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Beyond Bioethics

A Proposal for Modernizing the Regulation of Human Biotechnologies

Reproductive medicine and biomedical research are advancing quickly—though few seem to notice outside the medical and scientific communities. According to the Centers for Disease Control, in 1995 over 280 fertility programs were operating in the United States. Nine years later, in 2004, this figure had risen by 47%, to 411. An additional 50 clinics were also operating but not reporting their success rates, according to the CDC.[1] Should this trend continue, procreation by technological means could become a serious option for a significant fraction of the American public. Meanwhile, investments in biomedical science, which includes several fields of research that involve the manipulation of reproductive tissue such as animal embryos, eggs and sperm, have grown significantly. The NIH budget rose from $12 billion in 1996 to $28.5 billion in 2006.[2]

What are we to make of all this progress? In this essay we argue that scientific and medical progress related to reproductive medicine and biomedical research is

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a mixed blessing. It promises to reduce pain and suffering for millions of people and to cure many hitherto incurable diseases. At the same time scientific and medical progress in this area raises many disturbing ethical questions. Some of these questions go at the heart of what it means to be human. We believe these questions shouldn't be answered by market forces or by the logic of the scientific inquiry alone. Nor is it appropriate for the government to take a wait-and-see attitude. Scientific and medical trajectories are shaped as much by internal debates as they are affected by external political forces. What rules should govern reproductive medicine and biomedical research is a question that should vigorously be debated.

This essay is a contribution to this debate.[3] In the next section we examine some of the ethical questions raised by recent developments in reproductive medicine and biomedical research. We then turn our attention to possible societal responses, their justifications and criticisms. In the third and final section we suggest that a new federal regulatory institution is needed and we outline its main elements.

WHAT ARE WE CONCERNED ABOUT?

We begin with a prosaic but important question: how safe are assisted reproductive technologies (ARTs)? ARTs practitioners are quick to point out the excellent safety record in their field, but on closer examination doubts emerge. The industry has never implemented a robust system for monitoring the health of newborn babies. Some data is available, but as pediatricians point out, many medical conditions do not become apparent before six months of age. This means that to assess the health and safety record of ART procedures all ARTs babies should have thorough medical examination around their first birthday, but this is not being done, at least in the United States. Thus for lack of longitudinal data the industry cannot reliably assess the health of children born through ARTs.

Spurred by an alarming article published in the New England Journal of Medicine, a panel of medical experts recently conducted a thorough review of the medical literature on this subject, on behalf of the American Society for Reproductive Medicine (ASRM), and found no reason for concern.[4] Unfortunately the study was never published; ASRM communicated its main findings to the public by means of press releases. It is also worth noting that the committee consisted exclusively of industry insiders and that critical parties were not invited to participate in the review—facts that raise questions about its credibility. In sum, as long as "we don't know what we don't know," categorical statements about the safety of ARTs procedures seem premature.

ART technologies are raising more than just health and safety concerns. New ethical questions also arise as medical practitioners resort to innovative treatments in their quest to meet the desires of potential parents. Such treatments involve novel, and usually untested, medical techniques designed to increase a couple's chances of having a baby. For example, in 2001 an ARTs clinic experimented with ooplasm transfer, a reproductive procedure that relies on the reproductive tissues

of three individuals: the mother, the father, and a second, younger woman. [5] Children born through this procedure in fact have three biological parents, although the child inherits only mitochondrial DNA from the third parent (the younger woman).

Human embryos that are grown for several days on cow tissues—a technique known as co-culture—are another instance of an experimental procedure that disregards several basic rules of medical research. By definition the child cannot give his or her informed consent for what amounts to human experimentation with unknown health and safety risks.[6] As a news story reported in 2003, this technique occasionally has been used to treat particularly difficult cases of infertility. The woman's eggs are retrieved, fertilized in vitro, and grown for several days on tissue obtained from a cow uterus. The embryos are then transferred back into the woman's uterus. The story provides an excellent illustration of both parental desperation and of the risky choices parents and their doctors are willing to make.

And what should we make of advances in the cryopreservation of eggs? Many women will welcome the chance to pursue a professional career while maintaining intact their chances to have a baby, but the consequences for society may be profound, and not necessarily be positive. The average birth age would slowly but steadily increase and the nature and form of family relationships will undergo significant change. This suggests we should carefully examine them before declaring this technology as unambiguously desirable.

The arsenal at the disposal of ARTs practitioners is rapidly expanding from basic forms of assisted reproduction, such as in vitro fertilization, to medical technologies designed to give prospective parents increasing control over the process and the end result. This kind of reproductive technology is designed not merely to facilitate procreation, but to let the parents manipulate certain (mostly biological) attributes of a future child. Pre-implantation genetic diagnosis (PGD) is a good example. This technique was initially developed to prevent the transmission of dreadful and fatal diseases. A cell is removed from an early-stage embryo and its genetic material tested for certain medical conditions. Depending upon the test results, an embryo is either selected for implantation or discarded. Over the years the number of conditions that parents and the medical profession consider to merit discarding of the embryo has expanded considerably, including non-fatal conditions and late-onset diseases. PGD was recently used to screen for congenital fibrosis of the extraocular muscles (CFEM), a hereditary eye movement disorder. [7] ARTs doctors also rely on PGD to select children for tissue matching—that is, children intended to be tissue donors for older siblings affected by severely debilitating conditions. Until now, tissue matching has been used only to help siblings, but the procedure could also be used to cure a parent or a relative.

PGD affords prospective parents a very limited control over the procreative process, if by control we mean the ability to select specific biological and higher traits. But even these limited possibilities are becoming quite popular, According to a recent survey conducted by the Genetics and Public Policy Center at Johns Hopkins University, PGD is increasingly being used to select the baby's sex. [8] The

survey also documents several instances in which researchers used PGD to create babies with specific disabilities, such as hearing impairments, which some parents in the deaf community have seen as necessary to promote "deaf culture." As prospective parents gain increasing control over the reproductive process, we may see not only a culture of procreative perfectionism but also the opposite tendency: the desire of parents with disabilities to have children in their own image.

Medical researchers are not only learning to extend reproductive options, but are also changing the biological foundations of human reproduction. Consider two European research findings reported by the media in 2006. First, in the UK, scientists are seeking a license from the Human Fertilisation and Embryology Authority (HFEA) to create human-animal hybrids. [9] They believe that hybrid embryos can help overcome the problems associated with collecting human eggs. Large numbers of human eggs are a basic requirement for conducting research cloning experiments. The hybrid embryo results when an animal egg is cloned with human DNA. The chromosomal DNA of a hybrid embryo would be human, but the mitochondrial DNA would be inherited from the animal egg. On its face, this approach seems promising indeed, but as for other promising scientific experiments, the transition from the lab to clinical settings raises serious ethical concerns: we do not know what the consequences of this kind of experimentation may be on the patients.

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Second, scientists at the University of Milan report successfully deriving human stem cell lines from eggs stimulated to divide without sperm.[10] This process, known as parthenogenesis, produces so-called parthenotes. Parthenotes normally do not survive more than a few days, but the team managed to keep the parthenotes alive until they reached the blastocyst stage when stem cells could be extracted. The scientists showed that, like ordinary embryonic stem cells, their cell lines can differentiate into neurons. The fact that parthenotes can be kept alive could open up new reproductive options, including asexual reproduction.

These experiments have no immediate clinical application at present because they have been conducted only on animal models. But why should we believe that scientific research will stop there? As the efficacy and reliability of these procedures improve over time, researchers will be tempted to apply them to human beings. We suspect that use of these techniques on human beings will be hugely controversial,

and should not be undertaken until there is a broader public discussion about their ethical implications. Which new reproductive possibility will eventually materialize is impossible to say with any degree of confidence, but the options are clearly many.

Nor should we think that commercialization will lag far behind. Last year, an entrepreneur in Texas began offering "made-to-order" human embryos.[11] At his clinic prospective parents can choose both egg and sperm donor, based on physical characteristics. If the present trend continues, human eggs may become an important source of revenue for low-income women and students. That the price for human eggs is rising suggests that demand is high and increasing and supply is not keeping up. And the sale of sperm can almost be considered an American cultural tradition. Not surprisingly, news reports on these developments have focused exclusively on possible health risks for the donors. While this is certainly an important consideration it is hardly the only one. It may be worth pondering whether these practices will undermine our view of children as a gift, or whether they are pushing us towards regarding children as made-to-order objects.

Against this background, we believe a discussion of possible societal responses, including legislative and regulatory interventions, is warranted. Before examining regulatory options however, we address some of the most common criticisms against regulatory action.

IDENTIFYING APPROPRIATE SOCIETAL RESPONSES

To libertarians, the examples just described may not be severe enough to justify regulatory intervention. In their view, government regulation is acceptable only when an activity can be definitively shown to cause harm, narrowly construed to mean physical and immediate harm. The excesses of the regulatory state offer many cautionary tales of ineffective or misguided regulatory interventions, and tend to reinforce a very cautious stance towards new interventions. But the libertarian position fails to consider another important fact: in reproductive matters, individuals are not making decisions just for themselves. Their choices have many potential consequences for a future human being. As is clear from the fierce opposition to PGD among advocates of the disabled, the debate about the consequences of new procreative technologies extends well beyond physical and immediate harm. One cannot really appreciate the full impact of these technologies on democratic politics without taking a more expansive view of harm.

Advocates of unencumbered medical and scientific progress also criticize fears of a slippery slope in which near-term precedents pave the way for longer-term abuses. But the examples above demonstrate that in the area of reproductive medicine and biomedical research we have already moved a considerably way down some slippery slopes already. Over time, we can expect more effective reproductive techniques and new cures to become available. At the same time, ART technologies will continue to evolve from purely assistive techniques to tools of reproductive control and customization. The term "reproductive customization" should be

understood literally: couples, and even individuals, will have access to a range of reproductive techniques that will let them make specific choices about the health, the sex and—eventually—other attributes, physical or cognitive, of a baby. More generally, it is hard to see how we can dismiss the notion of the slippery slope if we fail to renounce to its counterpart, the virtuous slope, which expresses an exaggerated and unwarranted optimism about the beneficial effects of scientific and technological progress. The notion of the slippery slope simply reflects a cautious approach to momentous medical developments.

Most people organize their daily lives on the assumption that the future indeed can bring undesirable consequences. That is why we take precautions even if we are in no position to prove beyond doubt that a given activity will have a harmful impact on us. We buy earthquake insurance, without knowing whether or not an earthquake will actually destroy our home. We exercise regularly because we know that a sedentary life may have serious negative health effects. We quit smoking, even though only about one smoker in ten will suffer serious negative consequences. And we wear helmets while riding bicycles, though we are not likely to have an accident on a given day. In all these cases we are taking precautions, even though no one can give us definitive proof of actual and immediate harm. Governments in all liberal democracies have been operating in a similar vein for a long time. Recognizing that laissez-faire attitude may be just as harmful, if not more so, than early regulatory interventions, governments often adopt regulatory actions even in the absence of immediate harm. In addition to recognizing that excessive regulatory intervention may be harmful, it is also important to consider the (possibly negative) consequences of government inaction and to do so on the basis of an appropriate notion of harm.

Existing federal agencies do not have the capability to carefully work through complex ethical dilemmas.

Virtually all other industrialized countries have already moved to create regulatory institutions to manage the ethical and safety dimensions of reproductive biomedicine. We believe the existing arsenal of laws and regulations in the United States will not provide adequate legal responses. As we discuss in some detail in our report,[12] the federal statutes in this area are patchy at best. Existing federal agencies do not have the capability to carefully work through complex ethical dilemmas. In particular, the Food and Drug Administration, the prime candidate for taking on new regulatory responsibilities, is permeated by an organizational culture that focuses on safety and efficacy rather than broad ethical concerns. Nor are state-level laws a good substitute for federal legislation. Very few states have enacted legislation pertaining to reproductive medicine, and none of them are designed to resolve ethical dilemmas. And as the history of the regulatory state clearly demonstrates, adopting reactive, sweeping legislation like bans on specific types of proce-

dures would most likely be counterproductive, making it impossible to draw the kind of fine distinctions that many biomedical developments require. Finally, self-regulation is not likely to succeed: conflicts over the use of novel reproductive techniques need to be resolved by public institutions, not by the medical profession and patient groups.[13]

THE NEW REGULATORY ARCHITECTURE

For all these reasons we believe that a new regulatory architecture is needed. Our regulatory proposal, which we outline below and discuss in much more detail in our report, consists of a set of ethical principles and a new regulatory institution responsible for interpreting and applying these principles.[14] The Congress for its part would be charged with resolving the most important controversies—such as the moral status of the embryo—by identifying those medical procedures that should be banned outright. It will be up to Congress to say, for example, whether research cloning is prohibited, allowed, or regulated. It would identify which activities can be performed under suitable regulatory oversight, and would establish in some detail the structure of the new regulatory institution. Finally, it would adopt several procedures, above and beyond the usual requirements of the Administrative Procedure Act, to ensure that the agency is independent, and to prevent administrative drift, what legal scholar describe as "arbitrary and capricious regulatory decisions."

The ethical principles outlined below touch upon several basic aspects of the human experience. They reflect what we believe are widely shared values, not only in the United States but also in many other Western democracies.[15]

- *The well-being and health of children should be protected.*
- *Biomedical procedures involving human embryos must respect their intermediate moral status.*
- *Access to ARTs for infertile couples should be promoted.*
- *The well-being and health of women should be protected.*
- *Free and informed consent must be required from everyone making use of ARTs.*
- *Therapeutic uses of biomedicine should be favored over enhancement uses.*
- *Limits should be imposed on the commercialization of eggs, sperm, and embryos.*

Some of these principles, like informed consent, and protecting the health and well-being of women, are hardly controversial. Others, such as ensuring children's health and well-being, should not be considered controversial, though some may eye them with suspicion. Still more controversial is the idea of requiring regulators to favor therapeutic over enhancing applications. We realize that our set of guiding principles is just that: an obligation to make determinations that in reality may be arduous and fraught with ambiguity. But these determinations are no different from those the courts are called upon to make every day. As a matter of practice, even uncontroversial ethical principles such as assessing the effectiveness of a drug or medical device can raise difficult interpretive questions. Yet the Federal Drug Administration, the agency responsible for ensuring the safety and effectiveness of

drugs, biological materials and medical devices, makes such determinations on a daily basis—without access to analytical, unambiguous definitions. [16]

Based on these principles, we believe Congress should ban several activities, including reproductive cloning, germ-line genetic modifications, and certain forms of human-animal chimeras and hybrids. It should regulate research cloning (i.e. somatic cell nuclear transfer for research purposes), pre-implantation genetic diagnosis, and biomedical research involving early-stage embryos, among other things. These suggestions are neither exhaustive nor definitive. Indeed, one could easily imagine prohibiting research cloning, at least for a certain period, or strictly regulating certain forms of germ-line genetic modification. And perhaps elective sex-selection should at least be regulated. In our view, the legal and ethical stance that Congress takes on any of these issues is ultimately less important than establishing a precedent for making legally binding distinctions between acceptable and unacceptable reproductive practices.

Neither scientific competence nor moral authority can stand alone.

Assuming that Congress takes control of such issues, how would its intent be implemented? We suggest a regulatory agency that operates according to a few basic principles. First, all affected constituencies should perceive it as independent, not as unduly influenced by interest groups. A second basic requirement is accountability: regulators should not be able to make what lawyers call "arbitrary and capricious" decisions. Third, the agency should be seen as authoritative by all interest groups, and the general public: regulators should be technically competent and regarded as morally credible. Neither scientific competence nor moral authority can stand alone.

Efforts to reconcile independence and accountability may appear mutually exclusive, since an agency with a great deal of independence would seem to be less accountable, but independence, in the jargon of administrative law scholars, has a fairly specific meaning. An independent agency is afforded considerable autonomy by the Office of the President—but it is not outside Congressional reach. Despite statements to the contrary, Congress often uses its budgetary authority to control and influence independent agencies. Formally, these agencies may be more independent than executive agencies, but some organized interest groups and affected parties may not see an independent agency as truly independent.

The new independent agency should be led by a commission, and not by a head of agency. An independent commission has several attractive attributes. Its members are selected by the president but confirmed by the Senate. Their appointment is staggered, and the president can remove them from office only in special circumstances. It also operates in a deliberative way. These facts make an independent commission particularly well-suited to perform a quasi-judicial function, particularly important in light of the need to interpret Congressional intent as expressed by the ethical principles laid down in the enabling legislation.

To protect an independent commission from regulatory capture—that is, undue influence from Congressional and interest groups—and also ensure accountability will require that the Administrative Procedure Act (APA) be complemented by a a novel procedure. The APA mandates that before regulatory agencies finalize a new rule, they must publish the proposed rule in the *Federal Register* and solicit comments from all interested and affected parties. This provision, simply known as notice-and-comment, was intended to ensure a measure of accountability: agencies must consider, and respond to, all substantive comments submitted by the public. The courts have repeatedly underlined the importance of regulatory agencies providing extensive and detailed justifications for their regulatory interventions.

For the first time in the history of modern administrative law it is becoming possible for the public to take on an active role in politics outside regular elections and referenda, a possibility that should be taken seriously.

These judicial decisions, known collectively as the hard-look doctrine, have had several unintended consequences. First, they have forced regulators to consult extensively with those organized groups most likely to make use of the court system. In the context of reproductive medicine and biomedical research, consultation with organized interest groups is likely to produce the kind of political gridlock we have seen at the Congressional level over the last several years. This outcome would be particularly problematic since, as we show in our report,[17] the general public is far more centrist on many controversial issues than either the pro-science or the pro-life camp. This kind of gridlock indicates a special kind of political failure: our current administrative system cannot ensure that all societal perspectives are being heard, and not just those of organized interest groups.

To prevent regulatory gridlock, in our report we propose complementing notice-and-comment with a robust procedure of public consultation.[18] One can envisage different ways to implement a consultative process, but we see three requirements that should always be met. The consulted sample of the public should be representative of the population at large. The consultation should be deliberative, and based on two-way communication. And the outcome of a consultation should reflect informed opinions. In addition, the process should be designed to avoid polarization: it should promote reciprocal understanding among all participants and help reduce pre-deliberation prejudices. By contrast, a process of public consultation is not designed to produce a consensus, though it is certainly intended to promote consensual views.

The results of such a consultative process would not be binding. Regulators would be free to propose a new rule that departs significantly from the recommendations emerging from a public consultation, but they would be required to provide a detailed rationale for their decision to ignore informed public opinion. This requirement represents a strong disincentive for regulators who might favor a special interest group over a clear consultative outcome. In its decision-making process the agency would have to consider the possibility that the judiciary could review this rule. Furthermore, in particularly controversial cases a blatant abuse of administrative authority would likely attract wide public attention, eventually triggering intense Congressional scrutiny. In most cases, the combined risk of judicial review and public scrutiny should deter the agency from heeding special interests. Note that a public consultation also protects an agency against Congressional influence: an agency facing an unambiguous consultative result would be very reluctant to consider Congressional demands informed by specific constituencies. In sum, a process of public consultation provides one more mechanism by which a formally independent regulatory agency can be held accountable, thereby hopefully reducing "arbitrary and capricious" decisions to a minimum.

The kind of political failure we have identified in our report[19] is not limited to reproductive medicine or biomedical research; it is quite common across the regulatory state. Regulatory agencies, ranging from the Environmental Protection Agency to the Department of Energy to the Occupation, Safety and Health Administration, have a long history of producing regulatory decisions driven by the most influential interest groups, to the detriment of the public at large. This phenomenon is certainly not new, but commentators and practitioners have long ignored it, for two main reasons. When the theory of public choice arrived in the 1960s scholars of the administrative state largely abandoned explanations of political action based on the notion of a general public interest, and started to see administration and politics as based merely on the aggregation of self-interested motives. The economic analysis of politics, which some consider to be excessively cynical, has succeeded extremely well in illuminating many administrative and political phenomena. On the other hand, it has prevented scholars and practitioners alike from focusing on some serious shortcomings of our regulatory system. The kind of political failure we have discussed here is a case in point. Our discussion suggests that, conceptual difficulties notwithstanding, it is quite easy to identify cases in which the public interest is being systematically ignored. To this end, no formal definition of public interest is needed, merely the empirical observation that on an issue of national import a key constituency—the public—is not being heard.

A second important reason for ignoring the kind of political failure discussed in this essay is the lack of practicable corrective measures. Until recently, no viable options were available to mobilize a large, unorganized political constituency. Information technologies are changing this situation. For the first time in the history of modern administrative law it is becoming possible for the public to take on an active role in politics outside regular elections and referenda, a possibility that

should be taken seriously.

The regulatory institution we propose seeks to break out of this kind of administrative deadlock. More importantly, it seeks to move decisions about reproductive ethics out of the realm of bioethics and individual choice, and into the political realm where they can be debated by the broader political community. Because these decisions can help shape the future of humankind, they should not be left simply to individuals and the market.

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    Christian Science Monitor 18/1/2007 ''Embryo bank': new hope or too far?'.
12. Supra, footnote 3, ch. 5.
13. Supra, footnote 3, ch. 5.
14. Supra, footnote 3, ch 10-12.
15. Supra, footnote 3, ch 3.
16. While we believe that it is up to the political process to make the ultimate determination about the moral status of the embryo, our own view is that the embryo as neither a mere clump of cells, nor the moral equivalent of an adult individual. We do not believe an embryo deserves the same legal protection as someone already born. At the same time we believe an embryo is more than just biological material and deserves some measure of respect. This position is consistent with the view expressed in 1999 by the National Bioethics Advisory Commission in its report on stem cell research. It will not satisfy pro-life advocates, but it is defensible and creates a much-needed space for political compromises. (National Bioethics Advisory Commission (1999): *Ethical Issues in Human Stem Cell Research*, Vol. 1. Rockville, MD)
17. Supra, footnote 3, ch. 8.
18. Supra, footnote 3, ch. 12.
19. Supra, footnote 3, ch. 10.