

## Observations on Ethical Problems and Terminal Care

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Received September 6, 1991

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Progress in medical diagnosis and therapy has raised new problems with far-reaching ethical implications. Medicine must remain a profession and not become a business. Textbooks must address ethical problems in the context of health care decisions and not restrict themselves to pathophysiology and practical therapeutics alone. The relative roles of the principles of autonomy, non-maleficence, beneficence, and justice must be balanced and appropriately applied to individual situations in biomedical ethics.

When therapy becomes futile and the suffering of the patient does not justify any anticipated benefit, the patient (and/or patient surrogate) may request withholding or even withdrawing life-prolonging interventions. In the persistent vegetative state, even nutritional support by an unnatural (tube) route may ethically be denied at the patient's (or surrogate's) informed decision.

New areas of ethical evaluation have been raised by the desire of some individuals to prolongation of their lives at high expense to the society such that other individuals are denied services because of limitation of available resources. There has been a long-standing conflict of interest between the acceptance by physicians and/or medical institutions of money or gifts from pharmaceutical companies whose drugs they prescribe, stock, or sell. This practice increases the cost of the drugs and is, in effect, a "sick tax," which is morally wrong.

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We are living in the midst of a great technological and biological revolution. It is almost impossible to keep up with the new knowledge, even in the narrowest of specialties. Yet in our litigious American society, we are in great legal peril if we do not fulfill the concept of the complete compassionate physician, who keeps all his patients alive indefinitely in perfect health. However difficult somatic medical decisions may be, moral choices are often more worrisome.

In this context, I was not surprised (although I was dismayed) to hear a colleague comment, "Don't bother me with what's ethical; I just want to know what's legal. Medicine is a business. Running a hospital is a business. We need attorneys to tell us what is legal, not 'starry-eyed' ethicists trying to tell us what is moral."

It seems that my colleague is drowning in an ocean of new facts and new devices and has lost his moral compass. He has forgotten why most of us became doctors—to make sick people well and to relieve pain and suffering. We entered medicine as a profession to help others. It is not a business, never was a business, and will be destroyed if it becomes a business. Ethics is right behavior and is central to how we go about our task as health care professionals [1].

If we judge by attendance at meetings and symposia on ethics or by publications in

*Abbreviations:* AMA: American Medical Association APACHE: acute physiology assessment and chronic health evaluation CPR: cardiopulmonary resuscitation DNR: do-not-resuscitate (order) FDA: Food and Drug Administration ICU: intensive care unit NCI: National Cancer Institute PVS: persistent vegetative state

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professional journals [2,3], nurses seem much more interested in discussing ethics than most physicians. In multidisciplinary team conferences, physicians seem to fixate on details of diagnosis, pathophysiology, and therapeutics, while nurses seem more concerned about the moral issues. Perhaps they have not forgotten the sage advice of Dr. Francis Weld Peabody [4]: “The secret of the care of the patient is in caring for the patient.”

### ETHICS DISCUSSIONS IN MEDICAL ONCOLOGY TEXTBOOKS

The flood of new knowledge in medical oncology in the past 20 years resulted in the development of this area as a medical subspecialty under the American Board of Internal Medicine and the publication of many textbooks in the field. In October 1985, Weiss and Vanderpool [5] contributed a “Point of View” article to the *Journal of Clinical Oncology*, entitled “Ethics in Oncology Textbooks.” They reviewed 16 textbooks in the field of oncology, published since 1979, and found that the only book with a chapter that included “ethics” in its title was *Cancer Therapy* by Fischer and Marsh [6]. Some of the others did mention aspects of ethical questions in the text that were referenced in the indices, but only one other textbook even listed a subheading of “ethics” in its table of contents.

Possibly as a consequence of the Weiss-Vanderpool critique, there is now a chapter on ethics in the revised editions of three cancer textbooks that did not include such a chapter in earlier editions, namely the second edition of Skeel [7], the third edition of Fischer and Knopf [8], and the second edition of Calabresi and Schein [9].

### PRINCIPLES OF BIOMEDICAL ETHICS

Although our western concepts of biomedical ethics derive from the Hebrew Bible, the New Testament, and from the Greek philosophers like Aristotle [10] and the Greek physicians like Hippocrates [11,12], modern medical ethics probably begins with the English physician, Percival [13]. The field has been extensively commented on by theologians and secular religious writers of many denominations—Catholic [14–17], Protestant [18–20], Jewish [21–24]—and by ethicists [25–31], economists [32–35], and attorneys [36,37].

A general consensus has evolved that there are some fundamental principles, perhaps three or four, that should help in making ethical decisions [30] in medicine.

1. *Beneficence* means that one ought to prevent and remove harm and evil and promote good; i.e., preserve life, relieve pain, restore health, and relieve suffering.

2. *Non-maleficence* is best characterized by the traditional injunction to “first do no harm.” This principle is not absolute, as we may harm a patient by amputating a leg to save a life and thereby avoid a greater harm. On the other hand, if we resuscitate a comatose patient in pain with a terminal illness for which there is no therapy and only a poor quality of life, then we may be violating the principle of non-maleficence. Generally, we do fairly well adhering to these principles.

3. *Justice* is the fair allocation of medical resources. Some people get more and some get less, and the problem is how to decide on rationing and the distribution of services when there is not enough for everyone [29,31–35]. This problem appears almost daily in the intensive care unit [38–41]. We struggle with guidelines and ad hoc solutions. As medications and hospitalizations become more expensive, we

ration by inconvenience to the patient [42], by hassling the physician [43], and by denying insurance coverage for what should be covered [44].

Clearly, the principle of justice in American health care is observed more in the breach than in the observance. Those who can afford it, with cash or insurance, can usually get good care, and the poor and the uninsured often do not [45] (although some teaching services provide the poor with excellent care). Prenatal care and care of newborns, the most vulnerable group, and the group in which any expenditure would yield the highest dividends, is frequently underfunded. Instead, we spend the bulk of our national health care dollars on people in the last years of their lives and on expensive technology like transplants [46]: heart transplants, liver transplants, bone marrow transplants, and the like, many of unproven or very limited value. While some advocate more spending for better technology in the belief that it will ultimately be cost-effective and improve the quality of life [47], others advocate the rationing of medical care [48] so that the limited resources can be distributed more justly and equitably. The suggestion has been made that we ration medical progress and the development of new technology [49] or else so much of our gross national product will be diverted to health care that we will have to reduce our other expenditures for desirable services such as education, art, and leisure activities, since in our egalitarian society, we are philosophically committed to making even the most expensive medications and procedures available to the poorest and least productive of our citizens [50] or even to non-citizen residents. At present, just the administrative costs of this effort [50] utilize between 20 percent and 26 percent of the total spending. To an increasing extent, the government is attempting to make the physician its instrument of rationing [51], whereas traditionally the physician's master has been the patient. Can the physician ethically serve two masters? Probably not, but the reality is that we are being forced to try.

4. *Autonomy* may be defined as respect for the individuality and "personhood" of the patient [52]. The physician must collaborate with the patient on all substantive decisions and, in case of a disagreement, the patient is the final authority, or, if incompetent, a properly chosen surrogate or family member serves to make the patient's decision, based upon the informed choices provided by the medical team. It sounds simple in theory but has been complex in its application and has resulted in much litigation, sometimes at the beginning of life [53] but more frequently at life's termination.

#### END-OF-LIFE DECISIONS

In chapter 3 of the biblical book of Ecclesiastes, we are told, "To everything there is a season, and a time to every purpose under the heaven; A time to be born, and a time to die." We all know that animals and people do not live forever, and that, sooner or later, all must die. What troubles most people is the personal experience of the death of a significant person in our lives, a family member, a friend, or a patient. Physicians were so reluctant to tell patients that they had cancer (and hence might die), that in the fifties [54] and sixties [55], they frequently, if not usually, lied to them. By the late seventies [56], that attitude had reversed itself, and most physicians told patients the awful truth, either because they thought it was the ethical thing to do or to protect themselves from malpractice litigation for "failure to inform."

In 1976, the Massachusetts General Hospital published its house recommendations for the care of the terminally ill [57] and, in the same issue of the *New England*

*Journal of Medicine*, the Beth Israel Hospital of Boston revealed its policy on do-not-resuscitate orders [58]. These were attempts to codify and legitimate practices that were becoming increasingly common. There has been some discussion of how much of the impetus for this was based on compassion for patients and families who might suffer unnecessarily from prolonging the act of dying, and how much of it was prompted by the hospitals' legal staffs to protect against litigation. Indeed, the editorial accompanying those two landmark articles was written by a professor (an attorney) at the Harvard Law School. He comments [59]:

The hospitals are coming out of the closet! It is an event of the first importance that responsible administrators at two great hospitals—independently, I believe—should promulgate and discuss publicly explicit policies about the deliberate withdrawal or non-application of life-prolonging measures. That such measures are in fact regularly withheld or withdrawn is an open secret, but the course of decision and the testimony in the Quinlan case show how wary the medical profession can be when the spotlight of publicity illuminates its practices.

To safeguard the patient's autonomy and to remove any ambiguity in the operation of the guidelines, a third article [60] in the same issue urges patients to prepare a living will so that their wishes will be known and executed. The purpose of the policies is to ensure that physicians do not keep terminally ill patients alive against their will. The decisions should be made by the physician and the patient together. In the editorial, a prescient comment has proven to be all too true [59]:

The last word, I fear, may be with the lawyers for the meaning and validity of these new departures are very likely to be tested in court. The fact of the matter is that lawyers have not been a constructive force in the shaping of the relation of the public to the health professions. We lawyers have supposedly been assiduous only to obtain redress for the negligence of an overbearing and excessively self-protective profession, but the result of this ferocious assiduity has been an atmosphere of distrust and excessive caution, which surely prejudices the public, and which the patient cannot even contract out of with any assurance. I suspect that the only people who have really done well out of the malpractice imbroglio have been lawyers.

As physicians and the public became more comfortable with open discussion of death and dying and end-of-life decisions [61], formal policies evolved and were published for do-not-resuscitate decisions. One of the earliest was that of Yale–New Haven Hospital, which was developed under the chairmanship of R.J. Levine and was reprinted in the Wong and Swazey symposium report [62] and also in Fischer and Marsh [6]. It delineated the identification of the responsible physician and the necessity of communications among health care professionals. It classified the approaches to management of the terminally ill, emphasized communication with the patient and family, and outlined the mechanics of writing do-not-resuscitate (DNR) orders. With time, many articles have examined the results of cardiopulmonary resuscitation (CPR) [63–66] and noted its low incidence of success. Others have questioned its routine use [67–70] and deplored its excessive employment. The evolving court cases and reports of clinical experience have refined the indications

and procedures [71–77]. The Yale–New Haven Hospital guidelines were revised in 1991 [78] to accommodate to the changing consensus.

In 1988, New York State passed a law [79] requiring physicians in hospitals or extended care facilities to discuss in advance with patients and/or their surrogates the patient's wishes in regard to CPR and DNR orders. In the absence of a written DNR order, which must be rewritten every three days, the law required resuscitation, even in the terminally ill metastatic cancer patient whose physicians view the CPR as futile at least, and possibly cruel [80,81]. The law also required all home-bound patients to be resuscitated regardless of their wishes by emergency paramedical teams. That aspect of the law was recently amended to allow home-bound patients to consent to a DNR order by filling out a standard form and wearing a special DNR identification bracelet [82].

### WITHHOLDING AND WITHDRAWING LIFE SUPPORT

The principles of biomedical ethics have been applied to try to justify medical interventions or the withholding or cessation of support with the expectation that the patient will die as a result [83]. The problem arises in the chronically critically ill patient in an intensive care unit (ICU) for weeks or months, with no chance to regain a tolerable quality of life. The APACHE (acute physiology assessment and chronic health evaluation) II classification system for acutely ill patients [84] showed that patients in the ICU with a single organ failure for one to seven days had a mortality of 20 percent to 40 percent; for two organ system failures, it was 50 percent to 70 percent, and for three or more organ system failures, mortality rose to 80 percent to 100 percent. Advanced age increased the likelihood of an organ system failure and death. The association of respiratory failure with sepsis, renal failure, liver failure, severe burns, or advanced hematological malignancy resulted in a mortality rate of 95 percent to 100 percent in the hospital. As hope of recovery fades, it becomes degrading to the patient to be sustained in a subhuman situation and, at some point, with the consent of the patient (or surrogate, if the patient is incompetent), it may be the obligation of the physician to help the patient passively to achieve a peaceful and dignified death.

To safeguard the patient's autonomy, guidelines have been established for the decision-making process. In its most recent update in 1991, the Council on Ethical and Judicial Affairs, of the American Medical Association (AMA) [85], stated:

It is widely acknowledged that patients have the right to refuse medical treatment, even when such refusal is likely to result in serious injury or death. A patient, therefore, may express in advance his or her preference that CPR be withheld in the event of cardiac arrest. Such refusal may serve as the basis for a do-not-resuscitate (DNR) order. A decision to withhold CPR from an incompetent patient can be made by a surrogate decision maker, based on the previously expressed preferences of the patient or, if such preferences are unknown, in accordance with the patient's best interests.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research [76] noted that a "competent and informed patient or an incompetent patient's surrogate is entitled to decide with the attending physician that an order against resuscitation should be written in the chart." Religious leaders in general have agreed. Pope Pius XII [86] stated that the rights

and duties of the physician are to correlate with those of the patient and that the rights of the family are subordinate to the patient's wishes and desires. Hence, health care professions were charged to use "ordinary means" of life support predicated on the circumstances of person, place, time, and culture in the care of serious illness, and such efforts were not seen as direct disposal of life and, therefore, not active euthanasia. A do-not-resuscitate order is an ethical and rational decision when warranted by the facts [68]. Unfortunately, sometimes it does not fulfill its major goals [87].

In the guidelines of the AMA Council on Ethical and Judicial Affairs [85], it is further stated that:

The second exception to the presumption favoring CPR is applicable to cases in which an attempt to resuscitate the patient would be futile in the judgment of the treating physician. A physician is not ethically obligated to make a specific diagnostic or therapeutic procedure available to a patient, even on specific request, if the use of such a procedure would be futile [67,88,89]. However, judgments of futility are subject to a wide variety of interpretations. The potential impact of this variability is profound, given recent evidence that perhaps, as many as 88 percent of all DNR orders are based in part on the physician's judgment that resuscitation of the patient would be futile [90,91,92].

Despite relatively similar prognosis, patients with AIDS or lung cancer are much more likely to receive DNR orders than patients with cirrhosis or severe congestive heart failure [93], presumably because physicians regard AIDS and lung cancer as less responsive to therapy than liver disease and CHF.

Frequently, physicians are reluctant to discuss DNR orders with patients [94,95], although many patients welcome an honest discussion. The new federal Patient Self-Determination Act (The Act) which took effect December 1, 1991, requires Medicare/Medicaid-receiving health care providers to inform patients of their existing rights under state law to refuse treatment and to prepare advance directives [96]. This legislation simply affirms rights in most (but not all) states already recognized under the common law, namely the right of every individual to the possession and control of his or her person and to the doctrine of informed consent and a privacy right. In the Cruzan case [97], the United States Supreme Court recognized that "a competent person has a liberty interest under the Due Process Clause in refusing unwanted medical treatment." Thus, patients in all states now have the right to refuse unwanted medical therapy. The full implications of The Act are not yet clear, but an evolving literature is attempting to evaluate it [98,99,100]. Patients are still well advised to have a living will or a health care proxy or both [101]. Of course, the patient's physicians must be informed of the living will and the health care proxy. The stringency of the policies in some hospitals require physicians to perform procedures that are useless or that add to the patient's suffering without corresponding benefit because a do-not-resuscitate order has not been approved by a family or surrogate. It has been suggested [102] that physicians should be allowed to write a do-not-resuscitate order over family objections when all four of the following conditions prevail: (1) the patient lacks decision-making capability; (2) the burdens of treatment clearly outweigh the benefits; (3) the surrogate does not give an appropriate reason in terms of patient values, preferences, or best interests; and (4) the physician has made serious efforts to communicate with the family and to

mediate the disagreement. Actually, a strong case had previously been made that a physician should not even offer resuscitation when the medical judgment is that resuscitation will be ineffective, further therapy is futile, successful resuscitation would offer no medical benefit, or deterioration is so far gone that resuscitation would only briefly postpone the act of dying and thus prolong the patient's final agony [67,68]. It has been suggested that too often physicians shirk their responsibility to make this decision because of a fear of liability in our litigation-conscious society and pass the decision on to the courts, at great economic cost to society and prolongation of patient suffering [103]. Nowhere is this problem seen more frequently than in the patient in a persistent vegetative state.

### THE PERSISTENT VEGETATIVE STATE

The term "persistent vegetative state" (PVS) is used to designate permanently unconscious patients who manifest irregular episodes of wakefulness and sleep with responses to verbal stimuli and light in a meaningless fashion. They often have facial signs of interest with suggestions of smiling or sucking or tearing of the eyes and groping of the hands. If given nutrition and other support functions, they can live for months, years, or decades [104]. Since heartbeat and respiration are spontaneous, they do not meet classical criteria of death; since they do not have flat brain waves, they do not meet the Harvard criteria of brain death [105]. These patients were therefore kept alive by extensive support systems for long periods.

The attempt of compassionate families to withdraw useless therapy generally met with little success until the public reaction to the case of Karen Ann Quinlan [106]. In this case, the New Jersey Supreme Court ruled, on the basis of a constitutional right of privacy, that a "substituted judgment" may be used to remove a patient in a persistent vegetative state from advanced life support. In this instance, the respirator was removed, but the patient continued to breathe on her own and lived a few years longer.

The principle of "substituted judgment" was extended in the Barber case [107]. The 55-year-old patient, Clarence Herbert, had severe brain damage after a post-operative myocardial infarction. His family and physicians agreed that he did not wish to be kept alive in this condition, based on his earlier comments, and they agreed to remove his respirator. He did not die then. Hence, in conformity with their understanding of his wishes, all life support was withdrawn, and he died. The Los Angeles district attorney charged the two attending physicians with murder. The California Court of Appeals ruled that further life support would have been medically futile and that the physicians had acted properly, with the consent of the family, and did not require prior judicial approval. The court did not distinguish between basic and advanced life support and chose to view the former as "more similar to other medical procedures than to typical human ways of providing nutrition and hydration" and recommended the "benefits and burdens" of basic life support "be evaluated in the same manner as any other medical procedure."

In a Connecticut case [108], the removal of a nasogastric tube was the crux of the litigation. Carol McConnell was an emergency room nurse who suffered traumatic brain injuries in an automobile accident and was being kept alive in PVS by a feeding gastrostomy tube which her family eventually sued to have removed. The State contended that every patient was entitled to food and fluids and that the State's interest in preserving the "life" of the patient took precedence over the family's

request to withdraw support, even though the patient had expressed a wish not to be sustained in a comatose state.

The court held that the family was the appropriate surrogate to act for a patient who was not competent and had not executed a living will or established a durable power of attorney but had expressed a preference of care. It further observed, "there is no legal, ethical, or moral distinction between a respirator and a gastrostomy tube which this court can attach to the facts in this case." The judgment was affirmed on appeal to the Connecticut Supreme Court. In an address commenting on the case subsequently, the Chief Justice of the Connecticut Supreme Court [109] said:

I think it is unlikely that we will quickly resolve the myriad of concerns that are raised by the conflicting views about the use and abuse of medical technology to preserve the life of those who, although not brain dead, are terminally ill. A just and caring society cannot help but be torn between its desire to honor the privacy of those who have been sorely afflicted, and its fears that the victims of accidents and disease may be further abused by the self-seeking caretakers. The obvious fact that there are no easy answers is why this conference is so important.

In closing, let me repeat what I have said on another occasion about the role of courts in cases like this. Courts are not eager to resolve new agendas on the forefront of the complex interrelation between medicine and the law. We decide the cases because they are here and won't go away, but we are keenly aware that we lack any special expertise in finding tolerable accommodations for these perplexing issues. It is our fervent hope that, working together, we can devise principles and protocols that will, whenever possible, provide guidance for private rather than public resolution of the questions of the appropriate level of health care to which we are all entitled.

In an attempt to clarify the issue for physicians, the AMA Councils on Scientific Affairs and on Ethical and Judicial Affairs issued a joint statement. They [110] reviewed the criteria for the diagnosis of permanent unconsciousness and PVS and the significant legal decisions in this area. They indicated that states have not enacted uniform laws nor have courts rendered uniform judgments, but "the record to date indicates that when physicians and families agree on a particular course, the prospect of adverse legal consequences is greatly diminished."

Not all physicians and ethicists agree that fluid and nutritional support should be withdrawn from PVS patients unless there is clear evidence that the patient indicated such a course [111]. This point was the central issue in the Cruzan case [97]. The State of Missouri asserted its right to continue to feed Nancy Cruzan in a PVS against the wishes of her family. The United States Supreme Court recognized that many states base the right to refuse treatment on the common-law right to informed consent and other states on the constitutional right to privacy, and some states invoke both. The court also recognized a federal liberty interest under the due process clause. It affirmed, however, the right of the State of Missouri to demand "clear and convincing proof of Cruzan's desire to have hydration and nutrition withdrawn," and denied the request of her family to remove the gastrostomy. Later, the Cruzan family returned to the state court with additional witnesses, who provided the necessary evidence, and the tube was removed. Twelve days later, on December 26, 1990, Nancy Cruzan died at age 33.



The case spurred several states to establish or update “health care proxy” legislation and stirred support for the Patient Self-Determination Act of 1990 [98,99] that requires (effective December 1, 1991) hospitals and nursing homes that receive Medicare and/or Medicaid funds to inform patients of their rights under state laws to make living wills or other advance directives. There has also been a flurry of articles suggesting guidelines [85,112,113] and discussions in lay publications [114]. The question of withdrawing intravenous fluids has also been raised, with the implication that it is moral in the near terminally ill [115]. There is, however, still no general consensus, and there are questions about how accurate proxy predictions may be [116] and how accurate the determination of terminal illness or moribund condition may be [117]. The feeling that many questions remain unanswered after the Cruzan decision is pervasive, and some [118] feel that the decision has potentially harmful effects in that it may undermine family decision making, encourage cynicism and disregard for the law, and promote defensive medicine. It also provides the basis for more litigation to define “clear and convincing,” which many feel is neither clear nor convincing in the 5–4 decision, with two separate dissenting opinions, and two separate concurring opinions, a total of five opinions [119].

### RIGHT TO LIVE LONGER

As the principle of patient autonomy begins to take on an aura of “divine law,” physicians are increasingly finding some patients and families making demands that seem medically unreasonable [120], and there need to be limits to the physician’s obligation or else medical ethics may erode traditional medical values [121].

Recently, in Minneapolis, Minnesota, a case went through the court that may be of this ilk. Hennepin County Medical Center went to court to get permission to discontinue a respirator on Helge Wangle, an 87-year-old comatose woman in PVS secondary to a cardiac arrest and severe anoxic encephalopathy for more than a year. All of her physicians felt that use of a respirator was medically inappropriate [122,123] and “non-beneficial.” Nonetheless, her husband and children demanded that the respirator be continued because they believed in miracles and hoped that a miracle would occur on Mrs. Wangle’s behalf. This hope had cost the taxpayers and society more than \$700,000 by the time the hospital filed court papers. The court awarded custody of the patient’s health care to her husband, who was committed to continuing the respirator and supportive care indefinitely. Mercifully, for the patient, the taxpayers, the doctors and nurses of Hennepin County Medical Center, and society in general, the patient died three days after the court decision.

To my surprise, the editorial in the *New England Journal of Medicine* applauded the decision as a vindication of the principle of autonomy [124]. Presumably good clinical judgment, considerations of beneficence, justice, and personal medical moral values must all be sacrificed to the almighty autonomy principle [121]. Money in large amounts must be spent to keep alive indefinitely an 87-year-old in coma, with no brain function. Might those resources be better spent on care of indigent newborns, on prenatal care, on food for the hungry, and shelter for the homeless? Will technology become our master? Just because something can be done does not mean that it should be done. Medical decisions should not be the province of the courts. They should be the job of the clinic and the medical care team, augmented, if necessary, by an ethicist or an ethics consultation team [125–128], although there are

some who question their value with the catchy title, “Godsend or ‘God Squad’?” [129].

Perhaps every hospital needs its own code of ethics [130,131] in addition to the AMA code of medical ethics and the opinions of the Council on Ethical and Judicial Affairs [132,133].

As technology progresses, the ethical problems will increase and require more thought and effort to decide who lives and who dies and to keep medicine a moral profession, instead of allowing it to become just another amoral business.

### SOME POTENTIAL CONFLICTS OF INTEREST

There are many ethical dilemmas that confront physicians treating cancer patients. For many cancers, the results of treatment are so poor that there is no standard therapy. Any therapy selected is then, to a greater or lesser extent, an experiment. Some of these experiments are done on an investigational protocol of a cooperative group under the supervision of the National Cancer Institute (NCI) or by a university cancer clinic with NCI approval, or the clinician may treat off protocol. In any case, there may be pressure by a pharmaceutical company to use its drug in preference to others. When that decision is based on an honest review of the available literature, the patient’s best interests are served. When the decision is influenced by gifts or money to the physician, then one must question the ethical basis for the decision.

Recently, it has come to public attention that pharmaceutical companies have been giving substantial gifts to physicians [134], so-called “payola” to influence their choice of drugs. Medical journals had been pointing out this fact for several years [135]. Doctors have received gifts ranging from pens and pads to all-expense-paid trips to vacation resorts, worth up to \$5,000, to attend promotional lectures for pharmaceutical products. Other physicians have received grossly extravagant honoraria for lectures that promote a proprietary product [136]. These practices indirectly use the patient’s money to reward and influence the physician to prescribe drugs that may or may not be in the patient’s best interest.

Most physicians deny that they could be so influenced. Rawlins [137], however, observed that

few doctors accept that they themselves have been corrupted. Most doctors believe that they are quite untouched by the seductive ways of the industry’s marketing men; that they are uninfluenced by the promotional propaganda they receive; that they can enjoy a company’s “generosity” in the form of gifts and hospitality without prescribing its products. The degree to which the profession, mainly composed of honourable and decent people, can practice such self-deceit is quite extraordinary. No drug company gives away its stockholders’ money in an act of disinterested generosity.

In addition, it has been noted that cash finders’ fees are being paid for research subjects [138]. This conduct is not far removed from fee-splitting, which organized medicine rejected as unethical many years ago. On a more subtle level, industry reimbursement to investigators and research institutes and universities, far in excess of the costs of the research, raises additional ethical issues [139]. So does the easy passage from the university to the pharmaceutical company, or the offering of academic titles and promotion in the university for referral of research subjects. This

aspect is an especially sensitive area because even the National Cancer Institute was funding some research studies based on "body counts." When investigators, sections, and departments in a medical school profit from increased numbers of research subjects [140], one should not be surprised to see them give a further incentive to such referrals by a reward in their "coin of the realm," academic titles and promotions. This behavior is not as blatant as the cash rewards of industry, is harder to track and prove, and can usually be rationalized. With the enormous profits of pharmaceutical companies comes great economic, political, and educational power. They can hire or give gifts to professors, deans, congressmen, newspaper and journal editors, and reporters.

Tentative answers to some of these problems have come from various representatives of organized medicine. In Britain, the General Medical Council added to its standards of practice the admonition [141] that acceptance of money or gifts from firms which sell items that doctors may prescribe should be regarded as improper.

A similar position was taken by the American Surgical Association at its annual meeting in April 1987. In 1990, the Board of Regents of the American College of Physicians endorsed and published a position paper by its Ethics Committee, which was also endorsed by the American Thoracic Society, The American Society of Hematology, and the American Diabetes Association. It stated, as position number 1 [142]:

Gifts, hospitality, or subsidies offered to physicians by the pharmaceutical industry ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgement. A useful criterion in determining acceptable activities and relationships is: Would you be willing to have these arrangements generally known?

The question of conflicts of interest in medical center/industry research relationships was dealt with in a joint report by the AMA Council on Scientific Affairs and the Council on Ethical and Judicial Affairs in May 1990, which recommended [143] that there be careful review and specific guidelines for the clinical staff on conflict of interest, and full disclosures by clinical staff about financial associations with commercial corporations.

As an aside, one may wonder what are the tax implications for a tax-exempt institution performing contract work, for a profit, for a commercial enterprise. It would seem that the local taxpayers carry an extra burden in that instance. Many institutions accept the money, but very few consider the ethical implications of the arrangement. The money is too good to pass up. To the best of my knowledge, this question has not been explored in any depth. In my opinion, it is worthy of high-level study and discussion.

In December 1990, after a year of deliberations, the Council on Ethical and Judicial Affairs of the AMA issued its opinion on gifts to physicians [144]. They suggested that any gifts accepted by physicians should primarily entail a benefit to patients and be of educational value, like textbooks, pens, and notepads. Support for educational conferences should be given to the conference sponsor possibly to reduce tuition costs, but no cash or indirect support should be given to physicians attending the conference to defray travel, lodging, or other personal expenses. Faculty at meetings may accept reasonable honoraria and reimbursement of expenses. Content of the conference should be determined by the organizers and not

by the industrial companies contributing to its support. I think the Council missed the point. All gifts create a reciprocal obligation and hence a conflict of interest. Furthermore, who elected the drug industry to “tax the sick” to support education? Legislatures are elected to make those decisions.

The new Food and Drug Administration (FDA) commissioner shared his concerns on this subject in July 1991 in the *New England Journal of Medicine*. He indicated [145] that “some of these industry-sponsored activities can provide health care professionals with excellent opportunities for education and scientific exchange. They can also be used for the illegal promotion of the sponsor’s products. It is important for the FDA and health care professionals to join forces in protecting free scientific exchange from commercial abuses.”

It has been estimated that drug company promotional spending totals \$2.5 billion a year, about \$200 million of which goes to continuing medical education [146]. The pharmaceutical industry, through the Pharmaceutical Manufacturer’s Association, has accepted the guidelines of the AMA Council on Ethical and Judicial Affairs [147]. If they implement the guidelines, there is a potential for saving more than \$200 million. With less advertising, they might save \$2 billion a year. It will be interesting to see whether any of this saving will be used to reduce drug costs to patients, or whether it will be used to enhance already generous salaries to company executives or to raise dividends to stockholders. This outcome will be a real test of commitment, generosity, or greed. At present, the pharmaceutical companies are regarded as just a business like any other. Their power over life and death for so many people should, however, put them in the category of enterprises (actually monopolies) concerned with the public interest, like the telephone company, the water company, the electric company, and other public utilities regulated by public service authorities.

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