How to regulate science

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SOME new technologies are frightening from the start, and the need to establish political controls over their development and use is obvious to all. When the first atomic bomb was detonated at Alamogordo, New Mexico, in the summer of 1945, not one of the witnesses to this event failed to understand that a terrible new potential for destruction had been created. Nuclear weapons were thus from the very beginning ringed with political controls: Individuals could not freely develop nuclear technology on their own or traffic in the parts necessary to create atomic bombs, and in time, nations that became signatories to the 1968 nonproliferation treaty agreed to control international trade in nuclear technology.

Other new technologies appear to be much more benign,

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and are consequently subject to little or no regulation. Personal computers and the Internet, for example, promised to create wealth, increase access to information, and foster community among their users. People have had to look hard for downsides to the information revolution. What they have found to date are issues like the so-called "digital divide" (i.e., inequality of access to information technology) and threats to privacy, neither of which qualify as earth-shaking matters of justice or morality. Despite occasional efforts on the part of the world's more statist societies to try to control the use of information technology, it has blossomed in recent years with minimal regulatory oversight on either a national or international level.

Biotechnology falls somewhere between these extremes. Transgenic crops and human genetic engineering make people far more uneasy than do personal computers or the Internet. But biotechnology also promises important benefits for human health and well-being. When presented with an advance like the ability to cure cystic fibrosis or diabetes, it is hard for people to articulate reasons why their unease with the technology should stand in the way of progress. It is easiest to object to a new biotechnology if its development leads to a botched clinical trial or to a deadly allergic reaction to a genetically modified food. But the real threat of biotechnology is far more subtle and therefore harder to weigh in any utilitarian calculus. It lies in the possibilities of human cloning, "designer babies"—eugenic selection for intelligence, sex, and personality—and eventually, the end of the human species as such.

A call for regulation

In the face of the challenge from a technology like this, where good and bad are intimately connected, there can be only one possible response: We must regulate its development—and set up institutions that will discriminate between those technological advances that further human flourishing, and those that pose a threat to human dignity and well-being. These regulatory institutions must have the power to enforce these discriminations on a national and, ultimately, an international level.

The debate over biotechnology is today polarized between two camps. The first, which is broadly libertarian, argues that society should not put constraints on the development of new technology. This camp includes researchers and scientists who want to extend the frontiers of science, the biotech industry, which stands to profit from unfettered technological advance, and those who are ideologically committed to free markets, deregulation, and minimal government interference in technology.

The other camp is a heterogeneous group with moral concerns about biotechnology. It consists of people with strong religious convictions, environmentalists with a belief in the sanctity of nature, Luddite opponents of new technology, and those on the Left who are worried about the possible return of eugenics. Members of this group, which range from Jeremy Rifkin to the Catholic church, have proposed banning a wide range of new technologies, from *in vitro* fertilization and stem cell research to transgenic crops and human cloning.

It is imperative that the debate on biotechnology move beyond this polarization. Both approaches—a totally laissez-faire attitude toward biotech development, and a prohibitionary mindset—are misguided and unrealistic. Certain technologies like human cloning do deserve to be banned outright, for reasons both intrinsic and tactical. But for most other forms of biotechnology, a more nuanced regulatory approach will be needed. While many have staked out ethical positions on various technologies, almost no one has been looking concretely at what kinds of institutions will be needed to allow societies to control the pace and scope of technological development.

It has been a long time since anyone has proposed that what the world needs is more regulation. Regulation—and particularly international regulation—is not something that should be called for lightly. Before the Reagan-Thatcher revolutions of the 1980s, many sectors of the economies of North America, Europe, and Japan were vastly overregulated, and many continue to be so today. Regulation brings with it many inefficiencies and even pathologies. But in the end, there are certain types of social problems that can only be addressed through formal government control, and biotechnology is one of them.

Who decides?

Who gets to decide whether we control a new biotechnology, and with what authority? During the 2001 debate in the U.S. Congress on bills to ban human cloning, Congressman Ted Strickland of Ohio insisted that we be guided solely by the best available science, and that "we should not allow theology, philosophy, or politics to interfere with the decision we make on this issue."

There are many who would agree with this statement. Opinion polls show that the public holds scientists in much higher regard than politicians, not to mention theologians or philosophers. Legislators, as we well know, like to posture, exaggerate, argue by anecdote, pound the table, and pander. They can speak and act out of ignorance, and are often heavily influenced by lobbyists and entrenched interests. Why should they, rather than the disinterested community of researchers, have the final say on highly complex and technical issues like biotechnology? Efforts by politicians to limit what scientists do in their own domain evoke memories of the medieval Catholic church branding Galileo a heretic for saying the earth revolves around the sun. Since the time of Francis Bacon, the pursuit of scientific research has been seen to carry its own legitimacy as an activity that serves the broader interests of mankind. This view is, unfortunately, not correct.

Science alone cannot establish the ends to which it is put. Science can discover vaccines and cures for diseases, but it can also create infectious agents; it can uncover the physics of semiconductors but also the physics of the hydrogen bomb. Science *qua* science is indifferent to whether or not data is gathered under rules that scrupulously protect the rights of human research subjects. Data, after all, is data, and better data can often be obtained by bending the rules or ignoring them altogether. A number of the Nazi doctors who injected concentration camp victims with infectious agents or tortured prisoners by freezing or burning them to death were in fact professionally trained scientists who gathered real data that could potentially be put to good use.

It is only "theology, philosophy, or politics" that can establish the ends of science and technology. Scientists may help to establish moral rules concerning their own conduct, but they

do so not as scientists but as scientifically informed members of a broader political community. There are very many brilliant, dedicated, energetic, ethical, and thoughtful people within the community of research scientists and doctors working in the field of biomedicine. But their interests do not necessarily correspond to the public interest. Scientists are strongly driven by ambition and often have pecuniary interests in a particular technology or medicine as well. Hence the question of what we do with biotechnology is a political issue that cannot be decided technocratically.

The answer to the question of who decides the legitimate and illegitimate uses of science has been established by several centuries of political theory and practice: It is the democratically constituted political community, acting chiefly through its elected representatives, that is sovereign in these matters and has the authority to control the pace and scope of technological development. While there are all sorts of problems with democratic institutions today, from special-interest lobbying to populist posturing, there is also no set of institutions that can better capture the will of the people in a fair and legitimate way. We can surely hope that politicians make decisions that are informed by a sophisticated understanding of science. History is full of cases where laws were made based on bad science, for example the eugenics legislation passed in the United States in the early twentieth century. But in the final analysis, science itself is just a tool for achieving human ends; the political community must decide which ends to pursue.

When we turn to the question of establishing a regulatory regime for human biotechnology, we face a rather different problem. The issue is not whether it should be scientists or politicians who make choices regarding scientific research, but whether it should be individual parents or the government who decide what reproductive decisions are permissable. James Watson has argued that it should be individual mothers rather than a group of male regulators:

> My principle here is pretty simple: just have most of the decisions made by women as opposed to men. They're the ones who bear children, and men, as you know, often sneak away from children that aren't healthy. We're going to have to feel more

> responsible for the next generation. I think women should be allowed to make the decisions, and as far as I'm concerned, keep these male doctor committees out of action.

Counterpoising the judgment of male bureaucrats against the concerns of loving mothers is a clever rhetorical strategy, but it is beside the point. Male judges, officers, and social workers (as well as a lot of female ones) already interfere in the lives of women all the time, telling them that they must not neglect or abuse their children, that they have to send their children to school rather than making them earn money for the family, and that they must not give their children drugs or arm them with weapons. The fact that most women will use their authority responsibly doesn't eliminate the need for rules, particularly when technology makes possible all sorts of highly unnatural reproductive possibilities (like cloning) whose ultimate consequences for children may not be healthy.

The automatic community of interest that is assumed to exist between parent and child under natural forms of reproduction may not exist for the new ones. Some have argued that we can presume the consent of a yet-to-be-born child to be free of birth defects or of mental retardation. But can we presume the consent of a child to be a clone, or to be born the biological offspring of two women, or to be born with a nonhuman gene? Cloning in particular raises the prospect that the reproductive decision will suit the interests and convenience of the parent rather than the child, and in this case, the state has an obligation to intervene to protect the child.

Can technology be controlled?

Even if we decide that technology should be controlled, we face the problem of whether it can be. Indeed, one of the greatest obstacles to thinking about a regulatory scheme for human biotechnology is the widespread belief that technological advance cannot be restrained, and that all such efforts are self-defeating and doomed to failure. This is asserted gleefully by enthusiasts of particular technologies and by those who hope to profit from them, and pessimistically by those who would like to slow down the development of potentially harmful technologies. In the latter camp, there is widespread de-

featism on the question of whether politics can shape the future.

This attitude has become particularly strong in recent years because of globalization and our experience with information technology. No sovereign nation, it is said, can regulate or ban any technological innovation, because the research and development will simply move to another jurisdiction. American efforts to control data encryption, for example, or French efforts to enforce a French-language policy on French web sites, have simply hobbled technological development in these countries as developers moved their operations to more favorable regulatory climates. The only way to control the spread of technology is to have international agreements on technology-restricting rules, which are extraordinarily difficult to negotiate and even harder to enforce. In the absence of such international agreements, any nation that chooses to place limits on internal development will simply give other nations a leg up.

A belief in the inevitability of technological advance is mistaken, though it could become a self-fulfilling prophecy if accepted by too many people. It is simply not the case that the speed and scope of technological development cannot be controlled. There are many dangerous or ethically controversial technologies that have been subject to effective political control, including nuclear weapons and nuclear power, ballistic missiles, biological and chemical warfare agents, replacement human body parts, and neuropharmacological drugs. The international community has regulated human experimentation effectively for many years. More recently, the proliferation of genetically modified organisms (GMOs) in the food chain has been stopped dead in its tracks in Europe, with American farmers walking away from transgenic crops that they had only recently embraced. One can argue about the rightness of this decision, but it proves that the march of biotechnology is not an unstoppable juggernaut.

Skeptics will argue that none of these efforts to control technology has been successful in the end. For example, despite the huge diplomatic effort that the West and especially the United States has put into nuclear nonproliferation, India and Pakistan nonetheless became the sixth and seventh pow-

ers openly to test nuclear devices in the 1990s. While nuclear power for energy generation was slowed down after Three Mile Island and Chernobyl, it is now back on the table due to rising fossil fuel costs and concerns over global warming. Ballistic-missile proliferation and the development of weapons of mass destruction continue in places like Iraq and North Korea, and there is a large underground market in drugs, spare body parts, plutonium, and virtually any other illicit commodity one cares to name.

All of this is true enough: No regulatory regime is ever fully leak-proof, and if one selects a sufficiently long time frame, most technologies end up getting developed eventually. But this misses the point of social regulation. No law is ever fully enforceable. Every country makes murder a crime and attaches severe penalties to homicide, and yet murders nonetheless occur. The fact that they do has never been a reason for giving up on the law or on attempts to enforce it.

In the case of nuclear weapons, vigorous nonproliferation efforts on the part of the international community were in fact very successful in slowing down the spread of nuclear weapons, and keeping them out of the hands of countries that might at different points in their histories have been tempted to use them. At the dawn of the nuclear era in the late 1940s, experts routinely predicted that dozens of countries would possess nuclear weapons in a few years; the fact that only a handful have developed them, and that none have been detonated in conflict by the end of the twentieth century, is a remarkable achievement.

Admittedly, nuclear weapons are easier to control than biotechnology. This is true for two reasons. First, since nuclear weapons development is expensive and requires large, visible institutions, private development is very unlikely. Second, the technology is so obviously dangerous that there was a rapid worldwide consensus on the need to control it. Biotechnology research by contrast, can be carried out in smaller, less lavishly funded labs, and there is no similar consensus on its risks.

On the other hand, biotechnology does not pose high enforcement hurdles the way nuclear weapons do. A single bomb in the hands of a terrorist group or rogue state like Iraq will

significantly threaten world security. By contrast, an Iraq that can clone Saddam Hussein does not pose much of a threat, unappetizing as that prospect may be. The purpose of a law banning human cloning in the United States would not be undermined if some other countries permitted it, or if Americans traveled abroad to have themselves cloned in such jurisdictions.

Some argue that regulation cannot work in a globalized world unless it is international in scope. But to use this argument to build a case against national-level regulation is to put the cart before the horse. Regulation never starts at an international level. Nations have to develop rules for their own societies before they can even begin to think about creating an international regulatory system. This is particularly true in the case of a politically, economically, and culturally dominant country like the United States. Other countries around the world will pay a great deal of attention to what the United States does in its domestic law. If an international consensus on the regulation of certain biotechnologies is ever to take shape, it is unlikely to come about in the absence of American action at the domestic level.

Biotechnology regulation today

Before we discuss how human biotechnology should be regulated in the future, we must understand how it is regulated today, and how the current system came into existence. The elements of the existing regulatory structure that are most relevant to future human biotechnology developments are the rules concerning human experimentation and drug approval.

Rules regarding human experimentation evolved in tandem with regulation of the drug industry in the United States, and were driven forward in each instance by the revelation of scandal or atrocity. In 1937, 107 deaths resulted from the untested commercial release of the Sulfanilamide Elixir, which was later found to contain the poison di-ethylene glycol. This scandal led very quickly to passage of the Food, Drug, and Cosmetic Act of 1938, which still remains the statutory basis for the Food and Drug Administration's regulatory authority over new foods and drugs. The Thalidomide scandal of the late 1950s and early 1960s led to passage of the Kefauver

Drug Amendments Act of 1962, which tightened up the rules governing the "informed consent" of a participant in drug trials. Thalidomide, which had been approved for use in Britain, led to horrifying birth defects in the children of women who had taken it while pregnant. Its approval had been held up by the FDA at the clinical trial stage, which nonetheless led to birth defects among the children of mothers participating in the trials.

Human subjects have been threatened not just by new drugs but by scientific experimentation more broadly. The United States developed an extensive set of rules protecting human subjects in scientific experiments largely because of the role played by the National Institutes of Health (and its parent, the U.S. Public Health Service) in funding biomedical research in the postwar period. Again, regulation was driven by scandal and tragedy. In its early years, the NIH set up a peer-review system for evaluating research proposals, but tended to defer to the judgment of the scientific community in deciding upon the acceptable risks to human research subjects. This system proved inadequate with the revelation of the Jewish Chronic Disease Hospital scandal (in which chronically ill and feeble patients were injected with live cancer cells), the Willowbrook scandal (in which mentally retarded children were infected with hepatitis), and the Tuskegee Syphilis scandal (in which 400 poor black men diagnosed with syphilis were put under observation but not told of their condition and in many cases not treated for it when medications became available). These incidents led in 1974 to new federal regulations protecting human research subjects, and to the National Research Act, which created the National Commission for the Protection of Subjects of Biomedical and Behavioral Research. These new laws laid the basis for the current system of Institutional Review Boards (IRBs) that now are required for federally funded research. Even now, the adequacy of these protections has been criticized. The National Bioethics Advisory Commission issued a report in 2001 urging new federal legislation to create a single, strengthened National Office for Human Research Oversight.

Advances in biotechnology have created gaping holes in the existing regime for the regulation of human biomedicine, which

legislatures and administrative agencies around the world have been racing to fill. It is not clear, for example, whether the rules for human experimentation apply to embryos outside the womb. The nature of the players and the flow of money within the biomedical and pharmaceutical communities has also changed, with important implications for any future regulatory system.

One thing is reasonably clear: The time when governments could deal with biotech questions by appointing national commissions that brought scientists together with learned theologians, historians, and bioethicists is rapidly drawing to a close. These commissions played a very useful role in thinking through the moral and social implications of biomedical research. But it is time to move from thinking to acting, from recommending to legislating. We need institutions with real enforcement powers.

Embryo research is only the beginning of a series of new capabilities for which societies must decide on rules and regulatory institutions. Others that will arise sooner or later include:

Preimplantation diagnosis and screening. This group of technologies, by which multiple embryos are screened genetically for birth defects and other characteristics, is the beginning point for "designer babies." This technology will arrive much sooner than human germ-line engineering. Indeed, such screening has already been performed for children of parents susceptible to certain genetic diseases. In the future, do we want to permit parents to screen and selectively implant embryos on the basis of sex and intelligence, of hair, eye, or skin color, or sexual orientation, once these characteristics can be identified genetically?

Germ-line engineering. If and when human germ-line engineering arrives, it will raise the same issues as preimplantation diagnosis and screening but in a more extreme form. Preimplantation diagnosis and screening is limited by the fact that there will always be only a small number of embryos from which to choose, based on the genes of the two parents. Germ-line engineering will expand possibilities to include virtually any other genetically governed trait, provided it can be identified successfully, including traits that come from other species.

The creation of chimeras using human genes. Dr. Geoffrey Bourne, former director of the Emory University Primate Center, once stated that "it would be very important scientifically to try to produce an ape-human cross." Other researchers have suggested using women as "hosts" for the embryos of chimpanzees or gorillas. One biotech company, Advanced Cell Technology, reported that it had successfully transferred human DNA into a cow's egg and allowed it to grow into a blastocyst before destroying it. Scientists have been deterred from doing research in this area for fear of bad publicity, but in the United States such work is not illegal. Will we permit the creation of hybrid creatures using human genes?

New Psychotropic Drugs. In the United States, the FDA regulates therapeutic drugs while the Drug Enforcement Agency and the states regulate illegal narcotics like heroin, cocaine, and marijuana. Societies will have to make decisions on the legality and extent of permissible use of future generations of neuropharmacological agents. In the case of prospective drugs that improve memory or other cognitive skills, they will have to decide on the desirability of enhancement uses, and on how these drugs are to be regulated.

A line in the sand?

Regulation is essentially the act of creating lines to separate legal from proscribed activities, authorized by a statute that defines the area in which regulators can exercise some degree of judgment. With the exception of some diehard libertarians, most people reading the above list of future possibilities in biotechnology will probably want to see such lines drawn.

Some practices should be banned outright, and one of them is reproductive cloning (that is, cloning with the intent of producing a child). The reasons for such a ban are both moral and practical, and go far beyond the National Bioethics Advisory Commission's concern that human cloning cannot now be done safely. The moral reasons have to do with the fact that cloning is a highly unnatural form of reproduction that will establish equally unnatural relationships between parents and children. A cloned child will have a very asymmetrical relationship with his or her parents. He or she will be both child

and twin of the parent from whom his or her genes come, but will not be related to the other parent in any way. The unrelated parent will be expected to nurture a younger version of his or her spouse. How will that parent look upon the clone when he or she reaches sexual maturity? While it is possible to come up with sympathetic scenarios where cloning might be justified (e.g., a holocaust survivor whose family would otherwise die out), these do not constitute a sufficiently strong societal interest to justify a practice that on the whole would be harmful.

Beyond these considerations inherent to cloning itself, there are a number of practical concerns. Cloning is the opening wedge for a series of new technologies that will ultimately lead to "designer babies." If we get used to cloning in the near term, it will be much harder to oppose germ-line engineering for enhancement purposes in the future. It is important to lay down at an early point a political marker that will demonstrate that the development of these technologies is not inevitable, and that societies can exercise some measure of control over the pace and scope of technological advance. There is no strong constituency in favor of cloning in any country, and considerable international consensus already exists in opposition to the procedure. Cloning therefore represents an important strategic opportunity to demonstrate the possibility of political control over biotechnology.

But while a broad ban is appropriate in this case, it will not be a good model for the control of future technologies. Preimplantation diagnosis and screening, for example, has begun to be used today to ensure that children are born free of genetic diseases. The same technology can be used for less laudable purposes such as sex selection. What we need to do in this case is not ban the procedure, but regulate it, drawing lines to distinguish between legitimate and illegitimate uses.

One obvious way of drawing lines is to distinguish between therapy and enhancement, directing research toward the former while putting restrictions on the latter. The original purpose of medicine is, after all, to heal the sick, not to turn healthy people into gods. We don't want star athletes to be hobbled by bad knees or torn ligaments, but we also don't want them to compete on the basis of who has taken the most steroids.

This general principle would allow us to use biotechnologies to cure genetic diseases like Huntington's chorea or cystic fibrosis but not to make our children more intelligent or taller.

The distinction between therapy and enhancement has been attacked on the grounds that there is no way to distinguish between the two in theory, and therefore no way of discriminating in practice. There is a long intellectual tradition, represented most powerfully in recent years by the French postmodernist thinker Michel Foucault, that maintains that pathology and disease are socially constructed phenomena in which deviation from some presumed norm is stigmatized. Homosexuality, to take one example, was long considered unnatural and was classified as a psychiatric disorder until the latter part of the twentieth century. Something similar can be said of dwarfism: Human heights are distributed normally, and it is not clear at what point in the distribution one becomes a "dwarf." If it is legitimate to give growth hormone to a child who is in the bottom 0.5 percentile for height, why can't it be prescribed for someone who is in the fifth percentile, or for that matter in the fiftieth?

While it is the case that certain conditions do not lend themselves to neat distinctions between pathological and normal, it is also true that there is such a thing as health. As Leon Kass has argued, there is a natural functioning to an organism that has been determined by the requirements of the species' evolutionary history, and that is not simply an arbitrary social construction. It often strikes me that the only people who can argue that there is no difference in principle between disease and health are those who have never been sick. If you have a virus or fracture your leg, you know perfectly well that something is wrong.

And even in the cases where the borderline between sickness and health, therapy and enhancement, is murkier, regulatory agencies routinely make these distinctions in practice. Take the case of Ritalin. The underlying "disease" that Ritalin is supposed to treat, Attention-Deficit/Hyperactivity Disorder (ADHD), is most likely not a disease at all but simply the label that we give to people who are in the tail-end of a normal distribution of behavior related to focus and attention. This is in fact a classic case of the social construction of

pathology: ADHD was not even in the medical lexicon a couple of generations ago. There is, correspondingly, no neat line between what one might label the therapeutic and enhancement uses of Ritalin. At one end of the distribution, there are children who almost anyone would say are so hyperactive that normal functioning is impossible for them. At the other end of the distribution are children who have no trouble concentrating or interacting, for whom taking Ritalin might be an enjoyable experience that would give them a "high" just like any other amphetamine. But they would be taking the drug for enhancement rather than for therapeutic reasons, and therefore most people would want to prevent them from doing so. What makes Ritalin controversial is those children in the middle, who meet only some of the diagnostic criteria specified in the DSM for the disease but are nonetheless given the drug by their family physician.

In other words, if there was ever a case where the distinction between pathology and disease in diagnosis, and therapy and enhancement in treatment, is ambiguous, it is ADHD and Ritalin. And yet, regulatory agencies *make and enforce this distinction all the time*. The U.S. Drug Enforcement Agency classifies Ritalin as a Schedule II pharmaceutical that can only be taken for therapeutic purposes with a doctor's prescription; it clamps down on Ritalin's recreational (that is to say, enhancement) use as an amphetamine. The fact that the boundary between therapy and enhancement is unclear does not make the distinction meaningless.

Institutions of the future

Deciding where precisely we should draw lines concerning technologies that have not yet come into being is not a fruitful exercise at this point. Many of these decisions will have to be made on a trial-and-error basis when the time comes. It is less important at this point to make up a definitive list of restrictions than to think about general principles that should govern the development and use of biotechnology, and to begin designing institutions that will enable us to make critical decisions in the future.

If we are going to regulate biotechnology, we need to think through what agencies we want to make and enforce the rules.

One possibility is to leave regulatory authority with existing institutions like the Food and Drug Administration, the National Institutes of Health, or consultative groups like the Recombinant DNA Advisory Committee. It is prudent to be conservative in the creation of new regulatory institutions and additional layers of bureaucracy. On the other hand, there are a number of reasons for thinking that we need new institutions to deal with the challenges of the coming biotech revolution. To rely on existing agencies would be like trying to use the Interstate Commerce Commission, which was responsible for regulating trucks, to oversee civil aviation when that industry came into being, rather than creating a separate Federal Aviation Administration.

An initial reason why existing institutions are probably not appropriate for regulating future human biotechnology is their narrow mandate. Human biotechnology differs substantially from agricultural biotechnology insofar as it raises a host of ethical questions related to human dignity and human rights that are not at issue for genetically modified organisms. While people object to genetically engineered crops on ethical grounds, the most vociferous complaints relate to their possible negative consequences for human health and to their environmental impact. These are precisely the issues that existing regulatory institutions like the FDA, EPA, and USDA are designed to handle. These agencies can be criticized for using the wrong standards or for not being sufficiently cautious, but they are not operating outside their regulatory mandate when they take on genetically modified foods.

Let us suppose that Congress legislatively distinguishes between therapeutic and enhancement uses of preimplantation diagnosis and screening. The FDA is not set up to make politically sensitive decisions concerning the point at which selection for characteristics like intelligence or height cease to be therapeutic and become enhancing, or whether such selection can be considered therapeutic at all. The only grounds on which the FDA can prohibit a procedure are effectiveness and safety. But there will be many safe and effective procedures in the coming biotechnology revolution that will nonetheless require regulatory scrutiny. The limits of the FDA's mandate are already evident: It has asserted a right to regulate human

cloning on the legally questionable grounds that a cloned child constitutes a medical "product" over which it has authority.

One can always try to amend and expand the FDA's charter, but past experience shows that it is difficult to change the organizational culture of agencies with a long history. Not only will the agency resist taking on new duties, but a shifting mandate will likely mean it will do its old job less well. This implies the need to create a new agency to oversee the approval of new medicines, procedures, and technologies for human health. In addition to having a broader mandate, this new authority will need different staffing. It will have to include not just the doctors and scientists who staff the FDA and oversee clinical trials for new drugs, but also those who are prepared to make judgments about the technology's social and ethical implications.

A second reason why existing institutions are probably not sufficient to regulate future biotechnologies relates to the changes that have taken place in the research community and the biotech and pharmaceutical industries over the past generation. There was a period up through the early 1990s when most biomedical research in the United States was funded by the National Institutes of Health or other federal agencies. This meant that the NIH could regulate that research through its own internal rule-making authority, as in the case of rules concerning human experimentation. Government regulators could work closely with committees of scientific insiders like the Recombinant DNA Advisory Committee, and could be reasonably sure that no one in the United States was doing dangerous or ethically questionable research.

None of this holds true any longer. While the federal government remains the largest source of research funding, there is a huge amount of private investment money available to sponsor work in new biotechnologies. Indeed, the massive government-funded Human Genome Project was upstaged by Craig Venter's privately held Celera Genomics in the race to map the human genome. The first embryonic stem cell lines were cultivated by Dr. James Thompson at the University of Wisconsin using nongovernment funding in order to comply with the 1994 rules on federally funded research that would harm embryos. Many of the participants at a workshop held on the

twenty-fifth anniversary of the Asilomar conference on rDNA concluded that while the Recombinant DNA Advisory Committee (RAC) had served an important function in its day, it could no longer monitor or police the present-day biotech industry. The committee has no formal enforcement powers, and can bring to bear only the weight of opinion within the elite scientific community. The nature of that community has changed over time as well: There are today many fewer "pure" researchers without ties to the biotech industry or commercial interests in certain technologies.

This means that any new regulatory agency must not only have a mandate to regulate biotechnology on grounds broader than efficacy and safety but must also have statutory authority over all research and development, and not just research that is federally funded. Such an agency, the Human Fertilisation and Embryology Authority, has already been created in Britain for this purpose. Unification of regulatory powers into a single new agency will end the practice of complying with federal funding restrictions by finding private sponsors, and will bring more transparency to the biotech sector.

What is the likelihood of the United States putting into place a regulatory system of the kind just outlined? There will be formidable political obstacles to creating new institutions. The biotech industry is strongly opposed to regulation (if anything, it would like to see FDA rules loosened), as is the community of research scientists. Most would prefer regulation to take place within their own disciplines, outside the scope of formal law. They are joined in this by advocacy groups representing patients, the elderly, and others with an interest in promoting cures for various diseases. Together, these groups form a very powerful political coalition.

But for the sake of its own long-term self-interest, the biotech industry should consider promoting formal regulation. Consider what happened to agricultural biotechnology. At the beginning of the 1990s, Monsanto, a leading innovator in agricultural biotechnology, considered asking the first Bush administration for stronger formal regulatory rules, including labeling requirements, for its genetically engineered products. A change of leadership scuttled this initiative, however, on the grounds that there was no scientific evidence of health

risks, and the firm introduced a series of new GMOs that were quickly adopted by American farmers. What the company failed to anticipate was the political backlash that would arise in Europe against GMOs and the strict labeling requirements that the European Union imposed in 1997 for genetically modified food imported into Europe.

Monsanto and other American firms railed at the Europeans for being unscientific and protectionist, but Europe had sufficient market power to impose its rules on American exporters. American farmers, without a means of separating GM from non-GM foods, found themselves closed out of important export markets. They responded by planting fewer GM crops after 1997 and by charging that they had been mislead by the biotech industry. In retrospect, Monsanto executives realized that they had made a serious mistake in not working earlier to establish an acceptable regulatory environment that would assure consumers of the safety of their products, even if this did not appear to be scientifically necessary.

Until now, the history of pharmaceutical regulation has been driven by horror stories like Sulfanilamide Elixir and Thalidomide. It may be the case that regulations concerning human cloning will have to await the birth of a horribly deformed child who is the product of an unsuccessful cloning attempt. The biotech industry needs to consider whether it is better to anticipate such problems now and work toward formulating a system that serves its interests by assuring people of the safety and ethical nature of its products, or by waiting until there is a huge public outcry following an outrageous accident or horrifying experiment.

The meaning of freedom

Ultimately, the technologies developed by these companies, as well as by researchers in government and academia, may lead us into a posthuman future in which we have the capacity, slowly but surely, to alter the essence of human nature. Many embrace this power under the banner of human freedom. They want to maximize the freedom of parents to choose the kind of children they have, the freedom of scientists to pursue research, and the freedom of entrepreneurs to make use of the new technologies to create wealth.

But this kind of freedom will be different from all other freedoms that people have previously enjoyed. Political freedom has heretofore meant the freedom to pursue those ends that our natures had established for us. Those ends are not rigidly determined; human nature is very plastic, and we have an enormous range of choices conformable with that nature. But it is not infinitely malleable, and the elements that remain constant—particularly our species-typical gamut of emotional responses—constitute a safe harbor that allows us to connect, potentially, with all other human beings.

It may be that we are somehow destined to take up this new kind of freedom, or that the next stage of evolution is one in which, as some have suggested, we will deliberately take charge of our own biological makeup rather than leaving it to the blind forces of natural selection. But if we do, we should do it with our eyes open. Many assume that the posthuman world will look pretty much like our own—free, equal, prosperous, caring, compassionate—only with better health care, longer lives, and perhaps higher levels of intelligence than today.

But the posthuman world could be one that is far more hierarchical and competitive than the one that currently exists, and full of social conflict as a result. It could be one in which any notion of shared humanity is lost, because we have mixed human genes with those of so many other species that we no longer have a clear idea of what a human being is. It could be one in which the average person is living well into his or her second century, sitting in a nursing home hoping for an unattainable death. Or it could be the kind of soft tyranny envisioned in *Brave New World*, in which everyone is healthy and happy but has forgotten the meaning of hope, fear, or struggle.

We do not have to accept any of these future worlds under a false banner of liberty, be it that of unlimited reproductive rights or of unfettered scientific inquiry. We do not have to regard ourselves as slaves to inevitable technological progress when that progress does not serve human ends. True freedom means the freedom of political communities to protect the values they hold most dear, and it is that freedom that we need to exercise with regard to the biotechnology revolution today.