Executive Summary

1 Overview

This report presents a proposal for a new approach to regulating reproductive medicine and biomedical research in the United States. It is the product of more than three years of research, and of a study group convened in Washington, D.C., dedicated to this subject. The members of the study group, numbering 42 people, were chosen to be representative of the different stakeholders in reproductive medicine and biomedical research, including the American Society for Reproductive Medicine (ASRM), the Federation of American Societies for Experimental Biology (FASEB), the American Association for the Advancement of Science (AAAS), the Council of Scientific Society Presidents (CSSP), the President's Council on Bioethics, the Biotechnology Industry Organization (BIO), the National Osteoporosis Foundation (NOF), and the Food and Drug Administration (FDA). While they have intensively discussed various issues raised in this report, these organizations have not been asked to endorse this report or its final conclusions, which the report's primary authors take full responsibility for.

It is our belief that the existing system for regulating reproductive medicine and biomedical research in the United States, while unrivaled in many respects by that of any other country, contains certain gaps or omissions that will render it increasingly inadequate to meet the challenges posed by new biotechnologies and medical procedures in the coming years. Other developed countries have put new regulatory institutions in place already, or are in the process of doing so in anticipation of new developments, and the United States must follow suit.

In putting forth the proposals laid out in this report, we fully understand the downsides of regulation. If you regulate something, you get less of it, and many people fear that excessive regulation of biomedicine will stifle innovation and progress in many areas critical to human health and well-being. While this fear is often well-founded, we believe that properly designed regulation can have the exact opposite effect: It can promote research and scientific advances by establishing a clear framework under which innovation can take place, a framework that reassures the broader society that the research is being conducted safely and ethically.

1.1 Domain of Inquiry

In this report, we intend to focus on technologies and medical practices related to human reproduction and on research activities focused on reproductive tissues. Our reasons for choosing these areas are that they encompass most of those technologies, existing, over the horizon, and possible in the more distant future, that bioethicists have pointed to as raising significant moral and ethical issues. Within this domain lie – among other things – human cloning, prenatal genetic diagnosis, genetic testing, germ-line modifications, embryonic stem cell research, the creation of human-animal chimeras and hybrids, and novel forms of reproduction (such as the creation of embryos from the genetic material from one, three, four, or more parents). It includes medical and clinical practices involving both old and new assisted reproductive technologies

(ARTs) as well as laboratory research involving embryos, both as an object to be manipulated and as a source of biological tissues like stem cells, and other reproductive tissues.

It should be noted at the outset that to say that these technologies are related to human reproduction does not necessarily mean that they are *intended* to produce children. This is particularly true of embryonic stem cell research, whose end is, of course, the development of treatments for diseases affecting already-living human beings. Nonetheless, the fact that such stem cells are derived from embryos and may in the future be capable of producing embryos means that it is impossible to regulate the broader field of human reproduction without regulating them. Indeed, the manipulation of stem cells may become the primary technological gateway through which many of the other reproductive technologies noted above become possible.

To say that these practices should be regulated is not to say that they should be banned or unduly restricted. As we explain in greater detail below, it is our view that stem cell research would greatly benefit from being placed within a regulatory framework. But precisely because embryonic stem cell research today requires the use of embryos and may at some point in the future lead to the creation of embryos, it is not possible to separate this kind of work from research and medical practices that aim directly at creating children.

1.2 Embryo Politics

It is safe to say that in the United States, all legislation in the general area of reproductive medicine and biomedical research is made vastly more complicated by the underlying societal controversy over the moral status of the embryo. Other developed countries that have passed legislation in this area have reached consensus either to permit (as in the case of Britain) or to prohibit (as in the cases of Germany and Canada) certain forms of embryo research. In the United States, there are passionate proponents of both the pro-life and pro-choice positions.

We do not begin from a pro-life position. We believe that human embryos have an intermediate moral status. They are, on the one hand, not the moral equivalents of newborns; destruction of an embryo, for us, is not tantamount to murder. On the other hand, we do not believe that embryos are just clumps of cells like any other tissue specimen; because they are potential human life, they deserve some degree of respect. We believe that a regulatory system that keeps track of such embryos, permitting them to be used for select scientific purposes but prohibiting their casual creation or destruction, is an appropriate way of recognizing this intermediate status. Our ethical concerns in this area relate not to embryo destruction per se as much as to other technological possibilities that are either emerging now or will appear in the coming years.

We raise this issue not to persuade others of our case, but rather to point out that there are several deeply held alternative views on this issue, over which it is not likely that there will be consensus any time in the near future. These large moral questions cannot possibly be delegated to a regulatory agency. They must rather be adjudicated at higher levels of the political system, in Congress and the state legislatures or, less optimally, through the court system (as has actually happened in the case of the legalization of abortion). Indeed, if any kind of regulatory system

involving human embryos is to succeed, it is critical to fence off the realm of delegated authority from the issues of abortion and embryos' moral status.

We believe that embryonic stem cell research should proceed with federal funding, and that a new regulatory system will actually promote that end. We note that Britain, with its Human Fertilisation and Embryology Authority (HFEA), has one of the world's strictest regulatory environments in this area, and yet is a leader in stem cell research.

1.3 Regulation: General Considerations

Most Americans rightly regard regulation as a necessary evil; with the rapid growth of the state sector in developed countries in the twentieth century, it became clear by the 1970s to many people that many parts of the American economy were over-regulated. Much of the thrust of policy in the United States since then has been to cut back on regulation in areas ranging from airlines to trucking to electricity to telecommunications. In some cases, like telecom deregulation, this has led to great success; in others, less so. The dangers of over-regulation remain, however, and the burden of proof ought to lie with anyone who argues that new regulatory bodies are necessary.

A useful prudential rule in public administration is not to multiply regulatory agencies unnecessarily when the new functions required can be performed just as easily by existing ones. On the other hand, certain historical precedents suggest that it is at times wiser to create a new institution to deal with a new problem. Take the case of transportation, for example. The former Interstate Commerce Commission (ICC) was created in 1887 to regulate the new railroad industry. At the beginning of the twentieth century, the rise of interstate trucking posed the question of who should regulate this new industry. The Hepburn Act of 1906 gave regulatory authority to the ICC on the grounds that trucking and railroads were similar, both being means of moving goods across state borders. Most experts in administrative law believe now, in retrospect, that this was a mistake: The economics of the rail and trucking industries were very different, the interest groups involved differed substantially, and the technical expertise require to regulate rail service did not spill over into trucks.

When commercial aviation emerged in the 1920s, regulation of this sector could have been given to the ICC on the grounds that airplanes are simply another means of interstate commerce. Instead, the Air Commerce Act of 1926 created a new independent Aeronautics Branch within the Commerce Department to promote and ensure the safety of civil aviation. With the advent of commercial jet aircraft after World War II, this branch eventually evolved into two independent agencies – the Federal Aviation Administration and the Civil Aeronautics Board. It is doubtful that anyone today regrets this choice to create new agencies to regulate aviation rather than building on the authority of the ICC.

The question to consider here, then, is not the broad one of whether or not to regulate reproductive medicine and biomedical research, as a positive choice was made in this area long ago. The question, rather, is whether we are currently at a juncture somewhat like the mid-1920s, when civil aviation first emerged as a new but highly promising industry. Do we regard the

issues raised by new biotechnologies as cases of problems with which we are already familiar, or are they sufficiently different in kind as to merit new regulatory powers? Surely, no one in a liberal society wants to multiply regulatory agencies unnecessarily or add more layers of bureaucracy. On the other hand, it is sometimes more efficient to begin afresh rather than trying to change bureaucratic cultures to handle problems they were never designed to handle.

2 Sources of Concern

2.1 General Ethical Principles

We believe that human reproduction is a particularly important and morally meaningful part of human life, and that society has an inherent interest in protecting the human values associated with it. We will begin by laying out a general set of ethical principles that we believe should guide regulation in the domain we have defined above – namely, medical practices related to human reproduction and research activities involving reproductive tissues. We believe that these general principles are ones that the American public will broadly support, and we have considerable polling data to back this up. The following is a set of principles that we believe any regulatory system touching on this domain should promote.

The well-being and health of children. Since reproduction aims at the creation of children, their welfare ought to be placed first and foremost as an objective of regulation. We believe that this means, in the first instance, better and more systematic monitoring of health outcomes. Compared to other developed countries, public oversight of assisted reproductive technologies in the United States is limited, and funds to carry out studies have thus far also been very limited.

It may seem obvious that the well-being and health of children ought to have priority over the interests of other stakeholders in reproductive medicine, including parents, doctors, clinics, and biomedical researchers. Many discussions of new reproductive technologies, however, often put the wishes and desires of potential parents foremost. Clearly, parents who want children also want the best for their children, and so the law generally allows them generous discretion in following their own instincts, under the assumption that this will also lead to good outcomes for their children. But it is not always necessarily the case that what parents want will correspond to the best interest of their children.

We interpret "well-being and health" broadly to mean not just physical health, but psychological and social well-being as well. We believe that this means that every child has the right to be genetically related to a mother and a father, even though they may be brought up in a variety of households in which the genetic mother and father may be absent. We believe that this right overrides the interest of parents in creating biological offspring through novel medical techniques like cloning or the harvesting of fetal eggs (see the following section on prohibited activities).

Equal access to ARTs on the part of infertile couples. At this point, more than one million children have been born worldwide through ARTs. The benefits of these technologies to infertile parents have been enormous, and equal access to them ought to be a priority. In the United States, however, treatment for infertility is often not regarded as an insurable medical condition, but rather as a health option. Insurance coverage varies by state, and many Americans do not have access to ARTs because of their cost. Expanding the availability of safe ARTs and equalizing their costs ought to be a policy priority.

The well-being and health of women. ARTs frequently involve special risks to women, particularly due to the need to take fertility drugs that stimulate ovulation. Most ARTs involve invasive medical procedures; new techniques that may become available in the future could lead to pregnancy complications that do not exist now. We place the priority of women's well-being and health somewhat lower than that of children and of infertile couples, only because the women who take these risks generally do so voluntarily and in full knowledge of possible adverse consequences.

Informed consent. It is important to recognize that a great deal of what happens in ART clinics constitutes a form of experimental medicine. It is very important, therefore, that parents be fully informed ahead of time as to existing risks, and in cases where procedures are genuinely novel, that they be informed of this as well. This, in turn, generates requirements for better data collection on actual risks.

Limits to commercialization. While the practice of medicine using assisted reproductive technologies constitutes a business for the doctors and clinics participating in it, we believe that there should be limits to the commercialization of many aspects of reproduction. This involves limits on production and sale of eggs and sperm, and particularly on the production and sale of embryos.

Therapeutic over enhancement uses of ARTs. We believe that the priority in biomedical research and clinical practice ought to be given to therapeutic ends – that is, healing the sick and relieving the pain and suffering of those suffering from pathological conditions.

These general principles, then, need to be translated into specific rules that would be used to guide regulators. The rules are divided into two categories: (1) activities that we believe ought to be banned outright, and (2) activities that should be permitted, but regulated.

2.2 Targets of Prohibition

On the list of banned activities are:

Reproductive cloning. All versions of the cloning legislation that have been introduced in Congress since 2001 have included bans on reproductive cloning. Human reproductive cloning is not today something that can be done safely, and for that reason alone should be banned on the basis of the principle of prioritizing the health and well-being of children.

Creation of chimeras and hybrids. We believe that the creation of human-animal chimeric and hybrid embryos for the purposes of reproduction should be banned. Other situations in which

human and animals cells, tissues, and organs are mixed for purposes of biomedical research are less problematic and should not be subject to significant restrictions. Animal-derived organs are now routinely implanted in humans, and animal-derived genes may be available in the future for treating human diseases; all of these are by and large legitimate activities. There may be complex cases where the degree of human and animal mixing may become ethically problematic; we believe that determining this boundary is something that can be left to the regulatory authority, at least initially.

Germ-line modification. Germ-line modification of human beings, of the sort that is now done routinely with plants and animals, cannot now be done safely, and should therefore be banned. It necessarily involves a kind of experimentation on human beings who will clearly not be able to give their informed consent, and therefore violates the first and fourth ethical principles laid out above.

New reproductive possibilities that alter the genetic relationship of parents and children. There are a number of technologies emerging that will make possible the creation of children who are not the offspring of one man and one woman, as every human child has been up to now in the history of our species. We believe that the first ethical principle enunciated, placing priority on the well-being of children, gives all children a right to be born out of the union of a man and a woman, and that technologies that alter this fundamental relationship ought to be banned.

Patenting of human embryos. We believe that property rights in a human embryo should be banned. Property rights are usually granted to stimulate research and innovation; there will be plenty of other incentives to conduct necessary embryo research in the absence of ownership rights in specific embryos.

2.3 Targets of Regulation

Other activities we believe are ethically legitimate, but ought to be carried out under carefully controlled circumstances, include:

Research cloning. We believe that research cloning should be permitted but tightly regulated. We see why many people who are not troubled by the use of excess embryos in stem cell research may yet oppose the deliberate creation of cloned embryos for research purposes. We believe, however, that whatever extra instrumentalization this act may imply does not outweigh the gains potentially to be derived from this kind of research. It is, however, particularly important for the regulatory authority to monitor and control this kind of research very carefully – not just because of what we call the intermediate moral status of embryos, but also because it is the only way to enforce a ban on reproductive cloning.

Pre-implantation genetic diagnosis. Pre-implantation genetic diagnosis (PGD) is a service performed by many fertility clinics. We believe it is an important way for couples with heritable genetic disorders to ensure that those conditions are not passed down to their children. On the other hand, PGD involves certain kinds of risks and creates incentives (for example, for the production of large numbers of eggs and embryos) that could pose serious health problems for

the women involved. Using PGD for non-therapeutic purposes raises a host of ethical issues, and should be strongly discouraged by the regulatory system.

Biomedical research involving early-stage embryos or blastocysts. We believe that medical research on embryos or blastocysts is important and legitimate, but that it ought to be done under carefully controlled circumstances, given the intermediate moral status of embryos. This means that the regulatory authority ought to monitor and control the creation and transfer of all embryos used for these purposes, much as the British HFEA does currently. This kind of regulatory capacity will also be necessary in order to enforce any reproductive cloning ban.

Commercialization of elements of human reproduction. We believe that the buying and selling of human embryos should be strictly regulated, again, given their intermediate moral status. We believe that embryos can be used for research purposes and that a limited market should be allowed to develop to facilitate their transfer (for example, excess embryos from ART clinics), but that all such transfers should be carefully tracked by the regulatory authority.

3 The Current Legislative and Regulatory Framework

3.1 Federal Regulators

Human biomedicine is and has for a long time been one of the most heavily regulated areas of endeavor in the United States. The FDA's "gold standard" of costly, double-blind clinical trials for pharmaceuticals is unmatched anywhere the world. On the other hand, the FDA regulates only drugs, medical devices, and biological products (or "biologics"), and can regulate them only on the basis of safety and efficacy. It does not directly regulate the practice of medicine, which means that the large area of medicine involving assisted reproductive technologies receives virtually no direct federal government oversight. While the FDA strictly enforces testing procedures for new drugs, it does not control their off-label uses, meaning that doctors are free to innovate and in effect experiment on their patients in such cases.

The other big regulatory institution in the United States is the National Institutes of Health (NIH), which through its control over federal funding exerts enormous control over the nature, scope, and direction of scientific research in biomedicine. It is the NIH that now oversees bodies like the Recombinant DNA Advisory Committee (RAC), and requires institutional review boards (IRBs) to monitor research involving human subjects. The NIH is not limited to considerations of safety and efficacy like the FDA; it can and has introduced moral and ethical concerns into its decision-making. President Bush's August 2001 decision limiting federally funded stem cell research to existing stem cell lines reflected his concerns over protecting embryos, and was implemented by the NIH. Here, the limits of regulatory authority are different than in the case of the FDA. The NIH can influence science only through its control of funding; it cannot prohibit privately funded research, and it has no say over what happens in the private biotech industry.

In addition to the statutes governing the FDA and the NIH, there are other federal statutes relevant to assisted reproduction, including the Clinical Laboratory Improvement Amendments

(CLIA) of 1988 and, more importantly, the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992. CLIA was designed to ensure that clinical laboratories meet a range of quality and safety standards, but it does not provide regulatory guidance for ethically problematic reproductive choices. FCSRCA did establish a model program for the certification of embryo labs that could play a central role in facilitating monitoring practices of reproductive medicine and compliance assurance. This program, however, has not been implemented by any state, and would in any event lack credible sanctions.

Publicly funded research on human subjects (by the NIH or any other federal agency) is governed in large measure by institutional review boards, as required by what is known as the "Common Rule." Privately funded research involving human subjects also is subject to IRB review, but in these cases, IRB review rules and procedures drafted by the FDA apply.

Neither the Common Rule nor the FDA's own set of regulations governing IRBs and privately funded research on human subjects establish clear jurisdiction and authority over potentially controversial research involving reproductive technologies. IRBs are designed to protect human research subjects, and not to make judgments about the ethical appropriateness of the research protocols.

There are, of course, any number of other agencies that have regulatory authority over various aspects of human biomedicine, including the U.S. Patent Office and the Drug Enforcement Agency. This agencies' main mission, however, is not to regulate reproductive medicine or biomedical research; their impact is not insignificant, but is indirect.

3.2 Direct Legislative Intervention

Since 2001, Congress has attempted more than 40 times to pass legislation related to cloning and stem cell research. None of these initiatives has become law. These legislative proposals fall essentially in two distinct categories – prohibitions of any kind of cloning research, and bills that explicitly ban, and often criminalize, cloning for reproductive purposes, but legalize cloning for research purposes.

An example of the latter is Senate Bill 303, referred to the Senate Judiciary Committee in 2003, where it has languished ever since. This bill establishes a legal framework for conducting research cloning, requiring that nuclear transplantation research be scrutinized by an institutional review board, and that informed consent must be obtained from the human subjects involved in the research. As indicated above, the ability of IRBs to make complex ethical determinations is very limited, and thus the oversight provided by this framework is inadequate. The British HFEA, which seeks to facilitate stem cell and embryo research, subjects researchers to much stricter scrutiny than is laid out in Senate Bill 303.

3.3 Regulation by States

States, and not the federal government, are the primary regulators of the practice of medicine. The rules they establish in this area may or may not be specific to assisted reproduction. State regulation includes the licensure of physicians, facility licensure, hospital

credentialing, requirements for DEA registration on the part of doctors and hospitals, enforcement of informed consent rules, establishment of requirements for malpractice insurance coverage, and other requirements. In theory, states could use these powers to revoke the licenses of physicians that practice unsafe procedures like reproductive cloning, though it is not clear how well any state agencies are set up to make rules in this area and to enforce them.

Several states have enacted legislation in the area of reproductive medicine, but state-level legislations are generally limited to very specific aspects of reproductive medicine. Recent state laws either attempt to ban any kind of cloning or limit the ban to reproductive human cloning. Among the states that have banned both reproductive and research cloning are Arkansas, Iowa, North Dakota, South Dakota, and Michigan. New Jersey and California, both home to large biotech sectors, have passed legislation banning reproductive cloning but legalizing research cloning. In our view, these state measures have failed to provide sufficient regulatory oversight. California is notable insofar as it drafted model legislation in 2003 to provide for state regulatory oversight of embryo research, legislation that was then superseded by Proposition 71. The latter, which passed in November of 2004, removed most prior institutional safeguards, and is in our view totally inadequate as a regulatory model.

3.4 Self-Regulation

Both foes and advocates of regulation often see industry self-regulation as quite distinct from government oversight, but in fact the line between the two is often blurred. The government often relies on private sector groups to achieve public goals (for example, the Underwriters Laboratories' role in consumer safety), or else backs up private enforcement through an implicit threat of formal sanctions (for example, the Securities and Exchange Commission).

Over the last 25 years, the American Society for Reproductive Medicine has developed most of the currently existing medical and ethical guidelines in the area of reproductive medicine. The Society for Assisted Reproductive Technologies (SART), which comprises most of the nation's ART programs, has a well-established though narrow history of self-regulation that gathers data about ART success rates.

In our view, these programs rarely meet the standards of legal precision expected by legal scholars and policy-makers. Often, they come dangerously close to being simple exhortatory. Nevertheless, this admittedly incomplete system of private governance provides an important basis for incrementally and selectively strengthening the oversight of the ART industry.

4 Recent Regulatory Initiatives in Other Countries

4.1 The British HFEA

The British Human Fertilisation and Embryology Authority (HFEA) was established in 1990 on the basis of the Human Fertilisation and Embryology Act, which in turn sprang out of the earlier Warnock Commission. The act established the HFEA as a new regulatory body to oversee

the activities of both private and public clinics and laboratories dealing with ARTs, providing a licensing scheme for treatment services, the storage of gametes and embryos, and embryo research. The HFEA monitors and tracks all embryos in the United Kingdom. Violation of the act is considered a criminal offense under British law. The HFEA's statute creates a governance mechanism consisting of a 17-member board, appointed for three-year terms that are renewable once. The board must consist of both men and women, and the number of "lay" members must exceed the number of those connected with the clinical or scientific research communities. Positions on the board are advertised, and the selection is made by officials in the UK Health Ministry. The HFEA is ultimately accountable to Parliament through the minister of health.

Both stem cell research and research cloning are legal in the United Kingdom. While some decisions by the HFEA have been criticized for being excessively restrictive of the reproductive rights of potential parents, the organization has by and large facilitated Britain's emergence as a leader in reproductive medicine and stem cell research.

4.2 The Assisted Human Reproduction Agency of Canada

The Assisted Human Reproduction Act (AHRA) of 2004 established the Assisted Human Reproduction Agency of Canada (AHRAC), which as of early 2006 is still in the process of implementation. This agency was created after a decade-long process of public consultation in Canada, and it reflects consensus views of Canadian society. The AHRA established a set of guiding principles from which is derived a list of proscribed and regulated activities. It bans both reproductive and research cloning; it permits stem cell research, but only that involving excess embryos. Treatment, storage, and research on human embryos are regulated through licensing. Both public and private research are covered by the AHRA, which also regulates the sale of gametes, embryos, and surrogacy.

The AHRAC is an administrative agency modeled on the British HFEA. It is different, though, in what it regulates, as in Canada, neither research cloning nor stem cell research not derived from excess embryos is legal. This underlines the fact that similar regulatory powers and institutional designs can serve societies that make different decisions on the question of the moral status of the embryo.

4.3 Other Legislative Initiatives

In addition to Britain and Canada, many other countries have enacted legislation to deal with new reproductive technologies in recent years. Often, the scope of these legislative initiatives is quite broad. In our report, we have identified 10 issues that these legislations tend to address. They are embryo research broadly defined, reproductive cloning, research cloning, stem cell research, pre-implantation genetic diagnosis, chimera and hybrid creation, germ-line genetic engineering, reproductive services, and the trade and sale of gametes. The table below summarizes the situation for a subset of these issues, namely reproductive cloning, research cloning, and PGD. The first column indicates whether a country, as part of its recent legislative efforts, has established a new regulatory entity.

	New Regulatory Authority	*Reproductive Cloning*	*Research Cloning*	*PGD*
Canada	Yes	Prohibited	Prohibited	Legislated
Australia	Yes	Prohibited	Three-year moratorium	Prohibited
Germany	No	Prohibited	Prohibited	Prohibited
UK	Yes	Prohibited	Regulated	Legislated/regulated
France	Yes	Prohibited	Prohibited	Legislated/regulated
Italy	No	Prohibited	Prohibited	Prohibited
Spain	No	Prohibited	Prohibited	Legislated/regulated
Sweden	No	Prohibited	Legal	Legislated
Japan	No	Prohibited	Legal	No action
China	No	Prohibited	Legal	Legislated
Singapore	No	Prohibited	Legal	No action
South Korea	No	Prohibited	Legal	Legislated/regulated
US	No	Prohibited (de facto)	No action	No action

Limited space prevents us from including the entire table here, but the essential point is clear enough: With regard to most of the 10 issues identified above, the United States is an outlier. See Appendix G for additional information.

5 Pros and Cons of Alternative Approaches

5.1 Maintaining the Status Quo

Pros. Maintaining the status quo, in the eyes of the proponents of this strategy, has one distinct benefit: It doesn't cost anything, either to the taxpayer or in terms of opportunity costs. It is not so much a strategy as the expression of the belief that no government action is needed at this time. Should the need for governmental intervention arise, it may be possible to simply use existing statutory and regulatory tools. The FDA de facto prohibition of reproductive cloning is a case in point. In 2001, the FDA restricted reproductive cloning by requiring that anyone seeking to provide cloning services receive IRB approval and submit an investigational new drug (IND) application, conditions that no practitioner of reproductive medicine is likely to fulfill. Until this administrative decision is successfully challenged in court, reproductive cloning in the United States is effectively banned.

Cons. The failure to anticipate the need for new regulatory powers invites societal overreaction when the inevitable scandal, abuse, or disaster happens. Agricultural biotechnology provides a vivid example. During the early 1990s, the agricultural biotech firm Monsanto, which had initially favored certain forms of regulation like the labeling of genetically modified foods, changed policy and argued before the Bush administration that no new regulations were needed. After the company began marketing its Bt corn and roundup-ready soybeans in Europe, the BSE scandal broke in the United Kingdom, convincing many European consumers that food safety regulators were not doing their job. Much of the opposition to genetically modified foods in Europe was irrational, but some was based on a view that consumers had a right to decide for

themselves whether or not to eat foods that had been genetically modified. By not supporting relatively modest forms of regulation like labeling, U.S. biotech firms like Monsanto found themselves shut out of European markets as the EU imposed its own extremely strict safety rules on genetically modified products.

The argument that existing statutory powers can be used to deal with new technologies is very limited. While it is true that the existing FDA regulatory authority has been interpreted as giving the agency power to regulate reproductive cloning, the legal grounds for this decision are weak. Human embryos do indeed consist of "cellular products," but it is doubtful that the courts would consider them just another biological material. And there are clear limits to what the FDA could do. The FDA's enabling statutes establish that the agency is to regulate on the basis of safety and efficacy only, and that it does not have authority over the practice of medicine. Apart from the legal question of whether the statute can be stretched to in effect sneak in new powers, there is also a legitimate question of whether the FDA has the right kind of bureaucratic culture and expertise to exercise this kind of authority. Specialists in public administration point out that agencies are often built around a traditional goal, and that when they are given new goals, they often have a hard time adapting.

5.2 Incrementally Expanding Statutory and Regulatory Authority

Pros. A regulatory strategy designed to incrementally and selectively expand existing statutory and regulatory authority has several distinct benefits. From a pragmatic standpoint, it may be considerably easier to accomplish most if not all of the intended policy goals. Small, incremental changes may attract broader political support. Congressional representatives may conclude that the benefits of implementing this strategy compare favorably to the costs. It may also be easier to generate sufficient support among stakeholders who are likely to bear some of the costs associated with new regulations. In addition, selective interventions, by their nature, are likely to produce fewer unintended consequences. For example, one could envisage modifying the regulations that govern IRBs so as to make IRBs a more credible institution of ethical scrutiny. One could also envisage making implementation of the FCSRCA model program mandatory, and bolstering its implementation by including credible sanctions.

Cons. Nothing speaks against selectively expanding statutory and regulatory powers, per se. It could make eminent sense, for example, to update the regulations governing IRB review or to strengthen the FCSRCA. At the same time, minimalist interventions alone are very unlikely to provide an adequate response to the challenges raised by new reproductive treatments and medical research. Nor it is necessarily true that it would be easier to have Congress pass them. It is quite possible that proposals for the incremental expansion of statutory and regulatory authority would be ignored by the Congress until an egregious case of abuse receives extensive media coverage.

5.3 Direct Legislative Intervention

Pros. Congress can obviously speak the most authoritatively on important moral questions, and we assume that large ethical issues will have to be decided in this fashion. Proposed legislation in the area – like Senate Bill 303, which would ban reproductive cloning but permit research cloning – has some provisions for regulatory oversight, as do similar bills proposed or adopted at the state level.

Cons. Typically, legislative interventions are narrowly focused on a single, idiosyncratic problem; the intervention may be effective, but its cost rarely justifies its benefits. Legislation, by its nature, tends to be rigid and difficult to amend. In addition, Congress does not have either the administrative resources or the technical expertise to debate and discuss the large number of issues that will emerge as new technologies are developed. For example, specific legislation like Senate Bill 303 that was introduced into the Senate to permit research cloning does not contain adequate provisions for regulatory oversight of embryo research, relying as it does on IRB review alone. Nor does it require that the production and use of embryos be tracked.

5.4 Self-Regulation

Pros. The practice of reproductive medicine already has an elaborate system of self-regulation in place. Some measure of self-regulation is indeed a necessary requirement for any effective regulatory system. Designing a credible and effective rule often requires information and expertise available only to the regulated community. Perhaps surprisingly, self-regulation can have a significant impact on the practice of reproductive medicine and on medical research, even in the absence of formal mechanisms of monitoring and enforcement. In some cases, informal mechanisms of sanction can be quite effective. The case of the Recombinant DNA Advisory Commission is a case in point.

Cons. Trade associations and professional societies are almost always likely to favor self-regulation over more formal regulatory approaches; how effective this is depends on the nature of the sector and the incentives facing the actors in it. Prior to the collapse of Enron, the American accounting industry believed that its system of self-regulation was adequate to counter possible abuses; the fact that it was not led directly to passage of the Sarbanes-Oxley bill, which created a host of new formal accounting rules.

The record of self-regulation in reproductive medicine raises questions as to whether the procedures currently in place will be sufficient to guard against potential future abuses. There is considerable evidence that trade associations, absent powerful selective incentives, are reluctant to take measures that could be interpreted by their members as policing activities. And the RAC remains an effective tool of self-regulation only as long as the risk of a major public health disaster is perceived by the scientific community as a real possibility.

5.5 Creating a New Regulatory Institution

Pros. There are important reasons why ARTs should be singled out as an area deserving special legislative scrutiny. Assisted reproduction is not just another branch of medicine dedicated to restoring a patient's health; it makes children. The ART field is structured to meet the needs and desires of potential parents; it is less well-organized to protect the long-term interests of the children it produces. It is also the area in which new technological possibilities for reproduction will be developed. Overall, a new regulatory system would more effectively protect the safety and well-being of children. It would also forcefully protect new areas of promising but controversial medical research. Last but not least, it would endow the United States with an infrastructure of government geared toward addressing genuine public questions in a public way, rather than de facto delegating these societal choices to business and scientific interests.

Cons. Most arguments against a new regulatory system in the area of human reproduction stem from considerations germane to government regulation, per se. If the government regulates an activity, there is less of it, and there is a prima facie reason to support the most rapid possible advance of scientific research into human biomedicine. Regulation always produces unanticipated consequences as private agents seek to avoid them; one consequence here could be the moving abroad of both researchers and biotech companies seeking a more favorable regulatory climate. The United States is the world leader in biomedical research, and would be hobbling its own competitive advantages by over-regulating itself, not to mention denying patients the advantages of the latest technologies.

A new regulatory system is costly. These costs include not just the direct cost to researchers and businesses of complying with new regulations, and the costs to the U.S. government of running regulatory agencies, but also the opportunity costs of the new research, services, and products that do not come into being as a result of regulation. That is, a new regulatory institution risks slowing down the pace of technological advancement and innovation, imposes opportunity costs, and risks unintended consequences. In addition, new federal regulatory powers over ARTs will set a precedent for the federal regulation of the practice of medicine.

6 A New Regulatory Institution

6.1 General Design Considerations

In this report, we are proposing that the United States consider creating an entirely new regulatory institution to deal with human reproduction. We believe that rather than trying to reinterpret or augment the statutory powers of current regulators like the FDA or the NIH, or passing new targeted legislation, it is much better to start afresh with a federal agency designed *de novo* to deal with the problems and challenges that will be posed by new reproductive technologies. To pick up an analogy used earlier, rather than trying to add airlines to the ICC's

regulatory portfolio of railroads and trucks, we want to create the equivalent of a new Federal Aviation Administration.

We begin with several general institutional design considerations. Highest among our priorities is the need to design a regulatory institution that cannot be manipulated by any political constituency. Much of the discomfort among scientists with federal legislation originates with the fear that the scientific enterprise will fall victim to ideological manipulations. On the other end, opponents of unencumbered scientific and medical research believe that science and medicine are on their way to becoming "rogue" societal institutions accountable only to themselves. A credible regulatory institution effectively must dispel these widespread perceptions; it cannot be perceived as pandering to powerful interest groups. It must operate in an independent manner.

Ensuring independence in this context is similar but not identical to preventing regulatory capture. All good regulatory institutions, if they are to do their jobs, must avoid being "captured" by the sector or interests they are meant to regulate. On the other hand, the regulators need to work closely with those they regulate, because the agency will be dependent on the latter for information, implementation, and other matters. Just as institutions should avoid capture, they should also avoid falling into a highly adversarial relationship with those they regulate.

The second, seemingly contradictory design consideration pertains to accountability. A "rogue" regulatory agency that operates in an arbitrary and capricious way is bound to quickly loose its credibility and to invite intervention by the Congress and the president, not to mention judicial review. In certain circumstances, technical decisions provide an effective check against unaccountable behavior. Agencies such as the Federal Aviation Administration (responsible for aviation safety) and the Nuclear Regulatory Commission (responsible for the safety of nuclear power plants) are certainly no example of "bureaucratic drift," even though they do enjoy a measure of formal independence. The situation in the case of reproductive medicine and biomedical research bears only limited similarity to these cases. Ensuring the health and safety of future generations would require our agency to make choices largely based on scientific and medical evidence. In other cases, however, the agency would have to resolve difficult ethical dilemmas for which no independent or scientific guidance is likely to exist. Under these circumstances, independence may be perceived as "bureaucratic drift."

A third, related design consideration is avoiding political gridlock. The practice of medicine involving assisted reproduction as well as the scientific research community doing work in the area of reproductive medicine, stem cells, and developmental biology would strongly prefer to work without regulatory constraints, and indeed with substantial government funding for research in this area. There are, on the other hand, pro-life groups that strongly oppose any research that involves the destruction of embryos, including stem cell research and research cloning. Both groups are just politically strong enough to block the other from achieving its agenda.

Our report shows that these polarized interest groups actually do not represent the views of the general American public, which in many ways is more flexible and centrist on issues

regarding reproductive biomedicine than the current debate would suggest. Looking over 120 survey questions asked from 1993 to 2004, three consistent tendencies emerge. First, large majorities of Americans oppose reproductive cloning outright. Second, there is considerable ambivalence about research cloning: It is opposed by a two-to-one margin if the question is posed in a "neutral" fashion; opposition rises to 80 percent if the question mentions only embryo destruction, and falls to approximately 50 percent if only the benefits of cloning are mentioned. Third, there is fairly strong support for embryonic stem cell research; a recent Harris poll, for example, shows 72 percent of respondents favoring human embryonic stem cell research if excess embryos are used, compared to only 13 percent opposed. The public, in other words, favors policies that lie somewhere between the libertarian scientific community and the restrictive pro-life community, and would be favorable to proceeding, as we suggest, with embryo research that was closely regulated.

The governance structure for this new agency would be built on three levels. Congress would delegate regulatory authority to a newly established administrative agency, just as is done currently in the British, Canadian and Australian cases. The agency could be either an independent or an executive agency. Our report explores design options for both. The main benefit of establishing an independent agency lies obviously in its independence from the White House. An executive agency may not enjoy the same independence from the office of the president, but would have other benefits, chief among them being efficiency in decision-making. In either case, a regulatory agency should be sufficiently insulated from undue political influences and regarded by all affected parties as a credible and trustworthy regulatory institution.

The second level of this new regulatory structure is a permanent advisory board. The advisory board would have two main goals: to carefully explore all relevant ethical considerations pertaining to complex ethical dilemmas, and to provide medical and scientific advice to the regulatory institution. The board would operate in accordance with rules established in the enabling legislation designed to protect the appointment process against political manipulations. In particular, the statute would ensure that the board is broadly representative of the three main constituencies in this field – reproductive medicine, biomedical research, and the public at large. The statute also would establish the relative weight of each constituency on this board.

The third level encompasses a variety of novel mechanisms of public consultation in combination with a more structured rule-making process. Broad public consultation should protect the agency not only against undue political influence, but also against agency drift. It is, in other words, a quintessential accountability mechanism. These institutions of public consultation would have to meet several requirements: Participants need to be well-informed about the scientific and medical aspects of the controversy, the consultation process must be deliberative, and the participating sample should be representative of the public at large. Clearly, not all of these requirements can be met equally well and at the same time. We do, however,

believe that it is possible to design institutions of public consultation that are far superior to both current administrative practices and recent proposals designed to democratize science policy.

6.2 The Independent Commission

We believe the organizational format in the best position to meet a Congressional mandate is an independent commission. The newly established regulatory agency often will be called upon to adjudicate among competing ethical claims in the light of fairly generic statutory provisions. Resolving these controversies is not too dissimilar from issuing a judicial opinion. To be regarded as authoritative by all affected constituencies, these decisions must be based on a careful examination of all ethical aspects. The "finding of fact" would benefit from a deliberative approach to resolving ethical dilemmas. Deliberation also would contribute to produce consensus policies rather than simply majority positions. On the other end, decision-making would be relatively slow. In this case, however, a slow pace of decision-making must be regarded as a benefit rather than as a drawback. In areas as controversial as reproductive medicine and biomedical research, producing policies widely regarded as legitimate by all affected parties is more important than efficient decision-making. An independent commission is well-positioned to meet these requirements.

When it comes to the creation of an independent commission, many precedents exist, beginning with the Interstate Commerce Commission in 1887. Appointment rules are specified by statute to produce some combination of political balance, expertise, and independence. The commissioners are appointed by the president for a fixed term and have to be approved by the Senate; they do not serve "at the pleasure" of the president, and can be removed only "for cause." Furthermore, commissioners on the new agency would serve for fixed terms. The terms of office could be set so as not to coincide with the presidential term. Appointments could be limited to one term only, and neither political party should hold a clear majority on the commission. These are uncontroversial rules that have often been adopted throughout the history of the administrative state.

6.3 The Permanent Advisory Board

Regulatory interventions in reproductive decisions and scientific research are so sensitive and controversial as to warrant consulting all parties that are directly and negatively affected by these interventions. In addition, the commission would not embody the broad range of ethical, medical, and scientific expertise necessary to craft authoritative policies. A suitably designed permanent advisory board would fill this gap. The board should include specific positions for representatives of the ART sector, patients groups, the scientific community, and the biotech industry.

The permanent advisory body is not too dissimilar from a board of directors. To prevent this board from being dominated by the regulated interests, appointing independent board members might be a wise approach. Over the last 15 years, the private sector has recognized that there is considerable wisdom in appointing independent board members. These individuals are selected

to represent constituencies that are crucial to the financial well-being and the public image of the firm. In our report, we follow the spirit of this approach by recommending that the enabling statute explicitly require appointing a number of independent board members equal to or greater than the total number of board members representing specific constituencies.

The criteria for selecting and appointing independent board members, also included in the enabling legislation, must ensure that the selected individuals are regarded by all constituencies as genuinely independent. Thus, viable candidates for the position of independent board member should not have strong ties to the ART and biotech industries or to the scientific community. They should not have close relatives with medical conditions that could be cured by promoting certain types of research, nor should they have financial interests in companies that may be affected by the commission's policies. They should also bring with them the analytical skills and life experience required to navigate complex questions at the intersection of ethics, science, and medicine in a charged political environment. Importantly, they should not be advocates representing scientific, trade, professional, or religious groups.

Unlike the independent commission, the advisory board would make recommendations by majority vote, and would include minority positions in its recommendations as deemed appropriate. The advisory board task is not to develop consensual recommendations that would, by their nature, restrict the range of ethical considerations, but rather to provide the commissioner with a broad ethical and scientific analysis of the issue under consideration. The board would also serve as an institutionalized link between the commission and the regulated communities. In this role, it would also make negotiations between regulators and those regulated more transparent, and reduce the room for regulatory capture.

6.4 Traditional Mechanisms of Public Consultation

One of the most often recurring and most important themes in public administration is agency accountability. It is fair to say that no consensus exists among commentators on the proper balance between agency discretion and agency accountability, or on the appropriate mechanisms to ensure accountability. Our report suggests that this debate has placed too much attention on traditional mechanisms of accountability, such as Congressional oversight, executive scrutiny, notice-and-comment, and judicial review, and has ignored some relatively straightforward alternatives.

It has long been a common legislative and administrative practice to ensure some measure of accountability by requiring public participation in the regulatory process. Traditionally, this has often meant that agencies have resorted to public hearings, and in some cases to notice-and-comment (mandated by the Administrative Procedure Act) as their main vehicle to engage the general public.

Both approaches are ill-suited to engage a broader audience. By the time a proposed new rule is published in the Federal Register, it has already been extensively vetted by the agency in consultation with leading interest groups. Comments usually produce only marginal changes, and the process is used by the agency to build its record in the case of judicial review, and not as a

tool of public participation. Public hearings, for their part, are used most effectively by well-organized interest groups to express their views on controversial agency decisions. As a result, they tend to reflect only the views of established interest groups, and thus tend to distort the process of public consultation rather than broaden it. Agencies, for their part, can use public hearings in strategic ways so as to minimize interference with their decision-making processes. In sum, public hearings are ineffective at best and have a distorting impact at worst on the administrative decision-making process.

The call for the democratization of decision-making in the area of science and technology policy has produced a few institutional innovations, such as citizens' juries, citizens' advisory panels, and consensus conferences. The Environmental Protection Agency and the Department of Energy, in particular, have frequently relied on citizens' panels to implement highly controversial policies at the local level. In this role, these approaches generally have been beneficial. Their role in decision-making at the federal level is much more problematic, however, mainly because the relationship between citizens and regulators has never been specified, and because it is often unclear to what extent the views expressed by these small groups of citizens may be regarded in any way as indicative of broader public sentiments. Against this background, it is not immediately clear why a regulatory agency should take the recommendations adopted by such a small group seriously. In sum, neither traditional tools of public consultation nor more recent approaches for engaging the public provide sufficient safeguards against arbitrary and capricious agency behavior.

6.5 New Approaches to Public Consultation

We believe that formal rule-making authority should lie with the agency, but that the latter should be required to gauge public opinion through certain structured mechanisms for public consultation. As mentioned earlier, one of the main goals of this process is to reach out to the public beyond established interest groups; the credibility of the process should rest on two main elements: The consulted sample should be representative of the general public, and the participating individuals should be reasonably well-informed about underlying scientific facts. In addition, the consultation process should be deliberative – that is, it should seek to mold preferences through debate and discussion rather than simply to record preferences. More specifically, deliberation, if properly designed, may help expand the "argument pool," may facilitate finding common ground on controversial issues, and may generally push participants toward more nuanced positions. We suggest that the new agency make use of either one of the following mechanisms for public participation.

6.5.1 Deliberative Panels

Our first proposal expands and refines the concepts of consensus conferences and citizens' panels. As pointed out earlier, the modest size of the panels means that recommendations developed at consensus conferences are not representative and lack legitimacy. A simple and straightforward way to increase the legitimacy of these panels is to assemble several of them.

"Deliberative panels," the term we use in our report to identify this approach, could be organized around the country, both in urban and rural areas. Each panel would consist of up to a dozen participants; this size ensures that deliberation remains feasible, yet makes assembling the panels a manageable task. Recruitment would reflect key socio-demographic variables such as sex, age, and education. Locations would be selected to account for important cultural and regional differences. At each location, deliberative panels should be conducted more than once and with different participants.

This approach has existed in the form of town hall meetings, which are familiar means of engaging the public on matters of national importance. In the present case, however, we envision the agency conducting more than half a dozen deliberative panels, while reducing dramatically the number of participants. Clearly, the more deliberative panels the agency convenes, the more representative the results. Just how many panels can and should be convened is not as important as the observation that the upper bound is likely to be much higher than one might anticipate.

The decentralized nature of this process and the need to query scientific experts representing various positions (biotech industry specialists, academic scientists, regulatory scientists, and so on) call for making extensive use of new information technologies in the form of a centralized information and consultation clearinghouse. An Internet-based clearinghouse could greatly facilitate learning and information exchange among all lay panelists. In addition to providing basic scientific information, the clearinghouse would serve as a central repository for any question submitted by panelists to experts and for the answers provided by these experts. The clearinghouse would also serve as a repository for the conclusions reached by each deliberative panel.

At the present time, there are only few examples of Web-based resources designed as both informational and deliberative resources. Our own Human Biotechnology Governance Forum was intended to serve exactly these two goals, but constraints on our resources have prevented us from fully implementing it.[1] The Center for Genetics and Society Web site is probably the single best source of information available in this area, but it does not include an interactive component.[2] The Geneforum, a non-profit initiative launched in Oregon in 1998, pursues similar goals, but it is still under development.[3] None of these Web resources fully implements the concept of information clearinghouse as envisioned here, but taken together, they suggest that implementation is within reaching distance. They also demonstrate that implementing our approach is both a financially and organizationally feasible proposition that an average federal agency could easily accomplish.

Consultative panels are clearly superior to both traditional surveys and one-shot, small-group consultations such as consensus conferences and citizens' panels, and should be preferable and far more credible than traditional methods of public consultation such as hearings and

---

[1] See http://www.biotechgov.org.

[2] See http://genetics-and-society.org/.

[3] See http://www.geneforum.org/.

notice-and-comment. As such, it would be difficult for well-established interest groups and for elected representatives to dismiss the recommendations emerging from deliberative panels as unreliable or not representative.

6.5.2 Consultative College

The second option we examine in our report is what we call the consultative college. The consultative college is reminiscent of but not identical to James Fishkin's deliberative polling. A consultative college consists of a randomly selected, representative sample of the general population. Key to this institution of public consultation is the Internet. The members of the consultative college are not required to physically meet in one location for a limited period of time. Instead, the consultative process takes place over an extended period of time. For example, college members could meet online on a regular basis, say once or twice a week, for two months. To facilitate the discussion, participants would be assigned to smaller groups of approximately a dozen individuals. This is the approach that the Genetics and Public Policy Center took in the summer of 2004 to study public attitudes toward new reproductive technologies.

The consultative process follows a familiar plot: College members would first familiarize themselves with the scientific underpinnings of the issues at stake. This could be accomplished in the same way as discussed for deliberative panels. Participants will be given an opportunity to engage a panel of experts. Questions (and answers) posed by one group would be made available online to all members of the consultative college. The convening agency would then put several questions to the online groups, including questions designed to elicit ethical reasons for and against a new medical or reproductive procedure, and questions aimed at evaluating policy options. In the final step, the agency would summarize and evaluate the range of expressed concerns and attitudes toward various policy options.

Polling organizations for years have assembled permanent or semi-permanent representative panels. These panels are being polled on a regular basis on any number of current topics, mainly by telephone. In recent years, organizations such as Knowledge Networks have begun using the Internet to enable online discussions among the panel members. And, as mentioned above, over the summer of 2004, the Genetics and Public Policy Center conducted an Internet-based deliberative poll similar to what we are proposing here. The logistics of online deliberation are not trivial, nor are its costs. At the same time, the Genetics and Public Policy Center's experience with online deliberation clearly demonstrates that it is both possible and perfectly sensible to envision mechanisms of public consultation above and beyond either traditional surveys or focus groups.

Compared to other forms of public consultation, the consultative college has several benefits. It is more cost-effective, although perhaps not as much so as one might think. The entry barriers for average citizens are lower, since joining a consultative college does not encroach on the participants' daily routines. In addition, online discussion may have desirable attributes not shared by traditional, face-to-face communication. For example, in an anonymous setting, the

participants may be able to engage each other in a way much less encumbered by individual status and prestige.

Having emphasized the benefits of the consultative college, we should point out some difficulties. The quality of online deliberation may not be comparable to traditional, face-to-face deliberation. This may indeed be the price for ensuring representativeness. Just how much the quality of the dialogue would suffer from a shift to online deliberation is an important and still-open question. Heavy reliance on information technologies could prove a barrier for some, especially among the poor and the uneducated. Access to information technologies is less and less of a problem, however, as most public libraries, even in remote locations, provide free access to the Internet. A more important hurdle is literacy. Being required to read and write messages may constitute a serious problem for people with little education. Conceivably, the convening agency could recruit volunteers willing to help these individuals overcome what may be a significant barrier. There may well be other ways to address these concerns. We recognize that convening a consultative college may raise a host of issues and concerns that we haven't discussed or addressed. Our aim here is not to develop a full-blown proposal for reforming modern institutions of representative democracy. Rather, we want to make a sufficiently specific case for experimenting with new forms of public consultation. We hope our readers will find our discussion compelling enough to explore our proposals in more depth and offer suggestions as to how to develop them more fully.

6.5.3 Semi-Traditional Survey Techniques

Expanding the number of deliberative panels is a straightforward way to ensure representativeness. Similarly, assembling a large consultative college would all but ensure that the recommendations emerging from the consultation process would be quite reliable. Realistically, it may not always or even often be possible to fully implement this vision. Depending on the availability of time and resources, an agency may have to limit itself to assembling a sample that is not large enough to be considered representative of the whole U.S. population. To address this limitation, one could consider exploring the panoply of instruments nowadays available to survey researchers. Resorting to survey techniques would allow administrators and politicians systematically to assess the relative importance of ethical arguments in the general population. The agency responsible for the consultative process could compile a list of the highest-ranking ethical arguments in favor of and the against a controversial ART procedure or research field. It would then use this information to conduct a representative survey of the general population. The agency should control for several key variables, including *a priori* views and levels of expertise. Participants in this case would simply be asked to weigh on a scale the extent of their agreement or disagreement with the ethical arguments uncovered by the deliberative panels. A similar approach could be used to evaluate alternative policy options. While purists may find this suggestion distasteful, we believe that in combination with novel institutions of public consultation, survey techniques would provide regulators and

Congressional representatives with a picture of public attitudes unmatched by current approaches.

6.6 Final Remarks

Some commentators might criticize the institutions of public consultation proposed in this report as not being "open and transparent." We freely acknowledge that public consultation as envisaged here, perhaps paradoxically, would not appear to be as open or transparent as traditional mechanisms like public hearings. The legitimacy and credibility of the outcomes produced by our institutions of public consultation depend crucially on the convening agency maintaining tight control over the process itself. "Opening" the consultation process to anyone and everyone would obviously undermine any claim to representativeness and make the deliberative stage unmanageable, not to mention expose the entire consultative process to blatant manipulations by organized interests. The proper place for the general public and interest groups to provide their feedback is the notice-and-comment phase afforded to all citizens by the Administrative Procedure Act. To facilitate public feedback, the agency would be required not only to publish the proposed rule in the Federal Register, but also to take steps to make the consultation process and all related materials broadly available.

7 Constitutional Constraints

Deciding whether restrictions on the use of new reproductive technologies may be unconstitutional is a question fraught with difficulties. For starters, the label "new reproductive technologies" includes several and very diverse technologies that would have to be examined individually. The particular use of a given reproductive technology and the circumstances of its use do of course matter a great deal. Yet the Supreme Court, as a matter of general practice, renders its opinions on narrow grounds, and is very reluctant to generalize its rulings above and beyond the case under consideration. In addition, there are only a few judicial precedents relevant to this field of medicine, and there certainly are no well-established societal traditions that the Court could invoke absent relevant case law.

There is considerable agreement among legal commentators that the Constitution does not explicitly recognize a fundamental reproductive right, i.e., a positive right to reproduce. The same commentators also agree that the Supreme Court is likely to recognize this right under limited circumstances. A variety of precedents related to establishing a right to privacy and to family, intimate relationships, and reproduction support the view that the Court would probably recognize this right, at least in those cases that involve intimate relationships and traditional forms of procreation.

Whether the Court would be inclined to expand a fundamental but limited right to procreation to protect the use of any and every new reproductive technology designed not just to facilitate procreation but also to exercise an increasingly tight control over it is doubtful. The Court, more often than not, has ruled on negative reproductive rights, and has never defined the

outer limits of the right to privacy. The Court could invoke unenumerated rights, but it would also have to show that these rights are consistent with enumerated rights. We believe that technologies of reproductive control are not simply a natural extension of more traditional forms of assisted reproduction, but that they represent a radical departure from well-established assisted reproductive technologies. The Court should not grant them fundamental status before society and Congress have had an opportunity to properly debate their pros and cons.

8 International Considerations

There has been a great deal of legislative experimentation at the domestic level in many OECD countries. The scope of adopted legislative and regulatory measures varies significantly from country to country, and seems to reflect both cultural sensitivities and political realities. Our report has scrutinized numerous legislative approaches ranging from Europe to Asia, Australia, and Canada. The only consistent finding emerging from this review is that apart from a ban on reproductive cloning, there is very little agreement across nations on the nature and scope of legislative and regulatory interventions. Certainly, there is no agreement on whether to ban or regulate research cloning. Other less visible but just as controversial issues, such as the use of PGD for non-therapeutic uses, research on human embryos broadly defined, and the production of hybrids and chimeras, often do attract the attention of domestic legislators, but no coherent pattern has yet to emerge from this flurry of domestic legislative activities. They are documented in some detail in our report.

The divergence of national priorities and the widely different scope of these approaches suggest that it is far too early to envisage crafting broad international treaties. The repeated and failed attempts by the United States and Costa Rica to ban both reproductive and research cloning at the international level clearly illustrate this fact. Against this background, it would also be unwise to call for the criminalization of any or all of these technologies, as some commentators have suggested. Resorting to the International Court of Justice to render verdicts on matters that have just barely begun to be debated at domestic levels strikes us as ill-advised. For the time being, the least damaging course of action seems indeed to be simply allowing nations to develop their legislative responses, and addressing international disputes in this area on a case-by-case basis.