesome points in medical ethics. How often is a husband declared the guardian of a wife who he abandoned four months ago? How often are parents the guardian of a child admitted to the hospital last year for battered-child syndrome? How often is a child the guardian for a father he has neglected for twenty years?

The legal assumption in our society that a guardian has special rights should be seriously questioned. In fact, in the Jewish view ethical decision-making is not reserved to the parent, who has no special prerogative in medical decisions for a child. The parent's opinion as an interested, concerned person should be considered. But the parent's conscience and the parent's intuition must be weighed by an objective yardstick of right or wrong. Although the legal system gives special prominence to the opinion of the guardian, the ethical system based on biblical law does not.

Experiment and Clinical Use. The experimental nature of medicine is the next fundamental issue. When is a drug or a procedure experimental, when should it be used on humans—when do you "go clinical"? How does a medical researcher justify a Phase I study? A Phase I study is preceded by animal work; the previous patient was a beagle. What justifies the great leap of faith from a beagle to a human? In Jewish ethics, the human mind, the spark of divine intelligence which we speak of as the "godly image," is a functional spark. When a researcher has done the homework, gone through all the beagles, spoken to all the people whose opinions he or she respects, he then has the right to go clinical. He then has a right to say that, by natural law, there is an approach that may be of help to humanity.

Rational and Irrational Risks. What about the risk? Put it to the simple test: If I do not treat, what will happen? Will the patient die in-

evitably? If death is inevitable, then clearly the risk I'm prepared to take (and it must be a rational risk) is very great. I often ask the physician, perhaps a neurosurgeon, consulting me, "How much money would you invest in stock with these odds?" A doctor who tells me there's really no hope for this patient, the chance is 1:1,000, 1:1 million, has left the realm of natural law. Natural law is natural science applied by rational people. If rational people don't waste their money on a 1:1,000 risk, they should not waste someone's life on a 1:1,000 risk. In such high-risk surgery, the surgeon often remarks, "Rabbi, you pray and I'll do the surgery." My usual answer is, "If you need my prayers, I can pray so well the patient'll get better without your surgery." I don't want a surgeon who needs my prayers. A surgeon has to be confident enough without my prayers. This is the test. Irrational risk-taking is called murder even if it occurs on a surgical table, in an aseptic surgical theater.

What is sensible risk? Calculating it is complex, but surely any risk estimated at 1:100 we do not accept. A risk of 10:100, or 20:100, and cure is a possibility, we do accept. When cure is not in the offing, the risk has to be very, very small. When no hope for cure exists, risk is not easily justifiable.

Two cures are possible: one that cures the patient, and another that palliates the condition so that the patient's life is "cured" for some period of time. You can subject your patient to a significant risk when no cure is possible but the outcome will at least be palliation and relief from pain. Pain relief is something we're willing to pay for, for God did not intend us to live in pain. This is the fundamental analysis from primary biblical literature.

Some societal concerns for research that affects large numbers become less significant in a one-physician-one-patient relationship. Large-scale research decisions often undermine fundamental tenets of society. Here are some scary protocols.

In the Barber study, hypothetical cases worked out by professionals so that they appeared to be real protocols were posed to 293 of the leading human research directors of hospitals and institutions. The one protocol that stuck in my mind as disturbing was a protocol in which thymectomy was offered by random selection without patient consent to children undergoing heart surgery. The purpose of the research was to determine whether a thymectomy would be advisable in transplantation cases, to prolong the life of the transplant. Mind you, nothing was wrong with the children's

thymus glands; this was 1977, when people knew that the thymus gland is involved in general immunology. Only 72% rejected the protocol as an unacceptable risk for the benefit to be achieved; 28% approved it without reservation. This means that 28% of the people who may treat 28% of the patients of the world were willing to subject their patients to this risk without patient consent—for that is how the protocol read.

I was recently asked to comment on a protocol to be performed in New York City in which a cardiac bypass operation was proposed for asymptomatic patients—no pain, no angina—with coronary artery disease identified in routine examination. These patients were to be subjected to three catheterizations, then to the bypass operation, to learn whether the procedure would prevent sudden coronary death syndrome. Most of the medical people supported the protocol. Ethically, such a protocol is unacceptable. The risk to the individual patient, based upon knowledge, homework, available to everyone in the scientific literature, was unacceptable.

In the Barber study, only 6% of the 293 respondents claimed to have attended a lecture series longer than four hours on any issue of medical ethics. That is a real concern. Major research projects, involving hundreds of people and large commitments of social funds, can indeed undermine basic social tenets. Experimental treatment is justifiable only with good risk-benefit ratios, which means excellent benefit with minimum risk. When the benefits are less, the risk must also be less.

In the real, not theoretical case of the child Dr. Rosner asked about, for whom painful treatment offered 60% chance of remission and 15% chance of long-term life saving, with a prospect of the graft-versus-host response—which is not pleasant to see—the decision was to approve the treatment. I don't think I would vote the same way again. I would be more negative. In several later, similar cases, none of the patients have benefitted greatly from treatment. I begin to question the homework that was done.

The ethical dilemma is clear to those who attended synagogue last week and this week, when the reading of the book of Genesis began. Genesis records two sins. The sin of Adam was to eat of the tree of knowledge. The sin of the builders of the tower of Babel no one understands. They built the tower and tried to fight with God, or so the story goes. Our Jewish tradition tells it differently. God told us, go out and conquer my world; invent

new medication, divert my streams, uproot my mountains. It is your world. I trust you to do with it as you please. But these people, who had it made, refused. They decided not to expand horizontally but to build a big tower vertically and stay a closed society. God considered this a violation of earthly natural law and punished them. This is our dilemma. Adam was told: you can eat of all the trees of the garden, but for one tree—

keep your hands off. We can function in this world only under licensure, only with limitation. The people of Babel limited their lifestyle and didn't want to invade the world too greatly. Both sinned. A doctor who says I will not take advantage of the advances of medicine because the risks are great falls into the dilemma of the Tower of Babel; and a doctor who thinks he or she really knows how to cure a patient is guilty of the sin of Adam.