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Medical Ethics and Society

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Introduction

Medical Ethics as a discipline and even a profession for philosophers and others is only about 25 years old. During this quarter century there has been a burgeoning of articles, journals, books, institutes, and departments, all devoted to exploring this new field and subjecting every aspect of medical practice and public health to scrutiny. Stephen Toulmin has even characterized medical ethics as the salvation of professional philosophy.

By that he did not mean to imply that it is a set of problems invented by the current generation of stuffy academics as an artificial device to keep the leaky boat of contemporary philosophy from sinking into a sea of irrelevance. The emergence of this new discipline is symptomatic of profound concurrent changes in medicine, in society, and in the government's attitude toward its role in the lives of its citizen.

It is the purpose of this two-day conference on Society and Medical Ethics to explore some of those changes: to chart directions, to reflect on forces, to gain new perspectives. In a sense, this conference initiates for many of us a period of reflection on constitutional issues on the eve of our Constitution's bicentennial — aiming at a new understanding of ourselves as individuals, as members of communities, as subjects of what is easily viewed as unwarranted intrusion by government into our daily lives. Subsequent speakers will explore selected elements of these themes: personal responsibility for personal health, the incredible advances in the field of organ transplantation and the potential for their commercial exploitation, and some of the problems of the medical professional caught between increasing federal regulation and increasing consumer expectations in an increasingly litigious society that sees lawsuits as the ultimate recourse for medical disappointment.

My own task is to paint some of the broader features of the picture. I will seek in the remarks that follow to identify some of the historical factors that have made for the emergence of the field of medical ethics, to provide something of a structural history of the principles that have been explored and applied to medicine in recent decades, to note how the attention of biomedical ethics has begun to swing away from the understanding of the contract between physician and patient to understanding the broader social issues affecting the ways in which that contract arises and is executed. My chief thesis will be that medical ethics will increasingly become preoccupied with broader social issues, with the result that the scope of its subject matter will broaden and will focus more upon issues of prevention of problems of health rather than their cure.

The Scientizing of Medicine

We sometimes lose sight of the fact that the scientific cure orientation of modern medicine is a product of the 20th century, indeed of its last three or four decades. There has been an explosion in our scientific understanding of human processes and their disruption by disease and injury. With that increase in knowledge has come power in the form of medical technology. The past 25 years comprise the entire history of such fields as genetic engineering, organ transplantation, pharmacological psychiatry, fetal diagnosis and treatment, and a score of other innovative disciplines.

Medicine has been transformed from an essentially caring, palliative, occasionally repairing diagnostic aft that was the husband of nursing, to a cure-oriented, scientific discipline of body engineers whose appointed tasks have transformed patients into engineering problems and puzzles requiring solution. Hospitals have been changed from places where care was provided to the sick and dying to places of incessant drama, stages whereupon the battle against Death is fought with chemical, biological, and sophisticated technological weapons wielded by specialists trained and steeped in the heuristic devices of perceiving patients in terms of their specializations.

With the transformation of medical wisdom into scientific and technical knowledge has come a transformation in the social standing and role of the physician. No longer is the image of the physician the respected sage of his community, known in the homes of his patient families, ministers alike to the ills of the young, the breadwinner, the elderly, he who ushers us into life, counsels us in our brief stay on this mortal coil, and who sits quietly consoling as we shuffle off. Rather than a constant force in our lives, the modern physician is a specialist in only a part of our lives, is consulted through a referral for specific crises, and hopefully is dismissed by the satisfied consumer of his services, perhaps never to be seen again.

These transformations of medicine and of physicians are as much as anything products of the life styles of us who are their patients. It has been said that, in the 19th century one died of disease, but in the 20th century one dies of life style. Certainly in our society the vast majority of human premature deaths can be traced, in one way or another, to our technology or to the cumulative effects of our self indulgences. In this aspect of our history we perhaps discover the greatest ironies, and an indication of the direction of future developments in medical ethics.

Social Individualism

Perhaps the single-most important individual in the formulation of the present American ethos was John Stuart Mill. This British philosopher's 1869 essay, "On Liberty," articulated what for many remains the ideal of the relationship of the individual to his community. Mill wrote that the "only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others." Mill and subsequent utilitarians lay emphasis on the role of government in promoting the desires or preferences of each of its citizens.

Mill's influence on the development of medical ethics has been enormous. It is in service of the autonomous individual ruling over his life even during the rocky passage through periods of injury or disease that the requirement of informed consent was promulgated. For, that requirement places prominently in control of medical decision-making, at the level of determination of broad goals and limitations, the preferences of the individual patient, even when they vary from those of the physician. In order to equip the patient for this task, he or she must be provided with a diagnosis, a description of the alternative ways of proceeding together with a reasonably full statement of the benefits to be gained and the risks undertaken by election of each alternative. The standard

for the amount of information and detail to be disclosed has evolved to a patient-oriented standard: what a reasonable person would want to know in order to make a decision, plus any information of particular interest to the individual patient.

The logic of this individualism extends to the physician as well. While the physician may be obligated to inform the patient of all medically standard options, he or she is not obligated to provide them simply on the patient's demand. Patient and physician thus must negotiate an agreement that reflects the mutual rights and responsibilities of each toward the other. The Catholic physician who diagnoses an unwanted pregnancy may be obligated to inform his patient of the option of abortion, but he is not obligated to perform one on her demand.

Mill's principles of liberty and the narrow considerations that may properly limit it have served, during this period of medicine's transformation, as the patient's major protection against overzealous exercise of the power of the physician. For, despite the greatness of that power, its effects are not limited to good. Chemotherapy, one of the most powerful weapons against cancer, renders patients as it renders tumors, and the resultant side effects can be so terrible that the cure is aptly described as worse than the disease. Mill's principles place the power to decide whether to enter into a particular treatment, and whether to continue with it, in the hands of the patient on the grounds that the sole determinant of the rightness or wrongness of that treatment lies with the preferences of the patient who is to receive it.

Thus, in the Mill-dominated system of medical ethics, the individual becomes a risk-benefit calculator, one who, in cooperation with the physician who provides the information about options and their possible benefits and risks and attendant probabilities, assigns the values to those various outcomes. The perfectly rational patient would then simply compute the expected value or net utility of each option and then choose that option with the greatest preference utility. The decision whether to take particular risks is thus the decision of the individual patient.

This view of the individual decision-maker as autonomous has a number of important corollaries. One is that a decision about which options to select is solely that of the individual only when the preferences of others are not substantially affected by the choice. For, making a decision that does threaten the interests of others in a significant way transgresses the zone of privacy concerning strictly personal decisions. Thus, it was thought to be a legitimate interference in individual liberty for the National Artificial heart Panel of the Food and Drug Administration to ban development of a totally-implantable artificial heart powered by plutonium on the grounds that a wearer would expose others around him to the effects of radiation. It might be legitimate for an individual confronted with the prospect of a very shortened life without such a device to undertake the personal risk of such exposure, but it would not be legitimate for that individual to expose others to such a potential harm.

Another corollary of Mill's liberty principle is that it is illegitimate to coerce the individual for his own good, as conceived by others. Strong paternalism, the view that such coercion is legitimate, was strongly rejected by Mill. This rejection has been the basis for much criticism of federal attempts at regulation as well as physician attempts to substitute their own judgments for their patients'. It is to the subject of federal regulation and its justification that we now turn.

State Paternalism, Federal Regulation, and Public Health

The history of the federal government's attempts to regulate the behavior of its citizens has been checkered. Efforts to impose prohibition on the sale and

consumption of alcohol through a constitutional amendment met with widespread civil disobedience, introduction of dangerously adulterated spirits into unregulated commerce, that was ultimately repealed. Efforts to enforce certain restrictions on sexual morality have generated a class of what have been called "victimless crimes," and have led to some states heightening and others dropping all efforts at prohibiting acts of homosexuality as well as prohibition of various so-called "unnatural" heterosexual acts.

On the other hand, there are areas of federal regulation of individual behavior that have been by and large accepted by the general public and accepted with relatively little protest in the form of civil disobedience. How can we explain the difference between the public's acceptance of the restrictions of the Food, drugs and Cosmetics Act that bans from interstate commerce products identified by the governmental agency as unsafe, and the public's rejection of attempts to eliminate alcoholic beverages from its citizens' diets?

Let us first recognize that there was a strong element of imposing a particular set of moral values that motivated the national experiment with prohibition. Mill's point was that the sphere of values consisted in two sorts, the particular and individual commitments whereby we hammer out our peculiar sets of preferences, either individually or in groups sharing similar commitments, and the broader conditions that make the election of a wide variety of individual commitments possible. Mill thought that, as rational being, despite our differences we should recognize that it was only through the mutual support of the principle of liberty and its protection by the police power of the state that we could insure the opportunity for a particular set of values and beliefs to be adopted and practiced. While tyranny imposes no burden on those who are in perfect agreement with the tyrant, there is no way, short of delimiting a private sphere, to insure that one will be able to adhere to his or her favored set of values and beliefs. Hence, tolerance of variant views is required if I am to have my views tolerated. The place to draw the line, Mill argued, was where variant views began to interfere in the lives of others.

Prohibition, then, failed because it sought to impose the view that consumption of alcohol was immoral onto those who did not share that view. The proponents of prohibition crossed the line between the cultivation and enjoyment of a life free of alcohol's influences as a matter of personal commitment, and the imposition of that life as a matter of the legal enforcement of a particular set of moral beliefs. That their motivation was, n their own eyes, expressive of their judgment as to what was best for others, failed Mill's prohibition against strong paternalism.

By contrast, the federal government's efforts to regulate the marketplace in order to protect consumers from unsafe, dangerous products, has not met with widespread rejection as was occasioned by the prohibition amendment. Despite an increasing insertion of the state into much of our lives, this regulation has been accepted generally by the public at large (although not always by corporate interests). A brief review of the history of federal regulation of commerce will provide some useful insights.

Prior to 1906, there was virtually no regulation of medicines and remedies. Medicines containing narcotics, such as morphine and cocaine, were sold without restriction. Quack remedies — some claiming to cure cancer — and contaminated drugs were largely uncontrolled by the federal government. Resourceful entrepreneurs advertised a wide variety of purported simple and painless cures for cancer, including liniments made of turpentine, mustard, crude oil, eggs, and ammonia; infusions of peat moss; pastes made from glycerin and Limburger cheese, and "fountain of Youth" preparations made of spices, crude oil, and beef suet. Congress was finally persuaded to form a Food and Drugs Administration in 1906, giving it the limited authority to act against adulterated and misbranded drugs *after* such had been marketed to consumers and had

provoked a significant number of complaints. The FDA could force removal of a product from the market, but had no power to regulate the introduction of products into interstate commerce.

In 1937 a manufacturer mixed sulfanilamide (a drug still sued in the treatment of fungal infections of unknown origin) with a highly toxic solvent, diethylene glycol, to make a liquid preparation, "Elixir Sulfanilamide." This product was promptly put on the market without any safety tests, and the deaths of nearly 100 children in the next few months was reported to the FDA.

Congress reacted to the public outcry with a new set of regulations under the 1938 Food, Drug and Cosmetic Act. These prohibited the introduction into interstate commerce of any new drug that had not been approved following the provision of data establishing the safety and effectiveness of the drug. It mandated a sequence of animal and in vitro studies, together with reports of well-controlled clinical investigations of the drug in human experiments. No drug could be introduced into marketing interstate that had not obtained prior FDA approval, which approval would not be grated without the requisite data. This Act also for the first time gave the FDA the power to ban dangerous or fraudulent mechanical de vices (although pre-market review and approval powers for such devices were not granted the FDA until 1976).

The next step in federal regulation in this field was occasioned by another tragedy. The drug Thalidomide was distributed to over one thousand U.S. physicians as n investigational tranquilizer. Although it had already been marketed in Europe, the FDA blocked its commercial introduction into the U.S. on the grounds of lack of adequate evidence of safety. Seventeen cases of severe birth defects attributed to the use of this tranquilizer by pregnant women were reported in this country. Later to emerge was the result of the 1950-1952 experimental trials of the drug diethylsylbestrol, or DES, conducted by the drug's manufacturer and the University of Chicago as a preventative of miscarriages. DES turned out after a number of years to be implicated in a high incidence of cancer and other reproductive tract abnormalities of the offspring of women who had taken the drug. None of the recipients of either drug, DES or Thalidomide, was told that they were part of a medical experiment nor even what the drug was that they were receiving.

Congress' Drug Amendments of 1962 set forth additional provisions regulating investigational drugs. A requirement of informed consent before administration in a clinical trial was imposed. Tightened standards of safety and effectiveness were imposed, and FDA approval before either clinical trials or marketing occurred was required.

In 1976 Congress extended the preview and approval powers of the FDA to include medical devices after 16 Deaths and 25 miscarriages were attributed to the Dalkon Shield, a device that had been introduced in 1970 as a supposedly safe and effective contraceptive device.

But the greatest period of the growth of federal protectionism occurred during the Great Society years of the sixties and seventies. In a brief ten year periods, to the FDA were added agencies like the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), and the National Highway Traffic Safety Administration (NHTSA). The common task of these agencies was to regulate the activities of corporations engaged in the manufacture of consumer goods so as to set above the profit motive other common values of workers and consumers, particularly the values of health and safety, but also other supposed common values, such as the preservation of species placed at risk of extinction by human activities.

It is difficult to see how such regulation can be justified by recourse to the usual analyses of the Harm Principle. For, that usually justifies limitation of liberty where the unlimited exercise of it poses significant risk of harm to

another. And while the tragedies that moved Congress to act were poignant, the numbers of individuals that were affected were exceptionally small. If they justified such severe regulation, surely the fact that 40,000 Americans lose their lives annually on our highways would justify even greater restrictions. Moreover, for any particular individual, the risks of harm are small. Given that individuals are aware that there are risks involved in taking medicines, whether experimental or not, doesn't the natural tendency of individuals to pursue their own interests, together with accurate information, provide sufficient protection? We are, after all, voluntary risk-takers, whose preferences determine the acceptable levels of risk.

Congress seems to have accepted the notion that these forms of regulation are justified, not in the name of the pursuit of some limited morality, but by the fact that they protect interests shared by all individuals in common. Congress has sen itself as exercising its constitutional charge to provide for the common defense and promote the general welfare of the commonwealth. Thus, limitations under federal regulation of the types described seek to protect all citizens from hazards that, viewed individually, seem insignificant. Put another way, the interests of ourselves and our posterity need protection against not only clear and present dangers but also marginal and remote ones. The cumulative effects of individual actions loom much more significantly than when viewed in individual terms. The gamble that you take when you drive your car is roughly that of one chance in a million per trip of a fatal injury. The risk seems insignificant; yet, the exposure of the American public tot he automobile is so great that over 40,000 traffic fatalities occur per year. But in terms of risks to the community, one might well (and Congress does) judge that risking 40,000 deaths annually is unacceptable.

Hence, it is reasonable to view federal regulatory restrictions as aiming not to impose on individuals a particular morality, nor to impose on individuals strong paternalistic measures designed to protect them from themselves, but rather to impose restrictions on individuals to protect the interests of the community. The federal processes of this century may be seen as predicated on a different view of the individual citizen than held by Mill. The citizen is not merely an individual, but also a member. Hence, his actions always carry the potential of harm to the collective interests of the communities of which he is a member. Those collective interests may be harmed by the cumulative effects of many individuals' choices, even though no one individual's single act of choice significantly increases the risk to another's interests. "Most of the most serious risks to the public health confront the individual with relatively slight or moderate risks which millions of others take at the same time."

Dan Beauchamp, a philosopher who is a professor of public health at the University of North Carolina at Chapel Hill, has summarized the point nicely in a statement criticizing philosopher's perceptions in their mostly pro-Millian writings on paternalism:

> Most philosophers, when they think of serious risks, seem to think of such activities as automobile racing, hang-gliding, or sky-diving. Public health is, ordinarily, not concerned with these activities, nor mountain climbing or rodeos; these are not mass behaviors. Rather, public health is concerned with behaviors which are repeated countless times each day, bearing a slight risk of inadventure, but cumulating in the life of the society to a very high burden of disease and premature death. These are the ordinary, everyday consumer risks which corporations exploit with their promotion of alcohol, tobacco, guns, automobiles, and the like. It is only when we observe health and safety as the kinds of social goods which are common goods that we grasp this conflict clearly. Such a communal front against risks would help us

> sort out the true logic of lottery risks. We among the public are, most of the time, small-time winners; our benefits amount to avoiding minor inconveniences and/or continuing to enjoy the unrestricted exercise of established privileges. The big winners are some truly powerful corporations that reap a huge harvest of profits from the playing of the game. The truly awful ones in our midst — the handgun industry, the cigarette and tobacco industry, and the automobile industry — are the "blood sports" of our day. For the blood sports industries, risks are not a by-product. Risk is the product. The losers? They are insignificant, faceless statistics, quickly placed six feet under or in the back ward of some hospital (Dan Beauchamp, unpublished manuscript)

The public health perspective provides another basis for opposing attempts at imposing moral standards through prohibition. I referred to the category of victimless crimes, including certain homosexual and heterosexual acts. The current public health threat of Acquired Immune Deficiency Syndrome (AIDS) is exacerbated by laws that expose a person at risk for AIDS to misdemeanor or felony charges if he or she seeks diagnosis. In communities where sexual practices are not regulated by law, a much more rapid response to the problem at the community health level has been possible. In communities where oral sex, sodomy, and homosexual contacts generally are illegal, efforts at the community health level to contain and prevent spread of the disease are highly ineffectual. And, we are a society in which the interconnections of those at risk, because of lifestyle, for contracting AIDS and those whose lifestyles are "straight" are not so separate that we can regard the health of the public adequately protected by simply letting the disease run its course in the "immoral" elements of the population. Moral tolerance creates climates in which public health problems can be addressed as such by a community that seeks to limit them in a morally nonjudgmental way.

Thus, the public health perspective is consistent with Mill's general position on liberty. However, it provides a necessary and overdue recognition of the significance of the individual's membership in a community with common, shared interests that go beyond individual protection from the acts of others carrying significant risk of harm. In a society embodying forms of group health insurance, welfare, medicine and medicaid, common water supplies, etc., individuals have interests affected by the collective acts of others and the risks posed by those collective behaviors no less than by those acts of others who directly and personally posed risks.

Conclusion

As we enter the period of the bicentennial of our Constitution, that remarkably resilient document which constitutes us collectively as a people, a community, a society, let our thoughts turn with a fresh view to the insights of the Founding Fathers. It is my hope that the federalist papers will become best sellers once again! For there the vision of the commonwealth, the republic, is laid forth in much greater detail than we can hope to comprehend in the few hours of this conference.

Medical Ethics will swing in its next 25 years to address the broader social issues and processes that give rise to our life style-related rates of death. Not only will we find that preventive medicine, under the pressure of spiraling medical care costs, becomes increasingly in vogue, the preventive approach to public health will increasingly form the focus of medical ethics and congressional action. With the shift since the earliest twentieth century from the likelihood of death being caused by typhus, cholera, pneumonia, tuberculosis, or the many diseases of infants to the current fact that as much as half of all serious

disease and early deaths stem from things we do to ourselves — things like smoking, drinking, ignoring exercise or the seat belts n our cars, eating fatty foods — contributions of our life styles, there must come a shift from preoccupation with the relationship between physician and patient and its grounding in the libertarianism of Mill, to address the broader issues of public health, safety, and the prevention of the ills that are produced by unregulated life style.

It is ironic that we are returning to a view of the individual articulated by another Englishman more than 200 years before Mill wrote "on Liberty." I should like to close with the lines penned by John Donne in 1623 in his "17th Devotions":

> No man is an island, entire of itself;
> Every man is a piece of the continent, a part of the main;
> . . . [A]ny man's death diminishes me, because I am involved in mankind;
> And therefore never send to know for whom the bell tolls;
> It tolls for thee.