COMPLEXITIES IN BIOMEDICAL DECISION-MAKING

George P. Smith, II

Within the contemporary debate over medical ethics, without question the most striking weakness found is the lack of a basic yardstick against which either the "rightness" or "wrongness" of a physician's actions may be measured. No general agreement is to be found among physicians or ethicists acknowledging what ethical determinant the physician should or should not follow in a particular case. Yet, despite this conflict of uncertainties, a framework for principled decisionmaking does exist and can be found within the rubric of medical ethics.

Medical ethics is the oldest component of bioethics, tracing its formulations to Hippocrates and the ethical norms of conduct he articulated for physicians in treating patients. Insofar as medical ethics relates to specialized facts and concerns, and not because it embodies or

* George P. Smith, II, is a Professor of Law at The Catholic University of America in Washington, D.C. He began his teaching career in 1964 at Indiana University in Bloomington, where he received his B.S. and J.D. He completed his postgraduate studies at Columbia University where he earned an L.L.M. degree and the Yale Law School where he was a Senior Fellow in The Commonwealth Program in Law, Science and Medicine. In 1984, Professor Smith received an Australian-American Fulbright Foundation Award and appointment as a Fulbright Visiting Professor of Law and Medical Jurisprudence at The Faculty of Law, University of New South Wales, Sydney, Australia. His numerous research appointments include The Max Planck Institute, Heidelberg, Germany; The Hoover Institute, Stanford University; The Rockefeller Foundation Bellagio Study, Italy; The Kennedy Institute of Ethics, Georgetown University; The Center for Clinical Medical Ethics at The Pritzker School of Medicine, University of Chicago; University of Otago Faculty of Law and University Bioethics Research Center, Dunedin, New Zealand; The Center for The Study of Society and Medicine, Columbia University College of Physicians and Surgeons, New York; and King's College Center for Medical Law and Ethics, University of London, England. Professor Smith also served as a consultant to UNESCO's International Bioethics Committee in Paris, France from 1995–97, assisting in drafting The Declaration on The Protection of The Human Genome. This essay is derived in part from the author's book, Bioethics and the Law (1993).


appeals to special moral principles or methodology, it may be said to embody unique standing as a speciality. "It consists of the same moral principles and rules that we would appeal to, and argue for, in ordinary circumstances. It is just that in medical ethics these familiar moral rules are being applied to situations peculiar to the medical world." 374

A central focus of medical ethics is directed toward an effort to not only decide, but to make explicit what those duties are or should be for all physicians. The particulars will, of course, fluctuate according to different social structures, differing views of medicine, health, and cure, as well as different capabilities. 375 In a word, medical ethics is situational. One view postulates that medical ethics is essentially ordinary ethics--but applied to medicine. 376 Another view recognizes two elements: dilemma ethics and virtue ethics. Dilemma ethics concerns itself with the moral rightness or wrongness of human actions. Virtue ethics refers to the essential moral formation of the medical practitioner. 377 One must be cautious not to collapse ethics solely into dilemma ethics, for when this occurs, a strange phenomenon exists: a split between the role of ethics and the person normally seen. 378

ASPIRATIONAL GOALS

While it has been suggested that the physician's only business is focusing on the health of his patient, 379 a more balanced contemporary view, grounded in philosophy and ethics, recognizes the healing relationship as the architectonic or ordering a principle that shapes and defines clinical medicine. 380 Indeed, under this view, the phenomenon of medicine is recognized as a relationship of persons. 381

In structuring any ethics of medicine, the first moral requirement is competence. What might be properly viewed as the moral center of medicine occurs when, having considered all the medical actions that can be done, the physician concludes and proceeds to recommend what ought

375 Clouser, *supra* note 3, at 56.
376 See *id.* at 57.
378 See *id.*
380 Edmund D. Pellegrino, Address at the University of Texas Health Center Grant Taylor Lecture (1982) (citations available in Kennedy Institute of Ethics Library).
381 See *id.*
to be undertaken; or, in other words, what is in the best interest of the patient.\textsuperscript{382}

Contemporary medical ethics also imposes an obligation upon the physician to assist his patient in coping with or adjusting to disease that is either incurable or progressively debilitating.\textsuperscript{383} Although he need not do this directly, the physician has the major responsibility to supervise or to employ family, friends or spiritual advisers to this end.\textsuperscript{384} Thus, utilizing the healing relationship as medicine's organizing principle means that moral obligations that go well beyond the simple application of biology to clinical problems are imposed upon the physician.\textsuperscript{385}

**NORMATIVE AND METAETHICS**

There are two main divisions of ethics: normative and metaethics. Normative ethics focuses upon determining what actions are good or bad, right or wrong and with related evaluations, such as praiseworthiness and blameworthiness. Metaethics analyzes the meaning of ethical terms and also, at another level, structures and assesses criteria for evaluating competing normative ethical theories.\textsuperscript{386} Normative ethical theories are classed as either teleological (consequentialist), or deontological (formalist).\textsuperscript{387} The teleologist asserts that there is but one, ultimate right-making characteristic: namely, "the comparative value (nonmoral) or what is, probably will be, or is intended to be brought into being."\textsuperscript{388} The centermost deontological principle emphasizes maximizing the balance of good over evil achieved without any one, ultimate moral criterion.\textsuperscript{389} Thus, each person and each situation are viewed as unique.

The goal of reaching rational judgments, or those conclusions based on general applicable principles or universalized maxims, would, at first blush, appear to play havoc with those espousing moral judgments for each situation or action.\textsuperscript{390} Yet, when one utilizes the immutable first-order given as the maintenance of *purposeful* living -- both in the early potential for life (preconceptionally and prenatally) and its subsequent

\textsuperscript{382} See id.
\textsuperscript{383} See id.
\textsuperscript{384} See id.; see also ERNLE W.D. YOUNG, ALPHA AND OMEGA: ETHICS AT THE FRONTIERS OF LIFE AND DEATH 16–17 (1989).
\textsuperscript{386} MICHAEL SHAPIRO & ROY G. SPECE, BIOETHICS AND LAW 73 (1981).
\textsuperscript{387} See id. at 80; see also James F. Childress, The Normative Principles of Medical Ethics, in MEDICAL ETHICS (Robert M. Veatch ed., 1997).
\textsuperscript{388} See SHAPIRO & SPECE, supra note 15, at 81.
\textsuperscript{389} See id.
\textsuperscript{390} See id. at 85.
continuation and use as a human or fundamental right, there is no uncertainty of focus at all for the deontologist or situationalist. When the goal of life is viewed as a quest for total maximization—economic, social, spiritual, cultural, intellectual or political, this norm is the clear direction or reference point advanced by the situation ethic. Any action that challenges this goal, then, is balanced out. In other words, the costs of changing the course of a present action are balanced against the benefits of inaction. This balancing mechanism affords a far better opportunity to achieve the goal of distributive justice than unyielding application of a theological a priori standard.

**THE METAETHICAL QUAGMIRE**

Metaethics examines specifically how normative standards should be structured and what the standards should be for applying genetic rules of research and development to future generations. A uniform core of standards is needed. Individual judgments of scientists, which have proven faulty and inadequate, should be replaced by an ethic that assures collective social responsibility. An a priori ethic, which rests on the faith that certain acts are inherently immoral, does not meet this requirement. A pragmatic ethic, which requires that one make choices that offer a maximum of desirable consequences, does seem to fulfill the goal of collective responsibility. If the results of biomedical research will contribute to human well-being, a practical ethic would sanction the research.

Two types of pragmatic ethics exist within the general metaethical category: rule utilitarianism and case utilitarianism. Rule utilitarians stress the need for weighing the good that an entire class or category of experiments, such as reproduction in the laboratory, would produce. If they conclude that the research would not provide sufficient benefits, they would disapprove the entire class or category of experiments. Case utilitarians, on the other hand, would weigh the good that each individual

---

392 See Callahan, supra note 20, at 6.
397 See Fletcher, supra note 23, at 82; see also SIDNEY ZINK, THE CONCEPTS OF ETHICS 93–94 (1962).
398 See Fletcher, supra note 23, at 82.
Either type of practical ethic is consistent with the need to seek a consensus ethic to guide biomedical research that is not aligned with humanism, metarationalism, or assumptions of faith, but is tied solely to a communion of shared values derived from observable experiences. No condemnation of laboratory reproduction would be made pursuant to a consensus ethic unless either the means or the ends of the research were incompatible with human needs or unless a common consent, achieved through verifiable reasoning, required ending the experiment. One scholar has suggested that, in the final analysis, reason together with imagination can produce a "reasonable guess" and that is about all that can ever be done.

The creation of life and the remaking of man frame the ultimate ethical issues resulting from increased genetic knowledge. Genetic modifications are intermediate expressions of this ultimate capacity; cloning exemplifies the final consequences. To illustrate the issues that an ethical system must resolve in dealing with biomedical technologies, consider the consequences of surrogate motherhood. If sperm donors have no claim over children born of their sperm through artificial insemination, an ovum donor should have no superior rights over the real mother. When a physician seeks to implant an ovum into another woman, he should obtain permission from the donor for the transfer or implant. But, what if the donor woman has strong religious or other objections to in vitro fertilization that would have led her to refuse permission if she were told that her ova were to be used for that purpose? Even if the doctor has obtained permission to use a donor's ova for in vitro fertilization, what happens if, after fertilization, an embryo begins to develop abnormally? Who should make the decision to discard or to keep a defective embryo: the donor woman, the desiring couple, the geneticists, the obstetrician, or all of these individuals together?

These dilemmas may be upon us rather quickly.

---

399 See id. at 82–83.
400 See id. at 88–89.
401 See id. at 89.
402 See id.; see also James M. Gustafson, Basic Ethical Issues in the Bio-Medical Fields, 53 SOUNDINGS 151, 177 (1970).
406 See id. at 37–38.
407 See id. at 34–35.
The prospect of producing "optimum babies" introduces another issue that bioethics must resolve. Many people may raise objections to the regulation of life beginning in the laboratory, rather than in the home. This issue forces consideration of the interests of a new participant: the scientist. For some, this depersonalization of the procreative process is most undesirable;\textsuperscript{409} human procreation for them "is more complete human activity precisely because it engages us bodily and spiritually as well as rationally."\textsuperscript{410}

II. THE DECISIONMAKING PROCESS

VARIATIONS ON A CENTRAL THEME

There are three approaches to bioethical decisionmaking, with the first being termed, casuistical.\textsuperscript{411} Under this form, particular cases are identified which "represent unquestionably immoral acts."\textsuperscript{412} They are then distinguished "from morally permissible and obligatory acts,"\textsuperscript{413} with the overall goal being to settle "cases of conscience" arising under circumstances where rules are either unclear or in conflict.\textsuperscript{414} As a genre of moral inquiry, then, casuistry\textsuperscript{415} utilizes paradigms and presumptions as devices to solve real-life moral problems.\textsuperscript{416}

The second approach to bioethical decisionmaking relies upon agreement and adoption of a unified theory with derivative rules described otherwise as a universal or basic public morality to which all rational persons would espouse.\textsuperscript{417} The major tension within this approach is the inherent struggle for seeking both consensus and compromise.\textsuperscript{418}

Finally, with principalism, the third and strongest approach, metaphors and analogies are used to either describe or direct actions and relationships built upon three or four basic principles: autonomy, beneficence and/or

\textsuperscript{409} See Kass, \textit{supra} note 34, at 53–54.
\textsuperscript{410} See id. at 53.
\textsuperscript{411} JAMES F. CHILDRESS, \textit{PRACTICAL REASONING IN BIOETHICS} 27 (1997) (examining the approaches by their application to the debate regarding fetal tissue in transplantation research).
\textsuperscript{412} See id.
\textsuperscript{413} See id.
\textsuperscript{415} "Casuistry is defined as '[t]he application of general ethical principles to particular cases of conscience or conduct.'" RANDOM HOUSE UNABRIDGED DICTIONARY (2d ed. 1983).
\textsuperscript{416} See MILLER, \textit{supra} note 43, at 5.
\textsuperscript{417} CHILDRESS, \textit{supra} note 40, at 29.
\textsuperscript{418} See id.
maleficence, and justice. The goal of these principles, when applied, is to provide a structure for the application of moral theory for the identification and analysis of moral problems in medicine, as well as their resolution of them.

It is often argued that principles are frequently advanced as a total replacement for both moral theories and rules arising within the practice of medicine. In reality, however, moral principles actually conduce to ten moral rules for successful or ethical living: do not kill; cause pain; disable; deprive another of his freedom and his pleasure; deceive; cheat; disobey the law; fail to keep promises; or fail to live up to a standard of duty. Principles are, indeed, drawn from not only laws, but policies and practices as well. They in turn become binding through the application of rules. When a conflict arises, principles and rules are balanced and applied, as observed, in judgments.

III. AUTONOMY, BENEFICENCE, AND JUSTICE

There is continuing debate over the dependence or independence of the three principles of autonomy, beneficence and justice and the role they play in bioethical decisions. Rather than perceive conflict and disharmony, however, what should be recognized here is the complementary focus and blending of all three principles in the ultimate goal of minimizing human suffering and maximizing the social good. Thus, autonomy, beneficence, and justice are all balanced against one another in an effort to maximize the social utility and personal good of an individual in controversy. Their relationship is inextricable. The state exists to better life for its citizens and, indeed, each citizen seeks to better himself by the conferral of positive benefits that, in turn, promote his personal good. Autonomous, reasonable people thus act accordingly in undertaking those courses of action designed to advance well-being. Thus, justice becomes an aspirational codification of the common good.

AUTONOMY

Autonomy, or self-determination, finds its essence and current expression in the rich and evolving tradition of human rights which, in turn, has had such a significant impact on Western social and political

---

419 See id. at 25 (other derivatives are truthfulness, privacy, confidentiality, and fidelity).
420 Id. at 30.
421 Id. at 33.
422 Id. at 32.
423 Id. at 30–31.
424 Id. at 26; see also Carl E. Schneider, Bioethics in the Language of the Law, 24 Hastings Center Rpt., July–Aug. 1994, at 16.
thought over the last four centuries. 426 This newly refined and activated right of self-determination has fast become the benchmark of the new patients' rights movement. It is integral, as well, to issues of informed consent in clinical and research settings, abortion (where the right of control of one's body is asserted under the rubric of "free choice") and euthanasia 428 (where the right to die with dignity is asserted). Autonomy also applies to a wide range of other health care delivery issues ranging from allocation of limited resources and regulation of health care to responsibility for dependent persons. 430

Put directly, "a claim for autonomy is a claim for self-ownership and self-governance that each person has for his own body or person and the labor it generates." 431 Some would seek to distinguish between the ideal or principle of autonomy and the principles of respect for personal autonomy; the latter obligates a respect for the autonomous choice and the actions of others. 432 It is important for the maintenance of moral life that individuals be competent, informed, and act voluntarily in their decisions. 433 First order decisional power, or that power and responsibility to make decisions regarding the rightness or wrongness of particular patterns of conduct, may, as a matter of personal choice, be delegated. Accordingly, an individual may wish to yield to his physician when a particular medical procedure is proposed, or to his religious institution or affiliation in matters of sexual ethics. 434

BENEFICENCE

The prevention of harm and the production of good are the two distinct but related foci of the principle of beneficence. Medical ethics emphasizes harm prevention under the normative command, "Do no harm." Accordingly, for the health care professional, this principle means that he must take care in his actions not to compound an ill patient's condition by

426 Walters, supra note 2, at 51; see also Symposium, Ethics, Bioethics, and Family Law, 1992 UTAH L. REV. 735.
427 Walters, supra note 2, at 51.
429 Walters, supra note 2, at 51.
430 Walters, supra note 2, at 50–51.
433 See id. at 13.
causing or complicating further illness. This beneficence principle is expanded and applied by bioethicists to their research by adhering to a standard of concern for the protection of human subjects. It is coupled with an advance assessment of the possible negative social consequences which may result from new biomedical technologies in order to protect large groups of individual from potential harm. Since biomedical advances carry significant social costs, it has been argued that society should be willing to adopt a less permissive and more critical stance toward new technologies in this field.

Even though no sharp breaks can be found on the continuum between "preventing harm" and "producing good," beneficence, as a positive principle, is regarded as being more directive since it requires conferring of benefits rather than avoiding harm. In the sense that it allows at least the risk of some harm in the ultimate course of attempting to produce great benefits, the positive principle may thus be less stringent than the negative. Indeed, it is because of the promise of advances in scientific or medical knowledge or general progress that biomedical research is often justified. In the field of gene experimentation and therapy as well as in vitro fertilization, advocates of new biomedical and behavioral technologies contend that the long-term societal benefits accruing from this technology far outweigh their micro, negative side-effects.

JUSTICE

Any use of biotechnology brings with it the ever-present problem of how to distribute its benefits justly and fairly among various social groups. Presently, the vast majority of distributional problems are decided on a local ad hoc basis. Since demand will normally exceed supply, the threshold question becomes, for example: who should receive a kidney transplant, artificial heart or be candidates for gene therapy? What is the fairest principle for distribution: first come, first serve; or medical compatibility? How equal should access to health care be recognized as an important social goal? To what extent is there an inequitable distribution of biomedical research risks to the institutionalized? And, finally, is it unjust to distribute health care as a free

436 Walters, supra note 2.
438 Kass, supra note 66; see also George P. Smith, II, infra note 87.
439 Walters, supra note 2, at 50–51; see also Russell Scott, Legal Implications and Law Making in Bioethics and Experimental Medicine, 1 J. CONTEMP. HEALTH L. & POL’Y 47 (1985).
market commodity or to consider the social utility of persons in distributing scarce medical services? No definitive "answers" can be postulated.441 Indeed, as Richard McCormick has cautioned, the operative watchwords should be, "Beware of ethicists bearing solutions!"442 Anyone claiming to have explicable rules that cut through the philosophical agonies of ambiguity and uncertainty in our present pluralistic society, is guilty of deception.443 All too often, the question of just distribution is reduced to who shall decide the distribution.444

Thus, wide social consensus will never be achieved in developing a framework for resolving difficult medical issues of the new biology, simply because the criterion of final selection will vary with the nature of the medical dilemma or particular biomedical technology used. Despite this lack of consensus, policies that aid in decisionmaking can and must be advanced. Such a set of policies must be formulated to not only provide protection for the vulnerable while respecting familial and personal autonomy and privacy, but to recognize not the centrality of technical expertise so much as of inherent communal values. Such values foster humility as well as tolerance and grace.445

IV. TOWARD A BIOETHICAL RESOLUTION

Human beings will act ideally with rational purpose and design in addressing the ethical problems of biomedical research. Some urge a cessation of all research, observing that we lack total knowledge.446 Significant dangers do exist in undertaking research and in applying the fruits of that research;447 man often chooses the path of ignorance to escape the burdens of responsibility that arise from new knowledge. To end research now, however, will foreclose any opportunity to grow in wisdom and to use that wisdom to act with dignity and responsibility. Since man cannot escape responsibility, we should continue research in

---

441 Kass, supra note 66, at 72; see also Walters, supra note 2, at 50–51.
442 McCormick, supra note 6, at 358.
443 See id.
the new biology and increase the public debate over the social and legal consequences arising therefrom.  

Ethics and science interact continuously as the scientific process creates new possibilities that influence ethical judgments. The set of values and ordering of commitments to which the scientist ascribes influences not only the research objectives he seeks, but also the results he can recognize. Science is descriptive and attempts to resolve the question: what is? Ethics is prescriptive and attempts to resolve the question: what ought to be? Paradoxically, the law is charged with structuring a standard for present behavior and remains simultaneously a step behind science in a reactive capacity. Exclusive reliance should not be placed on legal remedies, however, to resolve the complex ethical problems that biomedical research presents. Similarly, the law should not embrace nor, indeed, advance one particular scientific ethic over any other in its problem-solving function.

Much of the ethical theory surrounding biomedicine attempts to harmonize individual desires with the greater social welfare. Moral dilemmas in biomedicine may be thought of as arising from real or apparent conflicts between perceived obligations to distant generations and to the present generation. In determining whether continued investigations into genetic engineering will jeopardize future life, one should inquire whether an act with uncertain consequences would be harmful to one's own children. Man should not inflict on future generations that which can be disastrous to a present generation.

**ACHIEVING STABILITY**

Bioethics can be seen as having no defined essence that sets it apart as a distinct study or discipline. Rather, its individuation derives from a *de*
**facto** set of issues interrelated by what might be termed "family resemblances." While a common thread joining all of the issues is exceedingly difficult to find, the central core comprising the list of issues, without question, is a concern over the technology of control of man's body, his mind and quality of life. Many of the concerns of bioethics relate to public policy--or to legislation, policies and guidelines--at state, local and federal levels that need to be enacted and enforced with respect to all of the issues comprising the de facto set. It has been suggested that bioethical concerns are but those prohibitions all rational people urge everyone to follow in an effort to avoid evils upon which common agreement exists.

Outside the individual context of determining how one treats another, on a broader societal level for moral acceptability to be given, a democratic consensus must be reached acknowledging that a certain good must be promoted though its very promotion causes some degree of harm. It is within this setting where much of what is recognized as "bioethics" is focused. While individual morality operates primarily within a system of restraints, policies affecting society as a whole operate on a level where promotion of goods is a moral option. The pivotal question thus becomes, "What goods ought to be restrained (e.g., scientific research)?" Priorities, values and goods must all necessarily be weighed, balanced and compared. Whenever the benefits and the risks of a particular course of action are weighed, it is well to remember that those very elements in the balancing test are based upon value judgments; the penultimate goal is the formulation and validation of a final action which minimizes human suffering and maximizes the social good.

**INITIATING A NEW DEBATE**

Bioethics should be viewed as a natural response to not only socio-politico-religious-medical dilemmas, but to increased knowledge and threatened rights and not as a new discovery of basic principles. As

---


460 Clouser, *supra* note 3, at 63.

461 *See generally* *Bioethics* (Thomas A. Shannon ed., 1993).


such, bioethics does not require application of a new morality. Morality is neither invested nor legislated. Rather, it is "discovered" by an unpacking, explication and articulation of individual intuitions about what ought be undertaken and what ought not be done.

When new lines of action are discovered, derived rules will then emerge that, in turn, lead to defined results presenting new conflicts with basic ethical and moral norms. While this process of discovery evolves, it would be well to promote a new debate on human rights among members of the legal community as well as scientists, technologists and philosophers which, in turn, would hopefully guide and shape the whole process itself. Of necessity, the debate will focus its analysis on an examination of the extent to which the plethora of legal, medical, scientific, philosophical, and technological considerations combine within the brave new world to either challenge or complement the more traditional rights of humanity. Once considered, it will then be necessary to decide whether a redefinition or reshaping of these rights is needed as a direct consequence of a set of new contemporary values and standards emerging from the complex bioethical conundrums of the twenty-first century. If realized, this debate will then give rise to and promote a structure for legal coherence to complex bioethical decisionmaking heretofore absent.

466 Clouser, supra note 3, at 62.