SCIENCE POLICY AND THE LAW: REPRODUCTIVE AND THERAPEUTIC CLONING

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INTRODUCTION

This paper highlights some of the limitations of the law's current role in shaping American bioethics and science policy, and explores the ways in which the law can help shape science policy to facilitate the anticipation of scientific developments. The law can help ensure that science policy both incorporates, and remains informed by, ethical debates. Recent legislative responses to reproductive and therapeutic cloning in the United States provide illustrative case studies and raise the following questions:

I. How does the law currently respond to developments in the life sciences?
II. What are the limitations of the American method of creating science and bioethics policy?
III. What are some considerations for improving the use of the law in this regard?

I
DEFINED TERMS

When considering the creation of science policy regarding cloning, it is important to understand what cloning *is*.[1] Natural human clones are called "identical twins" when produced without the benefit of human intervention. In the laboratory, particularly in animal research, cloning has taken place for many years through the process of

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1. For a general explanation of the cloning process, see NAT'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 13-34 (1997) [hereinafter CLONING HUMAN BEINGS], *available at* http://www.bioethics.gov/pubs.html.

embryo splitting or "twinning."[2] Before Ian Wilmut announced the birth of Dolly, the cloned sheep,[3] human cloning was largely the subject of science fiction. Since Dr. Wilmut's announcement, articles discussing the ethics and science of human cloning have appeared in the hundreds, if not thousands.

A primary reason why Dolly's creation is such a remarkable scientific breakthrough is that Dolly was created using a cloning technique called somatic cell nuclear transfer (SCNT), rather than by splitting an embryo.[4] In SCNT, the nucleus of a differentiated somatic cell is removed and inserted into an enucleated, unfertilized egg. The result is an egg that contains the complete complement of the donor cell's nuclear DNA. The egg is then prompted or stimulated and, as in Dolly's case, may develop into an embryo. If that embryo is successfully implanted into a surrogate and brought to term, the resulting animal will be the genetic replica of the DNA donor. The process of using SCNT to create an embryo in order to produce another living being is commonly referred to as "reproductive cloning." This type of cloning has been widely condemned by the international community.

It is thought that SCNT can be used to create replacement tissues or organs for patients with damaged or diseased tissues.[5] Medical research in this area has been the subject of intense international debate, for this process involves the creation of embryos to provide a source of embryonic stem cells (ES cells) which can be isolated and extracted from the inside layer or the inner cell mass of a pre-embryo (known as a blastocyst). These cells are said to be pluripotent in that they are undifferentiated and have the potential to become any type of tissue except placental tissue. Once removed from the embryo and cultured, an immortal cell line of stem cells can be produced.

Though scientists are currently unaware of how to prompt ES cells to differentiate into specific types of tissue, it is hoped that researchers will overcome this practical hurdle in the near future. In order to overcome the immunological response of "rejection," often a

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2. For a general history of the development of the use of cloning, see GINA KOLATA, CLONE: THE ROAD TO DOLLY, AND THE PATH AHEAD 120-208 (1998).

3. In February 1997, Dr. Ian Wilmut announced that he had cloned an adult mammal (Dolly, a ewe) for the first time. Gina Kolata, *Scientist Reports First Cloning Ever of Adult Mammal*, N.Y. TIMES, Feb. 23, 1997, at A1; Thomas H. Maugh II, *Scientists Report Cloning Adult Mammal*, L.A. TIMES, Feb. 23, 1997, at A1; *Scientists Succeed in Cloning a Sheep*, ST. LOUIS POST-DISPATCH, Feb. 24, 1997, at A1.

4. *See* CLONING HUMAN BEINGS, *supra* note 1, at 19-22.

5. *See, e.g.*, LEE M. SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 128-29 (1997) ("[W]hat will almost certainly happen over the next twenty years is that scientists will discover what signals are needed to convert embryonic cells into every tissue that exists in the adult human body.").

major complication in the recovery of organ or tissue recipients, it is posited that SCNT could be used to create embryos genetically identical to the donor/recipient from which stem cells would be harvested.[6] In this way, the cultured stem cells and the resultant tissue would be genetically identical to the donor/recipient.

The use of SCNT to create autologous stem cells is properly known as "therapeutic cloning." Scientists hope that they will be able to use this technique to prompt ES cells to develop into skin that could be used to treat burn patients. Additionally, those with nerve damage or spinal cord injuries might benefit from the ability to produce nerve tissues. Even whole organs could be developed in order to solve organ donation problems.

It is important to understand that in both reproductive and therapeutic cloning an embryo is created. Thus, the salient distinction is not the means, but the ends of each procedure. In the case of reproductive cloning the embryo is created for reproductive purposes, whereas in therapeutic cloning the embryo is created to provide a source of stem cells genetically identical to the intended recipient of transplant therapy.

II
CREATION OF BIOETHICS POLICY

It is important to understand this scientific background when considering how to use the law to develop scientific policy. Using cloning legislation as a case study allows us to consider our current methods of creating such policy. Thus, it is worth examining how we, as a nation, have responded both to the advent of SCNT and the isolation of ES cells. Such an examination reveals an emerging pattern in which law and ethics become part of the public policy discussions at a time when the scientific experimentation is largely completed, and sometimes even after specific technologies have entered the market.[7] For example, when a technique is developed (such as SCNT) or a gene or compound is discovered (such as ES cells), scientific experimentation most often precedes the announcement of the discovery or innovation by many years.

Although the announcement of a scientific development traditionally takes place in a scientific publication, recent increases in industrial funding for scientific innovation has resulted in these

6. *See* CLONING HUMAN BEINGS, *supra* note 1, at 19-22.

7. This was the case, for example, in 1998 with the gender selection technology currently marketed under the name Microsort, developed by the Genetics and I.V.F. Institute. Lisa Belkin, *Getting the Girl*, N.Y. TIMES MAG., July 25, 1999, at 26.

announcements increasingly being made in newspapers.[8] Announcements of new technologies or scientific applications, particularly in the biotechnology field, often spark public reaction and prompt legal and ethical analysis and discussion. So, while science progresses behind metaphorically closed doors, little or no discussion of policy or regulation intersects with this process. Hence, those engaged in public policy and ethical discourse must struggle to understand the new science or technology, as well as the implications of these scientific developments for society. Therefore, not only does ethical deliberation begin much too late, but it also develops more slowly. This process can be depicted on a timeline:

SCIENTIFIC WORK → ANNOUNCEMENT → PUBLIC REACTION → LEGAL RESPONSE → ETHICAL DEBATE

Careful science develops over a very long period of time, but once a development is announced, public reaction follows swiftly, and in many cases, pressure mounts to quickly introduce a legislative response. The announcement or public reaction may spark ethical discussion. Deliberation, however, has often just begun, and is certainly not concluded by the time the law has been drafted, introduced, and, often, passed.

In this framework, the law functions to fill gaps: it functions to address specific applications of a scientific or technological development. As Professor Frank P. Grad noted, such legislation is an effort to solve particular problems.[9] More often than not, such legislation criminalizes, bans, or punishes what is widely regarded by public opinion as "bad" or socially unacceptable behavior. In essence, this is *ad hoc* legislation—legislation that is very narrowly defined, and reactive, rather than proactive in nature.

What are the limitations on using the law to shape bioethics policy in this manner? First, it is clear that in this framework the law cannot be properly informed by ethical discourse. The relevant ethical discourse initially takes place in tandem with the development of legislative responses. However, although ethical deliberations initially coincide with legislative responses, ethical deliberations require much

8. *See supra* note 3 (discussing Dr. Ian Wilmut's announcement of successful cloning of Dolly).

9. Frank P. Grad, Comments at the New York University Journal of Legislation and Public Policy Symposium, *Legislating Morality: The Debate over Human Cloning* (Nov. 19, 1999) (transcript on file with the *New York University Journal of Legislation and Public Policy*).

more time to develop carefully and completely, and therefore continue well beyond the advent of the legislation.

This phenomenon is well illustrated by examining the circumstances surrounding the drafting of the National Bioethics Advisory Commission's (NBAC) report on the reproductive cloning of human beings.[10] When President Clinton commissioned the report, he afforded the Commission only ninety days in which to write it, even though many members of the Commission were not scientists. It goes without saying that this was an extremely demanding deadline under which to draft a document so important to national policy. Yet, even while the Commission was holding its deliberations and drafting its recommendations, several bills already came before Congress proposing laws banning human cloning.[11] Even more illustrative is the fact that even before the Commission issued its report, President Clinton announced that federal funding would not be available for the cloning of human beings.[12] In this instance, the government shaped its legislative response before allowing the ethical discussion to get well underway, let alone completed.[13]

Similarly, when the announcement that human ES cells had been isolated and cultured made it into the popular press, public and political reaction swiftly called for laws both expanding and restricting the funding for ES cell research.[14] While President Clinton charged the NBAC to respond to the ethical implications raised by the creation of an ES cell line, members of both the Senate and the House were already proposing bills supporting or denouncing such research.[15] Yet again, the NBAC was given only a short time to compile its response; and even before the report was tabled, the President announced that federal funding for embryo research to isolate ES cells would not be

10. *See* CLONING HUMAN BEINGS, *supra* note 1, at i.

11. *See, e.g.*, *The Prohibition of Federal Government Funding of Human Cloning Research: Hearings on S. 368 Before the Subcomm. on Tech. of the House Comm. on Sci.*, 105th Cong. (1997), *microformed on* CIS No. 98-H701-14 (Cong. Info. Serv.) [hereinafter *Hearings*]; Human Cloning Research Prohibition Act, H.R. 922, 105th Cong. (1998), *microformed on* CIS No. 98-H701-14 (Cong. Info. Serv.).

12. Katharine Q. Seelye, *Clinton Bans Federal Money for Efforts to Clone Humans*, N.Y. TIMES, Mar. 5, 1997, at A13. The NBAC report was issued in June 1997. *See* CLONING HUMAN BEINGS, *supra* note 1.

13. For criticism of the report, see generally John A. Robertson, *Wrongful Life, Federalism, and Procreative Liberty: A Critique of the NBAC Cloning Report*, 38 JURIMETRICS J. 69 (1997).

14. *See, e.g.*, Nicholas Wade, *Primordial Cells Fuel Debate on Ethics*, N.Y. TIMES, Nov. 10, 1998, at F1.

15. *Id*.

provided.[16] This decision had tremendous ramifications for the privatization of research and the corresponding public involvement with, and ownership of, related developments. Ultimately, the NBAC did publish its report, and it recommended that the existing ban on federal funding for embryo research be lifted to permit the derivation and use of ES cells in research. By that time, however, the direction of relevant policy had largely been decided.[17]

These examples illustrate the need for increased transparency and dialogue between scientists, ethicists, and policy makers. In addition, international applications of biotechnological innovations augment the need for greater integration of scientific experimentation, ethical discourse, and legislative responses.[18] It can only be beneficial to take note of the wisdom and experience of international thinkers and policymakers on a bioethical issue of domestic import. A comparative international analysis can be useful in confirming a society's beliefs or in highlighting societal differences and responses. Unfortunately, comparative analysis requires more time than policymakers have when faced with the pressure of responding swiftly to an existing scientific application already set to be implemented or marketed.

Informed and thorough ethical discussion addresses both the present and future applications of technology and science. In fact, a common role for ethicists and policymakers alike is to speculate on future applications and implications associated with a scientific innovation. This speculation requires time not often afforded those charged with shaping the development of bioethics policy or law. The isolated examination of a scientific application often results in recommendations for oversight, or the creation of advisory bodies within a particular sphere, such as: a stem cell commission for the consideration of stem cell protocols; a cloning commission for cloning protocols; and an embryo research commission for embryo research protocols. For exam-

16. Warren E. Leary, *Clinton Rules Out Federal Money for Research on Human Embryos Created for That Purpose*, N.Y. TIMES, Dec. 3, 1994, at A8.

17. NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH (1999) [hereinafter ETHICAL ISSUES], *available at* http://www.bioethics.gov/pubs.html. Note, however, that very recently the National Institutes of Health issued rules that would permit federally funded researchers to work on human ES cells. Nicholas Wade, *New Rules on Use of Human Embryos in Cell Research*, N.Y. TIMES, Aug. 24, 2000, at A1.

18. For a discussion of international applications in regard to therapeutic cloning, see Lori P. Knowles, *International Perspectives on Human Embryo and Fetal Tissue Research*, *in* ETHICAL ISSUES, *supra* note 17, at H-1. For a discussion of international applications in regard to reproductive cloning, see Bartha Maria Knoppers, *Cloning: An International Comparative Overview*, *in* CLONING HUMAN BEINGS, *supra* note 1, at G-1.

ple, NBAC recommended a national, federally funded stem cell oversight panel solely dedicated to stem and germ cell protocols.[19]

Our current approach to addressing bioethics policy in an *ad hoc* manner is reflected in the division of oversight responsibilities for clinically related medical and scientific technologies. A host of regulatory agencies govern closely related scientific applications with little interaction between the agencies. The recombinant DNA advisory committee (RAC) considers gene transfer,[20] while the Food and Drug Administration (FDA) contends that it has the ability to regulate human cloning proposals under the authority of the Public Health Service Act (PHS) and the Federal Food, Drug and Cosmetic Act (FD&C).[21] Finally, *ad hoc* federal legislation and *ad hoc* state legislation governing stem cell research, genetic research, and cloning also exist.[22] These different advisory and legislative mechanisms are, in essence, separate regulatory schemes. Although this system has the advantage of allowing the development of very specific expertise, each body works in isolation from the others. This isolation presents a significant weakness since the different bodies do not benefit from each other's expertise, nor do they acquire a comprehensive picture of the state of the science at any given time.

Not only does the lack of integrated ethical, scientific, and policy debates affect the ethical background of regulatory responses, but it also affects the laws drafted under these circumstances. Such laws tend to be narrowly drafted and reactive, rather than broadly drafted, dynamic, and capable of adapting to scientific advances that tend to follow quickly on the heels of one another. There is scant recognition of any interaction between new and existing technologies in related fields. Reproductive and genetic technologies, for example, are very often used in concert in clinical settings, yet they are not subject to coherent oversight or regulation. Furthermore, there is even less recognition that the technologies currently being tested on animals may be applied to human research subjects in the near future. Thus, Presi-

19. *See* ETHICAL ISSUES, *supra* note 17, at 67, 74-75.

20. *See* André C. Frieden, *Regulating Gene Data*, NAT'L L.J., Mar. 27, 2000, at C1.

21. *See* Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (May 14, 1998) (proposing that FDA has authority to regulate human cellular and tissue products under Public Health Service Act, 42 U.S.C. § 262 (1994), and Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321-395 (1994)); William S. Feiler, *'Birth' of Dolly Raises Patent Issues on Clones: In Absence of Statutory Amendment, Controversy May Remain Unsettled*, N.Y. L.J., Mar. 9, 1998, at S2.

22. Examples of state legislation include, for example, CAL. HEALTH & SAFETY CODE § 24185 (West 2000); MICH. COMP. LAWS ANN. § 333.16274 (West 2000); MO. ANN. STAT. § 1.217 (West 2000); R.I. GEN. LAWS § 23-16.4-2 (1999).

dent Clinton's announcement that federal funding would not be available for "human cloning," although intended to apply only to reproductive cloning, appeared on its face to also cover therapeutic cloning at a time when stem cell technology would shortly be available. Another result of such isolated actions, therefore, is that laws may be drafted too vaguely, broadly, or narrowly so as to inhibit the development of scientific innovation.

III
IMPROVING THE ROLE OF LAW IN BIOETHICS POLICY

In light of these considerations, it seems clear that rather than using the law to react in an *ad hoc* manner to specific scientific innovations, we should attain a more comprehensive understanding of new developments, and draft laws that reflect that understanding. It is possible to develop a broadly framed legislative mandate and to structure regulatory bodies that are responsive to change. In so doing, we could use the law to promote flexibility and continued conversation regarding the issues involved, and to make transparent the ethical commitments implicit in our governing policies. Public discourse is needed so that the law may move forward in a way that complements not only these ethical commitments, but also the scientific commitments the country has made through its public funding of research.[23]

A different model exists in the United Kingdom, a nation which first considered assisted reproductive technologies (ART) through the Report of the Committee of Inquiry into Human Fertilisation and Embryology, otherwise known as the Warnock Report, issued in 1984.[24] The Committee had a very broad mandate that included the continued pursuit of knowledge; the identification of current and future areas of public concern and ethical problems; recommendations for oversight; and the articulation of guiding principles and basic standards of practice in ART and human subjects research.

In making decisions about using embryos in research or ART, the Warnock committee adopted a long-term vision. It intended to create a broad regulatory framework using general propositions that would allow issues to be specifically addressed as they arose. The report also built mechanisms for adaptation into its proposed system. This meant that policy recommendations were drafted in general terms to allow

23. *See* Harold Shapiro, *Reflections on the Interface of Bioethics, Public Policy, and Science*, 9 KENNEDY INST. ETHICS J. 209 (1999), *available at* http://muse.jhu.edu/journals/kennedy_institute_of_ethics_journal/v009/9.3shapiro.html.

24. MARY WARNOCK, A QUESTION OF LIFE: THE WARNOCK REPORT ON HUMAN FERTILISATION & EMBRYOLOGY (Basil Blackwell 1984).

for flexibility and adaptability in the face of future developments.[25] Furthermore, the report also sponsored the Human Embryology and Fertilization Act, endowed it with overarching authority over these issues, and created a number of subcommittees to consider problems associated with assisted reproductive technologies.[26] The HEF Act enumerates a number of purposes considered appropriate for embryo research, and these do not include therapeutic cloning. Written into the Act, however, is a mechanism for expanding the purposes of embryo research in the face of new scientific developments. The HEF Authority recently recommended that the United Kingdom add therapeutic cloning to its list of acceptable purposes—a recommendation only recently considered by the government and soon to be the subject of an open vote in Parliament.[27]

In order to have a broadly framed legislative policy such as that of the United Kingdom, we need to be able to discuss the context in which new scientific developments arise. We must also understand where such developments fit into science policy and research regulation generally. We must, for example, ask where ES cell technology fits in embryo research; how it may pose problems for our human subjects research guidelines; and even how we can design a comprehensive regulatory system. This last inquiry poses problems in our culture because it requires an acceptance of the proposition that regulation can be a positive force in upholding the values deemed "good for society," and that it requires an open discourse about what *is* good for society.

Unlike the United States, the United Kingdom and Canada do not fear talking openly about what they hope for in a particular society and what measures will promote or thwart that vision. In addition, and perhaps consequently, those nations are generally unafraid of regulation. In the United States, however, there is a widespread belief that mere political discourse about the collective good inevitably threatens individual conceptions of what is good. Americans tend to believe that the collective good is somehow oppressive. It is widely touted that one person cannot be stopped from doing something until it harms another. Of course, we cannot know if something is harmful until it actually does harm. A cautious scientific approach, which

25. *Id.* at 6-7.

26. Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.), *reprinted in* BLACKSTONE'S STATUTES ON MEDICAL LAW at 188 (M.A. Jones & Anne E. Morris, eds., 1992).

27. Richard Stone, *U.K. Backs Use of Embryos, Sets Vote*, 289 SCIENCE 1269-70 (Aug. 25, 2000).

would only allow us to proceed once our innovations are proven safe, may in fact hinder scientific development.

Conclusion

In sum, these views lead to a kind of ultimate paradox with respect to the role of the law in bioethics policy. As a society skeptical or even hostile to regulation, the United States fails to discuss the larger scientific and societal context relevant to cloning technologies. Because we have no big picture regarding these issues, we respond to each new scientific development without the benefit of previously articulated commitments. New developments take us by surprise because we are not discussing these issues prospectively. We respond by using law in a reactive, *ad hoc* manner, not anticipating that we may in fact ultimately restrict scientific progress, including applications from which many may benefit.