

Gene REGIME

*Imagine the World Trade Organization (WTO) striking down a national ban on importing cloned embryos because it is a barrier to trade. Neither the WTO, nor individual governments, nor scientists, nor ethicists can effectively regulate human biotechnology on a global scale. So who will settle the troubling questions it raises? | **By Francis Fukuyama***

Human biotechnology intimately connects good and evil. The same technology that promises to cure your child of cystic fibrosis or your parent of Alzheimer's disease presents more troubling possibilities as well: human cloning, designer babies, drugs that enhance rather than heal, and the creation of human-animal hybrids. In the face of the challenges this technology poses, only one response is possible: Countries must regulate the development and use of human biotechnology by political means, setting up institutions that will discriminate between those technological advances that help humans flourish and those that threaten human dignity and well-being. These regulatory bodies must first be empowered to enforce these decisions on a national level and then ultimately extend their reach internationally.

Why should this technology be regulated by government? Biotechnology is clearly unlike nuclear technology, whose destructive potential was immediately clear and was from the outset tightly ringed with political controls. But neither is biotechnology as benign as information technology, for example. The Internet has promised benefits such as wealth creation, information access, and the ability to foster communities of users. While it has downsides—among them, it can facilitate money laundering and the distribution of pornography—many of these problems can be addressed without heavy-handed government regulation.

Biotechnology falls between the two extremes. It is easiest to object to new biotechnology if it yields a botched clinical trial or a deadly allergic reaction to a genetically modified food. But the real threat of biotechnology is far more subtle and harder to weigh in any utilitarian calculus. Biotechnology offers the

potential to change human nature and therefore the way that we think of ourselves as a species.

The debate on biotechnology is polarized. At one end are libertarians who argue that society should not and cannot put constraints on the development of technology. This camp includes researchers and scientists, the biotech industry, and, particularly in the United States and Britain, a large group that is ideologically committed to some combination of free markets, deregulation, and minimal government interference in technology. At the other end of the spectrum is a heterogeneous group with moral concerns about biotechnology, consisting of those who have religious convictions, environmentalists who believe in the sanctity of nature, and people worried about the possible return of eugenics. This group has proposed banning new technologies ranging from in vitro fertilization and stem cell research to transgenic crops and human cloning.

The debate on biotechnology must move beyond this polarization. Both approaches—a completely laissez-faire attitude toward biotech development and the attempt to ban wide swaths of future technology—are misguided and unrealistic. Certain technologies like reproductive human cloning should be banned outright, for moral and practical reasons. The moral reasons have to do with the asymmetric relationship of a cloned child with his parents:

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the child will be a twin of one and not related to the other. Practically speaking, cloning is the opening wedge for a series of technologies that ultimately lead to designer babies. If cloning is allowed now, it will be harder to oppose germ-line engineering to enhance babies in the future.

But for most other emerging forms of biotechnology, a more nuanced regulatory approach than outright bans is necessary. While everyone has been staking out positions on various technologies, almost no one has been looking concretely at what kinds of institutions would be needed to let societies control the pace and scope of technology development.

Regulation—particularly international regulation—is not something anyone should call for lightly.

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Regulation brings with it many inefficiencies and even pathologies that are well understood. The excesses of regulation sparked a great deal of innovative work in the past generation on alternatives to formal state regulation, including self-regulation by businesses and more flexible models for rule generation and enforcement.

However, schemes for self-regulation tend to work best where an industry produces few costs to society, where the issues are technical and apolitical, and where the industry involved has strong incentives to police itself. These criteria apply, for example, in the development of a wide variety of technical standards or in areas such as bank settlements. They do not apply, however, to the biotechnology industry or to many of the technologies it is likely to produce. The community of research scientists has done an admirable job up to now in policing itself in areas like human experimentation and the safety of recombinant DNA technology, but there are too many commercial interests chasing too much money for self-regulation to continue to work. The U.S. biotech industry by itself spent nearly \$11 billion on research in 2000, employs over 150,000 people, and has doubled in size since 1993. Most biotechnology companies simply do

not have the incentives to observe many of the fine ethical distinctions that will need to be made.

One of the greatest obstacles to thinking about a regulatory scheme for human biotechnology is the widespread belief that technological advance cannot be controlled, and that all such efforts are self-defeating and doomed to failure. This view is asserted gleefully by enthusiasts of particular technologies and by those who hope to profit from their development and pessimistically by those who would like to slow the spread of potentially harmful technologies. In the latter camp, particularly, there is a kind of defeatism as to the ability of politics to shape the future.

Belief in the inevitability of technological advance has become particularly strong in recent years because of the advent of globalization and recent experience with information technology. No sovereign nation-state, many argue, can regulate or ban any technological innovation, because the research and development will simply move to another jurisdiction. In fact, this trend is apparent in the highly competitive international

biotech industry, where companies are constantly searching for the most favorable regulatory climate. Because Germany, with its traumatic history of eugenics, has been more restrictive of genetic research than many developed countries, most German pharmaceutical and biotech companies have moved their labs to Britain, the United States, and other less restrictive nations. In 2001, Britain legalized therapeutic or research cloning. Should the United States join Germany, France, and a number of other countries that do not permit this type of research, Britain will become a haven for it. Singapore, Israel, and other countries have indicated an interest in pursuing research in stem cells and other niches if the United States continues to restrict its own efforts out of ethical concerns.

But pessimism about the inevitability of technological advance is wrong (though it could become a self-fulfilling prophecy if adopted by too many people). The speed and scope of technological development can indeed be controlled. Many dangerous or ethically controversial technologies—weapons and nuclear power, ballistic missiles, biological and chemical warfare agents, replacement human body parts, and neuropharmacological drugs—are subject to effective political control and thus cannot be freely

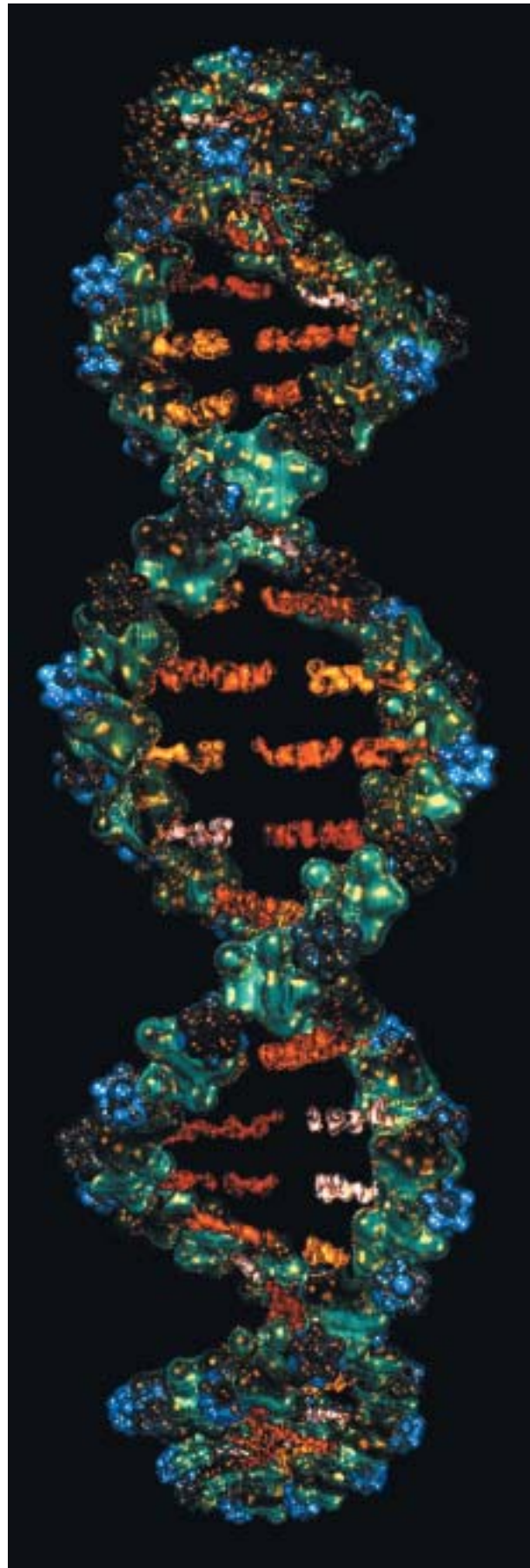
developed or traded. Even more benign technologies like the Internet may be controlled. The Chinese authorities, for instance, have forced Internet sites like Yahoo! and Microsoft Corp.'s msn to restrict publication of unsympathetic stories on their Chinese-language Web sites by simply threatening to revoke their rights to operate in China.

Skeptics will argue that none of these efforts to control technology have been successful in the end. Certainly, no regulatory regime is ever fully leakproof. But social regulation does not need to prevent all breaches to be effective. Every country makes murder a crime and attaches severe penalties to homicide, yet murders nonetheless occur. But the prevalence of murder has never been a reason for giving up on the law or on attempts to enforce it. 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.

LAWS DON'T CLONE EASILY

It is true that regulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level: Nation-states have to develop rules for their own societies before they can even begin to think about creating an international regulatory system. In particular, other countries will pay a great deal of attention to developments in U.S. domestic law, just as they did in the cases of food safety or in pharmaceutical regulation. 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 a national level.

No one knows whether an international consensus to ban or strictly regulate other technologies like cloning or germ-line modification will emerge, but there is no reason to rule out the possibility at this early stage [see sidebar on page 61]. Consider reproductive cloning—that is, the cloning of a human child. As of November 2001, 24 countries had banned reproductive cloning, including Germany, France, India, Japan, Argentina, Brazil, South Africa, and the United Kingdom. In 1998, the Council of Europe approved an added protocol to its convention banning human reproductive cloning, a document that was approved by 24 of the council's 43 member states. The U.S. Congress was just one of a number of legislatures deliberating similar measures.



Views on the ethics of certain types of biotechnology, and particularly genetic manipulation, span a continuum. At the most restrictive end are Germany and other countries in continental Europe. Continental Europe has also been home to the world's strongest environmental movements, which as a whole have been quite hostile to biotechnology in its various forms. At the other end of the spectrum are a number of Asian countries, which for historical and cultural reasons have not been nearly as concerned with the ethical dimension of biotechnology. If there is any region that is likely to opt out of an emerging consensus on the regulation of biotechnology, it is Asia. A number of Asian countries either are not democracies or lack a strong domestic opposi-

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tion. Asian countries like Singapore and South Korea have the research infrastructure to compete in biomedicine and strong economic incentives to gain market share in biotechnology at the expense of Europe and North America.

An international consensus on the control of new biomedical technologies will not simply spring into being without a great deal of work on the part of the international community and the leading countries within it. In August 2001, Germany and France called on U.N. Secretary-General Kofi Annan to introduce a draft reproductive cloning ban worldwide, with an eye to bringing the United States back into a global agreement after its withdrawal from the Kyoto Protocol. As in the case of national-level bans, controversy exists at the international level over whether the ban should be restricted to reproductive cloning or whether it should extend to research cloning as well.

No magic formula for creating a consensus on such issues is possible. Building consensus will require the traditional tools of diplomacy: rhetoric, persuasion, negotiation, and economic and political leverage. But in this respect the problem is not different from the creation of any other international regime. The international governance of human

biotechnology does not inevitably mean creating a new international organization, expanding the United Nations, or setting up an unaccountable bureaucracy. At the simplest level, it can come about through the efforts of nation-states to harmonize their regulatory policies.

FIELD TESTING NEW RULES

The attempt to build an international regime for human biotech can draw lessons from regimes governing genetically modified organisms (gmos) and human experimentation. In the United States, the regulatory environment is relatively relaxed and has permitted the field testing and eventual commercialization of such gmos as *Bt* corn, Roundup-Ready soybeans, and the *flavr-savr* Tomato. For the most part, American regulators have not adopted an adversarial relationship with the companies and individuals seeking approval of new gmos. They do not themselves evaluate the long-term environmental impacts of biotech products but rely instead on the applicants or outside experts to provide assessments.

The European regulatory environment for biotechnology is considerably more restrictive, due in part to strong political opposition to gmos but also to the cumbersome nature of regulation that exists at both national and European levels. Biotech regulation varies considerably among European Union (eu) member states. Denmark and Germany, for example, have passed relatively stringent national laws regulating safety and ethical aspects of genetic modification. The United Kingdom, by contrast, has maintained a relatively hands-off approach. Until 1989, the French relied on self-regulation by their scientific community. By eu rules, individual member states are allowed to be more restrictive than the community as a whole, though the degree to which this is permissible is a matter of dispute. Austria and Luxembourg, for example, have banned the planting of certain genetically modified crops that are legal in the rest of the eu.

The regulatory regime is much less developed for human biotechnology than for agricultural biotech, largely because the genetic modification of human beings has not yet progressed as it has for plants and animals. Parts of the existing regulatory structure will be applicable to the new innovations over the horizon; other parts are just now being put into place, particularly those having to

do with straightforward issues related to safety and efficacy. But future innovations in biomedicine will involve ethical choices concerning, for example, enhancement rather than therapeutic uses of genetic technology or the introduction of nonhuman genes into the human genome. In these areas, the most important elements of a future regulatory system have yet to be designed.

The existing regulatory structure concerning human experimentation is also relevant to a regime for human biotech. These rules would apply to future experiments with human cloning and germ-line engineering, and they represent a case in which

significant ethical constraints are effectively applied, both nationally and internationally, to scientific research. This case runs counter to the received wisdom concerning regulation: It shows that there is no inevitability to the unfettered advance of science and technology. Indeed, rules concerning human experimentation are strongest in the country that is supposedly the most hostile to government regulation, the United States.

The United States developed an extensive set of rules protecting human subjects in scientific experiments largely because of the role of the National Institutes of Health (nih). In its early years, nih set

Nascent Embryo Laws

Do the realities of international competition mean that the United States or any other country will fatalistically jump into a technological arms race? In fact, many have not. Legislatures and administrative agencies around the world have been racing to fill the gaping holes in the existing regime for regulating human biomedicine. One of the first and most contentious policy issues they have grappled with concerns the uses that may be made of human embryos, and the result has been a wide variety of national-level rules.

As of November 2001, 16 countries had passed laws on human embryo research, including France, Germany, Austria, Switzerland, Norway, Ireland, Poland, Brazil, and Peru. In addition, Hungary, Costa Rica, and Ecuador implicitly restrict research by conferring on embryos a right to life. Finland, Sweden, and Spain permit embryo research but only on extra embryos left over from in vitro fertilization clinics. Germany's laws are among the

most restrictive. Since passage of its 1990 Act for the Protection of Embryos, several areas have been regulated, including abuse of human embryos, sex selection, artificial modification of human germ-line cells, cloning, and the creation of hybrid organisms, or chimeras, that possess genes from both human and other species. Britain in 1990 passed the Fertilisation and Embryology Act, which established one of the most clear-cut legal frameworks in the world for the regulation of embryo research and cloning. This act was thought to ban reproductive cloning while permitting research cloning, though in 2001 a British court ruled that reproductive cloning would actually be permitted under it. In September 2001, the European Parliament passed a resolution calling for bans on both reproductive and therapeutic cloning and calling for Britain to reconsider its 1990 law.

Embryo research is only the beginning. Other developments that will come up sooner or later include preimplantation

diagnosis, which permits screening for birth defects but also could allow for other characteristics such as intelligence and sex; germ-line engineering, which expands the potential of genetic manipulation to include nonhuman traits; new psychotropic drugs that could improve memory or other cognitive skills; and the creation of chimeras. 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, Massachusetts-based Advanced Cell Technology, reported that it had successfully transferred human dna into a cow's egg and gotten it to grow into a blastocyst before it was destroyed. 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.

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up a peer review system for evaluating research proposals but tended to defer to the scientific community in establishing acceptable risks to human research subjects. This system proved inadequate with the revelation in 1963 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

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children were infected with hepatitis in the mid-1960s; and the 1972 Tuskegee syphilis scandal, in which it was revealed that 399 poor black men diagnosed with syphilis had been put under observation during a 40-year period but not told of their condition and in many cases not treated for it when medications became available. These incidents led to new federal regulations in 1974 to protect human research subjects and to create the National Commission for the Protection of Subjects of Biomedical and Behavioral Research. These laws laid the groundwork for the current system of Institutional Review Boards, which 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 creation of a single, strengthened National Office for Human Research Oversight, and the U.S. government briefly suspended clinical trials at Johns Hopkins University later that year in response to the death of a human subject.

Then, as now, scientists pursuing ethically questionable research defended their actions on the grounds that the medical benefits that could be derived from their work outweighed possible harms to the research subjects. They resisted the intrusion of federal law, arguing that the scientific community alone was best able to judge the risks and benefits of biomedical research.

Rules on human experimentation also exist on an international level. The Nuremberg Code, born in the aftermath of the revelations of experiments by

the Nazis in concentration camps, established the principle that medical experimentation could be performed on human subjects only with their consent. In this case, international law preceded national rules, and the code had little effect on actual practice in other countries, where many doctors resisted it as being too restrictive of valid research.

The Nuremberg Code was largely superseded by the Helsinki Declaration, adopted by the World Medical Association (the global organization representing national medical associations) in 1964. The Helsinki Declaration established principles such as informed consent, and the international medical profession liked it better because it was a matter of self-regulation rather than formal international law. Actual practice among developed nations

nonetheless varies a great deal.

Despite variations in practice and occasional lapses, the case of human experimentation shows that the international community can place effective limits on how research is conducted while balancing the need for research against respect for the dignity of research subjects. This issue will need to be revisited many times in the future.

NOT A JOB FOR THE WTO

It is too early to prescribe a particular sort of international regime for regulating human biotechnology because most countries do not yet have national institutions capable of making the decisions that technology advances will force upon them. While some smaller countries may be influenced by passage of a U.N.-sponsored global cloning ban, to take one example, the United States and other large countries with important interests in biotechnology likely will not. They will first have to make up their own minds on how to deal with these problems. The international community can talk about harmonization only after there is something to harmonize.

That said, it is clear that existing international institutions will not be adequate to meet future challenges. At the moment, the WTO is the only global body with jurisdiction over biotech issues. Under its sanitary and phytosanitary provisions, for example, national food safety standards can deviate from those laid out by the international body, the Codex Ali-

mentarius Commission, only if they are “science-based.” In dealing with genetically modified food, there is currently an acrimonious fight between the United States and Europe over whether Europe’s “precautionary principle”—the notion that products should be presumed guilty until proved innocent of potentially threatening the environment or health—is in fact science-based.

The dispute over gmOs is just a foretaste of what is to come when dealing with human biotechnology. What will constitute a science-based rule concerning cloning, preimplantation diagnosis and screening, or germ-line engineering? National-level rules in these areas will be based in good measure on ethical considerations, with science having little to say. Will the wto dare to strike down a national ban on, say, the import of cloned embryos on the grounds that it constitutes a non-tariff barrier to trade?

The September 11, 2001, terrorist attacks and subsequent anthrax mailings reveal another motive for greater oversight of the global biotech industry. The next generation of bioweapons will involve recombinant dna to make biological agents resistant to antibiotics and vaccines. The biotech research community is not used to having to police itself, yet the threat of a rogue researcher or lab producing dangerous agents, even if inadvertently, is a real one that needs somehow to be addressed.

If international rules on human biotechnology are to be taken out of the trade realm and put into an alternative institutional framework, careful thought will have to be given to its design. Formal, top-down international regulation faces formidable enforcement hurdles and has a poor record of success. Coming up with different, more creative approaches to designing international institutions is a crucial item on the agenda for the new century. **FP**

[[Want to Know More?](#)]

This essay is based on arguments developed in Francis Fukuyama’s *Our Posthuman Future: Consequences of the Biotechnology Revolution* (New York: Farrar, Straus & Giroux, 2002). The most readable introduction to the revolution in genetics is Matt Ridley’s *Genome: The Autobiography of a Species in 23 Chapters* (New York: HarperCollins, 2000). Another accessible general guide is *Biotechnology Unzipped: Promises and Realities* (Washington: Joseph Henry Press, 1997) by Eric S. Grace.

For a synopsis of the issues in the cloning debate, see Brian Alexander’s “(You)2,” (*Wired*, February 2001). Often cited as a useful explanation of the ethical issues surrounding biotechnology is the exchange between Leon Kass, head of President George W. Bush’s panel on bioethics, and political scientist James Q. Wilson in *The Ethics of Human Cloning* (Washington: AEI Press, 1998). The Biotechnology Industry Organization’s Web site outlines the industry position on many bioethics issues, including human cloning, and *Reason* magazine offers pro-cloning arguments on its Web site.

A key work on the development of international rules for human experimentation is *The Ethics and Politics of Human Experimentation* (Cambridge: Cambridge University Press, 1993) by Paul M. McNeill. Jeffrey Brainard’s “A Friendlier Tone on Research Volunteers” (*The Chronicle of Higher Education*, December 14, 2001) discusses the evolving U.S. approach to federal oversight of human experimentation.

In the collection of articles entitled *Can Biotechnology End Hunger?* (*Foreign Policy*, Summer 2000), Mark Strauss, Klaus M. Leisinger, and Miguel A. Altieri discuss developments in agricultural biotechnology. Robert Paarlberg looks at similar issues in “The Global Food Fight” (*Foreign Affairs*, May/June 2000). Especially critical of government efforts to regulate agricultural biotech are Henry I. Miller and Gregory Conko in “The Science of Biotechnology Meets the Politics of Global Regulation” (*Issues in Science and Technology*, Fall 2000).

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