In its most recent report, the President's Commission on Bioethics discusses the U.S. regulatory framework for reproductive technologies. We offer three perspectives, from the U.S. and from abroad.

essay

Something Old and Something New

BY KATHY HUDSON

The President's Council on Bioethics has explored a range of reproductive technologies over the last two years. It has now issued its findings and recommendations in a new report, *Reproduction & Responsibility: The Regulation of New Biotechnologies.* The report raises some important issues, but also overlooks some important concerns while overemphasizing others that are less immediate.

The report begins by laying out the "human goods" at stake. For some of these goods, such as protecting the health and well-being of children born with the aid of new reproductive technologies, the report endeavors to provide targeted recommendations. On others, however, the report is largely silent. To be sure, some of these goods may be less amenable to specific actions. But others, such as protecting the privacy of medical and genetic information and preventing inequality and discrimination based on genetic information, are ripe for policy and regulatory action based on a robust ethical and policy analysis. Regrettably, the report merely enumerates privacy and nondiscrimination as important goods, then dismisses them from consideration because these issues "have been the focus of professional self-regulation and legislative enactments." In truth, the nation has as yet been unable to enact legislation to protect against genetic discrimination, and clear and strong recommendations from the council on this matter would have been of considerable value in spurring legislative action.

Although the title of the report suggests its subject is "new biotechnologies," the focus is actually split between the now quarter-of-a-century old technology of in vitro fertilization and some "new" technologies that are, as yet, only imagined. What links the old and futuristic technologies considered in this report is that they all involve the creation or manipulation of the human embryo outside a woman's womb.

This presents another gap. Technologies involving the creation and manipulation of human embryos in the laboratory do indeed raise important safety and ethical concerns, yet other biotechnologies that are in widespread and growing use in reproduction, namely prenatal and carrier testing, are not considered at all. Millions of prospective parents each year are using genetic testing to find out about their own genetic makeup or that of their developing fetus and to make profound reproductive decisions. For many, planning for and building a family is the first time they must confront the many issues that attend genetic testing. As the number, type, and complexity of genetic tests continues to grow, so too will the questions that parents, prospective parents, and society must face regarding safety, equity, discrimination, human worth, and the meaning of a good life.

The report shines klieg lights on some issues in reproductive medicine that have not received enough attention. In particular, the report focuses attention on assisted-reproduction technology (ART) and the need for more data regarding the long-term health effects of ART on women and children. Like the council, I am deeply troubled that, with greater than 1 percent of all newborns in the United States getting their start with ART, we in the United States have done very little to assess the health and developmental outcomes of this growing segment of our population. When prospective parents are making decisions about bringing a child into the world and how they will go about doing it, they should have access to complete and accurate information on the risks and benefits to themselves and their future child. Thus I support the report's recommendations that a federally funded longitudinal study be undertaken to assess the impact of

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ART on children. The council also recommends that the planned NIH National Children's Study be used as a vehicle for collecting this data. This proposal is initially tantalizing because of its simplicity and minimal relative cost, but the NIH study would be unlikely to provide much meaningful data on ART children because the numbers will simply be too small. One would predict that 1,000 of the 100,000 children enrolled in the study would be conceived with the aid of ART. But 1,000 is too few to reveal increases in anomalies such as Beckwith-Wiedemann syndrome, which normally occurs in only one in 15,000 births. (The ART Children's Health Study that the Genetics and Public Policy Center has undertaken in conjunction with the American Academy of Pediatrics and the American Society for Reproductive Medicine will, we hope, provide the necessary foundation to design the sound prospective studies called for by the council).

The report also spends significant time analyzing (and calling for prohibitions of) several rather freakish processes that are at present largely in the realm of science fiction. The possible novel life-forms posited by the council—animal-human hybrids, cross-species gestation, and chimeric embryos, to name a few—would give any reasonable person the heebie-jeebies, and no one in good conscience could argue that these are activities we should pursue at the present time. But here, too, one may wonder about the practical relevance of this domain of the report's inquiry. Moreover, I fear that this focus on the freakish will convey a distorted, falsely negative impression of biomedical research and the reproductive medicine community as a whole, notwithstanding the report's laudatory remarks concerning the ethics and standards of the majority of scientists.

Policymakers have shown little interest in the recommendations of governmental ethics advisory committees: while past commissions have issued myriad recommendations, only a handful have been translated into concrete action, as measured by new legislation or regulations or the pursuit of new research priorities. To be sure, the value of bioethics commissions lies not only in how many new laws are passed, but also in the manner and scope of their inquiry and the public discourse that they foster. As noted repeatedly in the report and indeed, in the charter of the council, the charge of this commission extends beyond merely receiving testimony from organized stakeholder groups; it is also to provide "a forum for a national discussion of bioethical issues." Indeed, the report recognizes that many of the problems it identifies "demand serious public deliberation" and that certain recommendations would be premature if made without broad-based public input. Yet despite the aspirations of the mission statement, the council and its predecessor bodies have not been given the tools to conduct the broad-based public discussion that is needed here.

As one who has closely followed the progress of the council's deliberations, I have witnessed the metamorphosis that this report has undergone. The scope of the document's inquiry has expanded and its analysis is far more nuanced and balanced than were its early drafts. This change is largely due, I believe, to the council's diligent efforts to solicit input from a wide variety of stakeholders, including representatives of the infertility advocacy and reproductive medicine communities, as well as recognized legal and government experts.

Since its formation, the council has been the subject of extraordinary criticism about its composition and conduct. This report suggests that such concerns may have been overblown. Recent changes to the membership of the council have renewed criticism that the council is dangerously unbalanced. One can only hope that those concerns are likewise overblown, and that the council will continue to seek diverse points of view.

Paradoxes and Political Problems:

The U.S. Approach to ART as Seen from the U.K.

BY SANDY THOMAS

Viewed from a country where the development and application of new assisted reproductive technoloies (ART) are primarily regulated by a single statutory body, the U.S. approach seems something of a patchwork. A complex mix of federal, state, indirect governmental, and non-governmental regulation govern research and practice in ART. The President's Council on Bioethics' recent report, *Reproduction and Responsibility*, acknowledges and explains the complexity in the context of the U.S. legal landscape. In doing so, it concludes that the U.S. regulatory framework lacks coherence and that much within it is unenforceable. It ar-

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