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Recommendations

Over the past two years, the Council has devoted much time and energy to examining the current oversight and regulation of the uses of biotechnologies that touch the beginnings of human life—practices arising at the intersection of assisted reproduction, genetic screening, and human embryo research. The Council has heard from various experts and stakeholders, engaged in its own diagnostic review of current regulatory mechanisms and institutions, outlined the key findings emerging from that review, and surveyed various general and specific policy options. As the previous chapters indicate, the Council now understands a great deal about today's regulatory landscape and has identified concerns that suggest the need for improved monitoring and oversight and, perhaps, new forms of governmental regulation. Yet we are very far from being able to offer clear and well-considered recommendations regarding major institutional reforms. We do not know the precise costs and benefits of overhauling existing regulatory institutions and practices or of creating new regulatory authorities. We do not even know enough about the incidence and severity of some of the possible risks and harms that we have identified as causes of concern to decide whether they are serious enough to justify changing the present arrangements. We do not accurately know, for example, how the technologies and practices at the heart of our inquiry affect the health of those

whose lives are touched by them—most notably, the children conceived with their aid. Similarly, we do not know how widely preimplantation genetic diagnosis or preconception (and preimplantation) sex selection will be practiced, and for which purposes. Without the answers to such questions, it would be premature at best to recommend dramatic legal or institutional changes. Further research and inquiry, and additional consultations with all those affected, are clearly needed.

Yet even as such inquiry and consultation proceed, the Council believes that some modifications can and should now be implemented to address some of the concerns identified by the present inquiry. The recommendations we offer fall into three general categories: studies and data collection, oversight and self-regulation by professional societies, and targeted legislative measures.

In Sections I and II of this chapter, the Council proposes several measures it believes the federal government and the various relevant professional societies should adopt immediately. Most of these suggestions are aimed precisely at addressing the remaining empirical questions described above. These include a call for comprehensive information gathering, data collection, monitoring, and reporting of the uses and effects of these technologies. They also address the needs for increased consumer protection, improved informed decision-making, and more conscientious enforcement of existing guidelines for practitioners of assisted reproductive technologies (ARTs).

In Section III of this chapter, we identify several matters that may warrant prudent interim legislative action, especially in light of rapidly emerging innovations that signal new departures in human reproduction. Familiar disquiet regarding human cloning or commerce in human embryos and gametes is augmented by recent reports of, for example, fusion of male and female embryos into one chimeric organism and of the derivation of gametes (in animals) from embryonic stem cells (in principle enabling embryos to become biological parents). Accordingly, while policymakers monitor and gather information and while deliberation continues about the need for better and more permanent monitoring and oversight arrangements, it may be necessary and desirable to enact a legislative moratorium on a few boundary-crossing practices, thereby provid-

ing interim prophylactic limitations. Such limitations would prevent the introduction of certain significant innovations into human procreation in the absence of full public discussion and deliberation about their ethical and social implications and consequences.

In offering these interim recommendations for improvements in data collection, monitoring, and professional self-regulation and in proposing limits and restraints on some potential applications of ARTs, the Council does not intend to challenge the current practices or impugn the ethical standards of most practitioners of assisted reproduction. The Council recognizes the efforts of professionals and patient groups working in this field to devise and implement appropriate ethical guidelines and standards of care. Yet we have identified areas of concern that have not been sufficiently studied or addressed. And there are at present no effective mechanisms for monitoring or regulating some of the more problematic practices or for preventing unwelcome innovations introduced by irresponsible practitioners. Indeed, it is our belief that responsible professional participants, patients, policymakers, and interested citizens should be able to recognize the merit of our proposals and work to see them implemented.

The recommendations we offer here are recommendations of the Council as a whole. Though we differ about certain fundamental ethical questions in this field, and especially about the moral standing of human embryos, we have nevertheless been able to agree on several policy suggestions that we believe should command not only the respect but also the assent of most people of common sense, good will, and a public-spirited concern for human freedom and dignity. These recommendations emerge quite naturally from the diagnostic survey and analysis presented in the previous chapters, and they are best understood only when read in that context. We have sought to frame the recommendations with sufficient specificity that they might be adopted by the relevant target audiences.

I. FEDERAL STUDIES, DATA COLLECTION, REPORTING, AND MONITORING REGARDING THE USES AND EFFECTS OF THESE TECHNOLOGIES

A. Undertake a Federally Funded Longitudinal Study of the Impact of ARTs on the Health and Development of Children Born with Their Aid

A most important unanswered question before the Council concerns the precise effects of ART and adjunct technologies on the health and normal development of children who are now being born or who will in the future be born with their aid. There have been a few studies, mostly undertaken abroad, reaching different and sometimes contradictory results. An effort has been undertaken, by the Genetics and Public Policy Center at the Johns Hopkins University, in collaboration with the American Academy of Pediatrics (AAP) and the American Society for Reproductive Medicine (ASRM), to review all of the existing literature on this question. This retrospective study is a laudable start, capable of identifying harmful health and development outcomes that should be monitored in the future. The Council strongly believes, however, that what is needed now is a *prospective* longitudinal study—national, comprehensive, and federally funded—that looks at both the short-term and the long-term effects of these technologies and practices on the health of children produced with their assistance, including any cognitive, developmental, or physical impairments. Such a study would require an adequate control sample, and a sufficiently large population of subjects to yield meaningful statistical results. Participation in such a study would, of course, be voluntary.

A seemingly ideal vehicle for this study is the National Children's Study (NCS) now being planned by a consortium of federal agencies led by the National Institute of Child Health and Human Development (NICHD). This study, which (if funded) is scheduled to begin in 2005, would track the health and development of 100,000 children across the United States from before birth until age 21. Given its great demographic, temporal, and substantive scope, the NCS would be uniquely suited to studying the health of children conceived with the aid of ART. It would be national in scope, it would not require

the special recruitment of a population of children conceived with the aid of ART, and all participation would be voluntary. Correcting a major defect in other studies of the impact of ART, the NCS would have a built-in control sample, namely, children conceived without the aid of ART. It would allow researchers to observe and consider health impacts that reveal themselves only years after birth. It would analyze an exceptionally wide range of biological, physical, social, cultural, and other factors that may significantly influence a child's health and development. The NCS would have enormous resources at its disposal, as it would be undertaken by a partnership of federal, state, and local agencies; universities; academic and professional societies; medical centers; communities; industries; companies; and other private groups. Finally, the NCS would release its results as the study progresses; thus, it would not be necessary to wait until 2025 to review the information gathered. The study would publicize results as the children reached certain developmental milestones. In short, the NCS would offer an unprecedented and perhaps unrepeatable opportunity to answer questions relating to the well-being of children conceived with the aid of ART.

Should the planned NCS not go forward for any reason (or should it not include a suitable or statistically significant study of children conceived using ARTs), the Council recommends that an independent federally funded longitudinal study be undertaken on the health and development of children who are born with the aid of ARTs.

B. Undertake Federally Funded Studies on the Impact of ARTs on the Health and Well-Being of Women

Another area where better information is needed regards the health and well-being of women who use ARTs and of women who donate their eggs for the use of others. One or more studies, either in conjunction with or separate from the above-mentioned longitudinal study, should be conducted to discover the effects, if any, of the use of ARTs on women's health, including any short-term or long-term hormonal, physical, or psychological impairments. Participation in such a study would, of course, be voluntary.

C. Undertake Federally Funded Comprehensive Studies on the Uses of Reproductive Genetic Technologies, and on Their Effects on Children Born with Their Aid

As noted above, assisted reproduction and genomic knowledge are increasingly converging with one another. Practices such as preimplantation genetic diagnosis (PGD) and gamete sorting represent the first fusion of these disciplines. Before these practices become routine, it is desirable that policymakers and the public understand their present and projected uses and effects. To this end, there should be federally funded comprehensive studies, undertaken ideally with the full participation of ART practitioners and their professional associations, on how and to what extent such practices are currently and may soon be employed, and their effects on the health of children born with their aid. Mechanisms need to be developed for ongoing monitoring of the outcomes of these practices and other practices to which they may lead. Participation in any such studies would, of course, be voluntary.

D. Strengthen and Augment the Fertility Clinic Success Rate and Certification Act

As currently written, the Fertility Clinic Success Rate and Certification Act (FCSRCA) is aimed at providing consumers with key information about the pregnancy and live-birth success rates of assisted reproduction clinics in the United States. We believe that the Act should be augmented and strengthened, both to improve this original function of consumer protection and to allow for better public oversight (through the already existing ART surveillance program at the Centers for Disease Control [CDC]) of the development, uses, and effects of reproductive technologies and practices. Toward these ends, the Act, or the regulations propounded pursuant to it, or both, should be improved and strengthened in the following ways.

1. Enhance Reporting Requirements.

a. Efficacy. Provide more user-friendly reporting of data, including adding "patients" as an additional unit of measure.

Currently, data are reported only in terms of "cycles" of treatment (beginning when a woman starts ovarian stimulation or monitoring), rather than in terms of individual patients treated. Thus, it is impossible to know how many individuals undergo assisted reproduction procedures in a given year, how many patients achieve success in the first (or second or third) cycle, how many women fail to conceive, and the like. Presenting results in terms of "numbers of individuals" (in addition to "numbers of cycles") would be very helpful to prospective patients and would yield more precise information for policymakers.* Also, this information should be presented with any qualifying language or additional information that would help to avoid confusion for prospective patients or the public.†

b. Risks and side effects. Require the publication of all reported adverse health effects. Adequate consumer protection requires informing prospective users of the known hazards connected with the services or products they are using. Yet there is today no mechanism for the publication of information regarding adverse effects of ARTs, either on the health of adult patients or on that of their children. At the present time, the CDC does collect data on complications and adverse outcomes of pregnancy, including low birthweight and birth defects for each live born and stillborn infant, but this information is not made public. Knowledge of such adverse effects is of paramount concern for prospective patients, policymakers, and the public at large. The CDC should publish its data on the incidence of adverse effects on women undergoing treatment, as well as on the health and development of children born with the aid of ART. In order not to confuse or unduly alarm prospective patients or the public, the CDC should include in its publication comparative data on the incidence of such effects in

* The Council is not calling for the abandonment of "cycles" as a unit of measure. Rather, we urge the inclusion of "patients" as an additional unit of measure.

† The CDC collects but does not publish information regarding ART patients' prior attempts to conceive using assisted reproduction. This information might prove useful in helping the CDC to analyze and present information on a per-patient basis in a way that does not distort success rates and the like.

unassisted births, as well as any other relevant information that could help prevent misimpressions regarding the nature and magnitude of the hazards associated with ART.

c. Costs to the patients. Require the reporting and publication of the average prices of the procedures and the average cost (to patients) of a successful assisted pregnancy. There is currently no comprehensive source of information regarding the costs borne by the patients seeking treatment involving assisted reproductive technologies. Not surprisingly, prospective patients are keenly interested in this information. Moreover, policymakers interested in questions regarding equality of access, insurance coverage, and related matters would greatly benefit from such information. It would also shed light on whether incentives currently exist that may induce patients and clinicians to engage in potentially risky behavior, such as the transfer of multiple embryos in each cycle, in an effort to reduce costs (especially in those places where in vitro fertilization (IVF) is not covered by insurance). While the publication of such information may cause some confusion or, worse, may create a perverse incentive to cut costs at the expense of health and safety, the Council believes that the consumer benefits of providing such information outweigh such speculative harms. This is especially true if this information about costs to the patient is published alongside the information, recommended above, regarding patient health and safety.

d. Innovative techniques. Include information on novel and experimental procedures. A key area of concern for the Council is the ease and speed with which experimental technologies and procedures (such as intracytoplasmic sperm injection [ICSI] or PGD) move into clinical practice, even in the absence of careful clinical trials regarding their efficacy and their long-term effects on children born with their use. It would be useful for consumers and policymakers to understand more fully how each clinic manages the process of introducing new technologies and practices and what safeguards are employed. Such information would include the human subjects protections in place; the extent to which technologies are first tested in animals; the stan-

dards that must be satisfied before a given procedure is deemed fit for clinical use; and the measures taken to evaluate safety and efficacy.

e. Adjunct technologies. Require more specific reporting and publication of the frequency of, and reasons for, uses of specialized techniques such as ICSI, PGD, and sperm sorting for sex selection. Little is understood about the frequency and uses of the various adjunct technologies and practices complementing standard IVF. Under the present system, the CDC already collects and reports information relating to the incidence and uses of some adjunct technologies.[*] The present approach could be greatly improved, however, by modestly changing the relevant law to require information on additional adjunct procedures (particularly those that combine assisted reproduction with human genetic technologies), as well as to require the reporting and publication of somewhat more detailed information relating to the reasons patients elect to use those procedures that are already subject to reporting requirements. For example, the present system of reporting sheds little light on precisely *why* patients chose ICSI as their preferred method of fertilization. Also, because results are reported in terms of cycles rather than patients (as discussed above), it is impossible to know how many *individuals* used ICSI.

Other techniques, particularly those fusing reproductive technology and genomic knowledge, are not reported at all under the present version of the Act. There is no requirement to report the number of cycles using PGD, much less the reasons for using PGD. For example, how many patients using PGD are infertile? How many have family histories of genetic disorders? What sort of genetic screening is being done? For aneuploidy and single-gene mutations? For donor siblings? For non-disease-related traits? There is also no reporting of any practices in which sex selection occurs or of the reasons for undertaking them. Consumer protection and public policy would be enhanced if this information

[*] For example, the CDC publishes information on the percentage of IVF cycles involving ICSI (49.4 percent in 2001); the CDC also reports the percentage of the cycles using ICSI that involve patients with male factor infertility (57.8 percent in 2001).

were available and published. Consumers would benefit from knowing how much experience a given clinic has in performing such procedures. The public would benefit from knowing how, why, and to what effect genomic knowledge is being used in human reproduction.

2. Enhance Patient Protections: Informed Decision-Making.

a. Provide model forms for decision-making. The present Act would be greatly improved by providing for the promulgation of easy-to-read model consent forms that include information on the possible health risks to mother and child, the novelty of the various procedures used, the number of procedures performed to date, the outcomes, and the various safeguards in place to ensure that such procedures are safe and effective.

3. Improve Implementation.

a. Enforcement. Provide stronger penalties to enhance compliance with the Act's reporting requirements. Under the Act as currently written the only penalty for noncompliance is the publication of the names of nonreporting clinics. This is insufficient, given the importance of clinic compliance to ART consumers and the greater public. The penalties should reflect the magnitude of harms to be avoided. We leave to legislators the question of what precisely these should be.

b. Funding. Increase funding for implementation of the Act. CDC's budget should be augmented sufficiently to enable it to undertake the additional measures suggested above. In this way, the increased oversight called for will be borne by the government rather than by the individual patient. We leave to legislators the question of how much additional funding would be required.

II. INCREASED OVERSIGHT BY PROFESSIONAL SOCIETIES AND PRACTITIONERS

Professional oversight has traditionally been the principal mechanism of regulation for the practice of medicine, and the practice of reproductive medicine is no exception. There is a well-developed body of professional guidelines and standards for the clinical practice of assisted reproduction, and as far as the Council can determine (in the absence of a more comprehensive investigation of physicians' actual conduct), 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 the following substantive areas that it believes require attention and improvement:

A. Strengthen Informed Patient Decision-Making

Clinicians and their professional societies should make efforts to improve the current system of informed decision-making by patients to conform to the concerns and suggestions described above. ASRM and SART (the Society for Assisted Reproductive Technology) should pay attention not only to helping devise improved consent forms, but also to recommending procedures to their members for discussing the subject properly with patients and for securing their meaningful consent. For this purpose, they should consider making training sessions on this subject a requirement of membership.

B. Treat the Child Born with the Aid of Assisted Reproductive Procedures as a Patient

ART clinicians should take additional measures to ensure the health and safety of all participants in the ART process, *including the children who are born as a result*. Thus, in making decisions and undertaking clinical interventions, such practitioners should carefully consider how these actions will affect the health and well-being of these children. We recognize, of course, that health care services tend in general to be disaggregated among different specialties, and that collaboration is not always feasible. In the domain of assisted reproduction, once pregnancy has been achieved, the prenatal care of the

pregnant woman is transferred to her obstetrician. But the Council urges clinicians and professional societies to seek out ways to improve the continuity of the services offered to their patients and their children. ART clinicians and their professional societies should consult with pediatricians (and their professional societies) to learn how their practices may be affecting the health and safety of the children born as a result. Clinicians and professional societies should also cooperate fully and vigorously with any efforts (such as the studies described in Section I of this chapter) to ascertain the effects of ART and related practices on the health and development of such children. In addition, the Council strongly endorses a specific substantive recommendation: clinicians and professional societies should take additional concrete steps to *reduce the incidence of multiple embryo transfers* and resulting multiple births, a known source of high risk and discernible harm to the resulting children.

C. Improve Enforcement of Existing Guidelines

There are today a host of reasonable guidelines in place for clinicians and practitioners engaged in ART, and, to repeat, they are apparently followed by most practitioners. However, the relevant professional societies need to take stronger steps to ensure that these guidelines are followed. For example, one such professional society "actively discourages" the use of PGD for sex selection for nonmedical purposes, yet several prominent members of that society openly advertise the practice. Professional societies must clarify the contours of appropriate conduct and adopt reasonable mechanisms of enforcement.

D. Improve Procedures for Movement of Experimental Procedures into Clinical Practice

Professional societies and clinicians should develop a more systematic mechanism for reviewing experimental procedures before they become part of standard clinical practice. Such a system might include requirements for animal studies, institutional review board (IRB) oversight, and formal discussion and

ongoing (and prospective) monitoring of the significance and results of novel procedures.

E. Create and Enforce Minimum Uniform Standards for the Protection of Human Subjects Affected by Assisted Reproduction

At present there is no systematic, mandatory mechanism for protecting human subjects who are engaged in experimental ART protocols not affiliated with institutions receiving federal funds. This problem is compounded by the fact that in the practice of assisted reproduction (as in the practice of medicine more generally), there is not a clear distinction between research and innovative clinical practice. Investigational interventions that could affect the health and well-being of children born with the aid of ART should be subjected to at least as much ethical scrutiny and regulatory oversight as investigational interventions affecting other human subjects of research. Current research policies establish special protections for children and fetuses in research. For similar reasons, there is a need for special protections when research involves interventions in embryos that could later affect the health and welfare of the resulting live-born children. Clinicians and their professional societies should adopt measures (such as IRB-like oversight) to provide necessary safeguards.

F. Develop Additional Self-Imposed Ethical Boundaries

Clinicians and professional societies would be well-advised to establish for themselves additional clear boundaries defining what is and what is not ethically appropriate conduct, regarding both research and clinical practice. Without such guidance, irresponsible clinicians and scientists may engage in practices that will, fairly or unfairly, bring opprobrium on the discipline as a whole. Practices such as, among others, the fusion of male and female embryos, the use of gametes harvested from fetuses (or produced from stem cells) to create embryos, and the transfer of human embryos to nonhuman uteri for purposes of research fall squarely into this category. The relevant professional societies should preemptively take a

firm stand against such practices and back that stand up with meaningful enforcement.

III. TARGETED LEGISLATIVE MEASURES

In the course of our review, discussion, and findings, we have encountered and highlighted several particular practices and techniques (some already in use, others likely to be tried in the foreseeable future) touching human procreation that raise new and distinctive challenges. Given the importance of the matter, we believe these practices and techniques require special attention, not only from professional societies but also from the people's representatives. Especially because technological innovations are coming quickly and because there are today no other public institutions charged with setting appropriate limits, we believe Congress should consider some limited targeted measures—bundled together perhaps as a "Reproduction and Responsibility Act"—that might erect boundaries against certain particularly questionable practices.[*] These measures, proposed as moratoria, would remain operative at least until policymakers and the public can discuss the possible impact and human significance of these new possibilities and deliberate about how they should be governed or regulated.

The benefits of such congressional legislation, as we see it, are multiple:

(a) It could help educate the public about the transformative character of some new reproductive biotechnologies; and it could enhance public awareness of the need for research and practice in this area to be guided by respect for the women using assisted reproduction and for the children born with its aid (on which see below).

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[*] The listing (below) of these activities should not be taken to imply that we believe that the reputable practitioners of assisted reproduction are interested in engaging in them. Our goal is rather to establish boundaries and guidelines for future practice, and barriers against those irresponsible practitioners who, indifferent to the standards of the profession and the community, might not only endanger patients and the public, but also unfairly cast a pall over the entire field.

(b) It would institute a temporary moratorium on certain practices, imposing a few carefully defined boundaries on what may be done and preventing any individual from committing acts that could radically alter what the community regards as acceptable in human reproduction without prior public discussion and debate.

(c) If carefully drafted, it would not interfere with important scientific research. On the contrary, it could serve to protect the reputation of honorable scientists and practitioners of assisted reproduction against the mischief done by "rogues," whose misconduct might invite harsh and crippling legislative responses.

(d) Practically, it would place the burden of persuasion on those innovators who are inclined to transgress these important boundaries without adequate prior public discussion or due regard for social or moral norms.

(e) It would show that there is a way forward for continuing public oversight in these areas, and it would demonstrate that scientists and humanists, physicians and laymen, liberals and conservatives, "pro-lifers" and "pro-choicers," can find certain shared core values that they are willing to defend collectively and by deliberate agreement.

Legislative interest in responsible reproductive practices might give rise to a fairly wide range of specific provisions, and Congress should consider these in their full array. But the concerns we have taken up in this report, and which emerge from our findings, suggest to us a few that are especially crucial, and also especially likely to command fairly broad assent. They may be usefully grouped under four principles or desiderata, each pointing to one or two particular provisions that we believe to be in order and that we now recommend[*]:

[*] The particular provisions that follow below (in boldface type) have been carefully drafted, with a view to specifying accurately the Council's concerns. Yet they are to be read not as precise legislative provisions but as articulations of possible boundaries that we would like to see erected and defended.

A. Preserving a Reasonable Boundary between the Human and the Nonhuman (or, between the Human and the Animal) in Human Procreation

The question of the human-animal boundary in general can, in some respects, be quite complex and subtle, and the "mixing" of human and animal tissues and materials is not, in the Council's view, by itself objectionable. In the *context of therapy and preventive medicine*, we accept the transplantation of animal organs or their parts to replace defective human ones; and we welcome the use of vaccines and drugs produced from animals. Looking to the future, we do not see any overriding objection to the insertion of animal-derived genes or cells into a human body—or even into human fetuses—where the aim would be to treat or prevent a dread disease in the patient or the developing child (although issues would remain about indirect genetic modification of egg and sperm that could adversely affect future generations). Likewise in the *context of biomedical research*, we now see nothing objectionable in the practice of inserting human stem cells into animals—though we admit that this is a scientifically and morally complicated matter. But in the *context of procreation*—of actually mixing human and nonhuman gametes or blastomeres at the very earliest stages of biological development—we believe that the ethical concerns raised by violating that boundary are especially acute, and at the same time that the prospects for drawing clear lines limiting permissible research are especially favorable. One bright line should be drawn at the creation of animal-human hybrid embryos, produced ex vivo by fertilization of human egg by animal (for example, chimpanzee) sperm (or the reverse): we do not wish to have to judge the humanity or moral worth of such an ambiguous hybrid entity (for example, a "humanzee," the analog of the mule); we do not want a possibly human being to have other than human progenitors. A second bright line would be at the insertion of ex vivo human embryos into the bodies of animals: an ex vivo human embryo entering a uterus belongs *only* in a *human* uterus. If these lines should be crossed, it should only be after clear public deliberation and assent, not by the private decision of some adventurous or renegade researchers. We therefore recommend that Congress should:

- **Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a nonhuman species; and**

- **Prohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm.**[*]

B. Respect for Women and Human Pregnancy, Preventing Certain Exploitative and Degrading Practices

Respect for women with regard to assisted reproduction encompasses many things, including respect for their health, autonomy, and privacy; these are by and large properly attended to in current assisted-reproduction practices. But in the face of some new technological possibilities, we recognize that respect for women also involves respecting their bodily integrity. A number of animal experiments using assisted reproductive technologies have shown the value of initiating pregnancies solely for the purpose of research on embryonic and fetal development or for the purpose of securing tissues or organs for transplantation. We generally do not object to such procedures being performed on other animals, but we do not believe they should, under any circumstances, be undertaken with humans, or that human pregnancy should be initiated using assisted reproductive technologies for any purpose other than to seek the birth of a child. A woman and her uterus should not be regarded or used as a piece of laboratory equipment, as an "incubator" for growing research materials, or as a "field" for growing and harvesting body parts. We therefore recommend that, in an effort to express our society's profound regard for human pregnancy and pregnant women, Congress should:

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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 a negligible likelihood that one might be formed, given the wide gap between the species. Thus, we do not believe that such procedures run afoul of the letter or spirit of the above recommendations.

- **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.**

C. Respect for Children Conceived with the Aid of Assisted Reproductive Technologies, Securing for Them the Same Rights and Human Attachments Naturally Available to Children Conceived In Vivo

We believe that children conceived with the aid of ARTs deserve to be treated like all other children and to be afforded the same opportunities, benefits, and human attachments available to children conceived without such assistance. If some care is taken, this can surely be accomplished, as it largely has been for twenty-five years with IVF as ordinarily practiced. But as we have seen, certain applications of embryo manipulation and assisted reproductive techniques could deny to children born with their aid a full and equal share in our common human origins, for instance by denying them the direct biological connection to *two* human genetic parents or by giving them a fetal or embryonic progenitor. We believe that such departures and inequities in human origins should not be inflicted on any child. We therefore recommend that, in an effort to secure for children who are born with the help of ARTs the same rights and human attachments naturally available to children conceived in vivo, Congress should:

- **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.**[*]

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[*] 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.

D. Setting Some Agreed-Upon Boundaries on How Embryos May Be Used and Treated

What degree of respect is owed to early human embryos will almost certainly continue to arouse great controversy, as it does among members of this Council. But we all agree that human embryos deserve, as we have said, "(at least) special respect." Accordingly, we believe some measures setting upper age limits on the use of embryos in research and limits on commerce in human embryos may be agreeable to all parties to the ongoing dispute over the moral status of human embryos. Along these lines, we believe that Congress should:

- **Prohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization);[*] and**

- **Prohibit the buying and selling of human embryos.[†]**

Furthermore, these concerns about commerce in the domain of human reproduction suggest to us the need for legislation

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[*] 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 fewer). *This recommendation should not be construed as silently endorsing (or opposing) embryo research at earlier stages.*

[†] This provision is not intended to preclude those 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.

instructing the United States Patent and Trademark Office **not to issue patents on claims directed to or encompassing human embryos or fetuses at any stage of development**; and amending 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**. 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.

These recommendations indicate the kinds of specific measures that could give concrete expression to widely shared goals and that might serve as safe interim boundaries, as public deliberation tries to catch up with rapidly changing technologies. We do not presume here to make detailed suggestions regarding specific legislative language or the assignment of penalties, as Congress, should it choose to take up these recommendations, would most appropriately determine these in accordance with its usual procedures. Also, of course, these are by no means the only possible legislative measures Congress might take up to limit practices that put at risk important shared public values. But we offer these recommendations for what in our view are reasonable and moderate measures, which could do genuine good and which might command relatively broad assent across the usual spectrum of opinion on these subjects.