Policy Making and the New Medicine: Managing a Magnificent Obsession

George P. Smith, II*

I. Setting Parameters?

On November 20, 2007, independent teams of researchers in Wisconsin and Japan announced the achievement of a scientific advancement which, over time, may well force a conclusion of the long standing debate on whether embryonic stem cell research is "appropriate" morally.1 Specifically, these scientists created human embryonic stem cells from human skin cells, without destroying any human embryos.2 The hope is that, in due course, these new cells could yield eventually the very same medical promise as embryonic stem cells being developed, as such, to treat heart disease, diabetes, and Parkinson's, and also to create heart and nerve tissue.3

When this technique was presented for discussion at a meeting sponsored by the Vatican, a spokesman stated that there was "no moral problem with it at all.4 The chief domestic policy adviser to President George W. Bush observed that this new scientific achievement held the promise of allowing medical progress without

* Professor of Law, The Catholic University of America, Washington, DC; B.S., J.D., Indiana University; LL.M. Columbia University; LL.D., Indiana University.


2 Id.


compromising moral standards. Indeed, this new laboratory success shows "science has overtaken politics" and that real progress can be achieved without having "a culture war."

Others in the scientific community are quick to remind that this level of medical research, while indeed promising, could take many years before it could be used clinically and applied to humans. Accordingly, they urge a continuation of research and experimentation in all other "traditional" areas of stem cell research. And, this continuation means that the ethical and moral issues surrounding legal status of embryos remain in play.

Earlier in November 2007, another new stem cell research achievement was recorded when a group of Oregon scientists announced that they have not only created, but harvested, stem cells from fully formed monkey embryos. As such, this success becomes a world-wide "first." Created from a skin cell from a single monkey, this research validates what has heretofore been subject to wide speculation: namely, whether primates are capable of being cloned biologically. The scientists undertaking this research did not transfer the embryos which were created to the wombs of female monkeys with the purpose of growing them into full-blown clones as has been done with other species (e.g., mice). Rather, the Oregon experiment merely retrieved, successfully, embryonic stem cells from the embryos.

Although this research was limited, specifically, to the development of stem cells, concerns have been raised that this cloning technique could be applied to humans. Indeed, this scientific achievement could well re-ignite the on-going congressional debate over the extent to which restrictions on the cloning of human embryos should be either loosened further or tightened. While no legal restrictions have been imposed for private work here, federally funded scientists are prohibited from engaging in research of this nature.

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6 Id.
7 Id. See generally Thomas B. Okarma, Human Primordial Stem Cells, 29 HASTINGS CTM. RPT. 30 (1999) (discussing the debate surrounding the use of human stem cells).
9 Id.
10 Id.
11 Id. (reporting on the concern of Rev. Thomas Berg, Executive Director, The Westchester Institute).
This scientific achievement in Oregon must be added to other equally path breaking ones which seek to perfect human cloning, develop more fully in vitro fertilization and other forms of assisted reproduction, and to perfect organ transplantation, face and womb transplants, cryogenic preservation pre or post mortem, genetic enhancement through eugenic experimentation, and genetically modified genes and foods designed, as such, to enrich and prolong a life resistant to disease. Additionally, a new dimension was added to what has been become known as the “New Medicine” when, in September 2007, the British Human Fertilization and Embryo Authority ruled that it was proper for part-human-part-animal embryos, termed chimeras, to be developed and used in medical experimentation. This particular scientific option is a source of considerable concern for some because it is feared that some hybrid embryos could be transferred, illegitimately, to wombs of

23 Rick Weiss, Britain to Allow Creation of Hybrid Embryos, WASH. POST, Sept. 6, 2007, at A11.
women where they might well develop. Present British regulations required all “human” embryos used in research to be destroyed within fourteen days after their creation.

A significant part of contemporary bioethics, under which the complex ethical, philosophical, socio-legal and medical issues of the New Medicine are presented, has been seen as being “biopolitic” in that it has become “embryocentric”—this, because of limitations on federal funding for human embryonic stem cell research. Rather than develop policy that is viewed as part of a national “political agenda” designed to limit embryonic research to pre-existing stem cell lines, it is argued that policies should be developed and pursued which seek to advance liberal care for the present millions of uninsured Americans and one which thereby work to achieve respect and dignity for all people—not just embryos.

Regrettably, scientific issues become—inevitably—political issues because of one principle fact: they put in focus the extent to which the government can restrict private medical research undertakings—either in the name of generational safety, morality or the public good. The multiple and varied concerns of applying the New Medicine, derived as such from the New Biology, conduce—essentially—to a suspicion “continued reductionism in the biological analysis of humans will erode the notions of autonomy, dignity and personal integrity that have traditionally justified the constitutional protection of civil liberties.”

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24 Id.
25 Id.
27 Id.
II. The American Ideal

There is a strong, lingering sense—if indeed nothing less than a magnificent obsession—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.\(^{32}\) The fundamental concern, then, becomes to what degree of usefulness is there in pursuing goals beyond therapy towards genetic enhancement.\(^{33}\) Are there, in other words, limits to the right of scientific investigation?\(^{34}\) And, if there are, what are they?\(^{35}\) Finally, is there a standard of “genetic responsibility”\(^ {36}\) that 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?\(^ {37}\)

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 criteria—continued to have both circulation and

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\(^{32}\) President’s Council on Bioethics, Beyond Therapy: Biotechnology and the Pursuit of Happiness xviii (2003).

\(^{33}\) Id. at 277. It has been suggested that genetic enhancement should not be viewed as part of basic health care entitlements and, thus, should be excluded from the domain of distributive justice. \(\text{Id.}\) Allen Buchanan, et al., From Chance to Choice: Genetics & Justice, 17, 129 (Cambridge University Press 2000); see Leon Kass, The Pursuit of Biohappiness, WASH. POST, Oct. 16, 2003, at A25; \(\text{see also}\) George P. Smith, II & Thaddeus J. Burns, Genetic Determinism or Genetic Discrimination, 11 J. Contemp. Health L. & Pol’y 23, 30-31 (1994).


\(^{35}\) Id; \(\text{see also}\) George P. Smith, II, The Province and Function of Law, Science, and Medicine: Leeways of Choice and Patterns of Discourse, 10 U. New So. Wales L. J. 103 (1987). \(\text{But see}\) AP, Rules Are Clarified to Spur Medical Advances, N.Y. Times, Jan. 31, 2003, at A23 (reporting on how the Food and Drug Administration has clarified, and some claim relaxed, its requirements for approval of research on new products).


respiration maintained artificially by medical ventilation.\textsuperscript{38}

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 that not only maintain qualitative existence but extend life.\textsuperscript{39} 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."\textsuperscript{40}

Since the end of this century, the public has been almost overwhelmed with scientific information regarding the genome, the complexities of gene therapy and stem cell research.\textsuperscript{41} 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.\textsuperscript{42}

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.43 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.44

Essentially, all efforts to achieve justice in the distribution of health care resources of the New Medicine are utilitarian in character and definition.45 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.46

For utilitarians, the general good is seen as superior to personal goal satisfaction.47 Because of the difficulty in calculating the net good deriving from a utilitarian approach to decision making,48 some have argued that this approach to health care decision making is not only unjust but unfair.49 Not only is utilitarianism viewed as

43 William A. Haseltine, Genomics: The Path Ahead for Science, Medicine and Society, 19(1) BROOKINGS REV. 23 (2001). See also Caplan & Magnus, New Life Forms: New Threats, New Possibilities, 33 HASTINGS CTR. RPT. 7 (2003); Commoner, Unraveling the DNA Myth: The Spurious Foundation of Genetic Engineering, HARPER'S MAG., at 39, 47 (Feb. 2002) (cautioning that the potential consequences of transferring a DNA gene between species before the consequences of its release are fully understood is problematic); Rich Weiss, Synthetic DNA on the Brink of Yielding New Life Forms, WASH. POST, Dec. 17, 2007, at A1 (detailing the scientific progress in handcrafting a chromosome which, in turn, contains the basic instructions for a microbe to live and reproduce, and the plans to transplant it, subsequently, into a cell which will have the ultimate effect of rewriting the genetic codes for developing new medicine, fuels and novel chemicals, and, ultimately, hold the potential for mischief, as well).


46 Id.

47 See id. at 53, 62.

48 See id. at 54.

49 See Häyry, supra note 45, at 54.
cold and calculating, but it is seen as denying the individual of what is his due. The needs of those who are worse off are either ignored or neglected.

III. Participatory Democracy

It is a noble sentiment that “active liberty refers to a sharing of a nation’s sovereign authority among its people,” and is tied—out of necessity—to connecting frameworks grounded in responsibility, participation and capacity. The hard reality is that ordinary individuals have little interest in considering complex policy issues and have little aptitude for evaluating complex intellectual matters, 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 understandably reluctant to accept public oversight and direct participation in regulating the parameters of the new biotechnology and its offspring, the new medicine. It is important to remember that even though “[s]cience 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.”

50 Häyry, supra note 45, at 54.
51 Häyry, supra note 45, at 54. Utilitarian logic does not discount the life of the individual, but instead balances the interest of one individual against the interests of other individuals. GERALD R. WINSLOW, TRIAGE AND JUSTICE 83 (University of California Press 1982) (relying on ideas of Joseph Fletcher). It has been argued that explicit quantifiable utilitarian principles, together with decision analysis, should be applied by bioethicists in reaching ethical judgments. See JONATHAN BARON, AGAINST BIOETHICS 5 (Basic Bioethics Series, MIT Press 2006).
53 Id. at 16.
54 See RICHARD A. POSNER, LAW, PRAGMATISM, AND DEMOCRACY 107 (Harvard University Press 2003).
55 See William J. Broad & James Glanz, Does Science Matter?, N.Y. TIMES, Nov. 11, 2003, at F1 (commenting on inability of most Americans to endorse scientific rationality).
56 POSNER, supra note 54, at 107. This situation is more understandable when it is realized that half of the U.S. population has an IQ below 100. Id; see RICHARD J. HERRNSTEIN & CHARLES MURRAY, THE BELL CURVE: INTELLIGENCE AND CLASS STRUCTURE IN AMERICAN LIFE 276 (Free Press 1994); see also HERRNSTEIN & MURRAY, supra, at 29-91, 269-369.
59 FRANCIS MACDONALD CORNFORD, MICRO COS MOS M O G R A P H I A ACADEMIA 9 (Bowes & Bowes
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 expected is that a level of information will be provided. Quite often then, owing to a failure to develop adequately the moral dimensions of formulating public policy in a liberal pluralistic society, presumptions in favor of reproductive autonomy and scientific freedom, for example, are indulged and, indeed, advanced.\textsuperscript{60}

Driven by “painful technologies and sciences,” the new medicine runs the risk of being seen as no longer “patient based.”\textsuperscript{61} The ideal of philosophical reasoning and meanings for such ethical terms as responsibility, rights, duties, interests, beneficence and justice is mired often in confusion and conjecture.\textsuperscript{62} Indeed, many of the new ethical questions raised from the development and practice of the new medicine are set within a “blurred outline.”\textsuperscript{63} Perhaps all that can be hoped for is that the Cartesian aspiration of reaching a “clear and distinct idea” be pursued with objectivity.\textsuperscript{64} 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.\textsuperscript{65}

Although, traditionally, the ethics of medicine has focused on the obligations 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.”\textsuperscript{66} “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.

\begin{footnotesize}
\begin{enumerate}
\item Id. See also Russell C. Coile, Jr., \textit{The New Medicine: Reshaping Medical Practice and Health Care Management} (1990).
\item Jonsen, \textit{supra} note 22 at 1.
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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.”

67 Pellegrino & Thomasma, supra note 66 at 18.
68 Id.