

## EXECUTIVE SUMMARY

Advances in biotechnology in recent decades have made available an increasing capacity to intervene in the beginnings of human life, especially life initiated outside the body, whether in the clinic or in the laboratory. This capacity emerges from a confluence of work in reproductive biology, developmental biology, and human genetics, and raises ethical issues involving a number of important human goods. There is little question that the way these new technologies are used could have far-reaching consequences, not only for the individuals involved but also for society as a whole.

Yet it is not clear just how the interests of those individuals and of the public at large can best be served as these new technologies are developed and applied. What challenges and public policy concerns arise together with the use of new technologies affecting human reproduction? Whose responsibility is it to monitor, review, and offer guidance where guidance is needed, in order to safeguard the diverse human goods at stake? Should there be more or less oversight and regulation? Should there be any? Just how much is there now? Only partial answers are available to these questions, and much basic data remain to be gathered before they could be answered.

Since its very first meeting, in January of 2002, the President's Council on Bioethics has taken an interest in these subjects, and the Council has sought a way to advance public understanding of the challenges that confront us in this arena—beginning with the most basic information regarding what is being done and with what results. In the Council's report, *Human Cloning and Human Dignity* (2002), members observed that, with regard to assisted reproduction, genetic testing, and human embryo research,

we lack comprehensive knowledge about what is being done, with what success, at what risk, under what ethical guidelines, respecting which moral

boundaries, subject to what oversight and regulation, and with what sanctions for misconduct or abuse. If we are to have wise public policy regarding these scientifically and medically promising but morally challenging activities, we need careful study and sustained public moral discourse on this general subject, and not only on specific narrowly defined pieces of the field.

Following the release of that report, the Council decided to undertake a thoroughgoing inquiry into the current regulation of those biotechnologies that touch on human reproduction. This report is the fruit of that inquiry. Its principal aim is to describe and critically assess the various oversight and regulatory measures that now govern the biotechnologies and practices at the intersection of assisted reproduction, human genetics, and human embryo research.

## **I. WHAT IS AT STAKE?**

The Council saw a number of powerful reasons for taking up this subject. It involves some of the key concerns of bioethics and is likely to be an area of increasing importance, one in which both public understanding and public policy lag well behind the rapid advance of technological developments. Among the goods and ideals that are at stake, and that led the Council to point the public's attention toward this subject, are the following:

- The health and well-being of the human subjects directly affected by these technologies, not only the individuals or couples seeking their use, but also and especially the children who may be born with their aid.
- Relief of the suffering and sorrow of those afflicted with infertility.

- Compassion for children with serious genetic diseases, and relief of the sorrows and burdens that they and those who love and care for them must bear.
- The intrinsic value of new knowledge of human development and genetic function in addition to the inestimable practical value of new treatments for diseases and disabilities.
- Privacy of genetic information and reproductive practice.
- The foundational value of human life and the respect owed to it in its various stages.
- Several expressions and avenues of human freedom, including the freedom of parents to make their own reproductive decisions or to use or refuse genetic screening, and the freedom of scientists to conduct research. As important, as well, is the necessity to protect the freedom of children from improper attempts to manipulate their lives through control of their genetic make-up or from unreasonable expectations that could accompany such manipulations.
- The promotion of justice and equality, including equitable access to the use and benefits of new technologies, equal respect and opportunity in a world that places great emphasis on genetic distinctions, and the prevention of discrimination against or contempt for genetic “defectiveness” or “inferiority.”
- The protection of human dignity, including the dignity of the human body and its parts, the dignity of important human relationships (parent and child, one generation and the next), and the humanity of human procreation.

The Council's review of the field has been guided and motivated by these concerns.

## II. A DIAGNOSTIC OVERVIEW

This report is fundamentally a diagnostic document, and even most of the recommendations with which it concludes aim largely at improving the nation's capacity for future diagnosis of the state of this field. The diagnosis begins by examining policies and practices related to assisted reproduction. This is our starting point because assisted reproduction is, in practice, the necessary gateway to all the newer technologies—present and projected—that affect human reproduction. Preimplantation genetic diagnosis (including sex selection), germ-line genetic modification, human embryo research, and similar techniques all presuppose *in vitro* fertilization and the existence of developing human life *in vitro*. As a consequence, any oversight or regulation of the use of genetic technologies in human reproduction will necessarily depend on the systems that oversee and regulate assisted reproduction itself. Also, the addition of genetic technologies to existing techniques of assisted reproduction has made it clear—if it had not been clear before—that we are dealing here with a most unusual branch of medicine. In no other area of medicine does the treatment of an ailment—in this case, infertility—call for the creation of another human being. Our deep concern for the safety and well-being of children suggests to us the need for special attention to the uses and outcomes of these new biotechnologies.

The report then proceeds to review the regulatory policies and practices involved in screening and selecting for genetic conditions and traits; modification of traits and characteristics; research involving *in vitro* human embryos; and commercial and financial interests in this arena.

In discussing each area we review the relevant techniques and practices, the principal ethical issues, and (especially) the existing regulatory activities. This extended diagnostic discussion explores in detail precisely who currently provides oversight and guidance in each area, pursuant to what authority,

according to what principles and values, and with what ultimate practical effect.

### III. THE COUNCIL'S FINDINGS

The Council's diagnostic review of these areas has led us to several general conclusions:

- The fields of assisted reproduction, human genetics, and embryo research are increasingly converging with one another.
- There is no uniform, comprehensive, and enforceable system of data collection, monitoring, or oversight for the biotechnologies affecting human reproduction.
- There is minimal direct governmental regulation of the practice of assisted reproduction.
- There is extensive professional self-regulation of the practice of assisted reproduction, but compliance with the standards invoked is purely voluntary.
- There is no comprehensive, uniform, and enforceable mechanism for data collection, monitoring, or oversight of how the new reproductive biotechnologies affect the well-being of the children conceived with their aid, the egg donors, or the gestational mothers.
- There are no nationally uniform laws or policies relating to access to assisted reproduction.
- Given the present framework of regulation, novel technologies and practices that are successful move from the experimental context to clinical practice with relatively little oversight or deliberation. Once in practice, these techniques are used at clinicians'

discretion, with little or no external oversight. Use of effective technologies becomes widespread rapidly.

- As in other areas of medicine, there is no uniform system for public review and deliberation regarding the larger human or social significance of new reproductive biotechnologies.
- Preimplantation genetic diagnosis is an unregulated practice.
- Gene transfer research, by contrast, is regulated robustly.
- There is no comprehensive, uniform, and enforceable mechanism for data collection, monitoring, or oversight regarding the use and disposition of in vitro human embryos in the context of clinical practice or research.
- There is no comprehensive mechanism for regulation of commerce in gametes, embryos, and assisted reproductive technology services.
- Patenting of embryonic or fetal human organisms is prohibited for the fiscal year 2004.

The Council does not take these findings in and of themselves to mean that any public policy response is called for, but any consideration of potential public policies in this area must take these basic facts into account.

#### **IV. POLICY OPTIONS AND RECOMMENDATIONS**

The Council's findings, combined with the concerns that animate our interest in this area, point toward a fairly wide array of possible regulatory approaches. In this report, the Council considers these options in some detail, laying out a range of potential institutional options—from doing nothing to

developing entirely new regulatory institutions—and offering a number of possible aims and principles that might guide future regulators.

However, given the preliminary character of this report, and the fact that our review of the field has turned up a number of areas where crucial data are simply lacking, the Council was not prepared to recommend any sweeping institutional reform or innovation. Rather, members agreed upon a series of modest measures to alleviate some clear and significant present problems, including especially the lack of information on certain key practices and their consequences.

The report concludes, therefore, with a set of recommendations that the Council agrees should be adopted immediately. These recommendations are not for structural or institutional changes; we do not propose the wholesale creation of new regulatory institutions or even the reform of existing ones. Rather, we offer these recommendations as interim measures with two goals in mind: first, to strengthen existing legislation and regulatory mechanisms in order to gather more complete and useful information; and, second, to erect certain legislative safeguards against a small number of boundary-crossing practices, at least until there can be further deliberation and debate about both the human goods at stake and the best way to protect them.

The recommendations fall into three general categories: studies and data collection, oversight and self-regulation by professional societies, and targeted legislative measures. In each case, the Council has detailed its precise recommendations in the report and has offered extensive supporting arguments and reasons. The recommendations are as follows.

***A. Federal Studies, Data Collection, Reporting, and Monitoring Regarding the Uses and Effects of These Technologies***

As the Council's findings demonstrate, the incompleteness of basic information on the uses and impact of new reproductive technologies makes any conclusive policy judgments very difficult to formulate. The Council therefore recommends that the federal government take a number of specific steps to improve our knowledge and understanding:

- Undertake a federally funded longitudinal study of the impact of assisted reproductive technologies on the health and development of children born with their aid.
- Undertake federally funded studies on the impact of assisted reproductive technologies on the health and well-being of women.
- Undertake federally funded comprehensive studies on the uses of reproductive genetic technologies, and on their effects on children born with their aid.
- Strengthen and augment the Fertility Clinic Success Rate and Certification Act to better protect consumers and patients:
  - Provide more user-friendly reporting of data.
  - Require the publication of all reported adverse health effects.
  - Require the reporting of the average prices of the procedures and the average cost (to patients) of a successful assisted pregnancy.
  - Include information on novel and experimental procedures.
  - Require more specific reporting and publication of the frequency of, and reasons for, uses of specialized techniques such as ICSI, preimplantation genetic diagnosis, and sperm sorting for sex-selection.
  - Provide model forms for decision-making.
  - Provide stronger penalties to enhance compliance with the Act's reporting requirements.
  - Increase funding for implementation of the Act.

***B. Increased Oversight by Professional Societies and Practitioners***

Most oversight in this area currently takes the form of self-regulation by professional societies, and as far as the Council can determine the vast majority of practitioners abide by these



guidelines and standards and are dedicated to the welfare of their patients. Yet the Council has identified a few ways in which self-regulation could be meaningfully improved:

- Strengthen informed patient decision-making.
- Treat the child born with the aid of assisted reproductive procedures as a patient.
- Improve enforcement of existing guidelines.
- Improve procedures for movement of experimental procedures into clinical practice.
- Create and enforce minimum uniform standards for the protection of human subjects affected by assisted reproduction.
- Develop additional self-imposed ethical boundaries.

### ***C. Targeted Legislative Measures***

In the course of its review, discussion, and findings, the Council encountered and highlighted several particular practices and techniques (some already in use, others likely to be tried in the foreseeable future) touching human reproduction that raise new and distinctive challenges. Given the importance of the matter, we believe these require special attention, and we therefore recommend that Congress should consider some limited targeted measures that might institute a moratorium on certain particularly questionable practices. The report includes an extensive discussion of the reasons for these recommendations as well as the aims we hope they might serve. The Council recommends that the Congress should, at least for a limited time:

- Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a non-human species.

- Prohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm.\*
- Prohibit the transfer of a human embryo (produced ex vivo) to a woman's uterus for any purpose other than to attempt to produce a live-born child.
- Prohibit attempts to conceive a child by any means other than the union of egg and sperm.†
- Prohibit attempts to conceive a child by using gametes obtained from a human fetus or derived from human embryonic stem cells.†
- Prohibit attempts to conceive a child by fusing blastomeres from two or more embryos.†
- Prohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization).‡

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\* It bears noting that, in testing for male-factor infertility, practitioners of assisted reproduction now use hamster eggs to test the capacity of human sperm to penetrate an egg; yet there is no intent to produce a human-animal hybrid embryo, and there is negligible likelihood that one might be formed, given the wide genetic gap between the species. Thus, we do not believe that such procedures run afoul of the letter or spirit of the above recommendations.

† Operationally, in each of the three cases listed, the prohibited act comprises the creation ex vivo of any such human embryo *with the intent* to transfer it to a woman's body to initiate a pregnancy.

‡ Some members of the Council are opposed to any experimentation that harms or destroys human embryos, but, recognizing that it is legal and active, they see the value in limiting the practice. Other members of the Council favor allowing such experimentation during the early stages of embryonic development, but nonetheless recognize the need to establish an upper age limit beyond which such research should not proceed. Some Council members believe that this upper limit should be 14 days after the first cell division; others favor 10 (or less).

- Prohibit the buying and selling of human embryos.\*
- Prohibit the issuing of patents on claims directed to or encompassing human embryos or fetuses at any stage of development; and amend Title 35, United States Code, section 271(g) (which extends patent protections to products resulting from a patented process) to exclude these items from patentability.†

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\* This provision is not intended to preclude patients who receive donated embryos from reimbursing donors for reasonable expenses, storage costs, and the like. Also, because the compensated giving of sperm is a long-established practice, and because payment to egg donors is now also fairly common, efforts to ban payment to gamete providers would likely prove controversial and untenable for purposes of actual legislation. Thus, we decline to recommend such a ban here. That is not to say, however, that the Council approves of the buying and selling of gametes. Indeed, many Council members have raised serious concerns regarding this species of commercialization in the domain of human reproduction.

† The language of any such statute would in our view need to take some care not to exclude from patentability the processes that result in these items, but only the products themselves. Similar language has been included in a component of the federal budget for fiscal year 2004 (the Consolidated Appropriations Act of 2004, H.R. 2673, 108th Congress [January 23, 2004], Division B, §634), but we believe this provision should also be made a clear and permanent element of the patent law.