

A BIOETHICAL PERSPECTIVE ON RISK ASSESSMENT MODELS FOR
MANAGING TOXIC WASTES, RADIOACTIVE OR NON-RADIOACTIVE

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"It may well be said of man in the twentieth century that he spent most of his creative genius in trying to dispose of his own waste."

Human beings are virtually immersed in a sea of naturally occurring toxic elements in potentially lethal quantities. Nonetheless, the human species has managed not only to survive, but also to enjoy an ever increasing life expectancy. Given this state of affairs, human reason and value judgments are severely tested in the attempt to define bioethical problems raised by producing and disposing of by-products or "wastes" entailed by technological applications of toxic elements derived from nature's resources. A fundamental problem must be addressed if ethical reflection is to proceed: What is the goal for managing toxic elements in our environment? Is it to master the wind or to determine the set of the sail? Bioethics requires a clear definition of how and to what extent toxic wastes pose such a unique threat to basic human rights (e.g. equal protection of life and health, access to basic material well-being, etc.) that only more costly research into more esoteric methods of managing toxic wastes will best serve to protect basic rights.

Professionals in the physical and health sciences and in engineering have developed risk assessment models to facilitate the development of technical options as well as public policy options. These models have come under particular scrutiny by critics and proponents alike, since risk assessments purport to evaluate the likelihood and magnitude of potential threats to health and safety. If a lesson can be learned from public perception and mounting alarm about just how many risks life holds, the consequences of engaging in risk assessments with worst case scenarios are ambiguous at best. It is commonplace today to hear such slogans as "Not in my backyard!" or "Hell, no, I won't glow!" or "I demand equal protection under the law." These slogans indicate that, according to popular public perception, the presumed quantities of toxic waste inventories and technical difficulties about their successful management are sufficient reason to argue that morality imposes limits to growth of our industrialized, high-technology society. If it is true that we no longer have an "away" to throw things into, then diminished protection of public health and safety -- resulting in an immoral violation of presumed human rights -- seems unavoidable.

Is toxic waste management as intractable as the public is induced to believe? Does popular perception accurately reflect an actual state of affairs verifiable by scientific evidence? More to the point, should current levels of public perception about waste management problems become the guiding light of public policy? Or should a policy-making process exert leadership by insisting upon a more adequate ethical framework for decision making?

As these questions indicate, the management of toxic wastes has become a symbol and prototype of the ethical and moral problems we must wrestle with if we are to act responsibly toward present and future generations. They also dramatize the urgency of the need to become morally serious about problems we are all responsible for creating and resolving. To engage in fault-finding or to stake out claims to moral superiority, only reinforces a common tendency to trivialize and escape from the burdens of living in a complex society. As an alternative to moral superiority, moral seriousness requires us to develop an adequate, logically consistent ethical framework for resolving conflicts of value judgments. Such a framework should enable us to organize empirical data and scientific evidence, as well as derive principles to serve as guidelines for a proper management of toxic materials.

In the interest of developing an adequate and consistent bioethical perspective for reflecting on the ethical issues raised by toxic wastes, this brief paper focuses on the question of whether or not public opposition to past and proposed methods for waste management has been induced as much by technical incompetence as by deficiencies in using risk models for bioethical problem definitions. The subject for this workshop session implies that the trials and tribulations of devising policy for radioactive waste management might possibly serve as a model for managing nonradioactive wastes by way of providing instructive risk-comparisons, technological applications and an avoidance of costly public opposition. Whether such applications are technically desirable, I leave to experts qualified in making such a judgment. The focus of concern here is whether they are ethically desirable. I do not consider it a constructive line of inquiry to rehearse the historical record of radwaste management -- either as a vehicle for ridiculing or excusing the efforts of government officials to fashion a publicly acceptable policy on waste management. Not only is that record incomplete and open to conflicting interpretations, but it may distract us from dealing with more substantive questions. Of these substantive questions, I propose to examine at least two that have particular significance for developing an adequate bioethical framework:

(1) Can bioethical problems of toxic waste management be properly defined by adopting conceptual tools currently used in risk assessment models for radwaste management?

(2) Secondly, how should bioethical and moral considerations relate to or derive from the present status of scientific

data concerning the likelihood of harmful health effects from toxic elements in our environment, particularly toxic wastes?

CONCEPTUAL TOOLS FOR BIOETHICAL PROBLEM DEFINITION

At the outset, a bioethical perspective requires clarification concerning the terms in which ethical issues are to be defined. Much more than an inventory and description of the physical properties and locations of toxic wastes are necessary for an adequate definition of the ethical problems they pose.

Deficiencies in Conceptual Tools

Contrary to a popular misconception, "hazards" have neither a bare facticity nor an intrinsic morality predetermining how public policy should be fashioned in relation to them. Hazards are not baldly "there" in nature or in human transactions with it. What people regard as hazardous in any given era reflects what they have come to know about their environment and what they value as essential or desirable on a scale of real possibilities. In short, human beings structure hazards. They are, in that sense, human artifacts. A hazard cannot accurately be defined as "toxicity of substance" or "violence of event" or "magnitude of consequences" that can be known, classified and predicted. A hazard exists only when and to the degree that harmful exposure of and assimilation by the human body or other valued living systems becomes a genuine and not merely an imaginable possibility. That possibility exists only when there is an inability or failure to devise and maintain controlling actions or safeguards.

Not only is there a widespread misconception about what constitutes a "hazard" or serious threat to public health and safety, but there is also a common misconception about "risk" as it relates to public well-being. Many have adopted the uncritical assumption that risk is a normative concept for certifying consequences to human beings that are harmful, dangerous, or "bad." These contrast sharply with consequences that are beneficial, pleasurable or good -- hence by implication risk-free. As a result, a false antithesis has been set up between risks and benefits -- as if there were a way to have one without the other. To the contrary, in concrete decisions, what is actually "at risk" is the possibility that the intended benefit from risk-taking may not materialize and some harm may occur. Any such harm is clearly unwanted and unintended. Far from being antithetical, risks and benefits are inseparable.

Besides misleading conceptions about hazards and risks, and an uncritical identification of risks with harm, there is little if any clarity of degrees of "harm" or of "benefit." An adequate bioethical framework requires a greater refinement in these notions if they are to serve as conceptual tools in setting priorities in health protection.

Three qualitatively distinct degrees of benefit are suggested by Okrent and Whipple. First, there are goods essential to

members of society (e.g., food, clothing, shelter, water, energy) or basic goods; secondly, there are goods advantageous to society (e.g., most manufacturing); thirdly, there are goods of peripheral, if any, value to society (e.g., aerosol deodorants having substitutes at lower cost and less likelihood of harm). Each qualitative benefit has corresponding levels of harm. Basic harms may result from being deprived of goods essential to subsistence and material well-being.

This nomenclature suggests that there are corresponding degrees of health problems. (1) Among potential kinds of biological and psychological impairment, the most severe would be a crippling, disabling disease measured by its effect on an average life-expectancy. Detection, prevention or avoidance of such impairment is clearly a basic good or benefit which social structures of accountability for health protection should assure citizens as a basic need. (2) An advantageous increment would accrue from those goods which enhance a sense of well-being and contribute to a perceived "quality of life." (3) There is a third class of clearly superfluous or peripheral forms of health care which amount to an aesthetic or cosmetic enhancement only. Ethical principles for justice and equity, and the functional need of society for good health, require institutionalized structures to provide access to basic goods or benefits and to avoid basic harms. It is the second- and third-level benefits and harms that pose the most contentious problems for social policy, as well as for ethical reflection.

Still another deficiency in conceptual tools used in risk analysis arises from a failure to acknowledge that there are degrees of harm corresponding to degrees of benefit. A harm that is trivial or so negligible as to be undetectable or unavoidable, if another greater harm is to be prevented, provides an ethical basis for a category of "justifiable harm." Such harm is in contrast to a serious, unavoidable "unjustifiable harm." For example, if one accepts statistical estimates based on a linear hypothesis, diagnostic X-rays may cause some potentially detectable harm by "killing" or disrupting repairable cells. But preventing the greater harm of serious health impairment to a patient renders a comparatively negligible cellular harm ethically justifiable. The most lamentable aspect of an undifferentiated use of "harm" language -- or, for that matter, a statistical estimate to describe biological effects -- is that an unsuspecting citizen is led to think that actual body-counts of certified injury and death to human beings are the scientific basis for stating that exposure to low-level radiation doses cause harm. To the contrary, the basis is only speculative.

Rising expectations about improvement of public health and safety, as well as the prevention of varying degrees of harm, necessarily entail estimates of economic costs. Monetary costs of protecting health and preventing harm have invited the interpretation that they are a callous, utilitarian measurement for an incommensurable good, namely the "value of a human life." According to critics, a human life is of infinite value, and its loss or impairment cannot be put in a class with other "negative

consequences," much less be given a finite monetary value. To do so indicates the moral bankruptcy of our "materialistic, consumerized, decadent society." Cost/risk/benefit quantifications, say its critics, manifest a loss of respect for the sacredness of human life. However, the public must be confronted with the fact that any society has but a finite amount of money to spend on health protection, and that the ethical problem is to get the most protection for the most people from this finite amount.

As a conceptual tool which attempts to enhance informed consent, cost/risk/benefit quantifications are simply one tool among many others whereby policy makers endeavor to allocate finite amounts of money in a just and equitable manner. They are not tools for putting some callous dollar-value on human life or injury as a moral judgment of individual worth -- much less of using economic losses to society as a measure of personal expendability. We are in fact maximizing the value we place on human life when we endeavor to allocate limited amounts of money in such a way as to reduce widespread hazards, thereby preventing as much loss of life and protection from injury as possible.

Deficiencies in Systemic Risk Assessment

These misconceptions and inaccuracies are compounded by a second deficiency in bioethical problem definition. One or another technology (in this case, the generator of a waste inventory) is being considered in such a way that the public is led to conclude that it represents only incremental risks, as if these were simple additions to a current risk background. To the contrary, any "new" risk reorders an entire system by displacing, offsetting or otherwise restructuring a prior pattern of benefits and harms. Only systemic risk-accounting does justice to this modification.

To illustrate: Several recent studies demonstrate that a positive correlation exists between income, improved health and life expectancy.² Steady economic growth has meant improved housing, better nutrition, environmental sanitation, more plentiful food from mechanized agriculture and has reduced accidents in the workplace, etc. Heretofore, programs to improve health have been based on biomedical epidemiology and ameliorative projects. However, evidence now indicates that greater advances in protection of public health could be better achieved by improving socio-economic conditions among the disadvantaged segments of society rather than through sophisticated advances in biomedical knowledge. Excessive governmental regulations for "safety" have dramatically affected increasing costs and decreasing availability of energy and other basic necessities. Consequently, any adequate assessment of risks from toxic wastes must be so conducted that it includes the risks to an entire social economic system if disposal costs result in causing reduced incomes, hence negative health effects from deprivation of basic needs.

From a bioethical perspective, systemic risk accounting is a necessary precondition for any social policy. A preoccupation

with biological health effects from one or two categories of toxic wastes does not do justice to the full spectrum of threats to public health and safety.

Deficiencies in Fundamental Philosophy

A third deficiency in ethical problem definition results from a failure to base technological risk assessments on a "philosophy of congruence" with a pattern of benefits and harms already established by naturally occurring toxic elements with which human beings have lived, evolved and gradually increased their life expectancy throughout recorded history. A philosophy of congruence and consistency requires a policy maker to undertake risk assessments by first taking account of wide variations of personal exposures and population exposure from naturally occurring background sources. Human tolerance for -- indeed demonstrated dependence upon -- such wide variations in exposures to naturally occurring toxic elements demonstrates that increments from man-made applications of those natural sources can be kept well within the range of variation (e.g., standard deviation from background) without inflicting either unjustifiable harm or deprivation of basic goods and benefits to members of society.

BIOETHICAL STATUS OF SCIENTIFIC DATA AND EVIDENCE

These deficiencies in problem definition suggest a second substantive question -- namely, the status of ethically pertinent empirical data and scientific evidence concerning health risks from presumed exposure to toxic wastes. At least three factors call in question the adequacy of an ethical framework from which a moral argument declares that risks of toxic wastes pose unacceptable threats to health and the quality of our environment. If risk assessment models for the management of radioactive wastes are to be applied to non-radioactive wastes, we must examine the scientific status of the linear hypothesis and its relationship to bioethical reflection.

Status of Linear Hypothesis

Moral objections to technological applications of radioactive substances are based on the claim that any radiation exposure, no matter how small, has some health effect which it seems wise to assume does some harm. A linear, zero-threshold hypothesis has been applied to the development of radiation standards. Consequently, the public has been led to believe that "there is no safe dose of radiation" and "every radiation dose is an overdose."

It is ethically significant, however, that despite the vast amount of radiobiological data, there is no conclusive scientific evidence to prove the existence or absence of a threshold. A moral argument which categorically condemns the production of radioactive wastes originates from and depends upon what is taken to be an unassailable scientific conclusion. But in fact, it is only an untested theory, an extrapolated hypothesis, an ultra conservative and protective rule of prudence.

The absence of scientific evidence of harm from exposure to low levels of radiation is not due to incompetence or oversight or lack of attempts to find harmful effects. Lauriston Taylor's assessment of the situation merits close attention:

"No one has been identifiably injured by radiation while working within the first numerical standards set by the NCRF and then the ICRP in 1934. Let us stop arguing about the people who are being injured by exposure to radiation at the levels far below those where any effects can be found. The fact is, the effects are not found despite over forty years of trying to find them. The theories about people being injured have still not led to the demonstration of injury and, though considered as facts by some, must only be looked upon as figments of the imagination."⁵

A profound misunderstanding of the scientific status of the zero-threshold, linear hypothesis renders any moral argument dependent on it inherently flawed. There are, however, more compelling reasons to question the legitimacy of moral claims condemning the existence and harmful potential of exposure to radioactive wastes.

Alternative Hypothesis

Since it has been scientifically established that there are net beneficial effects from low-level exposures to other toxic elements (e.g., copper, selenium, fluoride), it is legitimate to ask if professional ethics should not require competent members of the scientific community to examine radiobiological data through the lens of an alternative hypothesis. T. D. Luckey's recent publications -- "Hormesis with Ionizing Radiation"⁴ and "Radiogenic Metabolism"⁵ -- suggest a strong case for the need of a definitive scientific study to determine whether or not exposure to low-level radiation may have net positive effects. Indeed, it may be essential for the well-being of living organisms.

Etiology of Cancer

A third reason for questioning the ethical significance of scientific data arises from the status of hypotheses about the environmental origin of cancer. Thirty years ago, John Higginson formulated a complex theory which, through misinterpretations and distortion, has led ordinary citizens to believe that some cancer-causing agent lurks in everything we eat, drink or breathe. He has attempted to correct distortions of his theory by pointing out that, when he ascribed the incidence of cancer in industrialized societies to "environmental causes," he meant the total environment -- cultural components of life-styles such as diet and behavior, agricultural practices, social pressures -- and not merely or exclusively physical chemicals or other toxic elements in the environment.⁶

In a major public statement on cancer policy, the late Philip Handler, former President of the National Academy of Sciences, stated that:

"We should lay to rest the idea that it is these man-made components, abroad in the land, that are responsible for the fact that 25% of Americans die of cancer. They are not. The possible effects of all known man-made chemicals, when totalled, could contribute only a miniscule fraction of the total of all carcinogens in our population."

John Totter reflects on the origin of spontaneous cancer in a recent article in the Proceedings of the National Academy of Sciences. He shows that, when corrected for competing risks, mortality from cancer appears independent of the level of industrialization in a country and, thus, of its man-made pollution. He suggests that it is not among man-made agents that one should look for primary carcinogens, but instead, among all-pervasive "normal" environmental components. Totter suggests that the culprit is oxygen: it is a recognized mutagen; experiments have shown that it causes tumors in fruit flies; in the Ames assay test for screening carcinogens, it shows up positive. Totter's revolutionary theory is favorably acknowledged by an increasing number of distinguished scientists.

To summarize: The moral argument claiming that the existence and potential harm from radioactive wastes renders them morally unjustifiable and a violation of human rights -- unjustified by any foreseen and intended benefits -- derives from and depends upon unsupportable scientific assumptions.

(1) The assertion that any and every radiation dose not only can, but does cause somatic and genetic harm rests on a profound misunderstanding of the scientific status of the linear hypothesis.

(2) Enough evidence for the possibility of net beneficial effects of low-level radiation exposure exists to merit the scientific investigation of this alternative hypothesis.

(3) Finally, since the etiology of cancer remains highly theoretical and uncertain, a moral condemnation of technologies using radioactive substances is seriously flawed since it unjustifiably presumes, as a scientific fact, that any exposure to a suspected carcinogen actually causes harm which can and should be prevented by government regulation. A hypothetical harm can entail only a hypothetical violation of rights.

In view of these scientific premises, I would like to raise a key issue: In what manner should ethical considerations relate to, depend upon or derive from scientific premises of a hypothetical standing? If unambiguous scientific facts do not exist, but instead, mere possibilities or probabilities of benefits and harms -- which can only be determined by risk analysis -- what if

any moral oughts and ethical imperatives can be derived from this state of affairs?

BIOETHICAL DERIVATIVES FROM HYPOTHETICAL SCIENTIFIC PREMISES

A first step in determining the proper relation between scientific hypotheses and bioethical considerations is to consider a rather severe form of criticism leveled by several academic ethicists against those engaged in making public policy, technology assessments and regulatory standards. Among numerous theoretical errors allegedly made by "pragmatic, hardheaded technocrats," one is regarded as the most ominous, namely, "the naturalistic fallacy."⁹ Simply stated, one commits this fallacy

- (1) whenever scientific reasons alone are used as the sole justification for ethical conclusions, or
- (2) when factual "is" propositions are the only basis for making moral "ought" statements as ethical conclusions, or
- (3) whenever something is defined as good without question solely because it happens to be a factual matter.

According to these ethicists, the naturalistic fallacy is compounded when regulators and policy-makers use a utilitarian risk/benefit calculus to argue that risks from low-level radiation ought to be morally acceptable because they are in fact not only within the range of already accepted risks, but outweighed by technological benefits and economic advantages of a lower-cost technology. A utilitarian ethic based upon a naturalistic fallacy stands accused of being the root cause of two dangerous consequences: first, it results in a violation of moral and inalienable civil rights to equal protection and due process; secondly, it leads to a socially unjust sacrifice of public health and safety to unprincipled economic growth and technological development.

When one examines the work of ethicists (and some scientists) making such serious charges, one discovers a striking paradox: they reach their ethical conclusions by committing the very fallacy they repudiate. That is to say, not only do they misinterpret the linear hypothesis as a scientific fact from which they presume that a utilitarian risk/benefit calculus seeks its justification, but their own moral claims and ethical conclusions have validity on the sole basis of a presumed scientific fact, namely, that all radiation exposure is unequivocally harmful. This is a worst case example of the naturalistic fallacy.

Even if the naturalistic fallacy has a valid place in ethical theory, it has nothing to do with how, in practice, ethical considerations should stand in relation to the hypothetical status of scientific premises such as those reviewed above. When technology assessment or standard setting makes use of limited conceptual tools such as risk models or harm/benefit estimates or economic cost-effective projections for optimizing the allocation of a

finite amount of money, it does not follow that this exercise amounts to drawing ethical conclusions based on a fallacious conversion of a scientific "is" into a moral "ought." For example, when a risk assessment concludes that the hypothetical risks from low-level radiation exposure to diagnostic X-rays are far below the actual risks of exposure to many other toxic elements encountered daily, one is not converting an "is" to an "ought" by reaching the conclusion that one set of risks ought to be morally acceptable because the other is. This interpretation is a profound distortion of the ethical problem posed by comparative risk analysis. The ethical conclusion to be reached is not that the acceptance of a greater risk should make the lesser risk equally, if not more, acceptable. The ethical problem posed by assessments of hypothetical versus actual risks (and other comparisons) is to induce the ethical conclusion that it is not morally justifiable to spend more money to reduce already trivial, hypothetical risks, rather than spend it to reduce other greater risks that can actually be diminished by that expenditure.

The principle of human rights to equal protection -- far from being violated by using such conceptual tools as risk analysis and harm/benefit estimates -- can best be safeguarded by a methodology which surveys a total spectrum of risks to health, proposes a series of risk-reduction alternatives and associated costs, and enables a policy-maker to determine which expenditure of finite funds will get the most equitable health protection for the most people.

CONCLUSION

The pressure of events should compel us, in conclusion, to act constructively on the questions posed by Aaron Wildavsky. He asks how it could happen that the United States has become a safer place to live in the past century without anyone intending or acting to achieve this outcome. He observes that "the greatest industrial revolution that led to (or was produced by) the mechanization of agriculture was not designed by anyone to improve the health and safety of the general population. Yet the extraordinary improvement in diet that resulted from cheaper and more plentiful food, which was a major consequence of mechanization, has done much to improve health and life expectancy and also to reduce accidents."

Heretofore, when social risk reduction was an indirect process or a byproduct resulting from a policy made on other grounds, everyone shared in the general risks of living and no one was singled out for protection in some special way. But in our current cultural climate, "risk reduction becomes a decision instead of a result" and "a deadly process is put into effect, by which individual or group safety is bought at the expense of the whole."

What is new about this situation is not really that a personal quest for safety is more intense (witness the increasing opportunities for personal risk-taking in sky-diving, white-water canoeing, mountain climbing, etc.). What is new, observes

Wildavsky, is that "the collective urge to risk reduction is so much greater than the sum of the individual urges it claims to represent. Each of us would do less for ourselves than we would insist the government do for us." He recommends, not a laissez-faire abandonment of government regulation, but rather a much more restrictive set of criteria for resorting to regulations as a means of dealing with risk:

The dice should be loaded against any 'right' to protection against risk. Only if risks are palpable and remedies ascertainable and populations limitable and dangers unavoidable, should government regulate risk. Killing people with kindness is only a subtle form of verbal aggression. Killing people with safety would be one of the supreme ironies of our time.

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