Biomedicine and Bioethics: De Lege Lata, De Lege Ferenda

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BIOMEDICINE AND BIOETHICS: DE LEGE LATA, DE LEGE FERENDA

"... The Law today, as laid down, and what tommorrow may bring."

George P. Smith, II*

I. INTRODUCTION

It was Plato who cautioned that "[w]e know how human nature may be degraded; [but] we do not know how by artificial means any improvement in the breed can be effected." The very essence, however, of biological existence is change—with no living things or their environment ever being in a state of constant equilibrium. Over history, man has not only sought to understand himself, but to control his identity. The mere availability of a means often impels us to seek for an end that it can accomplish. Yet, at the heart of biological engineering—recognized as but one facet of human engineering—is a concern for the well-being of others; a desire that others should have a bigger claim to the good life, with as little suffering as possible.

With the development of tests for genetic defects in the human egg before fertilization, a new and exciting gloss has been put on preconceptual and prenatal diagnosis and a previously unexplored avenue in genetic screening and ultimate engineering has been opened. Similarly, announcement of the

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The research and writing of this article began during the Summer of 1991 when I was a Visiting Professor of Research at The University of Auckland Law Faculty in New Zealand and at The University of Sydney Law Faculty in Australia. The final draft was completed during my Spring 1992 sabbatical when I was affiliated at the Center of Medical Law and Ethics, University of London, as a Visiting Fellow and the Center for Socio-Legal Studies, Wolfson College, Oxford University.

first attempt to conduct human gene therapy, the procedure by which diseases are cured by inserting foreign genes into a patient’s injured cells, has heightened interest in the genetics revolution.  

The federal government’s decision to map the precise location of each of the approximately 50,000 genes that make up the full human complement, referred to as the human genome, holds great promise that due to preconceptual and prenatal screening, chromosomal, polygenic, and somatic cell disorders will eventually become problems of the past. Even though it is estimated that it will take at least fifteen years before the genome is mapped, ethical concerns are being raised over possible genetic discrimination, such as differential employment and insurance treatment as a consequence of a negative genetic profile. There is the further danger of eugenic pressures being exerted upon individuals with dangerous recessive traits in order to prohibit them from procreating or forcing women carrying fetuses with genetic abnormalities to abort. The genome project has been termed one of the cultural challenges of the next several decades in that it will call into focus and directly challenge the extent to which a political commitment is made to equality in the face of the sciences of inequality; genetics being “preeminently a science of inequality of human difference.”

New medical technologies have the ability not only to shape life before it begins, but also—sadly—to prolong life past the time when it should have a dignified ending. Both the development of “life” in the test tube through in vitro fertilization and its prolongation in the intensive care units in hospitals throughout the country present yet another focus of concern for the bioethicist. The need to ration scarce and exotic medical resources becomes more and more an obvious reality at all junctures of the New Biol-

8. Robin Henig, Pitfalls of Genetic Screening, WASH. POST Jan. 29, 1991, at Health Mag., 14. Alternatively, it has been estimated that the human genome consists of up to 100,000 genes. See also GEORGE P. SMITH, II, THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY 6 (1989).
ogy. Rules that cut through the agonies of ambiguity and uncertainty simply do not exist—for the harsh dimension of reality brought within each situation of clinical conflict shapes the ultimate response.

Contemporary advances in biotechnology and medical science are creating new uses for bodily tissues heretofore considered to have no value beyond their original functions. Indeed, more and more Americans are engaged in the business of selling themselves piecemeal. The fast-growing market in human products includes not only blood, semen, eggs, tissues, organs, and subparts, but even children. This ultimately translates into profits from the sale, patenting, and transplantation of human materials. At the same time, troubling ethical possibilities for clinical researchers and the industry as a whole are raised by the bio-material boom.

Biotechnology may be defined broadly to include all techniques using living organisms (or parts thereof) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses. “New” biotechnology includes recombinant DNA techniques, cell fusion, and novel biopressing techniques, while “old” biotechnology includes the use of micro-organisms for brewing and baking, or selective breeding in agriculture and animal husbandry. Within the past fifteen years, biotechnology has broadened its impact to include research in a range of diverse fields, from cancer and AIDS to “super” dairy cows and tomatoes.


Perhaps the most startling and potentially lucrative of all the biotechnological advances with human tissue is seen in applied research where the development and subsequent therapeutic use of cell lines is being advanced. These lines are created from either healthy or cancerous human tissue and are used in turn to develop drugs and other useful biological substances.\(^{22}\)

The market for these cell lines and their human tissue by-products is valued presently in the billions of dollars and is likely to grow even larger.\(^{23}\)

The federal government, acting through its National Institutes of Health and reacting to pressure from scientific groups and the biotechnology industry, rescinded its plans to impose strict conflict-of-interest guidelines on health researchers who receive federal funding for research in biotechnology. The rules, if enforced, would have barred scientists from holding an equity stake in the companies that might benefit from their research and would have prevented scientists from consulting with companies on NIH-funded work and sharing information with private firms until it was publicly available.\(^{24}\)

Such a set of rules, it was contended, would not only stifle the spirit of capitalism but also, equally as important, would impede free scientific inquiry.\(^{25}\)

The contemporary challenge of bioethics is rather simple and direct in its mandate, but is exceedingly complex in its application. The legal and ethical evaluations and constructions of law, medicine, biotechnology, and genetic engineering need to be set within a continuing dialogue that is tied to a basic understanding of and respect for human rights and human dignity. More-


\(^{23}\) See Joan O'C. Hamilton et al., Biotech: America's Dream Machine, BUS. WK., Mar. 2, 1992, at 66 (discussing the success of biotech companies as publicly-held entities). See generally PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY (Feb. 1991) (calling upon federal agencies to—a among other things—implement the provisions of the Technology Transfer Act of 1986, codified as amended at 15 U.S.C. § s 3701 to 3714 (1988), advance opportunities for commercialization of scientific research; and develop and maintain risk-based regulations that, although maintaining safety in the field of biotechnology, do not unnecessarily burden the field's growth and create economic incentives for continued commercial development of biotechnology through favorable tax policies).


\(^{25}\) Shapiro, supra note 24, at 1-3.
over, what is needed today is a new human rights debate not only among the
members of the legal community, but also among scientists and technolo-
gists. Such a debate would, of necessity, consider anew the extent to which
the plethora of medical, legal, scientific, and technological considerations of
the brave new world would either challenge or complement both the tradi-
tional rights of humanity and those being redefined according to contempo-
rary values and standards. Mr. Justice Michael D. Kirby, President
Justice of the Court of Appeal, Supreme Court of New South Wales, Austra-
lia, has eloquently warned: “If lawyers are to continue to play a relevant part
in the human rights debate of the future, they must become more aware of
scientific and technological advances. Otherwise, they will increasingly lack
understanding of the questions to be asked, let alone the answers to be
given.”

Often, the law has responded or reacted to, rather than directed, an
agenda for social needs and demands. Indeed, the former Chief Justice of
the United States Supreme Court, Warren E. Burger, once observed: “Law
does not search out as do science and medicine; it reacts to social needs and
demands.” Law, science, and medicine must become full, unlimited part-
ers in the bioethical ventures of modern society. They must march in uni-
son as they approach the task of assuring the primary goal of society itself:
namely, that all citizens be provided with an equal opportunity to achieve
their maximum potential for human growth, development, interpersonal re-
lations, and intellectual fulfillment within the economic marketplace as well
as the marketplace of ideas, and to have not only their physical suffering
minimized and their spiritual tranquility assured, but also to have their
rights of autonomy and/or self-determination recognized.

Within whatever context or vectors of force bioethical conundrums arise,
the “simple” construct for decision making will be the application of a bal-

L.J. 170, 181 (1986); see George P. Smith, II, Assisted Noncoital Reproduction: A Comparative
28. Warren E. Burger, Reflections on Law and Experimental Medicine, in ETHICAL,
LEGAL & SOCIAL CHALLENGES TO A BRAVE NEW WORLD 211 (George P. Smith, II, ed.
1982); see also Zelman Cowen, Reflections on Medicine Biotechnology and the Law, 14 MELA-
NESIAN L.J. 1 (1986). Sir Zelman Cowen, commenting on the impact of rapid advances in
medicine and biotechnology, has stated that, “the time cushion which used to exist within
which lawmakers could prepare legal regulations to state society’s standards has virtually dis-
appeared.” Id. at 1.
29. George P. Smith, II, Biotechnology and The Law: Social Responsibility or Freedom of
ancing test that seeks to yield a final action that minimizes human suffering and maximizes the social good. If the contours of each situational dilemma are guided thusly, we will approach and utilize the new and startling discoveries of the twenty-first century with a spirit of beneficence, autonomy, and distributive justice and, as Daedalus, have a safe and rewarding journey. If, however, we set out with reckless abandon and are driven only by blind power and greed, we will be surely corrupted and, as Icarus, fall.

II. NORMATIVE ETHICS AND METAETHICS

There are two main divisions of ethics: normative and metaethics. Normative ethics concerns itself with 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.\(^30\) Normative ethical theories are classed as either teleological, consequentialist, or deontological (formalist).\(^31\) The teleologist asserts that there is but one, ultimate right-making characteristic: namely, “the comparative value (nonmoral) of what is, probably will be, or is intended to be brought into being.”\(^32\) The central principle espoused by the deontologist is to maximize the balance of good over evil without any one ultimate moral criterion.\(^33\) Thus, each person and each situation are taken as unique.

The goal of reaching rational judgments, or those conclusions based on general principles of applicability or universalized maxims, would—at first blush—appear to play havoc with those espousing moral judgments for each situation or action.\(^34\) 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 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 nonaction. This balancing mechanism affords a

\(^{31}\) Id. at 80.
\(^{32}\) Id. at 81.
\(^{33}\) Id.
\(^{34}\) Id. at 85.
far better opportunity to achieve the goal of distributive justice than does the unyielding application of a teleological *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 would contribute to human well-being, a practical ethic would sanction the research.

Two types of pragmatic ethics exist within the general category: rule utilitarianism and case utilitarianism. Rule utilitarians stress the need for a weighing of 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 of the entire class or category of experiments. Case utilitarians, on the other hand, would weigh the good that each separate case or situation would provide. Under this ethical approach, laboratory reproduction might be proper in certain cases but improper in others. Either type of a 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 rather is tied solely to a communion of shared values derived from observable experiences.

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40. Fletcher, supra note 38, at 83.
41. *Id.* at 82; see also SIDNEY ZINK, THE CONCEPTS OF ETHICS 93-94, 180-81 (1962).
42. Fletcher, supra note 38, at 82.
43. *Id.* at 82-83.
44. *Id.* at 88-89.
tion 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 and 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 donors of sperm have no claim over children born of their sperm through artificial insemination, a donor of an ovum 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. However, what if the donating 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? If the doctor has obtained permission to use a donor's ovum 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.

The prospect of producing "optimum babies" introduces another issue that bioethics must resolve. Many people might 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. To some, this depersonalization of the procreative process is most undesirable; human procreation for them "is more complete human activity precisely be-

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45. Id. at 89. See generally Richard A. McCormick, Therapy or Tampering? The Ethics of Reproductive Technology, 153 AMERICA 396, 397 (1985).
46. Fletcher, supra note 38, at 89; see also James M. Gustafson, Basic Ethical Issues in the Bio-Medical Fields, 53 SOUNDINGS 151, 177 (1970).
50. Id. at 37-38.
51. Id. at 34-35.
52. Id. at 53-54.
cause it engages us bodily and spiritually as well as rationally."53 Acts of laboratory procreation may threaten the sanctity of marriage and the human family.54 A scientific mastery should not drive out a spiritual mystery.

These criticisms of new biomedical research have led some to suggest a professional moratorium on human experimentation with in vitro fertilization and embryo transfer until safety procedures are perfected that will safeguard against "the further dehumanization of man."55 Development of such safeguards could take many forms: studies of the normality of the offspring produced by the technologies of the New Biology among lower order mammals; establishment of intraprofessional organizations to discuss and evaluate work in this area; promotion of interdisciplinary discussion to fully apprise all concerned of the consequences of continued in vitro fertilization and embryo transfer research in order to minimize any possible negative social consequences; development of an international forum for the full exploration of ways in which misdirections in biomedicine may be averted; and, ultimately, the creation of ethical guidelines for the application of the New Biology, drawing on the skills of lawyers, legislators, theologians, philosophers, humanists, social scientists, and laymen.56

Research into the impact of biomedical technologies and consideration of the ethical dilemmas involved does not require a moratorium on human experimentation; the two can continue concurrently. Yet, no federally funded research on in vitro fertilization has been undertaken since 1975, when the research moratorium went into effect.57 Society should encourage, not stifle,

53. Id. at 53.
54. Id. at 54.
57. Susan Abramowitz, A Stalemate on Test-Tube Baby Research, HASTINGS CENTER REP., Feb. 1984, at 5. Even though the 1979 Report of the Ethics Advisory Board of what was then the Department of Health Education and Welfare concluded that federal support of research on humans in order to establish the safety and the effectiveness of IVF procedures would be ethically permissible so long as certain conditions were met (44 Fed. Reg. 35,057 (1979)), the report has never been accepted or the moratorium ended; and there is no real likelihood such action will be taken soon. John C. Fletcher & Kenneth J. Ryan, Federal Regulations for Fetal Research: A Case for Reform, 15 LAW MED. & HEALTH CARE 126, 129-30 (1987). Yet, Congressman Henry A. Waxman introduced a bill entitled, The National Institutes of Health Revitalization Amendments of 1991 that—if enacted into legislation—would have had the effect of lifting the moratorium on federal funding of research on transplanting fetal tissue and allowing federal funding of such research if it complied with strict ethical guidelines prohibiting sales of fetal tissues or directed donations. H.R. 1532, 102d Cong., 1st Sess. (1991). This bill was subsequently substituted and replaced by Congressman Waxman’s introduction of H.R. 2507, 102d Cong., 1st Sess. (1991) (on the same topic) that passed the House on July 25, 1991. 137 CONG. REC. H5879 (daily ed. July 25, 1991). Senator Edward M. Kennedy has introduced S. 1523, 102d Cong., 1st Sess. (1991), parts of which in addition to
research; for a society unable to accept and encourage either current or future behavioral variations does not promote a hospitable environment for the free development and expression of ideas of any kind.58 Man cannot learn by merely thinking in this area.

III. AUTONOMY, BENEFICENCE AND JUSTICE

There are three principle duties, rights, and values within the field of bioethics: autonomy or self-determination, beneficence, and justice.59 There is continuing debate over the dependence or independence of these three principles and the role they play in bioethical decisions.60 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 the good life for him. Autonomous, reasonable people act accordingly in undertaking those courses of action designed to advance well-being. Justice, thus, becomes an aspirational codification of the common good.

A. 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 a significant impact on Western social and political thought over the last four centuries.61 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"), euthanasia62 (where the right to die with dignity is...
asserted), and within 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.63

Put directly, "the 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."64 Some would seek to distinguish between the ideal or principle of autonomy and the principles of respect for personal autonomy—the latter of which obligates a respect for the autonomous choice and the actions of others.65 It is important for the maintenance of moral life that individuals be competent, informed, and act voluntarily in their decisions.66 Personal choice may be exercised, however, that delegates this inherent first-order decisional power or that responsibility to make decisions regarding the rightness and wrongness of particular patterns of conduct. Accordingly, an individual may wish to yield to his physician when a particular medical procedure is proposed, or to defer to his religious institution of affiliation in matters of sexual ethics.67

In accepting the principles of respect for autonomy, not only must a determination be made regarding whether a patient is autonomous, but—additionally—a determination must be made as to what has in fact been chosen, with the patient's present consents and dissents being placed within a broad temporal context that encompasses both the past and the future, because obviously different preferences are expressed at different times.68 All too often, analysis and application of the principle of respect for autonomy focuses on the present; for example, has informed consent or refusal been given at this time?69 A central question raised as a consequence of this position asks when there is justification in overriding a patient's present autonomous choices or actions in light of his past or (anticipated) future choices and actions? Under proper conditions, the principle of respect for autonomy can be overridden or infringed upon. Thus, nonautonomous persons (traditionally children and the insane) would be likely candidates. Even when this

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63. Walters, supra note 59, at 50.
66. Id. at 13.
68. See Childress, supra note 65, at 13.
69. Id.
occurs, an explanation and justification of the action should be made to those whose autonomy has been infringed or to their surrogate agents.\(^\text{70}\)

**B. Beneficence**

The prevention of harm and the production of good are the two distinct but related foci of the principle of beneficence; with medical ethics emphasizing the first under the normative command: “Do no harm.” Accordingly, for the health care professional, in context, this principle means that he or she must take care in his or her actions not to compound an ill patient’s condition by causing or complicating further illness.\(^\text{71}\) This principle is expanded and applied by bioethicists to their research by adherence to a standard of concern for the protection of human subjects. It is coupled with an advance assessment of the possible negative social consequences that might come from new biomedical technologies in order to protect large groups of individuals from potential harm.\(^\text{72}\) Because 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.\(^\text{73}\)

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 because it requires conferring benefits rather than avoiding harm. In the sense that it allows the risk of at least 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 that biomedical research is often justified. In the fields of gene experimentation and therapy and \textit{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.\(^\text{74}\)

\(^{70}\) \textit{Id.} at 15, 16; \textit{see also} JAMES F. CHILDRESS, \textit{Who Should Decide? Paternalism in Health Care} (1982).

\(^{71}\) Walters, \textit{supra} note 58, at 50; \textit{see also} Tom L. Beauchamp, \textit{The Promise of the Beneficence Model for Medical Ethics}, \textit{6 J. CONTEMP. HEALTH L. \\& POL’Y} 145 (1990); Morgan, \textit{supra} note 18. \textit{See generally} EDMUND D. PELLEGRINO \\& DAVID C. THOMASMA, \textit{For the Patients' Good: The Restoration of Beneficence in Health Care} (1988).

\(^{72}\) Walters, \textit{supra} note 59, at 50.


\(^{74}\) Walters, \textit{supra} note 59, at 50-51; Scott, \textit{supra} note 13, at 47.
C. 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. Because demand will normally exceed supply, the threshold question becomes, for example: Who should receive a kidney transplant, an artificial heart, or become a candidate for gene therapy? What is the fairest principle for distribution—first come, first served or medical compatibility? Should equal 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? Finally, is it unjust to distribute health care as a free market commodity or consider the social utility of persons in distributing scarce medical services? No definitive answers can be postulated. Indeed, as Richard McCormick has cautioned, the operative watchwords should be: “beware of ethicists bearing solutions!” 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. “All too often the question of how to distribute justly often is reduced to who shall decide how to distribute.”

Although wide social consensus will never be achieved on 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), policies that aid decision making can and must be advanced. Such a set of policies must be formulated not only to provide protection for the vulnerable, while respecting familial and personal autonomy and privacy, but also to recognize inherent common values and not so much the centrality of technical expertise. Such values foster humility as well as tolerance and grace.

IV. The Principle of Double Effect

The principle of indirect or double effect, one of the basic principles of Roman Catholic medical ethics, and one also intuited by many others not of the Roman Church, is best understood by an understanding—or often times by a vague feeling—that the administration of a potentially lethal nar-
cotic that would relieve the intractable pain of a cancer patient is in some way morally different from a knowing act that would murder the same patient, justifying it on the grounds of acting mercifully. Stated otherwise, [t]he principle is intended to provide a halfway ground between a straightforward utilitarianism, which would simply consider the relative weights of the good and bad consequences of an action in order to make a moral judgment of it, and a variety of sterner moral positions, which would either deny the moral relevance of consequences to actions altogether or would judge immoral any action with bad consequences, no matter what other good consequences it had.

The net result of recognizing and applying the Principle of Double Effect is that certain actions that indirectly produce certain evil consequences are justified—so long as four conditions are met: the action undertaken, independent of its effect, must not itself be inherently held to be morally evil; the evil effect must not be utilized as a means to produce the good effect; the evil effect is merely tolerated and not sincerely intended; and, finally, regardless of its evil consequences, there is a proportionate reason for undertaking the action. Utilization of this principle provides the justification, for example, of removing a cancerous fetus-bearing uterus and the administration of pain-relieving narcotics that may produce respiratory depression. The principle’s legitimacy has been attacked, alternatively, because it leads to discriminations that are wrongful by excusing acts (thought to be killings by some) that should not be excused by and forbidding other acts that should be allowed.

A principle of such ambivalence is open obviously to these and other logical deficiencies. However, it has been suggested that validation is recognized because of its “psychological validity.” A use-hypothetical attempts to bring into focus this point. Faced with a patient’s intolerable pain and his or her pleas for relief that cannot be mitigated by lesser doses of non-lethal

82. Id.
84. Veatch, supra note 81, at 39; Richard A. McCormick, How Brave a New World? app. at 413 (1981); see also President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Deciding to Forego Life-Sustaining Treatment 80, n.110 (1983) (accepting that consequences of the principle of double effect may be justified but not in order to release people from responsibility for the foreseeable effects of their actions).
85. Veatch, supra note 81.
86. Veatch, supra note 81, at 235.
drugs, a physician chooses to administer a dose of an analgesic that will likely cause death. A crucial contrast is then undertaken between the attitude and the manner that the motive for relieving pain engenders compared with attitudes and manner pursued when a premeditated act to kill is pursued.\textsuperscript{88}

If the purpose explicitly were to kill, would there not be profound difference in the very way one would grasp the syringe, the look in the eye, the words that might be spoken or withheld, those subtle admixtures of fear and hope that haunt the death-bed scene? And would not the consequences of the difference be compounded almost geometrically at least for the physician as he killed one such patient after another? And what of the repercussions of the difference on the nurses and hospital attendants? How long would the quality and attitude of mercy survive death-intending conduct? The line between the civilized and savage in men is fine enough without jeopardizing it by euthanasia. History teaches the line is maintainable under the principle of double effect; it might well not be under a regime of direct intentional killing.\textsuperscript{89}

Whether the lessons of history substantiate the alleged "psychological validity" of the double effect principle and establish that it is efficacious—that it merits its ready use and retention today seem dubious, at best. Rather than continue to enshrine an awkward concept, it should be replaced by the relatively simple and enduring standard of what is, under a given set of facts, reasonable. Guided by the principle of triage and a consideration of what actions are in the best interests of the at-risk patient, a cost-benefit analysis should be undertaken in order to decide whether one modality of treatment or nontreatment should be pursued.\textsuperscript{90} Thus, reasonable, humane, and cost-effective actions should be both the procedure utilized and the goal sought here.

The intensive care unit found within the average hospital in the United States not only seeks to treat and to return patients suffering from serious injuries or acute diseases to their original working or stabilized environments but also seeks to serve as a sophisticated, state-of-the-art hospice.\textsuperscript{91} Even when there is no hope of recovery, studies have shown that approximately nineteen percent of patients in intensive care units are nonetheless admitted

\textsuperscript{88} Id.
\textsuperscript{89} Id.
\textsuperscript{90} George P. Smith, II, \textit{Triage: Endgame Realities}, 1 \textit{J. Contemp. Health L. \\& Pol'y} 143 (1985); see also \textit{Daniel Callahan, What Kind of Life: The Limits of Medical Progress} (1990).
and stay. It would seem to be a reasonable and sensible idea for at-risk patients to forego treatment in an intensive care unit; this choice not necessarily made with the idea of dying sooner, but rather with the view that access to family and friends will be more easily facilitated and that familial, social and economic resources will be appropriately conserved.

Choices of this nature should not be confused or tied to the principle of double effect. Rather, when a tragic choice must be made not between different chances of survival with different treatments but only between extending the process of suffering death or shortening it, the principle has little pertinence or significance. "Patients may very well sensibly decide to forego treatment or ICU care so that they may in fact finally die and end their travail. They may directly will their deaths and thus within one strict interpretation of moral theory, passively commit suicide."

Physicians in England are not allowed to initiate any actions that intend, as their primary purpose, to cause a patient's death. Accordingly, under the Suicide Act of 1961, if a physician were to endeavor to facilitate the request of a terminally ill patient for assistance in terminating his life, he would subject himself to criminal prosecution. A physician is also, under this legislation, not allowed to honor suggestions from the family of a gravely ill patient to end the life of such a patient. On the other hand, because one of the basic commitments of the medical profession is to ease pain, if acting to ease suffering, a physician must introduce and follow a modality of treatment that may in fact hasten death, his or her actions are ethically and legally permissible so long as the understanding is maintained that the course of treatment is only for the relief of pain or associated distress. This is a preeminently reasonable modus operandi for dealing with the double effect construct. In fact, it could be argued that medical actions of this nature are, in reality, beneficent and thereby advance the very direction of the principle of beneficience itself.

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92. Id.
93. Id.
94. Id.
95. Id.
97. Id.
98. Id.
V. THE INTERVENTION OF SCIENCE AND ETHICS

Several philosophers have attempted to structure a general system of bioethics. For Teilhard de Chardin, the "Omega Point," that cultural stage that will occur in the evolutionary process where "the minds of men have attained a common language of scientific humanism,"100 was a workable philosophy.101 Darwin constructed a general ethic dependent on a "scientific-philosophic" concept of progress.102 One contemporary scholar has stated that Darwin's concept rests on several premises regarding knowledge. The first assumption is that the limits of knowledge are infinite. Second, no individual alone can begin to encompass the knowledge that presently exists. Third, the only effective solution to what may be termed "dangerous knowledge" is more knowledge, which should be disseminated as widely as possible. Indeed, to Darwin it was wisdom, or the knowledge of how to use knowledge, that was the most important knowledge of all.103

Whether one defines wisdom in Kantian terms, as a policy of action that espouses "doing or letting be," or as Darwin did, as the knowledge of how to use knowledge, the principal focus of wisdom is society's competence to act.104 Moreover, this problem of how society should use knowledge for the social good must be considered in terms of the total volume of information society can manipulate.105

[M]oral status (our ethical integrity) depends upon two things at least: first, freedom of choice, and, second, knowledge of the facts and of the courses between which we may choose. In the absence of either or both of these things we are, in the forum of conscience, more like puppets than persons. Lacking freedom and knowledge, we are not responsible; we are not moral agents or personal beings. . . . [M]ankind is constantly growing and gaining ground both in knowledge of life and health and in human control over them. This is, indeed, the same as saying that the means to heightened moral stature are available. The appeal of moral idealism is that we take advantage of every opportunity to grow in wisdom and stature, that we assume our responsibility; in short, that we not like human beings."106

Human beings ideally will act with rational purpose and design in addressing the ethical problems of biomedical research. Some urge a cessation

100. VAN R. POTTER, BIOETHICS: BRIDGE TO THE FUTURE 34 (1971).
101. Id. at 31.
102. Id. at 45-46.
103. Id. at 49.
104. Id. at 184-186.
105. Id. at 186.
106. JOSEPH FLETCHER, MORALS AND MEDICINE 35 (1960) (footnote omitted).
of all research, observing that we lack the necessary knowledge. Significant dangers do exist in undertaking research and in applying the fruits of that research, and man often chooses the path of ignorance to escape the burden of responsibility that arises from new knowledge. To end research now, however, will foreclose any opportunity to grow in wisdom and use that wisdom to act with dignity and responsibility. Because man cannot escape responsibility, we should continue research in the New Biology and increase the public debate over the social and legal consequences arising therefrom.

Ethical and scientific factors continuously interact 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 or she seeks but also the results he or she 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 simultaneously remains 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. Indeed, the law should probably not support any one particular scientific ethic, however styled.

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

109. Id. at 1077.
111. Friedmann, supra note 108.
112. Fletcher, supra note 39, at 776.
115. Id.
116. See generally Alastair V. Campbell, Moral Dilemmas in Medicine 1, 13 (1972).
uncertain consequences would be harmful to one's own children.\textsuperscript{118} Humankind should not inflict on future generations that which can be disastrous to a present generation.\textsuperscript{119}

One scholar has suggested a bioethical creed for individuals. The creed states that "the future survival and development of mankind, both culturally and biologically, is strongly conditioned by man's present activities and plans."\textsuperscript{120} The creed encompasses a corresponding commitment to live life and to influence the lives of others to promote the evolution of a better world for future generations by avoiding actions that would detrimentally impact the future.\textsuperscript{121}

\section*{VI. Bioethics: The Present and the Future}

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 \textit{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 these issues is, without question, a concern over the technology of control of man's or woman's body, his or her mind and the quality of his or her life.\textsuperscript{122} Many of the concerns of bioethics focus on the legislation, policies, and guidelines that need to be enacted and enforced at the state, local, and federal levels with respect to all of the issues comprising the \textit{de facto} set.\textsuperscript{123} It has been suggested that bioethical concerns are no more than those prohibitions that all rational people urge everyone to follow in an effort to avoid evils on which common agreement exists.\textsuperscript{124}

Outside the individual context of determining how one treats another and at the broader societal level, in order for moral acceptability to be given, a democratic consensus must be reached acknowledging that a certain good must be promoted though its promotion causes some degree of harm. It is within this setting that much of what is recognized as "bioethics" is focused.

\textsuperscript{118} \textit{Id.} at 279.
\textsuperscript{119} \textit{Id.} at 279-80.
\textsuperscript{120} \textit{Potter, supra} note 100, at 196.
\textsuperscript{121} \textit{Id.}
Although 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)?" Of necessity, priorities, values, and goods must all be weighed, balanced, and compared. Whenever the benefits and the risks of a particular course of action are weighed, it is important to remember that those very elements in the balancing test are based upon value judgments.

It is suggested that bioethics should be viewed as but a natural response not only to socio-politico-religious-medical dilemmas, but also to increased knowledge and threatened rights and not as a new discovery of basic principles. As such, bioethics does not require application of a new morality. Morality is neither investigated 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 emerge that in turn lead to defined results presenting new conflicts with basic ethical and moral norms.

VII. LAW REFORM IN AMERICA

A. The National Conference of State Laws

In 1891, the National Conference of Commissioners of Uniform State Laws (the "Conference") was conceived as an undertaking that would unify the legal systems of the fifty states, and complement the national incentive toward unity. The Conference structured itself accordingly as an organization that would deal with the business of promoting a national uniformity of laws without displacing the state courts.

Although the drafting of uniform laws is central to any real effort to build and maintain uniformity, such efforts are only partially effective unless they are translated into law. Regrettably, many state legislators are either still

125. Clouser, supra note 122, at 63. See generally Samuel Gorovitz, Bioethics and Social Responsibility, in CONTEMPORARY ISSUES IN BIOETHICS 52, 52-60 (Tom L. Beauchamp & Leroy Walters eds., 1978).
126. Kirby, supra note 73.
127. Clouser, supra note 122, at 54.
128. Id. at 62.
131. Id. at 1, 11.
insufficiently aware of the activities of the Conference or perhaps unwilling to share their legislative prerogatives with the Conference and its commissioners. Still, the primary purpose of uniform laws—namely, the elimination of uncertainty—is advanced by the work of the Conference; and better legislation is enacted as a direct consequence of its work. Currently, the Conference achievement list includes ninety-nine uniform acts and twenty-four model acts as well as twelve other recommended acts—with one hundred and forty-one other works having been withdrawn as obsolete or superseded.

B. The American Law Institute

The American Bar Association founded the American Law Institute (the "Institute") in 1923 in response to a developing attitude among lawyers that they have a unique public function to perform in improving law and its administration. The Institute presents restatements of the law that explain undergirding principles used in formulating various laws, analyzes the existing conditions of those laws, and sets forth the legal problems involved in implementing them.

The object of each Restatement of the Law by the Institute is simple and direct: namely "to improve the law, not merely by clarifying and simplifying it, but also by better adapting it to existing needs." In meeting this object, the Institute, "not only ascertains what the law is but what it ought to be, bearing in mind that the changes advocated should be confined to those designed to carry out the policies which are generally admitted to be desirable and which do not touch subjects of general public controversy."

As a point of historical comparison, in England at the end of the sixteenth century, Sir Francis Bacon suggested that a commission be organized to conduct on-going studies to investigate obsolete and contradictory laws and that

132. Id. at 129.
133. Id. at 16.
134. Id. at 131.
135. Id. at 130. Perhaps the three most significant and enduring Conference enactments are the Uniform Partnership Act, over seventy-seven years old, the Reciprocal Enforcement of Support Act, over forty years old, and the Uniform Commercial Code, over thirty-three years old. Id. at 4. But see James J. White, Ex Proprio Vigore, 89 MICH. L. REV. 2096, 2132-33 (1991) (arguing that the growing power of the Federal Government in the legislative process poses a real threat to the Commission's effectiveness in legislative drafting).
137. Id. at 50.
138. Id. at 132.
these reports be submitted to Parliament.\textsuperscript{140} This practice continues today formally through the institution of Law Reform Commission in the United Kingdom.\textsuperscript{141}

**VIII. THE NEW BIOLOGY IN THE UNITED STATES**

Recognizing the growing complexity and interrelatedness of law, science, and medicine, on November 9, 1978, the Congress of the United States authorized creation of a presidential commission—styled subsequently as the President's Commission for The Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the "President's Commission").\textsuperscript{142} Although intended to have four years to complete its work,\textsuperscript{143} delays in funding the President's Commission and making appointments to it, meant it had little more than three years to complete its studies into not only ethical issues in research with human beings, fetal research, and psychosurgery, but also the grounds to forego life-sustaining treatment and others.\textsuperscript{144}

From 1975 to 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "National Commission"), whose membership was appointed by the Secretary of the Department of Health, Education, and Welfare, had sought to study basic legal-ethical issues involved with undertakings in human research.\textsuperscript{145} The National Commission's limited agenda was expanded and diversified by the establishment of the President's Commission (created to tackle, and thereby chart, the social, legal, ethical, medical, and scientific frontiers of The New Biology).\textsuperscript{146} Both this National Commission and the President's Commission provided a solid foundation upon which necessary work in law, science, and medicine could be conducted. And, in 1983, such a need was ad-


\textsuperscript{141} WILLIAM H. HURLBURT, LAW REFORM COMMISSIONS IN THE UNITED KINGDOM, AUSTRALIA AND CANADA 3 (1986); see also *THE LAW COMMISSION AND LAW REFORM* (Graham Zellick ed., 1988).

\textsuperscript{142} 42 U.S.C. s 300v (1988).


dressed—but not resolved.\textsuperscript{147}

IX. THE POLITICS OF ABORTION: A ROADBLOCK TO BIOMEDICAL ETHICS RESEARCH

By the 1985 enactment of Public Law 99-158, Congress created a Biomedical Ethics Advisory Committee (the “Advisory Committee”) that was to have been governed by a bipartisan Biomedical Ethics Board (the “Congressional Board”) whose membership was in turn comprised of three Republicans and three Democrats each from both the House of Representatives and the Senate.\textsuperscript{148} The Board appointed the fourteen members of the Committee and was charged with overseeing their activities.\textsuperscript{149} Almost a year elapsed before the twelve members of the Congressional Board were appointed and yet another year and a half passed before the Board appointed members of the Advisory Committee.\textsuperscript{150}

When on March 8, 1990, the Senate members of the Congressional Board met to elect a chairman, a rancorous debate erupted among various “pro-choice” and “pro-life” senators with the “pro-life” faction expressing their concern that, “they needed at least equal representation on the Committee, while pro-choice senators felt they had ceded representation far in excess of the pro-life segment of the general population. Neither side trusted that the committee would carry out its work in a way that would be both fair and useful.”\textsuperscript{151} Subsequent maneuvering forced an amendment to a pending appropriations bill that precluded funding the Committee’s budget until the Board elected a Chairman, and a Vice Chairman and filled a vacancy on the Committee itself.\textsuperscript{152} This action effectively killed the Congressional Biomedical Ethics Advisory Committee on September 30, 1990.\textsuperscript{153}

When discussion occurs from time to time about renewing efforts to establish a federal bioethics commission, it always acknowledges that the first-order issues of the commencement and conclusion of life and the abortion issue are simply too political for congressional study. Thus, any future bioethics commission would be mandated, instead, to study issues related to health care financing, genetics, and/or standards of conduct for undertaking


\textsuperscript{149} Id.

\textsuperscript{150} Id.

\textsuperscript{151} Id.

\textsuperscript{152} Id.

\textsuperscript{153} Id. at 5.
biomedical research.154

X. THE AUSTRALIAN INITIATIVES

Through a National Australian Law Reform Commission—and various complimentary commissions in its six states—together with, notably, a National Health and Medical Research Council, the Australian government has charted an enviable reputation as the leader in the law reform movement and is thus anticipating, and thereby legislating and regulating, an agenda for dealing with the advances in biotechnology.155 Early and on-going studies and proposals on artificial insemination, in vitro fertilization, embryonic research, tissue transplantation, and surrogation—to name but a few—have produced significant reports that have given rise not only to the development of general guidelines but comprehensive procedures concerning the new medical and scientific procedures in the field of biotechnology.156 To its credit, the National Health and Medical Research Council has also structured professional guidelines—acting as such in their promulgation after the pertinent legal issues have first been explored and charted by the various state law reform bodies.157

The Kirby Imperative

Before assuming the Presidency of The Court of Appeal of the Supreme Court of New South Wales, Michael D. Kirby served with national and international distinction as Chairman of the Law Reform Commission of Australia and as a Deputy President of the Australian Conciliation and Arbitration Commission. It was in his capacity as Chairman of the Law Reform Commission that he began to address the problems of law in action and its need to serve the ends of justice - especially in developing a framework for principled decisionmaking for advances with the New Biology.158

Now, as a wise, distinguished, and courageous jurist, Justice Kirby continues to be an eloquent voice, educating from both on and off the bench,159 as

154. Id. at 2.
156. Skene, supra note 155, at 389.
157. Id.
159. See generally A.J. Rodgers, Judges in Search of Justice, 10 U. New S. Wales L.J. 93
De Lege Lata, De Lege Ferenda

an internationally regarded commentator and teacher—educating, as to both the perils and the opportunities of the new and daunting biotechnology and the compelling need to recognize humaneness as an indispensable component of enlightened action. His unflagging commitment to education through full public discourse and his indefatigable pursuit of truth—without polemically—was acknowledged recently by his recognition as one of the thirteen men and women of the Australian Continent (of seventeen million people) who has made a significant and enduring contribution to the growth of Australia as a Nation. Truly, in Justice Kirby one sees the quintessential judicial role model who follows the admonition of Socrates to hear courteously, answer wisely, consider soberly, and decide impartially.

With Justice Kirby maintaining visible strength and, indeed, vigilance in the vanguard of the New Biology, the pathway for resolving the myriad and complex bioethical conundrums is a pathway that has been cleared and is being expanded—as it is marked—with illuminating guideposts. It remains for those traveling the pathway to but read, understand, and react in a positive and humane way to road signs that he has designed.

XI. CONCLUSION

It is seen that bioethics raises the central question of how to live, adjust, and relate to the new, and sometimes startling, reproductive technologies; or, as the late Professor Nancy Rhoden questioned, can the contemporary inquiry of bioethics be tempered through the assertion of humane values or must everything, including our very dignity and autonomy, be sacrificed up to it?

As the “chariot of science” drives forward with dazzling speed, the “time cushion” within which legislation can be enacted to thereby codify societal standards or preferential orderings has evaporated. This is especially evi-

(1987). But see, Alan A. Stone, Judges as Medical Decision Makers, 12 Hum. Life REV. 84 (1986) (arguing that it is not uncommon for judges to make misleading, costly statements about medical realities, thereby undermining the credibility of the courts in the eyes of the medical profession, and that of the medical profession in the eyes of the public).

161. Kirby, supra note 27.
162. See Jones, supra note 160.
164. Stated otherwise, “Bioethics attempts to develop a philosophy regarding the application of man’s biological knowledge in furtherance of the social good.” Potter, supra note 100, at 26.
166. Kirby, supra note 158, at 236; see also Skene, supra note 155.
dent considering that although a scientific discovery may often occur within an instance of time, working through the legal and social consequences of these discoveries tends to absorb an inordinate amount of energy.\footnote{Kirby, supra note 158, at 237; see also Kirby, supra note 140, at 201; Scott supra note 74. Roscoe Pound expressed doubt whether the science of law should wait for ultimate theoretical problems to be settled before seeking practical ways to conclude present controversies expeditiously. Roscoe Pound, Book Review, 61 Harv. L. Rev. 724, 737 (1948) (reviewing Julius Stone, The Province and Function of Law).}

Although in the past the problems of biomedical ethics have been viewed with diffidence and uncertainty and regarded as intractable,\footnote{Id. at 238; see Sheila Jasanoff, Biology and the Bill of Rights: Can Science Reframe the Constitution?, 13 Am. J.L. & Med. 249, 261 (1990) (listing nine major policy areas under which seventeen situations may arise that create constitutional controversies over implementation of the New Biology). See generally More Law Reform Now: A Collection of Essays on Law Reform (Peter Archer & Andrew Martin eds., 1983).} a new, educated, and institutional response is demanded "if democracy is to be more than a myth and a shibboleth in the age of mature science and technology . . . ."\footnote{Kirby, supra note 158, at 217.} If this response is not forthcoming, we "resign ourselves to being taken where the scientists' and technologists' imagination leads."\footnote{But see Larry Thompson, Alerting the Public to Scientific Advances: Early Announcements Can Cause Controversy and Confusion, WASH. POST, Mar. 19, 1991, Health Mag., at 8. See generally George P. Smith, II, Toward an International Standard of Scientific Inquiry, 2 Health-Matrix 101 (1992).} And, sadly,

that path may involve nothing less than the demise of the Rule of Law as we know it. It is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics, are just too painful, technical, complicated, sensitive and controversial for our institutions of government."\footnote{Kirby, supra note 158, at 239; see also Kirby, supra note 73; George P. Smith, II, The Province and Function of Law, Science and Medicine: Leeways of Choice, Patterns of Discourse, 10 U. New S. Wales L.J. 103 (1987).}

TIME is of the essence!