

Inside the Beltway Again

A Sheep of a Different Feather*

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ABSTRACT. The appearance of a sheep named Dolly, the first clone of an adult mammal, dramatically affected the agenda, pace of work, and visibility of the National Bioethics Advisory Commission. The Commission's approach to its task and some of the issues it considered in responding to President Clinton's request for review and recommendations within 90 days are described.

"Rapid" and "radical" are not the first words that come to mind when one thinks of governmental commissions, but a transformation that merits both these adjectives has taken place in the National Bioethics Advisory Commission (NBAC) in the past few months. Before the ink was even dry on my article analogizing NBAC to an egg that held a bird of unknown potential (Capron 1997), the Commission's agenda, visibility, and pace of work had been totally transformed. The change began on February 24, 1997, when President Clinton--responding to reports that day in the American media that scientists in Scotland had produced the first clone of an adult mammal--requested that NBAC:

undertake a thorough review of the legal and ethical issues associated with the use of this technology, and report back to me within ninety days with recommendations on possible

federal actions to prevent its abuse (William J. Clinton, letter to Harold Shapiro, Chair, NBAC, 24 February 1997).

To emphasize the seriousness of the issue, on March 4 the President followed up with a memorandum to the heads of executive departments and agencies. Recognizing that the announced advances in cloning technology "potentially represent enormous scientific breakthroughs that could offer benefits in such areas as medicine and agriculture," he emphasized again the "profound ethical issues" they raise, especially if extended to human beings. Therefore, the President directed that "no Federal funds shall be allocated for cloning of human beings" (Clinton 1997).

Coincidentally, NBAC's Human Subjects Subcommittee (HSSC) was meeting in Bethesda on February 24, so some of the commissioners were able informally to begin considering how the Commission should respond to the prospect of human cloning. Those first responses--like the views expressed in the press and at Congressional hearings over the subsequent several weeks--echoed what seems to be widespread public apprehension (even Harold Varmus, the head of the National Institutes of Health agreed with the view that human cloning was "offensive"). At the same time, the Commissioners cautioned that research using techniques labeled "cloning" is already important and promises to become even more valuable and productive in the near future. This is certainly a field where one has to be very circumspect

about what gets thrown out with the proverbial bath water.

NBAC's chair, Harold Shapiro, with help from other commissioners and staff members, quickly arranged for a number of witnesses to testify about cloning as part of an NBAC meeting already scheduled for March 13-14, as well as adding four meetings to allow quick preparation of a report. While it was agreed that the HSSC and the genetics subcommittee would continue with their work, the emphasis for all members and staff would be on fulfilling the president's 90-day assignment. Since the staff remains very small and still lacks a director, and since the only professional staff with expertise in bioethics are those working on federal agencies' compliance with human subjects regulations, arrangements were made to obtain the part-time services of Kathi Hanna, an experienced science and health policy writer in Washington. Reports were also commissioned from seven experts on science, philosophy, religion, law, and public policy, and additional inquiries were made (for example, to organizations in various scientific and clinical fields) to broaden the input available. Finally, in order to focus the flurry of memos, e-mail, and phone calls among commissioners, four "buckets" (science, ethics, law, and policy) were established--and then reduced to three by combining the latter two. Each bucket was assigned a leader and several other commissioners to develop, sort through, and organize relevant material and concepts. Like

the buckets themselves, however, the assignments were informal and all commissioners were welcome to attend any bucket meeting. The public, on the other hand, was not invited, as the buckets were treated not as official subcommittees (under the Federal Advisory Committees Act) but as ad hoc arrangements without any decision-making authority of their own.

TRYING TO DISTINGUISH LABORATORY STUDIES FROM MAKING BABIES

Having already been caught up by changing events, I will not attempt to predict exactly where NBAC will come out in its report on cloning, which should in any case be released by the time this piece appears. Certain things have emerged thus far, however, that seem likely to shape the Commission's final outcome. To begin, NBAC definitely will not pretend to have the last word on these issues. Even if it had been running at full speed, with several years of experience in deliberating together about bioethical issues, NBAC could not hope to have disposed of a topic as novel as human cloning in 90 days. The corollary is that the topic is genuinely controversial, unlike some issues in bioethics about which a general consensus either exists or can easily be generated based upon prior discussions, not only in academic circles, but also among the general public. Many of the issues in cloning are uncharted; and, to the extent that they do enter into mainstream bioethics, it is into the field's most

stormy waters--embryo research and reproduction generally. The winds that roil these waters blow from the poles, with scientific and reproductive freedom at one pole, and sanctity of life and traditional family values at the other.

Despite the difficulties of the topic, some agreement seemed quickly to emerge about the way NBAC should approach the subject. First, the report will address what has been termed "human cloning," that is, transfer of the genetic material from the nucleus of a somatic cell of an existing human being to a human egg from which the nucleus has been removed. It will not evaluate the merits of cloning other mammals or of creating "twins" by embryo-splitting. The report also will distinguish human cloning from the creation of "clones"--that is cell-lines--of nonembryonic cells, as well as from various techniques by which particular DNA sequences are copied or "cloned." The President's science advisors underlined the need to recognize that cloning, "a vital component of the biotechnology repertoire," covers a wide range of activities: "the biological replication of genes, cells, or entire organisms" which has "been used for decades by scientists to produce genes and cell lines for testing theories of gene expression, cell differentiation, or how the immune system recognizes foreign substances." (John A. Young, Co-chairman, President's Committee of Advisors on Science and Technology, letter to President William J. Clinton, 7 March

1997.)

Second, many Commissioners found it useful to distinguish between implantation of a cloned embryo in a woman's uterus with the object of a live birth (informally dubbed "baby-making") and research solely in the laboratory without uterine implantation. The separation of cloning solely to increase knowledge from cloning for baby-making, might allow the former to proceed on a regulated basis even if concerns about the creation of full-blown "human clones" resulted in the latter being banned. Such an outcome ought to appeal to those scientists who see promising avenues in laboratory cloning to improve our understanding of neoplastic, neurological, and other diseases. At the same time, it also should appeal to people who object to such potential benefits being cited as reasons to forgo all prohibitions on "human cloning."

Yet however useful this distinction is, it does not attend to a central difference between most types of laboratory work using human cells and research in which genetic material is transferred from the nucleus of a human somatic cell to an enucleated human oocyte. In the latter situation, once the transfer is followed by an appropriate stimulus (such as the microvolt of electricity used by the Scottish scientists on the sheep cells), the oocyte begins to function as an embryo, under the direction of the somatic cell's DNA, now reprogrammed by the

oocyte (in a manner that is not yet fully understood) to behave pluripotentially. Thus, for those who object to research on any human embryo, to say nothing of the creation of such embryos for research purposes, the distinction between baby-making and laboratory research using enucleated oocytes draws the line at the wrong place. Indeed, from this perspective, any attempt to describe the latter as cellular research would be disingenuous unless this problem is recognized.

Furthermore, the distinction could have one ironic result, to which President Clinton alluded in his 4 March memorandum when he stated that an explicit prohibition was needed because existing restrictions on the use of federal funds for human embryo research "do not fully assure" that such funds will not be used for the cloning of human beings (Clinton 1997). The restrictions that he placed in December 1994 on Federal support for the creation of human embryos for research purposes, like the prohibitions Congress placed in the FY 1996 and FY 1997 appropriations laws, would rule out the funding of laboratory studies using cloning to create human embryos but would not stop the creation of cloned embryos for implantation, even though the latter step is generally considered to be much more premature and, even if feasible, much more ethically problematic than the former. Cloning embryos to make babies may be "an experiment," but that does make it "research," as that term is defined in the

federal regulations, since it is not necessarily linked to a search for "generalizable knowledge."

Faced with these problems, the Commission seems likely to narrow its focus on "human cloning" to the creation of embryos for implantation and to leave laboratory research with cloned embryos as it now is. Since the latter cannot receive federal support under the present prohibitions applicable to all embryo research, the only question for the Commission was whether to address privately funded embryo research. Two disparate reasons counseled against doing so. First, any recommendations against the use of human embryos in cloning research would open the question whether all types of privately funded research using such embryos should likewise be discouraged or prohibited. The limited time available left the Commission with no opportunity--and no inclination--to investigate the scope and purposes of such research to the extent needed to support a sensible conclusion on this point. At the same time, it seems unlikely that cloning researchers will soon be using human embryos. Experts informed the Commission that cloning researchers would be concentrating on non-human animals for the foreseeable future; in effect, the scientists involved would be inclined, for prudential reasons, to follow an informal moratorium until further progress is made in animal research. Ideally, the findings from such research might make it possible to avoid the use of human embryos without

hampering the important potential non-baby-making uses of cloning to study disease process, create transplantable tissue or organs, and the like, if cells other than embryos could be manipulated to recapture genetic pluripotentiality. If this goal were achieved, such research could be classed with other types of current, accepted "cloning" practices that involve replicating DNA sequences or cell lines but that do not raise the ethical issues that have concerned the public in our post-Dolly era.

THE NUANCES OF PROHIBITION

A third point of consensus that seems likely to guide NBAC's conclusions is that care must be taken not to confuse one's dislike of the prospect of human cloning (of either the laboratory or baby-making variety) with grounds for prohibiting it. Just as it is a mistake to imply, as sometimes happens in ethics discussions, that everything we have a right to do is right to do, so too it would be a mistake to say that everything we believe would be wrong to do should be a wrong to do.

This is particularly true of cloning. First, restricting the most worrisome form of cloning, namely baby-making, involves interfering with reproduction. Not only is this a realm in which people enjoy strong constitutional protections against government interference but also it is one in which the enforcement of restrictions might be particularly intrusive and particularly subject to conscious and unconscious forms of bias and prejudice.

Second, once one moves beyond the physical risks that arise from the novelty of the procedure, the harms that are cited to justify prohibitions are largely speculative and many involve injury to the social order of a most generalized sort. For example, some commissioners argued that a strong reason against allowing cloning stems from the disruption it could cause in generational lines; if cloning occurred within a family, the product might be regarded socially as the child of the person whose DNA was copied, but in genetic terms it would be the offspring of the DNA-donor's parents. Other commissioners expressed the view that the labels of parent, grandparent, and the like could be adjusted to fit the new reality, just as previous challenges have forced revisions to the stereotyped "normative" family. But that may beg the question; perhaps the extreme results produced by cloning provide an occasion to revisit the other forms of "non-natural" reproduction introduced in recent decades and ask anew whether their consequences are more problematic than we have realized.

At first, commissioners struggled not to confuse their own views about the right way to produce children with the way society is justified, in moral or constitutional terms, in limiting individual actions. Once NBAC decided to place primary reliance on the argument that nuclear transfer involves too much uncertainty about physical risk to the potential child, it became free to discuss the ethical issues as points that individuals and

policymakers alike ought to consider without having to announce a definitive judgment at this time on the weight that such ethical concerns should be given by society. This leaves for the future --in the hands of NBAC or some other advisory body--the question whether, if the physical risk to a child born through cloning could be shown to be no greater than in other in vitro methods, the ethical objections to clonal reproduction are sufficient to bar using the technology for baby-making or, alternatively, to erect a presumption against its use and to place the burden of persuasion on those who want to use the technology.

Thus, rather than resolve the issues inherent in recommending a permanent ban (or conversely, no ban at all), NBAC seems inclined toward a moratorium--that is, various voluntary and mandatory prohibitions imposed only for a certain time period or only until certain conditions have been satisfied. As an aid to the enforcement of such a temporary scheme, as well as to lay the groundwork for on-going public debate, the "ethics bucket" reviewed the reasons that have been advanced for and against cloning a human being. It may also attempt to distinguish between better and worse grounds for using the technique in individual cases--for example, use purely for vanity by creating a copy of oneself might be judged a weaker ground than use to allow a person with otherwise untreatable infertility to produce a genetically related child. It seems unlikely, however, that

the Commission would favor placing a board or other social body in the position of acting upon such a ranking of reasons, not the least because such a system would invite misrepresentations of motivation that would be very difficult to police. Nonetheless, several commissioners did suggest that an ethical line could be drawn the use of cloning in individual cases (provided that they remain very rare) and its use as a widespread practice.

One problem lies in the fact that many of the reasons raised against cloning are, in effect, exaggerated versions of the actual reasons that underlie some people's decisions about bearing and rearing children--reasons that we do not necessarily applaud, but against which we are loathe to allow state intervention. Ultimately, then, a fundamental question is how one decides when differences in degree become differences in kind. We accept, with little or no objection, many things that parents do to shape the kinds of children they have, from obtaining good prenatal care (or even playing music for the fetus) to making choices about educational and religious instruction and prohibiting or encouraging certain conduct. Would cloning a child and then forcing it to adhere to the path trod by the person whose DNA has been copied be just more of the same? Or does it cross a line and become a form of manipulation and domination aimed at denying the child's individuality? And, in reaching one's conclusion, which is more significant: the

parent's hope that the use of cloning will provide a decisive measure of predictability and hence control or the scientist's insistence (which seems to be accepted by all commissioners) that this hope is misplaced because environmental influences will result in "genetic copies" being anything but identical.

Given the pluralism of views not only within the country but also among the Commissioners about what counts as a socially cognizable harm from cloning, it is not surprising that in the limited time available for its report NBAC may only be able to describe and not to resolve the ethical arguments. A further stumbling block to resolution arises because many of the relevant concerns fall outside of the traditional deontological realm of bioethics, in which particular conclusions stem from the interconnected duties of physicians and investigators, patients and subjects. The issues raised by cloning not only are less familiar, but also may be grounded in religious beliefs. Such beliefs vary widely within our society and are constitutionally protected from governmental regulation. This then poses a difficulty: can the Commission go beyond recounting these beliefs as factors that help to explain the concerns that Americans have about this new field? Can it--or, indeed, should it--attempt to translate the beliefs into secular terms? Or would such a move deny the essence of some faith-based beliefs?

Despite such difficulties, it seems likely that the members

of NBAC can reach agreement on many point, even those with a theological cast. Indeed, having paid special attention to such views in its first hearing on the subject and in commissioned and volunteered materials that it has considered since then, the Commission may perform a valuable service both in gathering such views and in indicating points of agreement among them--e.g., the conclusion that a person created through cloning is no different than anyone else in terms of moral worth or possession of a soul because of his or her genetic identity with another person. Analysis of this sort, along with a careful description of the scientific aspects of the technology, is a worthwhile contribution to the public education and deliberation that are the essential next steps in the development of sound policy in this area.

Assuming that NBAC concludes that it is unacceptable to attempt baby-making through cloning at this time and that the moratorium on this type of cloning should continue, public consensus will be needed to reinforce the private sector's readiness to abide by the moratorium. In addition to general public consensus, official opposition by professional organizations, along with threats of malpractice liability and loss of licensure, should further deter any rash action by a fertility clinic. If pressure from individuals who desire to use cloning to overcome their infertility and who have the means to

pay for the attempt, as well as the lure of being the first physician to produce a child in this fashion, were to overwhelm these existing barriers, most commissioners favor the enactment of state or federal legal prohibitions against such private conduct.

Finally, in order to promote public education and discussion, to continue the ethical and social analysis of human cloning, and to monitor progress in non-human cloning, some sort of on-going oversight mechanism will probably be needed. That could be NBAC itself, some specially created board on mammalian cloning, or a multi-part structure drawing on the capabilities of existing institutions. Depending on the type of moratorium created now, such an oversight body is likely to be essential. It may be needed to determine whether knowledge about cloning has developed to the point where limited use of human embryos is needed to translate the findings from animal studies into advances for biomedical science that cannot be achieved in another fashion. It may be needed to advise officials in the legislative and executive branches whether pre-clinical studies indicate that the physical risks to making a baby through cloning no longer provide "safety" grounds for prohibition. And it will most certainly be needed if a "sunset clause" is a part of any law today lest the current jumble of ethical and social issues simply reappear as the law's date of expiration looms near, with

our having made no further progress as a society--or as part of societies around the globe--in resolving the tension between reproductive freedom and reasonable protection of children and society against harm.

Whether or not the conclusions NBAC reaches about cloning transform our Nation's response to the prospect that this new technology would be used on human beings remains to be seen. But there can be no doubt that the process of deliberating about the subject has transformed NBAC, providing it with a sense of public visibility and relevance and knitting its members into a functioning group, much better prepared to tackle the issues it was originally assigned than they would have been without Dolly.

* The views expressed in this article are entirely those of the author and do not represent NBAC or any organization with which he is associated.

REFERENCES

- Capron, Alexander M. 1997. An Egg Takes Flight: The Once and Future Life of the National Bioethics Advisory Commission. *Kennedy Institute of Ethics Journal* 7:63-80.
- Clinton, William J. 1997. Memorandum For The Heads of Executive Departments and Agencies, Subject: Prohibition on Federal Funding for Cloning of Human Beings. March 4, 1997.

● Rachel E. Levinson

06/06/97 05:05:43 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:

Subject: Adhoc: cloning update

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----- Forwarded by Rachel E. Levinson/OSTP/EOP on 06/06/97 05:02 PM



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06/06/97 03:24:26 PM

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Subject: Adhoc: cloning update

The National Bioethics Advisory Committee (NBEC) is meeting tomorrow (Saturday June 7) to finalize their report to the President on cloning.

The report will be officially transmitted at a White House event on Monday morning. The Technology Subcommittee of the House Science Committee, chaired by Connie Morella (R-Md) has scheduled a hearing on the recommendations for Thursday June 12.

Preliminary press reports indicate the NBEC will recommend Congress enact legislation that would allow some private research to continue, but prohibit the implantation of cloned embryos and maintain the prohibition on federal funds for human embryo research.

In case you are interested, the ASRM statement follows:

**ASRM STATEMENT ON
HUMAN CLONING THROUGH NUCLEAR TRANSPLANTATION**

(Washington, DC) -- The American Society for Reproductive Medicine (ASRM) is issuing the following statement:

The American Society for Reproductive Medicine (ASRM) finds the practice of cloning an existing human being unacceptable. However, ASRM believes that the broader field of human embryo research is acceptable and important, and guidelines both promoting and limiting the research should be set on the national level. The current moratorium on federal funding of human embryo research should be overturned and oversight for such research should be given to the National Institutes of Health.

The American Society for Reproductive Medicine (ASRM) , founded in 1944, has more than 10,000 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology, including obstetrician-gynecologists, urologists, endocrinologists, research scientists, medical technologists, and allied health professionals.

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