1. Introduction

Reports from the Centers for Medicare and Medicaid Services and the Agency for Health Care Research and Quality released in 2006 showed—conclusively—that rising health care costs consume 16 percent of the nation’s economic output. In 1997, health care accounted for 13.6 percent of the gross domestic product. Health care costs are growing substantially faster than inflation and wages—increasing by almost 8 percent in 2004. Indeed, in 2004, the nation spent almost $140 billion more for health care than the year before. And, by 2016, it is expected that an annual increase of 5.3 percent will translate into a national expenditure of one dollar of every five dollars for health care, bringing the overall total close to $4 trillion in overall budget costs just for health maintenance.1 Sadly, as these costs escalate, many Americans—especially minorities and the poor—do not receive high quality of care.2 Medical providers, acting under constant pressure from insurance companies, who in turn are pressured from employers, are battling daily to find ways by which health care costs can be cut.3

The unraveling of health care services is driven by advances in medical technology which, in turn, have the effect of allowing physicians the luxury of simply spending more on patient care. This creates a domino effect because it leads to higher insurance costs which in turn push employers to cease providing coverage. The net result, then, is that significant numbers of citizens become uninsured and thus encounter difficulties in getting basic care. In a direct sense, “Peter” is robbed, proverbially, of basic care in order to provide “Paul” with state-of-the-art care and treatment.4

Essentially, all efforts to achieve justice in the distribution of health care resources are utilitarian in character and definition.5 Since these resources are not infinite, they cannot be offered to or used by everyone. This, of necessity, then forces choices between those individuals and among groups seeking their use. Allowing improper distribution of these scarce resources is not only inefficient, it is wasteful.6

For utilitarians, the general good is seen as superior to personal goal satisfaction.7 Because of the difficulty in calculating the net good deriving from a utilitarian approach to decision making,8 some have argued that this approach to health care decision making is not only unjust—but unfair.9 Not only is utilitarianism viewed as cold and calculating, it is seen
as denying the individual of what is his due.\textsuperscript{10} The needs of those who are worse off are either ignored or neglected.\textsuperscript{11}

\section*{QALYs}

Drawing upon the progenitor of utilitarianism, Jeremy Bentham, who asserted all legislative enactments and public policies deriving therefrom should have as their goal the attainment of the greatest happiness for the greatest number of citizens,\textsuperscript{12} proponents of finding an indicator for this level of contentment brought forward the notion that a “net good” could be determined by evaluating or ranking competing preferences or approaches to health care justice. Thus, it was (and is) believed today that “counting utilities provides a bridge to the quantification of the quality of human life.”\textsuperscript{13} In the 1970s, then, the quality of adjusted life year (QALY) came into its own and was advanced as not only a principle to account for an intuitive belief that most prefer, typically, ability to disability and contentment to distress,\textsuperscript{14} but as a construct to measure both the quantity and the quality of life with or without medical care.\textsuperscript{15}

Essentially, the QALY is a measuring tool which equals one life year for good health—without either disability or distress.\textsuperscript{16} Accordingly, for a patient expecting five years of additional life after major surgery, the value of this health intervention is determined to be five. If however, this treatment leaves the patient in a state of distress or disabled for an additional five years, the value is diminished.\textsuperscript{17} The ratio of the reduction is set by using a matrix based upon policy determinations derived from interviews with physicians, health care administrators and patients themselves.\textsuperscript{18} Patient preferences are central to any effort to assess the quality of life gained from each medical benefit conferred or health improvement developed.

Once the QALY is set, it has been suggested that a higher level of “rational rationing” can be achieved by making a calculation of the costs of each health service as well as the cost offset by future savings through actual prevention.\textsuperscript{19} With this informational base, a ranking of the various health services can then be undertaken—all according to the extent and nature of the benefit they offer per dollar expended (or, in other words, value for money). Within any given health plan, “services would be provided starting from the top of the list, down to the point where the insurance company’s or Medicare money runs out.”\textsuperscript{20} Thus, those services offering the most health value would—in turn—get the highest priority for coverage. Physicians, as traditional gatekeepers, would be entrusted, accordingly, with judging that value based on not only patient preferences, but the efficacy of scientific evidence.\textsuperscript{21}
A variant of this rational rationing approach was put in place in Oregon in the late 1980s. A state-wide rationing plan was designed as such to allocate scarce medical resources to treatments and establish policies which were seen as the most effective in terms of the quality and quantity of continued human life. Although relied upon, initially, by Oregon in determining what treatments to be covered by Medicaid, QALYs were subsequently abolished.

As will be seen in Chapter 2, QALYs are regarded by some as not only unjust and inevitably discriminatory—especially when applied to comparing the old with the young—but unfair because they force a decision to be made that one person’s better life, with medical care, is valued over a poorer life. Perhaps, in very large measure, this inequity explains why QALYs are regarded presently as primarily an academic tool—with marginal use being made of them by U.S. governmental bodies, except the Food and Drug Administration in its rulemaking. QALYs are used generally in cost-effectiveness studies, by physicians, hospitals, HMOs, insurers, health economists, scholars in public health and others undertaking research in health care economics. In cost-effectiveness studies, the health and the non-health impacts of differing choices affecting health are charted. In this regard, QALYs are beginning to compete with other metrics, such as the VSLY or value of statistical life year, for measuring health and longevity as a tool for monetizing mortality.

While dollars are used to measure non-health impacts, health impacts are measured by use of a nonmonetary scale—either a disease-specific scale, in cases where the health effects of the particular choices are confined to a single disease or, alternatively, a QALY scale. In order to determine which choice should be selected, cost-effectiveness ratios are then used. “Alternatively, the choice which maximizes health given a fixed budget for non-health costs is selected.”

THE AMERICAN IDEAL

There is a strong, lingering sense that the new powers of medical technology may narrow if not blunt the very meaning of the American ideal which promotes the right to live in a free society and to pursue happiness. The fundamental concern, then, becomes what degree of usefulness there is in pursuing goals beyond therapy towards genetic enhancement. Are there, in other words, limits to the right of scientific investigation? And, if there are, what are they? Finally, is there a standard of “genetic responsibility” which should be either self-imposed or set by society upon those working in the field—this, even though such a responsibility may very well
be viewed as an unnecessary burden on the freedom of scientific inquiry? These issues will be analysed in Chapters 2 and 3.

Medical technology is so uniquely powerful that its impact is felt not only in daily life but in the way life is viewed. For example, the technology of mechanical ventilators, combined with heart transplantation, brought a societal re-examination of how death should be defined and led to the conclusion that the death of the entire brain is equivalent to, for all purposes, death of the whole person. This new definition, in turn, allowed the “harvesting” of hearts and other vital organs from individuals who—although dead under a brain death criterion—continued to have both circulation and respiration maintained artificially by medical ventilation.36

While Americans might decide to limit “halfway” or exotic, science-fiction inspired technologies, such as artificial hearts or brain transfers into robot bodies, it would appear unlikely they would ever approve limitations on medical research whose focus is to discover technologies, drugs and scientific techniques which not only maintain qualitative existence but extend life.37 The reason for this position is simple and direct: “there is no coherent argument for arbitrarily ending a life that could be prolonged with reasonable quality at a reasonable price.”38

Since the end of the twentieth century, the public has been almost overwhelmed with scientific information regarding the genome and the complexities of gene therapy and stem cell research.39 Yet to come will be efforts to grow certain tissues for grafting—including skin, bladder and cartilage. Reportedly, cultured cells have been used successfully in an experimental setting to treat stroke victims; and in 2006 it was reported that seven children and teenagers had new implanted bladders grown from their own muscle and bladder cells.40

It is expected that the use of similar cells can be used to treat other disabling brain diseases. Genomics-derived drugs hold the potential to expand greatly the range of treatments achievable with human cells—this, because of their ability to control the cells as they grow and specialize.41 Even more opportunities for regenerative medicine will be charted when the insights from the clonal experiment with Dolly the sheep are realized first with a re-set of the genetic clock inside a cell and, subsequently, without the need for egg cells.42

SCIENCE AND POLITICS

The issues of science become, inevitably, political issues because of one fact: namely, they raise to the surface the extent to which the government can restrict private medical research undertakings—in the name of either
(generational) safety, morality (for example, non-coital reproduction) or the public good (for example, stem cell research).

As will be analysed in Chapter 3, a significant part of contemporary bioethics, under which the complex ethical, philosophical, socio-legal and medical issues of the new medicine are presented, is seen by some as “biopolitic” in that it has become “embryocentric”\textsuperscript{43}—this, because of limitations on federal funding for human embryonic stem cell research.\textsuperscript{44} These critics advocate a vision of global bioethics tied, inextricably, to fundamental principles of human rights. They would, in turn, tackle issues from a less restrictive present national “political agenda” designed to limit embryonic research to pre-existing stem cell lines and instead, for example, advance liberal health care for the present millions of uninsured Americans and one which thereby works to achieve respect and human dignity for all people, not just embryos.\textsuperscript{45}

In January 2007 the director of the National Institutes of Health charged with implementation of President Bush’s restrictive embryonic stem cell research policy suggested that this program is impeding medical research designed to seek medical cures for a variety of diseases. Indeed, the prohibition of research on newly derived stem cell colonies is precluding scientists from pursuing research to the fullest extent that could and should be done.\textsuperscript{46}

If the successful process of coaxing ordinary mouse skin cells to become what are essentially embryonic stem cells without first creating and then destroying embryos is replicated with human cells—as is expected over time—the current embryonic debate would be recast. This scientific achievement would mean that an individual’s own skin cells could be converted directly into stem cells without having to either collect healthy human eggs or destroy human embryos.\textsuperscript{47}

Another approach to stem cell research science designed to avoid the ethical pitfalls of human embryo experimentation was brought forward in 2007 by Dr. Donald Landry of Columbia University. Under this proposal, stem cells would be extracted from “dead” frozen embryos left over from other laboratory procedures and not viable for implantation rather than live ones.\textsuperscript{48} Instead of being disposed of, these moribund embryos could serve a useful scientific purpose. For Dr. Landry, a Catholic, an embryo is considered to be “dead” in those cases where “most of its cells have naturally and irreversibly stopped dividing.”\textsuperscript{49}

Legislative approaches in Congress—in both the House and the Senate—continue to be brought forward, all designed as such to loosen present restrictions on embryonic stem cell research\textsuperscript{50} with one in fact incorporating the Landry proposal.\textsuperscript{51} Indeed, in an attempt to accommodate those who wish to promote more stem cell research and—at the same time—
those who object to research of this nature which would harm embryos, in June 2007, President Bush issued Executive Order 13435 requiring the Department of Health and Human Services to develop guidelines for funding alternative approaches to embryonic research. This White House initiative is an effort to blunt criticism of his veto of proposed legislation which would have loosened present restrictions on the federal funding of such research.

Even with this conciliatory movement by the White House to expand research opportunities for creating new methods for creating embryonic stem cells without having to destroy human embryos, such action may be impeded by the federal policy of 2001 which forbids federal funds from being used to study embryonic stem cells created after 9 August 2001.

While prospective changes in NIH funding of stem cell research may ease, eventually, research concerns, yet another hurdle to wider rights of experimentation looms: namely, the degree of harm which may come to embryos from such laboratory procedures.

While some new technologies promise not to destroy embryos for necessary investigations, there is a real concern, for some, that they will come under congressional scrutiny and—indeed—run afoul of legislative restraints imposed on studies which cause “harm” to human embryos.

One new scientific approach, pioneered by a corporation in Worcester, Massachusetts, Advanced Cell Technology, is drawing particular attention. Under this method of investigation, stem cells are obtained from human embryos while leaving the actual host embryos functionally intact. Termed “blastomere biopsies,” a single cell, or blastomere, is first removed from an eight-cell human embryo and coaxed, subsequently, to multiply into a colony of stem cells in a petri dish.

The crux of the ethical issue here is whether this type of research subjects an embryo to more than an acceptable level of minimal risk and—if so—whether federal monies can be expended for the research. If such a level of research will benefit the embryo in question, greater risk is allowed. But, if the test embryo is subjected to more than “minimal risk,” then some argue no federal monies may be used for experiments of this nature. In the final analysis, perhaps the degree of harm to embryos utilized in this scientific research is truly in “the eye of the beholder” and, as such, subject to “interpretative discretion.”

In a very real sense, the scope of the new medicine is tied—inextricably—to issues of fecundity and immortality. In turn, these areas impact dramatically on the bulwark of American society—the family—and what many consider to be its glue: namely, religion. The promises of biomedical research are tantalizing in their anticipated translation into clinical applications which forestall death as well as alleviate pain and prevent disability.
Indeed, termed “translational, or bench to bedside medicine,” this research could serve easily as a foundation for enhancing a wide variety of human traits which would validate what could well be seen as a return to positive eugenics. While some perceive this eugenic drift as morphing, rather insidiously, into the field of genetics and, thus, becoming a “new genetics” as it promotes a move toward a program of social engineering, others see this research as both innovative and humane, designed as such to minimize human suffering and promote better genetic health.

A bold step taken recently by the American College of Obstetricians and Gynecologists could well be viewed as an effort to advance eugenics—this, as a consequence of its decisions to offer screening for Down syndrome to all pregnant women regardless of age. Previously, screening for this chromosome abnormality was recommended only for women 35 years or older. But, given the fact women are having babies later in life—with an astonishing 4.1 million babies being born to women ages 30 to 54 in 2005—perhaps the more enlightened view is to regard this policy as quite sound for improving genetic health. Indeed, coupled with the fact that more women are choosing to remain single during and after pregnancy, such a policy is both wise and judicious.

Social demographics show conclusively that, since the 1950s, more and more women are becoming less dependent upon men or the institution of marriage. For some, surrogate motherhood and artificial insemination present attractive alternatives. Assisted reproductive technologies offer countless opportunities for creativity in designing babies. In the final analysis, “whatever turns out to be possible, will be wanted.”

Chapter 3 analyses at two levels the costs and the opportunities to the social, legal, ethical and medical communities within contemporary society of pursuing the development and the use of the new medicine. The second level of analysis tests, more specifically, the extent to which the freedom of scientific inquiry and investigation and the countervailing right of privacy both advance and confound the mandate of the new medicine to improve, through genetic diagnostics, the overall genetic health of society. More and more, the great promise of do-it-yourself genetic tests will become popularized—thereby allowing individuals to be apprised of the risks of coming down with disease before the actual syndromes are manifested. Already, preimplantation genetic diagnosis (PGD)—designed to allow couples to test embryos that have been created in vitro when they are roughly three days old for serious genetic disease (for example, Down syndrome, Tay Sachs)—is seen by some as a potential means to expand a program to advance positive eugenics. As such, PGD could be used to test for milder risks or predispositions and then screen them out altogether from the reproductive cycle.
The study of the epigenome—or, the suite of biochemical or molecular sequences and signals that determine which genes in an individual’s DNA can be turned on or off—holds the awesome power to re-write, if and when mastered through clinical applications in epigenetics, the rules of disease, heredity and even identity. This new science is illustrative of both the opportunity and the peril of scientific research which, in turn, advances change and forces revisionism. So significant is this field of research that researchers in Japan, Europe and the United States have begun pilot studies designed to assess the difficulty of undertaking a human epigenome project designed, as such, to map man’s entire epigenome. The challenge here is that each individual does not have but one epigenome, but rather a multitude of them.

Information transfers across generations are inherited from one’s parents in the form of DNA. The chromosomes inherited from parents account, however, for only 50 percent of the DNA. The other 50 percent is composed of protein molecules—with these proteins carrying, in turn, the epigenetic marks and information. Research is showing that adaptive responses are neither innate nor passively emerging from the genome. Rather, they are “molded by the environment.”

The impact on public health responses to present and future generations of epigenetic research on the current epidemic of obesity is illustrative of the magnitude and far-reaching significance of this research. Some scientists have speculated whether the obesity epidemic, blamed commonly “on the excesses of the current generation, may partially reflect life-styles adopted by our forebears two or more generations back.” Continued study of epigenetics will impact dramatically on how contemporary society understands history, sociology, political science, sociobiology and, as seen, public health. For, if the environment is shown to have a decisive role in changing one’s genome, the great gap between social processes and biological processes will have been bridged. This, in turn, will change demonstrably the frame of reference used for explaining all human and social responses.

Cloning, designer pathogens, in vitro fertilization and other forms of assisted reproduction, organ transplantation and face and womb transplants, cryogenic preservation pre or post mortem, genetic enhancement through eugenic experimentation, stem cell research and even genetically modified genes and foods designed, as such, to enrich and prolong a life resistant to disease, shape the parameters of what is known today as the “new” medicine. In September 2007 a ruling by the British Human Fertilization and Embryo Authority heralded what is expected to be the subsequent creation of part human, part animal embryos—or chimeras—for use in medical experimentation. This scientific advancement has
raised considerable concern and fear that some hybrid embryos could well be transferred to wombs of women where they might well develop. Present British regulations require all “human” embryos used in research to be destroyed within fourteen days after their creation. The conditions under which human experimentation can be pursued in order to advance these and other creative and ambitious undertakings will be discussed in Chapter 4.

The micro and macro issues raised with human organ transplantation are examined in Chapter 5 and presented as a paradigmatic case study of a contemporary issue of distributive justice set within the boundaries of the new medical science. From this analysis, it will be seen that normative standards or principles of just distribution for those needing either organ or tissue transplants should strive to achieve equity rather than equality.

Medical judgments regarding the efficacy of organ allocation should remain paramount. Yet, oftentimes compromises to this principle are made when the urgently ill are given priority of access—this, because presently there are no incentives which encourage patients who are least likely to derive any significant benefits from a transplant from being triaged out of any procurement program. Even though policy agreements are advanced for keeping organs close to their source of origin—since it is believed prospective donors are more likely to donate organs when they are used by a person in need from a local social unit—prevailing sentiment remains that allowing organs to be kept within a local or regional area for transplantation is yet another compromise to medical efficacy. Well-intentioned differentiation in listing, prioritizing or allocation of organs nonetheless invariably raises socio-ethical issues, for these actions are subject to claims that non-medical judgments about patient differences are being made which, in turn, give rise to blatant or relative judgments about recipient worthiness.

In the final analysis, what should be sought is an organ distribution policy which follows principles that are capable of endorsement by reasonable people—one that seeks to balance competing micro and macro economic policies of distribution for scarce resources yet, essentially, a policy that promotes to the greatest number of disadvantaged citizens “the increased likelihood of receiving an organ or having a successful transplant.”

PARTICIPATORY DEMOCRACY

Noble though the sentiment may be that “active liberty refers to a sharing of a nation’s sovereign authority among its people,” and is tied—
of necessity—to connecting frameworks grounded in responsibility, particip-
ination and capacity, the hard reality is that ordinary individuals have
little interest in considering complex policy issues and—indeed—have little
aptitude for evaluating complex intellectual matters—and especially those
involving medical science. Consequently, it is unrealistic to expect either
sound and thoughtful ideas or sensible and understandable policies to
be shaped in public discourses under present conditions of “intellectual
disorder.” Because of this state, the scientific community is reluctant—
understandably—to accept public oversight and direct participation in reg-
ulating the parameters of the new biotechnology and its offspring, the new
medicine. It is well to remember that, even though science promises an
unpredictable future, futures are inevitably unpredictable. Accordingly, it
is well to understand that “doing nothing has just as many consequences as
doing something.”

Such a state of affairs means that there can be no direct way to move from
any level of moral assessment to a clear public policy. Instead, all that can
be hoped for is a level of information to be provided. Quite often, then,
owing to a failure to develop adequately the moral dimensions of formu-
lating public policy in a liberal pluralistic society, presumptions in favor of
reproductive autonomy and scientific freedom, for example, are indulged
and, indeed, advanced.

Driven by “painful technologies and sciences,” the new medicine runs the
risk of being seen as no longer “patient based.” The ideal of philosop-
ical reasoning and meanings for such ethical terms as responsibility, rights,
duties, interests, beneficence and justice is mired often in confusion and
conjecture. Indeed, many of the new ethical questions raised from the
development and practice of the new medicine are set within a “blurred
outline.” Perhaps all that can be hoped for is that the Cartesian aspira-
tion of reaching a “clear and distinct idea” be pursued with objectivity.
And from this may well come acceptance of a societal obligation not to
achieve all the good that can be achieved, but—rather—to effect all the good
that can be done within the limits morality imposes upon the development
and use of the technologies of the new medicine.

Although, traditionally, the ethics of medicine has focused on the obliga-
tions of physicians to their individual patients, there is—as well—a need
to appreciate broader ethical issues arising from a recognition that
medicine “is always practiced within a social context.” “Social medicine”
or, alternatively, “the medicine of society” becomes crucial to shaping the
parameters of application and use in the age of the new medicine.

Distinct from clinical medicine, which is directed toward healing and
relieving human suffering among individual patients, the medicine of
society is concerned with the use of medical knowledge to advance the
health of society. Yet, while these two fields of medicine have differing ends, they enjoy a symbiotic relationship—this, because “the end of each is essential for human well-being.” Advancing and pursuing health care, then, is an obligation that “a good society owes its citizens in justice.” A balanced moral relationship between the goals of the individual patient and the common good must always be sought. So long as this ethic and point of equilibrium guides the development and use of the new medicine, the moral compass is set correctly and humanely. Applying this ethic is always problematic, however, because “fiscal scarcity” drives the new medical economics and forces a “general tightening of health care ethics as government and business attempt to gain control over their skyrocketing expenditures.”

NOTES

4. Ibid., pp. 38, 40.
6. Ibid.
7. Ibid., p. 62.
8. Ibid., p. 54.
9. Ibid.
10. Ibid.
11. Ibid. Utilitarian logic does not discount the life of the individual. Rather, it balances the interest of one individual against the interests of other individuals. G. Winslow (1982), Triage and Justice, p. 83 (relying on the ideas of Joseph Fletcher). See generally J. Rawls (1972), A Theory of Justice. It has been argued that explicit quantifiable utilitarian principles, together with decision analysis, should be applied by bioethicists in reaching ethical judgments. See J. Baron (2006), Against Bioethics.
13. Häyry, “Utilitarian Approaches,” p. 54. Interestingly, today, economists are measuring utility as Bentham conceived it: as a quantum of pleasure or pain; and—led by Nobelist Dr. Daniel Kahneman—they ask people about their fallible memories of pleasure and pain and, in this regard, depart from Bentham’s thesis that the sovereign masters of the actions of all people are pleasure and pain. See “Economics discovers its feelings,” Economist, 23 Dec. 2006, p. 33.
15. Ibid., p. 56.
16. Ibid., p. 55.
18. Ibid. See also Häyry, “Utilitarian Approaches,” p. 55.
20. Ibid.
21. Ibid.
24. Ibid., pp. 4, 83.
25. Ibid., pp. 1, 2.
28. Ibid.


44. See note 43.


49. Ibid.


51. Naik, “The devout doctor’s prescription.” Senator Norm Coleman’s bill incorporates the Landry proposal. Senator Harry Reid has sponsored a rival bill entitled the Stem
Cell Research Enhancement Act which would allow government funds to be used for stem cell research derived from lines taken from viable embryos which fertility clinics would have discarded. Ibid.


53. See note 52.


55. Ibid.


57. See note 54.

58. Ibid.

59. Ibid. (quoting Prof. R. Alta Charo, University of Wisconsin).


66. Ibid.

67. See for example E. Black (2003), *War against the Weak: Eugenics and America’s Campaign to Create a Master Race*, chs. 20, 21.


72. Roberts, “51 percent of women.”

73. Mattes, *Single Mothers by Choice*.


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79. Ibid., p. 35.
80. Ibid., p. 36.
81. Ibid.
82. Ibid.
83. Ibid., p. 76.
84. Ibid.
85. Ibid.
89. Ibid.
92. Ibid.
93. Ibid., p. 351. *Triage*, of course, is designed to but screen patients—normally into three groups—in order to determine their priority of treatment: those not expected to survive even with treatment; those who will recover without treatment; and the priority group—or those needing treatment in order to survive. G. P. Smith II (1985), “Triage: endgame realities,” *Journal of Contemporary Health Law and Policy*, 1, p. 143.
95. Ibid., p. 350.
97. S. Breyer (2005), *Active Liberty*, p. 15.
98. Ibid., p. 16.
101. See R. A. Posner (2003), *Law, Pragmatism and Democracy*, p. 107. This situation is more understandable when it is realized that half of the U.S. population has an IQ


107. See note 106. See also R.C. Coile, Jr. (1990), *The New Medicine: Reshaping Medical Practice and Health Care Management*.


113. Ibid.


