3 Ethical Principles

No proposal for regulation can begin without a discussion of the larger ends that regulation is intended to serve. A great deal of regulation in the United States has come about as a result of specific harms or incidents, like the sulfanilamide elixir scandal that led to passage of the Food, Drug, and Cosmetics Act, or more recently the Enron and WorldCom accounting scandals that paved the way for passage of the Sarbanes-Oxley reforms. Our proposal to regulate human biomedicine is different: It is being driven not in response to pressing current problems, but rather in anticipation of possible future problems that fast-moving technologies might introduce.

We will begin by laying out a general set of ethical principles that we believe should guide regulation in the domain we have defined in the first chapter – namely, technologies and medical practices related to human reproduction and to biomedical research involving the use and/or destruction of human embryos. 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 (see chapter 8). These principles are similar in many instances to those laid out in the 2004 report by the President's Council on Bioethics, "Reproduction and Responsibility: The Regulation of New Biotechnologies." The following section will list the principles, and elucidate some of their more concrete implications.

3.1 General Ethical Principles Guiding the Regulation of Technologies and Medical Practices Related to Human Reproduction

We believe that human reproduction is a particularly important part of human life, and that society has an inherent interest in protecting the human values associated with it. The following is a set of ethical standards that we believe any regulatory system touching on this domain should promote. These guiding principles touch mainly on the means and the ends of assisted reproduction, and only secondarily on issues of access. Access is partly examined in chapter 7, in which we discuss possible constitutional constraints on the regulation of ARTs, but is otherwise not a subject of this discussion. The ethical principles that we endorse are as follows:

- The well-being and health of children should be protected.
- Biomedical procedures on human embryos must respect their intermediate moral status.
- Access to ARTs on the part of infertile couples should be promoted.
- The well-being and health of women should be protected.
- Free and informed consent must be required on the part of those making use of ARTs.

- Limits on the commercialization of eggs, sperm, and embryos should be imposed.
- Therapeutic uses should be favored over enhancement uses of biomedicine.

Let us discuss each of these principles in turn.

The well-being and health of children. Since reproduction inherently aims to create children, the welfare of children 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, including long-term longitudinal surveys, of IVF children. Compared to other developed countries, public oversight of ARTs in the United States is limited, and funds to carry out studies have thus far been 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. This is most obviously true in the case of mothers who drink alcohol or take drugs while pregnant. There is also the case of a deaf lesbian couple that wanted to intentionally disable the hearing of their child so that the child would be part of their deaf "culture."[1]

We interpret "well-being and health" broadly to mean not just physical health, but psychological and social well-being as well. This means, among other things, that every child has the right to be biologically related to a mother and a father, even though they may be brought up in a variety of households in which the biological mother and father may be absent. We believe that this right overrides the interests 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).

The intermediate moral status of human embryos. We do not believe that an embryo is the moral equivalent of a human being. The potential for an embryo to eventually develop into a child, per se, does not establish equality. Just like an acorn and an oak tree are not identical objects, so there are ethically meaningful differences between an embryo and a fully developed human being. At the other end, we don't share the view, common among scientists, that a human embryo is simply a tiny clump of cells that can be manipulated at will. Embryos occupy an ethically gray zone – they are due some respect, but not the same respect due to human beings.

Equal access to ARTs on the part of infertile couples. At this point, approximately two million children have been born worldwide through IVF. The benefits of this technology to

[1] M. Spriggs, "Lesbian Couple Create a Child Who Is Deaf Like Them," *Journal of Medical Ethics* 28 (2002).

infertile parents have been enormous, and equal access to it 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 for many Americans, IVF is cost-prohibitive. Expanding the availability of safe ARTs should be a policy priority.[2] An unproblematic focus of this policy should be infertile heterosexual couples, whether married or not. An important and largely unresolved question is whether the benefits of this policy should be extended to singles, minors, homosexual couples, and women who would like to procreate using the gametes of their recently deceased husbands. As mentioned earlier in this report, we focus mainly on the ends and the technological means, and only marginally on questions of access.

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.

Free and informed consent. It is important to recognize that a great deal of what happens in IVF clinics constitutes a form of experimental medicine, as techniques like intracytoplasmic sperm injection (ICSI) and pre-implantation genetic diagnosis (PGD) move from the laboratory directly to clinical practice. Many techniques have never been tested in animal models, and while there have not to date been any major problems experienced with new technologies leading to, for example, major birth defects, this remains a constant possibility. 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 makes doubly important the collection of comprehensive and comparable data on the long-term health consequences of different ARTs and procedures to ensure that doctors and clinics have the proper incentives to inform their patients fully and adequately of whatever risks are known to exist.

Limits to commercialization. While the practice of medicine using artificial 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. In particular, we believe that the U.S. Patent and Trademark Office should not issue patents on embryos or fetuses at any stage of development.

Therapeutic over enhancement uses of biomedicine. We believe that the priority in biomedical research and clinical practice ought to be given to therapeutic ends – i.e., to healing

[2] For an in-depth discussion of the economics of the ART market, see Debora L. Spar, *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception* (Boston, MA: Harvard Business School Press, 2006).

the sick and relieving the pain and suffering of those afflicted with pathological conditions. One of the large issues opened up by many new biotechnologies is the possibility that the very same techniques used for therapeutic purposes could also be used to enhance the qualities of children who suffer from no abnormal or pathological conditions. There is very little disagreement over the therapeutic uses of medicine, but there is a great deal of societal unease over so-called "enhancement" uses of biomedicine, for example, the use of growth hormone to make a child of average height taller than the mean.

We do not believe that this unease should translate mechanically into blanket prohibitions or red lines. Many people have argued (1s) that there is no clear distinction between therapeutic and enhancement uses of biomedicine;[3] (2) that in any case we permit many procedures like breast implants or cosmetic surgery that constitute enhancement; and (3) that enhancement technologies will be positively desirable as a means of overcoming limited existing human capacities.

We believe that these are serious arguments deserving full discussion – fuller, indeed, than we can provide here.[4] While the borderline between therapeutic and enhancement uses of biomedical technologies is often unclear, the distinction remains a valid and important one. Using PGD or gene therapy to prevent a genetic disorder like Huntington's or Tay-Sachs is clearly quite different from using these techniques to produce children with different hair color or height. The United States already sets regulatory boundaries between the therapeutic and enhancement uses of various psychotropic drugs like selective serotonin reuptake inhibitors (SSRIs) and Ritalin to treat depression and attention deficit hyperactivity disorder (ADHD), where the borderline between pathology and normality can be extremely ambiguous.

The use of biomedicine for enhancement purposes raises at least three complex social and ethical issues. The first concerns equality and equal access. While therapeutic uses of medicine pull people up to the mean, enhancement uses will potentially increase natural inequalities in ways that are likely to add to existing social inequalities. Second, many potential targets of enhancement confer only relative gains, which may be advantageous for the individuals seeking them, but not for society as a whole. An existing example is the widespread use of sex selection techniques in some parts of Asia, which has produced large-scale imbalances between boys and girls. While parents may think that having a son confers social advantages, most societies encounter an array of problems when sex ratios fall out of balance. Finally, enhancement raises ethically troubling arguments over the nature of human goods. Potential targets of enhancement, like skin color or proclivities towards homosexuality, are not generally accepted as bad things to be overcome. Enhancement may also produce unintended consequences, particularly if they lead

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[3] There are many other examples of cases where the distinction between therapy and enhancement is blurred. Is offering heart-bypass surgery or chemotherapy to an 85-year-old patient suffering from heart disease or cancer truly therapeutic, or does it amount in effect to an unnatural form of life-extension, and thus enhancement? Many drugs like Ritalin can be taken for either therapeutic or enhancement purposes; the diagnostic criteria for conditions like ADHD that distinguish one use from the other are flexible, and to some extent subjective.

[4] For an excellent discussion of the many dimensions of enhancement, see the President's Council on Bioethics, *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (Washington, D.C.: Government Printing Office, 2003).

to population-level changes in human characteristics (as is already the case with sex selection in Asia).

It is a well-established utilitarian principle that greater risks are permissible when treating a clearly pathological condition than in cases of elective treatment. Certainly, in terms of resource allocation, there is no question that therapy ought to have much higher priority than enhancement. Yet while it is neither possible nor desirable for society to ban enhancement outright, it is perfectly legitimate for the government to raise higher regulatory hurdles and steer resources away from practices aimed at enhancement rather than therapy.

3.2 Translating Principles into Rules

These general principles, then, need to be translated into specific rules that would be used to guide regulators. These rules would be divided into two categories: (1) activities that we believe ought to be banned outright, and (2) activities that should be permitted but regulated. Neither list is meant to be definitive; they reflect our interpretation of how the principles outlined above should be interpreted in light of technological possibilities that either exist now or can be anticipated based on current trends. Some of our choices – for example, whether research cloning ought to be banned or regulated – will be extremely controversial. It should be noted, however, that the same regulatory institution can preside over different sets of rules. For example, the new Assisted Human Reproduction Agency of Canada bans research cloning, while the British Human Fertilisation and Embryology Authority permits it. In most other respects, these agencies look very similar. (Indeed, the Canadian agency was modeled after the HFEA.)

3.3 Activities to Be Prohibited

We believe that there are several activities made possible by biotechnology that ought to be prohibited outright, with prohibitions enforced through criminal sanctions. The role of a regulatory body would be twofold – to enforce the prohibitions, with some scope for interpreting their meaning, and to promulgate regulations in accordance with the ethical guidelines established by Congress. We believe that prohibited activities should include the following:

- Reproductive cloning
- Human-animal chimera and hybrid creation
- Germ-line genetic modifications
- New reproductive possibilities that alter the biological relationship of parents and children
- Commercialization of certain aspects of human reproduction

Reproductive cloning. As indicated in chapter 8.3, a large majority of Americans do not favor reproductive cloning; all versions of the cloning legislation that have been introduced in Congress since 2001 have included bans on reproductive cloning. The reasons that Americans

give for opposing this practice vary; some cite safety reasons while others believe that the possibility is inherently wrong or distasteful. As the National Bioethics Advisory Committee and the President's Council on Bioethics have both stated in their reports on 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 that gives priority to the health and well-being of children.

Creation of chimeras and hybrids. Following the recommendations of the President's Council on Bioethics, we believe that the creation of human-animal hybrid embryos – the fertilization of a human egg with animal sperm or the use of human sperm to fertilize an animal egg – should be banned. Other situations in which human and animals cells, tissues, and organs simply are mixed are less problematic and should not be subject to an outright ban. These include the many forms of chimerism that are currently used in biomedical research, such as the implanting of human stem cells in animal tissues. Animal-derived organs are now routinely implanted in humans, and in the future, animal-derived genes may be available for treating human diseases; in our view, all of these are by and large legitimate activities. There may be complex cases where the degree of mixing of human and animal 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 genetic modifications. Germ-line modifications 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. Germ-line modifications would necessarily involve a kind of experimentation on human beings who clearly will not be able to give their informed consent, and therefore it violates the first and fourth ethical principles laid out above.

There is considerable debate over how far in the future human germ-line engineering lies. While many until recently have derided this possibility as a fantasy, it appears that stem cell research may provide a fast and safe route to germ-line genetic modifications.[5] If and when human germ-line genetic modifications become possible and predictably safe, it may be necessary to re-open the question of whether the technique should be banned or merely regulated. Some people believe that the technique itself poses ethical problems, because it involves changes not just to the genotype of the child in question, but to all of that child's subsequent descendants. If a safe and effective means of correcting heritable genetic disorders through germ-line modification becomes available, conceivably germ-line genetic modifications could be moved from the prohibited to the regulated category. The undeniable benefits of this move notwithstanding we believe human germ-line genetic modifications should remained banned. In our view the risk that this technology would be abused far outweigh its medical benefits.

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[5] Susannah Baruch et al., "Human Germline Genetic Modification: Issues and Options for Policymakers," (Washington, D.C.: Genetics and Public Policy Center, 2005).

New reproductive possibilities that alter the biological 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. Laboratory research has suggested possibilities such as reproductive cloning; the creation of artificial oocytes from stem cells (which will, in theory, allow males to produce eggs and females sperm); embryo fusing (which could lead to children with more than two biological parents); or the harvesting of fetal eggs (which would lead to an offspring whose mother had never been born). We believe that the first ethical principle enunciated above, 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 should be banned.

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

3.4 Activities to Be Regulated

There are other activities that we believe are ethically legitimate but ought to be carried out under carefully controlled circumstances. These include:[6]

- Research cloning
- Pre-implantation genetic diagnosis
- Biomedical research involving early-stage embryos or blastocysts
- Commercialization of elements of human reproduction

Research cloning. We believe that research cloning should be permitted, but that it should be 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. That is, if a large industry dedicated to producing cloned embryos ever comes into being, it will be much more difficult to take one of those embryos and implant it into a woman's uterus for the purpose of creating a child if the regulatory authority registers and tracks every such embryo.

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[6] Note that this list is not meant to be exhaustive. In chapter 4 we discuss many more instances of ethically problematic medical and scientific developments that may need to be regulated.

We recognize that for some people, the fact that we have put research cloning in the "regulated" and not the "prohibited" category will simply cause them to stop reading further, because they feel that our project is simply endorsing the deliberate creation and destruction of nascent life. We would point out, however, that if we were to move this activity from the regulated to the prohibited category, we would in effect be transforming the British system into the Canadian one – a system that in virtually all other respects would look identical. Thus, if a societal consensus develops that believes research cloning to be clearly wrong, one would still want to create the kind of institution we are laying out here.

Pre-implantation genetic diagnosis. PGD is a service performed by many fertility clinics. We believe that 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 biomedical 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 should 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 in keeping with 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 IVF clinics), but that all such transfers should be carefully tracked by the regulatory authority. We also believe that the donation of embryos, eggs, and sperm for reproductive purposes should be regulated, and that the free and unrestricted trade of human gametes, including sperm, should be prohibited.

3.5 Next Steps

While some readers may disagree with us on our suggestions to prohibit or regulate a given medical procedure or a certain type of research, few would reject the twin notions that distinguishing between ethically acceptable and unacceptable practices of biomedicine should be done by legislative means, and that these distinctions should be informed by a set a coherent ethical principles. In this sense, which medical procedures or research protocols should be banned and which ones should be regulated is less important than establishing the principle that a new regulatory infrastructure backed by a statutory framework is needed and that this new statutory framework should be informed by a set of broadly acceptable ethical principles.

Accordingly, our proposal for a new regulatory entity is largely immune with regard to changes in the medical procedures or research protocols to be banned or regulated. Ours, in other words is an argument for selectively strengthening the administrative state and not merely an examination of arguments for or against the medical procedure or the scientific experiment of the day, an argument that is laid out in the remainder of this report.

3.6 Bibliography

Baruch, Susannah, Audrey Huang, Daryl Pritchard, Andrea Kalfoglou, Gail Javitt, Rick Borchelt, Joan Scott, and Kathy Hudson. "Human Germline Genetic Modification: Issues and Options for Policymakers." Washington, D.C.: Genetics and Public Policy Center, 2005.

President's Council on Bioethics. *Beyond Therapy: Biotechnology and the Pursuit of Happiness* Washington, D.C.: Government Printing Office, 2003.

Spar, Debora L. *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. Boston, MA: Harvard Business School Press, 2006.

Spriggs, M. "Lesbian Couple Create a Child Who Is Deaf Like Them." *Journal of Medical Ethics* 28 (2002): 283.