Dealing With Dolly: Inside The National Bioethics Advisory Commission

Under politically charged circumstances, the commission has done its best to address cutting-edge ethical issues such as cloning.

by Franklin G. Miller, Arthur L. Caplan, and John C. Fletcher

In June 1997, seven months after its first meeting, the National Bioethics Advisory Commission (NBAC) showed the value of having a forum for public bioethics in its response to the controversy over cloning. The NBAC’s report, Cloning Human Beings, is a sober and balanced response to what had quickly become a sensationalized and emotionally charged issue as the press, some scientists, and pundits speculated about everything from the wisdom of creating armies of clones to fight in future wars to creating cloned humans as sources of organs, tissues, and other biologically valuable substances.

The NBAC report is far from perfect. It is deficient particularly with respect to its ethical analysis of the pros and cons of human and animal cloning. But this report is as much as, or more than, anyone could reasonably have expected from a new commission faced with an unanticipated bioethical crisis. And it contributed in an important way to quieting the public’s concern about cloning run amok. It is important to understand the value of a public forum for bioethical reflection and to see how further advances might be made in using such a forum to encourage serious ethical reflection in a pluralistic democracy.

The Commission’s History

The NBAC was created by President Bill Clinton’s executive order of 5 October 1995, and its members were appointed in July 1996. The commission consists of eighteen distinguished bioethics scholars, attorneys, health administrators, biomedical scientists, and lay members; it is chaired by Harold T. Shapiro, president of Princeton University. It held its first public meeting in October 1996. According to its charter, the NBAC is charged with making recommendations on “bioethical issues arising from research on human biology and behavior, and the applications, including the clinical applications, of that research.” The charter also specifies as priority issues the protection of human subjects of research and the use of genetic information.

The life of the NBAC was extended to October 1999, longer than its initial two-year term. The commission got off to a very slow start. Located deep in the bureaucracy of the executive branch, it had no staff, no executive director, and a minimal budget for research and data collection.

Dolly changed all that. On 23 February 1997 the media trumpeted the news that a Scottish research team had successfully cloned a sheep, named Dolly, using a somatic cell from the mammary gland of an adult sheep transferred to an egg whose nucleus had been removed. The resulting embryo was implanted in the uterus of another adult sheep, and Dolly was born.

The news sparked a storm of public debate, concern, and uncertainty, combining fascination with the novelty of this scientific

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feat with repulsion over its implications for the cloning of human beings. The next day, in response to a firestorm of public interest and concern, President Clinton requested that the NBAC “undertake a thorough review of the legal and ethical issues associated with the use of this [cloning] technology” and issue within ninety days a report containing recommendations about what to do about human cloning. Shortly thereafter, the president imposed a ban on federal funding for human cloning experiments.

The Political Context

In assessing the merits of the NBAC’s first report, issued 9 June 1997, one must bear in mind the political context. Public reaction to the prospect of human cloning was overwhelmingly negative, and the NBAC began its deliberations in the wake of the president’s ban on federal funding for human cloning experiments and decisions by other nations, such as Great Britain and Germany, to prohibit human cloning. There were numerous bills in state legislatures and a number of proposals in Congress to ban human cloning. Another key historical influence shaping the NBAC’s response was the acrimonious public debate over the use of human embryos in research. A special National Institutes of Health (NIH) advisory panel appointed by NIH Director Harold Varmus in 1994 had recommended circumscribed federal support for such research, including the special creation of embryos for research. The embryo panel was explicitly and deliberately overruled by President Clinton, who imposed a ban on research on human embryos, so Varmus never responded to the panel’s recommendations. It is safe to assume that the NBAC’s members were keenly aware of what had become of recommendations from the embryo research panel, since there was some overlap in the membership of the two groups. These antecedent events as well as the threat of very restrictive legislation prompted the NBAC to take a cautious approach.

Emphasizing concern for potential harms to a human fetus and future child produced by “somatic cell nuclear transfer cloning,” the NBAC recommended continuation of the moratorium on federal funding for such experimentation and voluntary compliance by private organizations not receiving federal funds. In addition, the NBAC recommended that Congress prohibit anyone in the United States from creating a child by means of somatic cell nuclear transfer. However, the commission wisely qualified this by strongly urging a sunset clause that would require reconsideration of the prohibition in three to five years, preferably with the advice of a commission.

It is politically inconceivable that the NBAC would have recommended experimental trials of human cloning. To do so would have been ethically irresponsible, if for no reason other than the scientific uncertainties and safety risks that cloning now poses to human beings made in this manner. Lacking a compelling reason to clone a human being, it would be *prima facie* wrong to conduct an experiment simply to see if a healthy person could be made in this fashion. Within the significant constraints of time and political pressure, the NBAC produced an intelligent and prudent 110-page report, with the potential to contribute to public education.

Falling Short On Complex Questions

The report bought valuable time for reflection and debate. Yet, despite its political value, the report’s central chapters on religious perspectives and ethical considerations are intellectually unsatisfying. The rationale for considering explicitly religious perspectives, in a political system governed by a core commitment to the separation of church and state and marked by pervasive pluralism, receives scant attention in the report. It fails to clarify why or how religious views and voices could or should shape public policy with respect to cloning. Nor is it clear how certain religious views were selected for consideration while others were ignored, nor why they should or should not be given equal weight.

The chapters on religious views and ethical
considerations mechanically array competing perspectives on the appropriateness of human cloning, which appear to cancel each other out. This eclectic approach has the effect of leaving the issue of safety to carry the full weight of moral consensus. However, if continued animal experimentation greatly diminishes these safety concerns, as there is every reason to expect that it will, then other moral arguments for or against permitting human cloning will have to come to the fore in support of future public policy. An ethically satisfactory public policy will need to reach a reasonable position on such perplexing moral questions as whether it is right to attempt to create a human being asexually; whether, and for what reasons, it is legitimate to seek to clone a human being; and whether human cloning constitutes an element of procreative liberty.

Future Challenges

Despite the problems with the NBAC’s ethical analysis of cloning, the commission did yeoman’s service in addressing human cloning under very trying circumstances. The NBAC now faces the challenge of whether it can do better with respect to examining the other bioethical questions on its agenda.

The legacy of its predecessor national commissions—the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974–1978) and the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1978–1983)—sets a high standard. The former developed a framework for protecting the rights and welfare of human research subjects, which was incorporated into federal regulations governing review of research at institutions receiving federal funding. The latter issued highly influential consensus reports on a range of topics—most notably, the report on forgoing life-sustaining treatment. Its recommendations, some of which may still have merit, were never incorporated into federal regulations because of opposition from the community of psychiatric researchers. The absence of explicit regulatory attention to research subjects who have different forms of mental illness has grown in significance in view of rapidly expanding knowledge about the function of the human brain and its pathophysiology and about treatment of mental disorders. Moreover, concern about and confusion over the morality of conducting research on mentally impaired persons has been heightened by a number of recent scandals, such as those at the Medical College of Georgia and the University of California, Los Angeles, where subjects with mental illness allegedly have been mistreated by researchers.

For research involving patients with progressive dementia, such as Alzheimer’s disease, procedures for surrogate decision making are required. Whether patients with severe psychiatric disorders, such as schizophrenia and manic-depressive disorders are capable of giving informed consent for research remains unclear and contested. Of particular concern is the exacerbation of symptoms that occurs when psychiatric subjects are temporarily taken off medications—a common occurrence in psychiatric research—or placed in the pla-
cebo arm of controlled drug trials. Regulations need to address how reliable assessments of decision-making capacity are to be made and monitored and whether family members or other surrogates should be involved in decisions concerning research participation for these classes of patients. Assurance of both initial and ongoing informed consent is vital. Additional important questions are whether research that poses greater than “minimal risks” without the prospect of therapeutic benefit to the subjects (especially those whose decision-making abilities are impaired) should be permitted; and, if so, with what safeguards. In developing guidelines for research in this area, the NBAC must accommodate potentially competing considerations of protecting vulnerable subjects, respecting and promoting their autonomy, and permitting socially valuable research.

■ Updating the moral and regulatory structure. More broadly, the NBAC has an opportunity to assess the adequacy of the moral and regulatory structure for research on human subjects, which has evolved over the past thirty years, and the principles governing this framework, articulated in the national commission’s Belmont Report. It is time for a national body to ask whether the rapidly evolving world of human research, with its multicenter trials (including sites in countries with very different cultures), pressures for expanded access to clinical trials, more rapid introduction of new drugs into clinical practice, private sources of funding, and increasing interest in commercialization of knowledge, remains well served by a system of protection that was not intended to address these emerging features.

■ Universal access. The NBAC faces another opportunity as it struggles with questions regarding the privacy of genetic information and research on human subjects. The most significant bioethical problem facing our nation continues to be the lack of universal access to health care, a problem that is unique among developed nations. Although outside the NBAC’s purview of “bioethical issues arising from research on human biology and behavior,” the access problem greatly influences the commission’s agenda, including compensation for research-related injuries and discrimination arising from the use of genetic information developed in research and clinical practice. If all Americans had a secure source of adequate health care, these and other related problems would be greatly attenuated or nonexistent.

The commission must now show that when bioethics is addressed in public, a commission can do justice to ethics while wrestling with contentious political and ideological issues. Its work on cloning was a start. It remains to be seen if public bioethics in the United States can fulfill its promise.

NOTES
5. Office for Protection from Research Risks, Evaluation of Human Subject Protections in Schizophrenia Research Conducted by the University of California, Los Angeles (Washington: U.S. GPO, 1994.)