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Regulating Human Cloning

Paul Berg and Maxine Singer

The announcement of the sheep Dolly's birth triggered a worldwide discussion about the scientific, legal, and social ramifications of applying that technology to the creation of cloned human beings. Now that mice have been similarly produced, the discussion is urgent. Before anyone knew whether cloning of adult sheep was reproducible, much less whether human cloning might even be feasible, there were urgent appeals for legislation to prohibit such attempts. In the United States, the president forbade federal funding for attempting human cloning and ordered the National Bioethics Advisory Commission (NBAC) to consider the ethical, legal, and scientific implications of the new technology. NBAC recommended legislation to ban the cloning of a human being for 3 to 5 years because its safety could not now be certified. Acknowledging that the scientific, ethical, and legal issues are complex, NBAC advocated assessing the issues while the ban was in effect. National and international bodies have enacted or are considering bans, including the Council of Europe, the European Parliament, UNESCO, Canada, and China.

Guidelines overseen by an interagency regulatory body ... would be better than legislation

Scientists and the general public agree that too many questions remain to allow creation of a human being by cloning. But the opportunities to learn more about the processes of early development and to capture the scientific and medical promise that cloning technology offers without sacrificing our human values are also of paramount importance. Legislation is a crude tool for accomplishing both purposes. Congress has attempted and several states have already enacted legislation that could inadvertently inhibit or stop research on diseases and the development of new therapies. Furthermore, the lengthy periods proposed for banning the research are inappropriate.

This is not the first time that new biological findings have catapulted us into difficult and contentious issues. Twenty-five years ago, the discovery of techniques for cloning and manipulating DNA molecules (the use of recombinant DNA) presented comparable concerns, while promising to advance the life and biomedical sciences. But no one knew whether organisms carrying DNA from unrelated species posed risks to public health and the environment. The strategy that resolved these issues is applicable to human cloning and renders legislation unnecessary.

The first steps were an international conference on safety concerns and the adoption of a voluntary worldwide moratorium on recombinant DNA experiments considered most likely to produce untoward results. Strict and rigorous guidelines defining permissible and forbidden experiments were rapidly promulgated. All research carried out with federal funds had to adhere to them; other governments enforced comparable guidelines. Industry rapidly and voluntarily agreed to follow the same rules. The National Institutes of Health (NIH) established the Recombinant DNA Advisory Committee to monitor compliance, establish institutional biohazard committees, review scientific data bearing on safety, foster public discussion of ethical and social issues, and revise the guidelines if appropriate. As evidence accumulated that recombinant DNA experiments did not pose a threat, the concerns dissipated, and the guidelines were revised and eventually judged to be largely unnecessary. This approach allowed fundamental advances in biology and growth in the biotechnology industry. The turbulent recombinant DNA debate roused public interest in biological research.

We are concerned that anticloning legislation will resurface in Congress. Sensitive and flexible guidelines overseen by an interagency regulatory body, including the Food and Drug Administration, NIH, and representatives of the general public, would be better than legislation—an approach that avoids the potential delays and vagaries of the legislative process, encourages research, and fosters public engagement.

P. Berg is director of the Beckman Center for Molecular and Genetic Medicine at Stanford University, Stanford, CA 94305, USA. M. Singer is president of the Carnegie Institution of Washington, Washington, DC 20005, USA.