Most People Unable To Assess Trade-Offs For the Health Risks Imposed by Society

By Madison Powers

Recent generations of Americans have enjoyed the benefits of an unprecedented growth in scientific knowledge and technological innovation. Only more recently, however, has the public begun to understand that those benefits have been achieved at hitherto unappreciated costs. Chief among those costs are additional health risks, including increased cases of cancer and other fatal diseases, and serious illnesses involving impairments of sight, hearing, memory, motor coordination, liver, lung, and kidney functioning, learning and intelligence, and reproduction.

As awareness of health risks increases, the expectation that regulatory agencies will act to protect the public’s health also increases. A number of factors help to explain this greater demand for government intervention. Most important are the difficulties associated with traditional methods of distributing risks. The primary methods of risk allocation have been market mechanisms and the judicial development of contract and tort law.

Market Approach

Advocates for the pure market approach argue that free markets contribute to greater efficiency and maximize individual freedom of choice. For example, employees in a free market are presumed to make their own determinations of acceptable occupational health risks, and to weigh those risks against other benefits such as additional compensation. Similar market-based approaches argue that individual consumers should decide how expected benefits and burdens are to be weighed. This approach faces several important objections. First, some of the most significant health risks are not susceptible to individual decision in the marketplace. Clean air is a public good rather than a private commodity. The benefits and burdens of air quality cannot be allocated according to individual willingness and ability to pay. Public goods such as clean air are available, if at all, only if they are available to everyone.

Second, critics have charged that sole reliance upon the market overlooks the difficulties that individual employees and consumers face in determining and evaluating health risks. Because such decisions depend upon complex and highly specialized information, it is unrealistic to assume that meaningful and informed choices can be made even by the most diligent consumers. Over 60,000 chemicals are used in industrial manufacturing, and almost 600 pesticides and an unknown quantity of other additives are used in agricultural production and processing. Individual choice does not foster greater autonomy as the proponents of the market assert; it fosters only an “illusion of autonomy.”

Judicial Alternative

The judicial system is the primary alternative to market allocation of risks. Courts have developed principles of tort and contract law that determine the duties citizens (and economic enterprises) owe to one another with respect to activities involving health risks. For example, principles of tort law establish which hazards create duties of due care, decide what conduct is reasonable in particular circumstances, and predicate legal remedies for injury upon judgments about the foreseeability of harm, which party is best situated to protect against harm, and which party ought to bear the social costs of certain activities. Reliance upon judicial allocation of risks is subject to several strong objections. The causes of many adverse health effects are often remote or unknown, undetected until much later, and difficult to prove, especially when the effect may be the product of a combination of causal contributors. Moreover, judicial risk allocation is inefficient. It requires a case by case enforcement of rights and involves unacceptably high transaction costs (e.g., litigation expenses and attorneys’ fees). In addition, judicial remedies are often inadequate to fully compensate individuals for their losses.

Reliance upon market or judicial means of allocating health risks is problematic perhaps for more important reasons. The balance between health risks and competing benefits rarely involve trade-offs that solely or even primarily affect individual decision-makers. The choices are often made among the interests of different segments of society or of the economy, alternative uses of social resources, and competing visions of national priorities. Such choices present fundamental questions of social justice. They involve collective decisions regarding who will bear certain burdens and who will be the beneficiaries of social policies. Consequently, governmental risk assessors assume a great responsibility for the protection (continued on page 2)
Most Can't Assess Health-Risk Trade-Offs

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of the public's health and for insuring that the standards used
to determine acceptable risk do not result in systematic bias
or unfairness to particular segments of society.

Public policymakers have sought a rational basis for deciding
questions regarding levels of health risk acceptable to
society. Governmental agencies increasingly have relied upon
formal decision techniques known as quantitative risk assess­
ment (QRA). The QRA process is divided into three stages.
The first stage consists in the identification of hazardous
substances that have toxic or carcinogenic effects. Investi­
gators must decide which of the many chemical compounds
require more detailed and careful examination. A compound
that exhibits structural toxicological properties similar to
known carcinogens may be presumed to be a carcinogen itself
until proven otherwise. Also, investigators may use biological
assays to determine if a chemical compound induces cellular
mutations. Mutagenicity is evidence that the substance under
investigation may be carcinogenic since most carcinogens are
also mutagens.

Animal Data Used

Using other methods, assessors conduct initial studies to
determine if chemical compounds exceed the "no-observed­
effect level" (NOEL). Establishing criteria for NOEL is itself
a controversial process. Because of ethical objections to
human experimentation, risk identification techniques depend
heavily upon extrapolation from data pertaining to animal
exposures to humans. More sophisticated epidemiological
studies are designed to identify clusters of harmful effects
that occur in human populations exposed to the substance
under investigation. But the success of this method is often
hindered by the difficulty of obtaining evidence, particularly
for low-level exposures over long durations. Moreover, these
methods are of little help in the identification of risks as­
associated with new chemical compounds.

At the second stage, generally known as risk analysis or
risk evaluation, investigators attempt to integrate information
obtained from a variety of observations and hypotheses into
a numerical estimate of health risk. For example, health risks
from exposure to pesticides is expressed in terms of an incre­
mental increase in the average number of cancer cases over
a lifetime of exposure. By convention among risk assessors,
a risk is said to be "negligible" if a chemical is expected to
cause roughly one additional case of cancer per million over
a lifetime of exposure. The negligible risk standard is an
approximation; most risk assessors interpret this standard as
including up to four cases per million. Less stringent standards
may permit risks as high as a few case per 100,000 persons
over a lifetime of exposure.

Even at these first two stages of QRA, the identification
and computation of risk rest upon a variety of controversial
judgments and assumptions. First, risk calculations depend
upon an estimate of individual exposure. Risk estimates are
based upon averages, but some segments of the population
may be subject to far greater exposure. For example, the
Natural Resources Defense Council (NRDC) recently con­
cluded that the average child receives four times more expo­
sure than an adult to eight carcinogenic pesticides in food.
This is, in part, due to the fact that, relative to body weight,
children consume approximately six times more fresh fruits
and vegetables — and therefore more pesticides — than adult
women. The NRDC study concluded that children exposed
to daminozide (Alar) and its metabolite, UDHM, may cause
one cancer for every 4,200 children by the age of six. This
is 240 times what the Environmental Protection Agency (EPA)
considers an acceptable risk for the general population.

The assessment process does not end with a deter­
mination of a numerical estimate of risk. It still re­
mains to be determined what risks are acceptable.

In the third stage of QRA, policymakers must decide
whether a given numerical estimate of risk is one
that society is willing to take for the benefits as­
associated with the use of a chemical.

In addition to the differences in level of exposure among
sub-populations, some segments of society are also especially
susceptible to certain health risks. For example, the digestive
systems of young children are such that they absorb more
toxic chemicals than adults do. Similar differences associated
with race, gender and socioeconomic status may reveal sub­
populations with greater susceptibility than the population at
large.

More general uncertainties pervade the risk indentification
and evaluation processes. For example, the EPA does not
evaluate the health effects of inert pesticide ingredients. They
are considered inert because they have no pest-killing effect,
not because they are harmless. Many other risks of exposure
to pesticides are not even tested by the EPA. Effects on the
development of the nervous system, and on such things as
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Nancy Cruzan Case Is the Wrong One To Test Euthanasia

By John Collins Harvey

The Cruzan case was heard by the Supreme Court of the United States on December 6, 1989. It has been made the "test" case for and against euthanasia. Many organizations (medical, nursing, hospital and nursing home associations, citizens groups, and churches, among others) have filed briefs as friends of the Court. The decision of the Court is expected sometime in the spring of 1990, and is eagerly awaited.

Nancy Cruzan, now 31 years of age, a citizen of Missouri, as a result of an automobile accident some five years ago, is in a persistent vegetative state. Her parents, acting as guardians and employing substitute judgment, requested the court of first instance to permit removal of her gastrostomy feeding tube to stop the artificially administered food and fluids she has been receiving in the health care institution because the treatment was too burdensome, nonbeneficial, and prolonging her dying. They cited the constitutional right of privacy and the common law right to refuse treatment as a basis for their plea.

The Court was satisfied that Nancy had made advance directives verbally to friends that she did not want to be treated if she were in a persistent vegetative state. The Court gave permission for the withdrawal, but the case was appealed to the Missouri Supreme Court by the facility caring for her, and this Court by a 4 to 3 decision reversed the lower Court. The case, appealed to the Supreme Court by Nancy's parents, was accepted on July 3, 1989, the same day that the Webster v. Reproductive Health Services decision concerning abortion was handed down by the Court.

Bishops File Brief

The Prolife Activities Committee of the National Conference of Catholic Bishops has filed a brief urging the Court to affirm the decision of the Missouri Supreme Court. The brief indicates that the perceived constitutional right to privacy found in Roe v. Wade negates the state's interest in protecting life and preventing suicide. The organizations in favor of legalizing euthanasia in their briefs urge the Court to overturn the decision citing that the constitutional right to privacy does include the right to die. This case has now become the primary battleground concerning euthanasia.

In my opinion, this is the wrong case on which to make the fight for us who oppose legalizing upon the patient's request either assisted suicide or direct homicide by health care workers. This is not a case in which "euthanasia" (mercy killing) is a feature at all!

The evidence indicates that the patient is in a persistent vegetative state. She had made clear in verbal advance directives her wishes not to accept treatment that is burdensome and not beneficial. In a persistent vegetative state, the cerebral cortex is destroyed; the brain stem remains alive. Thus the patient has lost the biological substrate for, among other things, all sensory perception and all voluntary motor movement. She will never feel pain, thirst, hunger, or satiety. She cannot and will never be able to perform those voluntary motor movements involved in swallowing. The patient is clearly alive, continuing to breathe, and to have heartbeat. If the medical treatment of administering food and fluid artificially to bypass her functional physiological defect caused by the brain damage is maintained, the patient may live, if given proper skin care and proper monitoring of the mechanical feeding process, for a long period of time.

The administration of food and fluid artificially is a medical technological treatment. It requires expert action upon the part of the physician, nurse, and dietitian to place tubes, prepare the feeding mixture with proper amounts of fluid, protein, carbohydrate, and fat properly and under sterile conditions, and to administer and monitor the administration of it carefully. This medical treatment requires the same kind of medical technological expertise as using a respirator or employing renal dialysis treatment. The medical treatment of artificial feeding will not cure the patient for it cannot cause the dead brain cells to regenerate. This is not effective treatment. This treatment will merely prolong biological life and the patient's dying process. The burdens of this medical treatment far outweigh its benefits.

This is clearly an example of the principle of double effect. This is not "euthanasia" by omission! The patient dies because she cannot swallow food, and this is part of her illness: there is no medical treatment whatsoever that can restore the destroyed biological substrate that would then restore the physiological process of swallowing.

It is well established in the moral teaching of the Church from de Lugo to the present time (Sacred Congregation for the Doctrine of the Faith, "Declaration on Euthanasia," Vatican City, 1980) that when the burdens of treatment outweigh the benefits of treatment for proportionate reasons, an individual is under no obligation to undergo the treatment. That the patient is now unable to articulate this does not deny her the right to refuse; this may be expressed by her guardians based upon her clearly previously articulated advance directives. That the cessation of this medical treatment will result in her death is clear. It is a foreseen but unintended secondary effect of her decision, but this ontic evil, her death, is a result of, not the means to, the good effect of relief from the noneffective, burdensome, nonbeneficial treatment. This is clearly an example of the principle of double effect. This is not "euthanasia" by omission! The patient dies because she cannot swallow food, and this is part of her illness; there is no medical treatment whatsoever that can restore the destroyed biological substrate that would then restore the physiological process of swallowing.

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Books

Recent Acquisitions

(New additions to the collection of the National Reference Center for Bioethics Literature.)


Group for the Advancement of Psychiatry. Committee on Child Psychiatry. HOW OLD IS OLD ENOUGH? THE AGES OF RIGHTS AND RESPONSIBILITIES. New York: Brunner/Mazel, 1989. 124 p. Legal and cultural views of the rights and duties of minors are discussed from a psychiatric viewpoint. The ages of reason and accountability are described in historical and developmental contexts. Consent to medical treatment, participation in research and decisions concerning sexual behavior by those under 21 years old are some of the bioethical issues considered.


PROCEEDINGS OF THE SECOND INTERNATIONAL CONGRESS ON ETHICS IN MEDICINE. New York: Beth Israel Medical Center, 1988. 224 p. Death and dying, the doctor-patient relationship, genetic manipulation, ethics in research, and allocation of health resources are among the subjects examined in 19 papers from a meeting held in June, 1987, in New York by the International Congress on Ethics in Medicine.

Steinberg, Avraham, ed. JEWISH MEDICAL LAW: A CONCISE RESPONSE. Woodmere, N.Y.: Beit-Shamai Publications, 1989. 180 p. (Kampelman Collection of Jewish Ethics.) Selected from Rabbi E.Y. Waldenberg's Tzitz Eliezer, the contents of this compilation include the doctor-patient relationship, contraception and infertility, organ transplantation, psychiatry, euthanasia, and experimentation.

Stevens, Rosemary. IN SICKNESS AND IN WEALTH: AMERICAN HOSPITALS IN THE TWENTIETH CENTURY. New York: Basic Books, 1989. 492 p. The history of hospitals and their influence in their communities is described. The struggle to use new, expensive medical technology and maintain the social welfare goals of hospitals as charitable institutions is outlined.


By Marlene Johnson
learning ability, vision, and hearing generally are not studied. Moreover, sampling and testing techniques used by the Food and Drug Administration (FDA) to measure pesticide residues in food can only detect the presence of approximately 40 per cent of the pesticides the FDA itself judges to be moderately to highly toxic.

The assessment process does not end with a determination of a numerical estimate of risk. It still remains to be determined what risks are acceptable. In the third stage of QRA, policymakers must decide whether a given numerical estimate of risk is one that society is willing to take for the benefits associated with the use of a chemical. The contrast between EPA and FDA standards of acceptable risk for pesticide residue of food illustrates the issue. The FDA regulates the maximum allowable concentrations of pesticides in most processed foods. The 1958 Delaney Amendment to the Food, Drug and Cosmetic Act requires a negligible risk standard and it prohibits any further weighing of economic or social benefits against health risk. In effect, the FDA standard reflects an implicit risk-benefit approach that assigns priority to health. By contrast, the EPA regulates the maximum acceptable amounts of pesticide residues in raw or unprocessed foods such as fresh fruits and vegetables. The Federal Insecticide, Fungicide and Rodenticide Act permits the EPA to weigh risks to human health and environment against economic, social, and environmental benefits of the use of any pesticide. Among the benefits considered are increased crop yields, prolongation of storage life of produce, and purely cosmetic enhancements involving color, shape, size, and texture. Because the EPA is permitted to trade off health benefits against presumed benefits of pesticide use, EPA regulation of health risks for fresh foods may be far less stringent than allowed by the FDA for processed foods.

Current legislative proposals before Congress are aimed at replacing the different standards used by EPA and FDA with a single standard. Some favor the EPA model while others endorse the FDA approach. One proposal seeks to adopt a single standard for acceptable pesticide risks that also would preempt individual states from setting more stringent standards for the protection of its citizens.

Critics of the current EPA standards argue that governmental authority to balance health risks against economic and other social benefits undermines the safety of the nation's food supply. Critics of the FDA standard argue that the negligible risk standard is too stringent, and that it unrealistically expects the government to guarantee a risk-free society. Though it seems unreasonable to claim that no additional amount of health risk should ever be accepted for other economic and social benefits, critics of the FDA standard mistakenly assume that negligible risk means that food must be risk-free. Quantitative risk assessment, even in its first two stages is not an exact science. Even wide safety margins may not provide enough protection for the most vulnerable members of society. Given the scientific uncertainty inherent in all stages of quantitative risk assessment, sound public policy would be to encourage rather than prohibit the development of risk assessment techniques through independent state programs. Clearly, we need more rather than less scientific investigation, just as we need more public participation at all levels of government in the development of health policy.

Cruzan Case Is the Wrong One for Euthanasia

In my opinion it is unfortunate that the Prolife Activities Committee of the NCCB has made the case one of being for or against euthanasia. I do not believe that the committee understands clearly that feeding artificially entails significant medical treatment. The committee, I believe, could have made a better fight by following the lead of the California Bishops' Conference when it attacked directly the initiative of Americans for Humane Death to get onto the state ballot in November 1988 "The Humane Death Act." Their statement is a beautiful, brilliant, and carefully reasoned one, pointing out the evils of legalizing assisted suicide or direct homicide by health care workers upon the patient's request.

That this type of initiative will be brought forward in other states in the near future by those organizations that favor legalizing euthanasia I have no doubt. It is against these initiatives that we should make our case directly. We should not try to fight euthanasia using the wrong case, which medically is very clear.

The Cruzan case involves two principles: evaluation by the patient of the burdens and benefits of treatment and a reasoned judgment of acceptance or rejection of same, and the principle of the double effect. It does not center on mercy killing.
Roundup

- The Fidia Research Foundation and Georgetown University's Center for the Advanced Study of Ethics are cosponsoring a symposium titled Transcultural Dimensions of Medical Ethics that will be held at the National Academy of Sciences on April 26-27. Pietro Corsi, professor of the history of sciences at the University of Cassino and Edmund D. Pellegrino, M.D., director of Georgetown University's Center for the Advanced Study of Ethics will chair the sessions. Participants will come from the Soviet Union, Italy, Switzerland, India, Thailand, Argentina, Israel and Nigeria. Participants from the Kennedy Institute of Ethics include Rihito Kimura and Ren-Zong Qiu. Further information can be obtained from the Fidia Research Foundation, 1640 Wisconsin Avenue, N.W., Suite 2, Washington, D.C. 20007.

- A conference on Issues in Medical Ethics: 1990 The Ethics of Surrogate Decision Making, will be held on March 9 at the Mount Sinai Medical Center, Hatch Auditorium, New North Pavilion, 5th Avenue and 100th Street, New York, N.Y. 10029. There is no fee for attendance and four hours of Category 1 CME credits are available. There will be session on The Law, The Physician’s Experience and Moral Perspectives. Participants include Justice Judith Kaye of the New York Court of Appeals and Jonathan Moreno, director of the division of humanities in medicine, Health Sciences Center of Brooklyn (SUNY).

- From March 11 to 15 the Kennedy Institute of Ethics will hold an advanced course called Frontiers in Ethics and Health Care Allocation. The course is restricted to past participants in the institute’s Intensive Bioethics Course. The fee is $1000, which does not include housing, and the registration deadline is Feb. 1. For additional information contact Karen Millan at the Kennedy Institute of Ethics, Georgetown University, Washington, D.C., 20057. The Intensive Bioethics Course this year will be held from June 3 to June 9.

- Stephen Klaidman, a senior research fellow at the Kennedy Institute, has won the $15,000 First Prize in the 1989 Wilson Center Media Studies Essay Competition. The winning essay, titled “Blowing Smoke,” is an account of how the news media covered smoking and health and how that coverage influenced public policy. It is a chapter in a forthcoming book by Mr. Klaidman to be published next year by Oxford University Press. The essay was cited for “clarity of writing” and “depth of analysis.”

- Edmund D. Pellegrino, M.D., has been named to an elite advisory committee charged with redesigning the job of director of the National Institutes of Health. The object is to make the job sufficiently appealing to attract candidates of exceptional stature.