# 9 Possible Societal Responses

In this chapter, we present an overview of the full range of regulatory responses to the challenges posed by new biomedical technology, from doing nothing to changing the status quo to the creation of a new institution along the lines of the HFEA in Britain. In each case, we will lay out both pros and cons of each approach before presenting our recommended option. As we will show below, none of the possible options are cost-free; each involves trade-offs, and each is likely to have unforeseen consequences down the road.

## *9.1 Maintaining the Status Quo*

*Arguments Pro*

There are several serious arguments for not intervening at this time. Advocates of maintaining the status quo have argued that existing federal and state statutes combined with an extensive system of industry self-regulation provide a regulatory framework that is more than adequate to respond to whatever challenges might lie ahead.[1] This argument is largely based on the assumption that at the present time, we are not facing a threat serious enough to justify creating an entirely new regulatory system, whereas the establishment of a new regulatory framework would have immediate and significant costs. Should a legislative intervention become necessary, one could simply rely on existing regulatory powers. Existing statutes could be used to bolster safeguards against ethically questionable practices, obviating the need for new regulatory powers or new bureaucracies. For example, the FDA responded in a timely and effective manner to attempts to clone human beings: It simply declared cloned human embryos a "cellular product" subject to its statutory authority.

The costs of a regulatory intervention are familiar. New statutes and regulations often have unanticipated and undesirable consequences; one consequence herein could be the moving abroad of both researchers and biotech companies seeking a more favorable regulatory climate. The United States remains the world leader in biomedical research, but adopting an extensive regulatory system could hobble its own competitive advantages, as well as deny patients access to the latest medical technologies. It is perhaps no accident that the first successful cloning of a human embryo, a procedure scientists believe is crucial to developing new cures for hitherto incurable diseases, has taken place in Korea and not in the United States. And it is no

[1] David Adamson, "Regulation of Assisted Reproductive Technologies in the United States," *Fertility and Sterility* 78, no. 5 (2002); Judith F. Daar, "Regulating Reproductive Technologies: Panacea or Paper Tiger?," *Houston Law Review* 34 (1997).

coincidence that U.S. scientists identified the hostile political climate as one of the main reasons why this scientific breakthrough took place in Korea and not here.

Crucially, regulatory costs include the opportunity costs of research outcomes and products that do not come into being or come into being at a slower pace as a result of regulation. In addition, regulatory intervention would reduce the range of available ART treatments and increase the costs of regulated ART services, as clinics would pass on to patients most if not all their compliance costs. For example, banning reproductive cloning would make it impossible for couples unable to procreate using their own gametes to have genetically related children, arguably a matter of great significance for a great many people.[2] New regulations may also mean that treatments themselves would become more bureaucratic and more costly. Other costs include the direct cost to researchers and businesses of complying with new regulations, and the costs to the U.S. government of running a new regulatory agency.

More generally, there are good reasons to protect the autonomy traditionally enjoyed by science and medicine. The amazing scientific and technological advances witnessed over the last 200 years would not have materialized had the scientific and technical community not been protected from major interferences by politics and the public. The prosperity of liberal democracies depends to a considerable extent on the ability of their economies to innovate. This ability could be compromised by unnecessary regulatory interventions.

As for possible harms, advocates of the status quo reject "slippery slope" arguments – the view that the uncontrolled development of reproductive medicine and biomedical research is likely to produced undesired outcomes. This argument, in their view, is a weak foundation on which to ground public policy. Regulatory intervention is justified only when actual harm has been demonstrated. As long as "symbolic" harm is the only demonstrable harm, it is premature for the Congress to prohibit or regulate technologies that could serve a genuine public purpose.[3]

The widely publicized cloning experiment conducted by Korean scientists in early 2004 deserves a separate discussion. It has become painfully obvious that the leading Korean scientist violated several widely accepted ethical standards and systematically forged scientific data. But it is also true that the peer review process was conducted in an unsatisfactory manner. What is needed in this case is a bolstering of existing safeguards, not the creation of new ones. Furthermore, the Korean experiment does not prove that we are on a slippery slope. The experiment merely has demonstrated that human embryos can indeed be cloned; it has not shown that the cloned embryos are free of the imprinting and epigenetic defects that have hampered efforts in animal husbandry. As long as safe and effective cloning techniques are not available, it is simply not possible to clone a human being, and therefore, no legislation is needed.

As for attempts to clone a human being by "rogue" scientists – the Zavoses and Antinoris of the world – and by groups such as the Raelians, advocates of the status quo could point out that

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[2] Robertson, "Two Models of Human Cloning."

[3] John A. Robertson, " 'Paying the Alligator': Precommitment in Law, Bioethics, and Constitutions," *Texas Law Review* 81 (2003).

Neither Zavos and Antinori nor the Raelians have ever produced any evidence for their claims. By all accounts, these groups are not credible and can safely be ignored. It is certainly possible that at some point someone will succeed in cloning a human being or in performing a procedure regarded by the public as repugnant and objectionable. Until that time arrives, advocates of the status quo do not see a reason to intervene.

*Arguments Con*

As our discussion of the current regulatory system in chapter 5 has shown, it is very unlikely that the FDA, or any other federal agency for that matter, could rely exclusively on its current statutory powers to untangle future ethical dilemmas.[4] The FDA de facto ban on reproductive cloning, often quoted by advocates of the status quo as a demonstration that the federal government, if necessary, can prevent harm caused by new biomedical technologies, provides a clear illustration of these limits. The FDA simply asserted its authority over reproductive cloning on the basis of its powers to regulate cellular tissues. The agency explained that any attempt to create a human being through cloning techniques would require institutional review board approval and submission of an investigational new drug (IND) application. It went on to explain that it deemed reproductive cloning unsafe, and that applicants would be denied IND approval until these safety concerns had been addressed.[5] As some commentators have noted, until a court is called upon to review the FDA rationale for asserting its jurisdiction over this procedure, reproductive cloning cannot legally be performed in the United States.

The FDA's haphazard response to attempts to clone a human being can hardly be regarded as a model of regulatory decision-making. As some legal scholars have noted, the FDA's

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[4] For an in-depth examination of this question, see President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*.

[5] The whole story is considerably more convoluted. Following the cloning of Dolly the sheep in 1997 in Britain, the U.S. news media reported that some U.S. scientists were contemplating offering cloning services to the general public. In response to these reports, the FDA, in a "Dear colleague" letter to all institutional review boards, simply asserted jurisdiction over reproductive cloning. The letter made clear that any attempt to create a human being through cloning techniques would require IRB approval and the submission of an IND application. The letter explained that the FDA deemed reproductive cloning unsafe, and that applicants would be denied IND approval until these safety concerns had been addressed. On March 28, 2001, Kathy Zoon, then-director of the FDA's Center for Biologics Evaluation and Research (CBER), reiterated the FDA position on reproductive cloning, and addressed the jurisdictional question during a hearing before the Subcommittee on Oversight and Investigations of the House of Representatives. Zoon made clear that the FDA jurisdiction over reproductive cloning was based on its authority to regulate "cellular products." See Center for Drug Evaluation and Research, "Endocrinologic and Metabolic Drugs Advisory Committee Meeting."; Stuart L. Nightingale, *Dear Colleague Letter* (October 26, 1998 [cited September 18, 2005]); available from http://www.fda.gov/oc/ohrt/irbs/irbletr.html; *Opposition to Human Cloning Will 'Blow over,' Scientist Says* (CNN, January 7, 1998 [cited September 18, 2005]); available from http://www.cnn.com/TECH/9801/07/cloning.folo/; Kathryn C. Zoon, *Statement before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce United States House of Representatives* (March 28, 2001 [cited September 18, 2005]); available from http://www.fda.gov/ola/2001/humancloning.html.

assertion of jurisdiction in this case rests on weak legal grounds.[6] While human embryos do indeed consist of "cellular products," we doubt that this legal argument would survive judicial scrutiny. In addition, health and safety concerns as the main rationale for regulatory interventions are of limited practical relevance. Not every new reproductive procedure is likely to raise safety concerns. MicroSort, which is designed to allow parents to choose the sex of a baby, does not seem to raise major health and safety concerns, yet there are good reasons for regulating this new reproductive technology. And not every questionable new use of an existing reproductive treatment is unsafe. Tissue typing also seems quite safe, yet it remains a very controversial application of pre-implantation genetic diagnosis.

Legal scholars might be able to show that in principle at least, the FDA statutory powers may reach beyond safety and efficacy, but the relevance of these legal constructions is bound to remain academic. Even assuming that by some obscure legal theory the FDA does have the power the adjudicate contentious ethical questions – i.e., to regulate the use of new reproductive technologies and biomedical research not exclusively in terms of safety and efficacy – it would be unsuitable for this task. Specialists in public administration have pointed out that agencies are often built around a traditional goal, and that when they are given new goals, they often have a hard time adapting. New goals often require a radical shift in an agency culture, a shift that is very unlikely to occur, tied as the agency is to dominant professional norms.[7] In the introductory chapter, we mentioned the case of the Interstate Commerce Commission being given the job of regulating trucking in addition to railroads, and how administrative law experts believe this to have been a big mistake. In chapter 2, we have shown how poorly prepared the FDA was to determine whether children of idiopathic short stature should be treated with synthetic human growth hormone, by some considered a case of an enhancing rather than a therapeutic treatment.

The FDA's ban on reproductive cloning could also be described as a usurpation of Congressional authority. The agency disguised what amounted to a political decision as a safety issue, thus depriving the Congress of its legislative prerogative on a matter of great import. In short, the FDA approach to banning reproductive cloning can be compared to saving the Apollo 13 astronauts with a shoebox and duct tape – a workable but hardly generalizable approach.[8]

As for the criticism that regulatory interventions may cause opportunity costs in the form of slower scientific progress and forgone medical advances, this is certainly accurate, but it is an observation too generic to justify legislative restraint. Opportunity costs may or may not be too high, but there is simply no way to demonstrate that they would outweigh the benefits. While we accept the fact that regulation can indeed entail opportunity costs, we do not believe that in the

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[6] Richard A. Merrill, "FDA Regulation of Human Cloning: Usurpation or Statesmanship?," *Harvard Journal of Law and Technology* 15 (2001).

[7] James Q. Wilson, *Bureaucracy: What Government Agencies Do and Why They Do It* (New York: Basic Books, 1989), Ch.6 and p.107-09.

[8] The selective augmentation of statutory powers suffers from similar limitations. A limited expansion of the FDA, CDC, and NIH statutory authority, just to name a few likely candidates, would do nothing to change their regulatory culture or their core values, or to expand their expertise in addressing normative questions.

present case there is any specific reason to be particularly concerned about forgone opportunities. To put it bluntly, we see no evidence that scientists' hopes to develop new and revolutionary cures are more credible or reliable than predictions made by scientists with respect to other scientific developments.

Consider, for example, gene therapy. In the early 1990s, the medical community was electrified by the prospect of developing a medical technology that would have made it possible to treat incurable diseases. The technology consists of inserting foreign genes into the DNA of diseased somatic cells in the hope that these genes would replace the diseased ones. Fifteen years later, it has become apparent that these hopes were unrealistic. To date, clinical researchers have conducted only a few trials; none of them has produced promising results, and in some cases, trials have ended with fatal consequences for the patients.[9] In sum, while regulatory interventions, almost by definition, are likely to be associated with opportunity costs, absent specific evidence to the contrary, decision-makers should receive with a healthy dose of skepticism scientists' predictions about likely medical breakthroughs.[10]

Opportunity costs must be weighed against known and unknown harms that regulatory interventions are designed to prevent. Just like opportunities, it is quite difficult to reliably predict the harmful consequences of any given scientific and medical development. How harm is defined is clearly an important question we cannot explore in great detail here. Suffice to say that "symbolic harm" is wholly inadequate category to convey the societal import of new biomedical technologies.

Advocates of the status quo tend to forget that *laissez-faire* itself is bound to entail significant costs. The failure to anticipate the need for new regulatory powers often invites legislative and regulatory overreaction when the inevitable scandal, abuse, or disaster occurs. Many bureaucratic excesses since the end of World War II can aptly be described as a vicious cycle of protracted legislative inaction followed by a highly visible, catastrophic event and a period of short but intense legislative activity.[11] These interventions are usually quite effective in the sense that they do achieve their stated goals, but their costs rarely justify their benefits. These are draconian interventions that often produce as much harm as good.

The Italian response to years of excesses in the ART industry precisely illustrates this point. Another example comes from agricultural biotechnology. During the early 1990s, the U.S. agricultural biotech industry, which had initially favored certain forms of regulation like the labeling of genetically modified foods, changed policy and argued that no new regulations were needed. After U.S. companies began marketing Bt corn and roundup-ready soybeans in Europe, the BSE (Bovine Spongiform Encephalopathy) scandal broke in the United Kingdom, convincing many European consumers that food safety regulators were not doing their job. Much

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[9] See http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml#status.

[10] For a revealing discussion of failed scientific forecasts, see Victor S. Navasky and Christopher Cerf, *The Experts Speak: The Definitive Compendium of Authoritative Misinformation* (New York: Pantheon Books, 1984).

[11] Marc Eisner, *Regulatory Policy in Transition* (Baltimore, MD: John Hopkins University Press, 1993).

of the opposition to genetically modified organisms (GMOs) in Europe was irrational, but some was based on a view that consumers had a right to decide for themselves whether or not to eat genetically modified foods. By not supporting relatively modest forms of regulation like labeling, U.S. biotech firms found themselves shut out of European markets as the EU imposed its own strict safety rules on GMO products.

### *9.2 Targeted Legislative Intervention*

Senate Bill 303, discussed in chapter 5.2.2, is a good example of a targeted legislative intervention. It is reactive, not anticipatory, and it is narrow in scope, addressing merely one of the many issues raised by new reproductive technologies and biomedical research. Finally, it neither requires nor intends to delegate any legislative authority to a regulatory agency.[12] A ban on all kinds of cloning, as illustrated by Senate Bill 245, the Human Cloning Prohibition Act of 2003, is another example of a targeted legislation intervention. H.R. 810, the most recent attempt by the Congress to address the stem cell controversy, is yet another example. It legalizes federal funding for donated, excess embryos, but says nothing about cloning or any other issue pertaining to reproductive medicine or biomedical research. It charges the NIH with developing appropriate guidelines, but does not delegate any real regulatory authority to this agency. When we discuss the pros and cons of targeted legislative interventions, we have regulatory interventions of this kind in mind.

The reason we are focusing our discussion on targeted legislative interventions is quite simple: In the area of reproductive medicine and biomedical research this is the kind of legislative response the Congress is most likely to adopt. In the current political climate, only highly visible, persistent, and controversial issues such as stem cell research and cloning stand a chance to receive Congressional attention. These are also issues of considerable interest to influential interest groups – those groups that in the quest for Congressional re-election loom large, both in financial and electoral terms.

*Arguments Pro*

There are both conceptual and pragmatic reasons for favoring targeted legislative interventions. Advocates of targeted legislative interventions could argue that the reactive nature and narrow scope of these legislative interventions match perfectly the extent of current controversies over new reproductive technologies and medical research. They are an excellent example of legislative incrementalism designed to minimize the risks associated with grand legislative visions. Legislative incrementalism forces legislators to focus on well-defined political problems and to avoid legislating issues that have not yet risen to the top of the national political agenda. In this sense, targeted legislative interventions can be described as a

[12] S. 303 delegates to IRBs the responsibility for approving research protocols involving the use of embryonic stem cells, but only with regard to procedural, not substantive matters.

disciplining tool. Furthermore, by their very nature, targeted legislative interventions are cost-effective; their implementation does not require the creation of costly new bureaucratic structures.

One could also argue that targeted legislative interventions are in fact the only acceptable response to biomedical dilemmas. The Congress is the only political institution with both the legitimacy and the authority to settle national controversies. It is the Congress' responsibility to provide ethical and legal guidance on issues such as stem cell research and cloning. Any delegation of legislative authority to an administrative entity in this view would amount to a violation of constitutional prerogatives.

From a pragmatic point of view, one could point out that targeted legislative interventions stand a better chance of being passed by the Congress than grandiose legislative visions. Polarization tendencies in Congress further exacerbate the tendency to craft narrow legislation – bills designed to achieve precisely one goal and to do so exclusively by legislative means.[13]

*Arguments Con*

The arguments in favor of legislative incrementalism are reasonable ones. One should be wary of excessively ambitious legislative projects. Experience has amply demonstrated that legislation often has unanticipated consequences that may exceed its benefits. Clearly, there is a place for incrementalism in any legislative system. The view that it is Congress' responsibility to address ethical dilemmas of national import is also eminently sensible. We do not want unelected officials to resolve ethical dilemmas of national import. But not every ethical dilemma is equally important. As for other policy areas, there are many questions of implementation whose delegation to a regulatory authority is not only unproblematic but also necessary. Forcing the Congress to retain control over each and every implementation issue would produce an immediate legislative paralysis. Congress' responsibility is to identify ethical dilemmas that need immediate legislative attention and delegate the resolution of the remaining ones to an administrative entity.

The kind of targeted legislative interventions introduced in Congress over the last few years would have been unable to take into account the views and attitudes of the general public. As we have shown in chapter 8, mainstream Americans hold fairly nuanced views about biomedical technologies. They are against reproductive cloning, but they are unsure about research cloning. They do not want embryos to be created exclusively for research, but they find it acceptable to use excess embryos for this purpose. Taking these views and other distinctions documented in chapter 8 seriously would have required Congress to delegate at least some legislative authority to an administrative agency. In this context, one could also speak of legislative failure.

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[13] The logic responsible for catapulting highly visible and controversial reproductive treatments and research protocols into the political limelight is also the reason for Congressional disinterest in issues not widely perceived by the public as being of sufficient ethical import, and whose resolution would require from Congressional representatives a considerable investment of time and resources.

More generally, it is shortsighted to address the challenges raised by the convergence of molecular biology, genetics, and reproductive medicine in a piecemeal fashion. Congress' responsibility, in our view, is not only to provide legislative guidance on the issue of the day, but also to reflect on whether it has the legislative and regulatory tools necessary to respond to present and future societal controversies.

### *9.3 Self-Regulation*

*Arguments Pro*

Representatives of the ART industry and scientific leaders have often argued that self-regulation is preferable to direct regulatory interventions. Self-regulation is certainly an important and often-overlooked element of many regulatory systems. It is neither a rare nor an uncommon or insignificant phenomenon. It has played and continues to play an important role in such disparate areas as fire safety, ocean transportation, cosmetics, electrical appliances, and nuclear power safety – and, as shown in chapter 5.3, in the ART industry as well.[14]

Advocates point out that self-regulation can address issues of public concern much more effectively, more rapidly, and at a fraction of the cost than a regulatory intervention would impose on the ART industry and on the scientific community. In this view, self-regulation is preferable to direct regulatory intervention for several reasons: Industry members have privileged access to crucial information not readily available to regulators, and industry members are in a better position to spot and correct violations. Federal regulators, by contrast, would be forced to implement a costly and often quite ineffective system of monitoring and compliance assurance.

Contrary to common belief, self-regulatory systems do have specific mechanisms of compliance assurance. These are generally not formalized, and therefore are not visible to an external observer, but they can be quite effective nonetheless. The few empirical investigations available on this question seem to support this view. In one study of self-regulatory practices among lawyers in the New York metropolitan area, the author found that subtle but effective mechanisms of reciprocal monitoring create what he called an "ethical climate."[15] Similar

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[14] Furger, "Accountability and Self-Governance Systems: The Case of the Maritime Industry."; Jennifer Howard, Jennifer Nash, and John Ehrenfeld, "Standard or Smokescreen? Implementation of a Voluntary Environmental Code," *California Management Review* 42, no. 2 (2000); Andrew A. King and Michael J. Lenox, "Industry Self-Regulation without Sanctions: The Chemical Industry's Responsible Care Program," *Academy of Management Journal* 43, no. 4 (2000); Krislov, *How Nations Choose Product Standards and Standards Change Nations*; Rees, *Hostages of Each Other: The Transformation of Nuclear Safety since Three Mile Island*.

[15] Jerome E. Carlin, *Lawyers on Their Own: A Study of Individual Practices* (Rutgers University Press, New Jersey, 1962); Carlin, *Lawyers' Ethics: A Survey of the New York City Bar*. See also Hubert J. O'Gorman, *Lawyers and Matrimonial Cases: A Case Study of Informal Pressures in Private Professional Practice* (Glencoe, IL: Free Press, 1963).

mechanisms of information monitoring and compliance assurance have been shown to exist among physicians at U.S. hospitals.[16]

As shown in chapter 5.3, the ART industry has developed an elaborate system of self-regulation over the years. Industry representatives have repeatedly pointed out that the professional and ethical standards developed by the American Society for Reproductive Medicine and other professional societies are more than adequate for the task at hand. The ASRM continues to monitor scientific developments in the field and to adopt specific recommendations as necessary. Scientific leaders, for their part, have advocated self-regulation as the best way to reassure an already wary public. How they intend to face controversial ethical questions has been described in a recent publication by the National Academy of Sciences.[17]

Finally, advocates of self-regulation submit that reproductive decisions and research priorities are essentially private choices the government has no business regulating. In this view, prospective parents and their doctors are in an excellent position to determine what is in the best interest of the children. As for biomedical research, the argument here is simply that setting research priorities is best left to members of the scientific community. The public, ever ignorant and driven by emotional responses rather than by rational analysis, is simply not in a position to assess the rationale for viewing certain research questions as worth pursuing. Nor are politicians, for that matter.

*Arguments Con*

A measure of self-regulation is a necessary requirement of any effective and efficient regulatory system. Federal regulators, indeed all regulators, depend to some degree on the regulated community for critical knowledge and information. In some cases, monitoring and compliance assurance rely heavily on private third parties. Our discussion of the Fertility Clinic Success Rate and Certification Act of 1992 in chapter 5.1.1 makes this point. The active participation of the Society for Assisted Reproductive Technology in gathering the data needed by the CDC on ART success rates contributes to generating better data at a lower cost.

That self-regulation is an important ingredient of any regulatory system does not demonstrate that self-regulation, by itself, may be considered a substitute for more formal regulatory approaches. Self-regulation is a complement rather than a substitute for formal regulation. For example, in the 1990s, the National Paint and Coating Association established Coatings Care,[18] an ambitious program of environmental management. By all accounts, Coatings Care has been instrumental in improving the industry's public image and its relationship to the EPA, and in reducing the likelihood of catastrophic accidents. The National Association of Chemical Distributors had a very similar experience with its "Responsible Distribution

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[16] Eliot Freidson, *Profession of Medicine. A Study of the Sociology of Applied Knowledge* (New York: Harper & Row, 1970), p.137-57.

[17] Committee on Guidelines for Human Embryonic Stem Cell Research, *Guidelines for Human Embryonic Stem Cell Research* (Washington, D.C.: National Academies Press, 2005).

[18] See http://www.paint.org/cc/index.cfm.

Process."[19] According to their initiators, these programs are designed to strengthen the regulatory system, not to replace it.

Contrary to industry claims, trade associations can rarely be considered impartial arbiters of societal disputes. The ART industry approach to resolving public controversies has little credibility not because it has avoided addressing these issues, but because its guidelines and recommendations tend to reflect the interests of the industry and its clients (in this case, the prospective parents) to the detriment of children and the general public. In other cases, recommendations are just that – hortatory statements of little practical significance. For example, ASRM recommends transferring no more than three embryos. ASRM also discourages the use of pre-implantation genetic diagnosis for elective sex selection. This language suggests that ART practitioners are not really expected to follow these recommendations if prospective parents wish otherwise.

As for compliance efforts, the balance of the evidence is not encouraging. As part of its certification program, the ASRM mandates periodic audits, but violations are met with considerable leniency, as laboratories are given up to one year to correct a violation. More importantly, compliance with ethical guidelines is not part of the mandatory certification and audit program. ASRM simply does not know whether and to what extent its ethical recommendations are being followed. Industry officials believe that ethical and professional guidelines have a strong normative power. Absent any systematic assessment of compliance rates, this conviction is of little relevance.

A final reason for being skeptical about the role of self-regulatory efforts in the ART industry is the absence of robust mechanisms of reciprocal learning. Twenty-five years after the first "test-tube" baby was born, this field of medicine has barely begun to take seriously the possibility that ART treatments may indeed be associated with higher health and safety risks. Often, reproductive practitioners simply believe that ART techniques are safe. Since the industry "doesn't know what it doesn't know," it is unable to identify possible areas of concern and to learn from its mistakes. Considerations of cost may prevent the ART industry from implementing expensive long-term follow-up studies, but cost considerations cannot dispel the impression, occasionally expressed by pediatricians, that the ART industry is focused exclusively on producing pregnancies, with little consideration for health consequences.

### *9.4 Regulatory Responses*

*Arguments Con*

There are several objections to a regulatory approach, of both a general and a specific nature. The general objections are well-known. Over the last 30 years, public administration researchers, economists, political scientists, and administrative law scholars have documented in excruciating detail the distortions, aberrations, hidden costs, and negative unanticipated

[19] See http://www.nacd.com/rdp/.

consequences brought about by ill-informed regulatory interventions. Health, safety, and environmental regulations are often singled out for achieving policy goals at exorbitant costs, or for failing to achieve their self-imposed targets. The AEI-Brookings Joint Center for Regulatory Studies has produced a long series of case studies documenting these distortions.[20]

Economists have also demonstrated that regulation in many cases seems to be designed to benefit or protect the competitive position of incumbent firms to the detriment of other competitors rather than to serve the public interest. Much of the literature on regulatory capture is informed by this basic observation.[21] For example, complex regulatory requirements tend to favor large companies with extensive technical and legal expertise, and with considerable financial resources, to the disadvantage of smaller but nimbler competitors whose competitiveness is threatened by these regulations.[22]

One also could argue that the delegation of legislative authority to a regulatory agency is an administrative expedient with questionable constitutional legitimacy, and should be envisaged only in the most unproblematic of circumstances. For example, delegating the responsibility for implementing the Congressional prerogative to tax U.S. citizens to a specialized agency is largely unproblematic. The agency in question is simply carrying out a Congressional mandate; it lacks the authority to pass new tax laws. It is an altogether different matter to charge a federal bureaucracy with adjudicating deeply divisive, fundamental questions of life and death. In this case, delegating legislative authority to an unaccountable federal bureaucracy is unacceptable. Only the Congress has the constitutional mandate to provide legal guidance on questions of national import.

One may also wonder why reproductive medicine is being singled out while other medical specialties have not received nearly as much attention. The field of reproductive medicine is just

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[20] A non-representative selection of these studies includes Jason K. Burnett and Robert W. Hahn, "A Costly Benefit: Economic Analysis Does Not Support EPA's New Arsenic Rule," *Regulation* 24, no. 3 (Fall 2001); Robert W. Hahn and Jason K. Burnett, "The Epa's Radon Rule: A Case Study in How Not to Regulate Risks," (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 2001); Andrew N. Kleit, "Impacts of Long-Range Increases in the Corporate Average Fuel Economy (Cafe) Standard " (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 2002); W. Kip Viscusi and James T. Hamilton, "Are Risk Regulator Rational? Evidence from Hazardous Waste Cleanup Decisions," (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 1999).

[21] Garry Becker, "A Theory of Competition among Pressure Groups for Political Influence," *Quarterly Journal of Economics* 98, no. 3 (1983); Sam Peltzman, "The Economic Theory of Regulation after a Decade of Deregulation," *Brookings Papers on Economic Activity. Microeconomics* 1989 (1989); Sam Peltzman, "Towards a More General Theory of Regulation," *Journal of Law and Economics* 19 (1976); Richard A. Posner, "Taxation by Regulation," *Bell Journal of Economics and Management Science* 2, no. 1 (1971); Richard A. Posner, "Theories of Economic Regulation," *Bell Journal of Economics and Management Science* 5, no. 2 (1974); George J. Stigler, "Free Riders and Collective Action: An Appendix to Theories of Economic Regulation," *Bell Journal of Economics and Management Science* 5, no. 2 (1974); George J. Stigler, "The Theory of Economic Regulation," *Bell Journal of Economics and Management Science* 2 (1971). An overview can be found in Robert D. Tollison and Roger D. Congleton, eds., *The Economic Analysis of Rent Seeking* (Hants, UK: Aldershot, 1995).

[22] Note that this is not a phenomenon limited to formal regulation, however. The complexity of some systems of self-regulation can be ascribed to the same phenomenon.

another branch of medicine. ART practitioners simply rely on a specialized body of medical knowledge to restore reproductive functions, functions necessary to fulfill a deep desire by infertile couples to have a biological offspring. Other areas of medicine are also unregulated and pose significant health and safety risks, yet they are only subject to professional oversight. For example, laser-based eye surgery is now widely practiced, yet the FDA does not regulate this activity, a surgical procedure beyond its statutory authority.[23] Nor is there a system in place to monitor the long-term consequences of this relatively new approach to eyesight correction.

*Arguments Pro*

The critique that the modern administrative state may be on shaky constitutional grounds may or may not be accurate, but this is largely a platonic question. For better or worse, the administrative state is here to stay. The contemporary United States simply could not function without regulatory agencies. The Congress itself could not fulfill its constitutional mandate without the support of the regulatory machinery. Nor is the regulatory apparatus unaccountable. Some agencies are more accountable than others, but it would be misleading to assume that unelected federal officials are accountable to no one. As we show in chapters 10 and 11, several options exist to hold a regulatory agency accountable for its action, including Congressional oversight, Presidential appointing and removal powers, and judicial review, among others.

We readily acknowledge that regulation may at times be problematic. To recognize that regulation can be costly, inefficient, and ineffective is, however, no demonstration that it is unnecessary. Determining the costs and benefits of a new regulation is important, but is by no means the only consideration governing whether a proposed new rule is necessary or desirable. Economic efficiency has never been the only principle guiding the administrative state. Economists are correct to characterize the maximization of economic efficiency as a social good that should inform any rule-making process. Just as correct are political scientists and ethicists when they note that economic efficiency is not the only possible social good. An agency could determine that a proposed new rule would produce more (economic) costs than benefits and still decide to move forward with the new rule. Conversely, a regulatory agency may decide that a net benefit to society is an insufficient foundation for proposing new regulations.[24] The Nuremberg Code provides an illustration. At least since the Nuremberg process, from which the Code derives its name, the medical community has accepted the principle that an individual cannot be

[23] The FDA does, of course, regulate the safety and efficacy of laser systems. It also provides an online information resource for prospective patients. See http://www.fda.gov/cdrh/LASIK/default.htm.

[24] A large literature exists on this topic. For an introduction, see, for example, Matthew D. Adler and Eric A. Posner, "Rethinking Cost-Benefit Analysis," *Yale Law Journal* 109 (1999); Henry S. Richardson, "The Stupidity of the Cost-Benefit Standard," *Journal of Legal Studies* 29 (2000); Amartya Sen, "The Discipline of Cost-Benefit Analysis," *Journal of Legal Studies* 29 (2000).

harmed for the greater good of the community. Yet cost-benefit considerations would show that on balance, experiments on individual patients produce more benefits than costs.[25]

We also do not dispute the well-documented empirical observation that the regulatory process may be distorted by undue political influence, and may produce outcomes that systematically benefit a certain societal group to the detriment of the broader public interest. Indeed, much of the discussion in chapters 8 and 5.2 shows just that. Yet this is clearly not an argument against regulation per se, as the demonstration that administrative checks and balances above and beyond the minimal requirements of the Administrative Procedure Act may be necessary. The last part of this report is devoted precisely to this question – i.e., to how undue political influence can be minimized at the regulatory level.

There are also positive arguments for a regulatory approach to the resolution of normative controversies. Political and economic rationality dictates that Congressional representatives will address only the most visible and divisive political issues. Legislators do not have the time or the expertise to familiarize themselves with the scientific and ethical aspects of each and every controversy that new reproductive treatments and biomedical research are likely to produce in the future. Political logic suggests that members of Congress will prioritize their efforts, at least in part, according to electoral payoffs. Obscure technical controversies are very unlikely to produce significant benefits.[26] Absent a suitable regulatory authority, these issues are likely to remain unresolved – or to be resolved either by the market or by organized interest groups.

It is also not accurate to claim that reproductive medicine is just another medical specialty. To be sure, ART specialists are in the business of curing physiological afflictions. But unlike any other medical discipline, reproductive medicine literally makes children. The ART field is structured around the needs and desires of prospective parents; it is less well-organized to protect the long-term interests of the children it produces. Medical practitioners argue that parents always have the best interest of their children at heart. This is undoubtedly true for the vast majority of parents. On the other hand, there are good reasons to believe that the interests of parents and their children could and occasionally do diverge. The discussion in chapter 4 provided many illustrations of possible conflicts of interest between different generations.

Reproductive medicine also differs from other branches of medicine in that it can affect in a subtle but important way societal values central to our understanding of equality and of political rights. These unintended consequences have little to do with reproductive medicine, per se. They have everything to do with contemporary notions of equality and tolerance – the very values on which our democratic society is grounded. Consequences of this kind may or may not be of broader import, but this determination needs to be made by the public and its political representatives, and should not be left to the medical profession and their patients.

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[25] This is assuming, of course, that one could solve the frustrating problems created by the comparison of interpersonal utilities.

[26] David Epstein, "Administrative Procedures, Information, and Agency Discretion," *American Journal of Political Science* 38, no. 3 (1994).

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