6. Legal Restrictions on New Technology: The Regulatory Gap and the Emergence of the Science Counselor

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• SIX •

Legal Restrictions on New Technology: The Regulatory Gap and the Emergence of the Science Counselor

When scientific developments lead to commercially important products, the legal situation changes dramatically. Gentle inquiries are replaced by intense scrutiny as technologically complex products are subject to regulation in countless arenas.

The Constitutional Basis for Regulating Technology

Here, as with basic science, the best place to begin an examination of the law is with the constitutional framework. Where in the Constitution is the federal government given the power to regulate technology? After all, the federal government is limited to those powers enumerated in the Constitution and there is nothing there that speaks specifically about the regulation of technology. Indeed, when the Constitution was written, and for many years thereafter, there was doubt about the federal government's power to regulate any local industry—many believed only the states had such power. But the Constitution did give Congress the power to regulate "interstate commerce" and in this century that power has been read so broadly that almost any form of technology is subject to regulation if Congress wishes.[1]

The courts have read the commerce clause broadly because they have come to believe that in a modern integrated economy very little is purely local. Thus, for example, when you buy a thermometer at your local drugstore to be used in your home, you may think the transaction is local, but it is well within Congress' power to regulate. After all, some of the materials that went into the thermometer probably came from other states. Even if they did not, use of this type of thermometer and similar medical devices by many people could affect the cost of medical care or the number of hospital admissions. In turn, this would somewhat affect the movement of doctors, patients, or financial resources across state lines. There is ample precedent under any of these theories for an exercise of congressional power.

If this example seems farfetched, consider an actual case concerning Congress' power to regulate the local sale of drugs. In 1946, a laboratory in Chicago shipped a number of bottles of sulfathiazole tablets to a wholesaler in Atlanta, Georgia. Sulfathiazole was used at the time to combat infections. When shipped from Illinois to Georgia, the bottles had warning labels on them as required by the Federal Food, Drug, and Cosmetic Act of 1938. One label, for example, read "Warning—In some individuals Sulfathiazole may cause severe toxic reaction." Six months after the Georgia wholesaler received the bottles from Illinois, one bottle was sent to Sullivan's Pharmacy in Columbus, Georgia. Three months later, the Columbus druggist removed some tablets from the labeled bottle, placed them in unlabeled pill boxes, and sold them to a Georgia resident. The druggist was then charged with violating the Federal Food, Drug, and Cosmetic Act.

Did Congress have the power to regulate the sale of pills that a Georgia druggist received from a Georgia wholesaler and sold to a Georgia resident? The U.S. Supreme Court said yes, emphasizing that the congressional effort to require labeling for drugs originally shipped in interstate commerce would be undercut if the Georgia druggist could remove the labels with impunity.[2] Given this type of precedent, there are few, if any, developments in modern technology that are beyond Congress' reach.

Nor is the commerce clause Congress' only source of regulatory authority. As we have seen, Congress has the power to fund scientific research because of its power to spend for the general welfare. But the power to fund includes the power to place lawful conditions on the receipt of funds, at least where the conditions are related to the funding.[3] Thus, for example, when the National Institutes of Health funds research involving human subjects, it requires the institution receiving the funds to establish an institutional review board to protect the subjects' rights.[4]

The states also have the power to regulate technology to protect the public. Indeed this "police power" of the state, and of local governments acting on behalf of the state, has been clear from the country's formation. The only major restriction is that state regulation cannot conflict with federal, because of the supremacy of federal law under the Constitution. Thus, if the federal government regulates a new type of aircraft, no state can have conflicting regulations.[5]

But what about First Amendment protection for scientists? As we have discussed, when scientists publish a paper, the Bill of Rights prevents the government from stopping them. But the rules change completely when scientists move from expressing their views to performing experiments or marketing products. In the latter cases, regulation is permissible to protect the public health and safety or for other valid goals.[6] Scientists may claim that performing an experiment is a way of expressing their beliefs, but that claim will be unavailing. The First Amendment protects speech, not action—punching your neighbor in the nose expresses your views, but it is not protected by the Constitution.[7] Thus biologists have no First Amendment right to perform experiments in their basement when those experiments endanger the safety of the neighbors or the environment. Properly drawn statutes, such as those relating to the use of plutonium, can and do limit scientific experimentation to protect public safety.[8]

Moreover, restrictions on experiments are allowed to protect the subjects of those experiments. Thus there are regulations concerning research using human, fetal, and animal subjects.[9]

There can be difficult cases when it is unclear whether government restrictions on research are based on an improper concern for the intellectual content of that research or a proper concern for public safety. Thus the government would not be free to restrict basement biology experiments if, in fact, the experiments were completely safe, and the government's purpose was to suppress the ideas that might grow out of the research. To hold otherwise would allow the government to practice censorship in the name of public safety. This is why the Supreme Court ruled, for example, that flag burning could not constitutionally be punished—the punishment was for the ideas expressed, not to regulate some other harm, such as pollution caused by the smoke.[10] But in the typical case involving technology, the government has ample constitutional power to regulate. There really are valid health, safety, and environmental concerns that come with the development and marketing of new products.

Thus the Constitution empowers Congress to regulate technology, and Congress has not declined that invitation. In a host of areas ranging from protecting the safety of drugs to producing clean energy, our government has imposed regulations that bear directly on the public availability of new technology. These issues undeniably have a high technical component in two senses: the regulators have to understand the nature of the new technology itself, and they have to understand the often technical questions involved when one looks at the consequences of that technology for the natural and human environment.

Right at the outset, it is clear that the issues involved here implicate a broader range of societal forces than the issues involved in funding basic research. In the latter case, to use Harvey Brooks's terminology, we are concerned with "policy for science," whereas in the former we are looking at "science in policy," a situation involving "matters that are basically political or administrative but are significantly dependent on technical factors."[11] In public issues involving new technology, those technical factors play a role, but they are rarely dispositive. Investors, workers, consumers, and other members of the public often have a stake and often have differing goals and values that cannot be reconciled in scientific terms.

Statutory Regulation through Delegation to Agencies

So how does Congress resolve public policy issues with a high technical component? In a few cases, such as those involving the safety of saccharine and the wisdom of building a supersonic transport plane, elected officials take direct action.[12] But generally speaking, as with basic research, Congress has delegated most of its authority over technology to administrative agencies.

The agencies that regulate technology—such as the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Food and Drug Administration—have the power to issue rules, which have the force and effect of law, and to adjudicate individual cases, such as license applications.[13] Just as there is no single "Department of Science" that controls research funding, there is no single "Department of Regulation." Approaches to controlling technology vary from agency to agency. Moreover, as with the spending agencies, the congressional delegations of authority to the regulatory agencies are so broad that it is the agencies, not Congress, that make most of the difficult decisions. Thus, for example, the Toxic Substances Control Act of 1976 gives the Environmental Protection Agency (EPA) the power to regulate the manufacture and use of new chemical substances. The statute says the agency should, in considering whether to regulate, weigh the costs and benefits of the substance, the economic consequences of the regulation, and act when there is "an unreasonable risk of injury to health or the environment."[14] Obviously the EPA, not Congress, has to make the hard choices.

To some extent, Congress delegates regulatory matters to the Environmental Protection Agency for the same reason it delegates funding matters to the National Science Foundation—the number of cases and the complexity of the technical issues involved outstrip Congress' institutional capabilities. But past that point, there is a central difference in the two areas of delegation. With science funding, as we saw, Congress was calling on the scientific community to govern itself. With regulatory policy, Congress is giving matters to agencies designed to consider a host of factors, including not only technical expertise, but the claims of competing interest groups. Indeed, it is precisely the explosive political nature of regulatory issues that sometimes encourages Congress to pass the buck to a government bureau. Thus the agencies, not Congress, often formulate and implement government policy. This may be wise or unwise, it may undermine or strengthen democratic principles, but it is undeniably the case throughout American government.[15]

When the issues become those of accommodating the interests of competing public groups rather than determining the will of the scientific community, attorneys begin to come to the fore. The relative role of lawyers in the regulatory as opposed to the funding agencies can be sensed by simply looking at who works where. The Nuclear Regulatory Commission, for example, has roughly the same number of employees as the National Science Foundation, but the commission employs over a hundred attorneys, whereas the foundation employs fewer than fifteen.[16] Within the regulatory agencies generally, lawyers, economists, and other nonscientists play large roles, with lawyers being the dominant professional group.[17]

Lawyers have this role because, as we have seen, they are the principle agents for the peaceful resolution of social disputes in American society, and agencies are a microcosm of that society. There is a feedback mechanism at work here: as we will note later, our culture insists on vigorous judicial review of regulatory agency decisions. Judicial review means that lawyers argue in court about agency policies, and it means further that when agencies begin their work they must plan for those court cases and thus they must rely heavily on lawyers.

Thus when regulatory agencies go about their business, they do not stress the consensus-oriented peer review model that the science community brings to the National Science Foundation or the National Institutes of Health. The agencies instead tend toward the adversary approach that mirrors legal norms. The stress is on having every viewpoint represented openly and vigorously. Consensus is seen as a chimera—the goal is giving people their say and reaching a politically acceptable solution, bounded by technical factors but not finally determined by those factors. One important effect is that scientists who enter the process are split apart rather than brought together because they often appear as representatives of particular points of view. Thus, for example, studies comparing American cancer policies with those in other countries find that "the formal and adversarial style of American regulatory decisionmaking . . . polarizes scientific opinion."[18]

Even if the scientific community happens to be in unanimous agreement on the technical aspects of a regulatory issues, that does not mean the scientists will agree on the appropriate policy. People can agree on how much radiation will escape from a reactor, but disagree on whether it makes sense to spend a million dollars to reduce that amount by 5 percent.

Most importantly, even if the science community happens to have a consensus on a particular regulatory policy, that hardly determines the agency's position. The scientific community may, in fact, be inclined in many cases to be supportive of new technologies compared to the public at large, because technology may be the fruit of research and technological success may lead to more research funding. But the validity of a regulatory policy is not a scientific question. Regulatory issues concern, in the end, value questions: how many jobs is it worth to slightly improve the health of a thousand people? How much should consumers pay to reduce the risk of auto accidents by 1 percent?

Questions like these can only be resolved through politics, broadly understood. When the Food and Drug Administration declines to approve a new drug, or when the Nuclear Regulatory Commission defers approval of a new reactor fuel, it is quite possible that most of the scientists in the relevant field would disagree. Regulatory agencies are regularly accused of being "captured" by industry, consumer groups, members of Congress, and bureaucratic inertia. They are never accused of being captured by scientists. The reason is that although scientists work for the agencies, the agencies reflect, to a greater or lesser degree, the whole spectrum of interest groups in American society, and the scientific community is hardly the most numerous or powerful of such groups.

It is true that regulatory agencies such as the Environmental Protection Agency and the Food and Drug Administration often call on science advisory committees to inform them by providing relatively unbiased technical data. There are several hundred such committees reporting to scores of federal agencies in a variety of ways.[19] But even these experts cannot turn political judgments into technical ones; they cannot make differences in values disappear. As Sheila Jasanoff concluded in her pathbreaking study of science advisors in the policy process:

> [A]gencies and experts alike should renounce the naive vision of neutral advisory bodies "speaking truth to power," for in regulatory science, more even than in research science, there can be no perfect, objectively verifiable truth. The most one can hope for is a serviceable truth: a state of knowledge that satisfies tests of scientific acceptability and supports reasoned decisionmaking, but also assures those exposed to risk that their interests have not been sacrificed on the altar of an impossible scientific certainty.[20]

The Stringent Judicial Review of Regulatory Decisions

The most dramatic contrast between the science funding and the regulatory agencies comes in the area of judicial review of agency action. When we looked at science spending, we were able to canvass virtually every judicial opinion handed down. There were, after all, only a handful of cases and every one upheld the agency making the funding decision. In the regulatory arena there are thousands of cases, many of them reversing agency conclusions. At the federal level, modern environmental law cases fill volumes. Major projects, from nuclear power plants to pipelines, have been slowed or stopped by litigation. Food and drug law is an entire area of study that includes cases where new products have been delayed in reaching the market or prevented from doing so altogether. In other areas ranging from communications to computers, regulation is a fact of modern life. At the state level, statutes and judicial decisions—in areas ranging from malpractice to products liability to tort suits for exposure to radioactive materials—have subjected technology to close scrutiny.[21]

When judges become involved in regulatory matters involving emerging areas of technology, they do not suddenly talk and act like amateur scientists, openly second-guessing the decisions made by those with technical expertise. Indeed the approach utilized by the judges is, on its face, the same whether the agency action being challenged is a funding decision or a regulatory one. Parties challenging the agency must first overcome various barriers to review by convincing the court that they have standing, that the matter has not been "committed to agency discretion," and so on. When the court does reach the merits, it will look to see if the agency has followed proper procedures and if the agency's decision is "arbitrary and capricious" in the case of a rulemaking, or supported by "substantial evidence on the whole record" in an adjudication. These formulations assume the agency will only be reversed in unusual cases, and, indeed there is still much talk by the courts of deferring to technical expertise. But the judges are acutely aware that the regulatory issues before them combine scientific and policy matters. They want to be sure that controversial policy decisions are made openly and persuasively, not under the guise of scientific neutrality. Thus, the courts apply the same verbal formulations with far more vigor in regulatory than in funding cases.[22]

Moreover, even when a court declines to resolve a technical issue, it still may cause a regulatory delay. In many cases involving judicial review of agency action, the court, if troubled, will remand the case to the agency to enable the agency to change its mind or to provide a better justification for its first decision. Thus, the court is not directly resolving the matter. But in such cases the court is often causing delay, and when the issue is whether to move forward, a delay is a decision. When, for example, a new drug is not available for a certain period of time, those who favor marketing it are losing profits, and potential users of the drug are losing health benefits. But the groups that oppose selling the drug are delighted—the harmful side effects they fear are being avoided, and the market situation may change, making the drug less attractive. That is why, in almost any litigated regulatory dispute, at least one side is happy with delay. Lawyers may not seek delay for its own sake, but if by making every credible argument they drag out a proceeding, they may make their client very happy. An ancient story, well-known to lawyers, illustrates the point. A man sentenced to die at noon, tells the king, "If you'll postpone my execution until tomorrow, I will teach your horse to talk." After the king agrees and leaves for the day, the man's friend asks, "What in the world is your plan?" The man replies, "Who knows? By tomorrow, I may die—the King may die—the horse may talk."

The centrality of the judicial role in regulation did not happen by chance. With science funding there were no important counterweights to the science community itself and thus no major role for the courts. With regulation, countless individuals and groups are immediately affected. But the agencies that make the initial decision are not fully trusted. Agency officials are not elected—they are appointed by the executive at the highest level and chosen by the civil service system below that. They use expertise as well as make value judgments. For most day-to-day issues direct involvement by Congress or the president is unrealistic. In the end, our society insists that judges vigorously review regulatory agency action. As James Q. Wilson concluded in reviewing a study that considered, among other things, judicial reversal of benzene and clean air standards formulated by agencies:

> This very diffusion of political supervision of regulatory agencies has facilitated a striking growth in judicial supervision of them. The courts provide a ready and willing forum in which contending interests may struggle over the justification and interpretation of specific rules and practices, matters that ordinarily are of little interest to congressional committees or the White House. . . . And though both industry and its critics grumble about the burdens of litigation, especially

when a decision goes against them, one suspects that each finds court appeals of regulatory decisions an economical way to advance or protect its interests.[23]

Thus in our complex, heterogeneous nation, with many citizens possessing legally protected interests, technological change is not allowed to proceed regardless of its impact. Indeed, the notion that somehow technology could proceed "without legal control" is virtually meaningless. A system of property laws is necessary if a new invention is to be worth anything, and legal protection of the public health and safety is a precondition to a functioning society.

Obviously, legal control of technology is not something new and different from the lawyer's point of view. From the railroad to the automobile to the airplane and beyond, legal doctrines have been shaped by technology and have, in turn, shaped technology itself. The law had to adjust to new issues raised by airplanes passing over property; airplanes had to be built with legal notions of tort liability in mind. The American legal system's adjustment to the industrial revolution suggests that it will adjust to the technological revolutions that lie ahead. Thus we see again the contrast between the scientists' sense of a world making progress and the lawyers' sense of a more or less endless process of mediating social disputes. J. D. Watson exuberantly described his pathbreaking work in formulating the double helix model for DNA as "perhaps the most famous event in biology since Darwin's book."[24] Yet in an early discussion of legal controls on recombinant DNA research, the prominent attorney and legal scholar Harold Green reported that he was "happy to say" that nothing "unique or novel" in such research insulated it from regulation.[25]

Thus, from the scientists' point of view, legal control of technology provides quite a jolt. The centrality of the science community in funding decisions gives way when the broader society becomes involved in decisions on the application of technology. Previously marginal scientists, with little impact on funding, move to center stage because of their involvement with citizen groups on technological issues. No longer do they fear ostracism from the science community because they now play a role in a new community dominated by non-scientists. Most often the jolt for the science community comes when a technology it regards as reasonably safe and valuable meets vigorous resistance. Nuclear energy provides an example. But the problem can arise in the other direction as well, when something viewed by the science community as pseudoscience (such as laetrile) gains public support.

The Regulatory Gap

Thus, the stage is set for what I call the *regulatory gap*—a gap between research and application that has enormous practical consequences. The gap stems from the fact that basic research receives unusually little public scrutiny while applications of that research receive an extraordinary dose of public involvement. We have discussed why basic research is largely left to the science community. Why is technology treated so differently? There is always, of course, less interest in theory than in application. When matters impinge directly on your personal life you obviously become more concerned. But something sharper is going on with modern technology. The level of public scrutiny is extraordinarily high; debates over novel energy sources, genetic engineering, new medical procedures, and other developments take on the characteristics of holy wars. The societal consensus represented by the views of the science community on research is utterly shattered.

Some of the reasons, of course, stem from factors we have already considered. The American legal framework provides freedom for scientific inquiry and invites public support for basic research, while limiting judicial review. With technology, the legal framework allows vigorous regulation supervised by equally vigorous judicial review. As a result, scientists and lawyers, two professional groups with varying value systems, dominate research and regulation respectively. Thus the stage is set for a gap when ideas become products and when peer review and consensus give way to adversary procedures and interest group politics.

But the regulatory gap is even deeper than this model would predict. The legal framework provides broad guidelines within which social conflict is resolved. If our culture were more comfortable with new technology the gap would, in practice, be reduced. Fewer interest groups would fight the latest technological developments and fewer judges would deploy the weapons of judicial review in an aggressive manner in this field. There would still be a gap, but it would be more modest.

Instead, the regulatory gap created by our legal structure is exacerbated by twentieth-century attitudes toward progress and technology. As we saw in our discussion of religion in American life, the unified

Enlightenment ideal of progress has fragmented. Whereas science still appears to make progress, the human condition does not. The horrors of twentieth-century totalitarian regimes and of modern war have engendered a deep pessimism about the human future. And technology has hardly been exempt. Indeed, since the atomic bomb, technology has been particularly implicated in many minds with the failures rather than the successes of the human race. Spurred by the Vietnam War and the growth of the environmental movement, the decades since the 1950s have seen ever-sharper questioning of technology.[26] At the same time, the continued march of theoretical science provides an endless stream of ideas that play a major role in American life. We are happy to learn of discoveries about the nature of the universe and to ponder their implications; we are more cautious about the actual products that appear in the marketplace.

Cultural patterns of this type are not the result of logical syllogisms. Countless Americans enjoy the conveniences of modern technology while remaining convinced that technology has "gotten out of hand." Whether rational or not, the transition from theory to practice in the realm of science and technology is remarkably rocky.

Comparisons with other fields illustrate the point. Of course, science is not the only area where theory is less controversial than practice. But the regulatory gap in science is far wider than in other areas.

Consider health policy. Since the Truman administration, the American polity has, at various times, debated the broad issue of medical coverage. Should basic care be provided for the needy, for the aged, for everyone? This debate—the "basic science," if you will—has involved wide segments of the public. We have not delegated to a narrow professional group (such as economists or doctors) the task of shaping policy. When government agencies such as the federal Department of Health and Human Services promulgate broad guidelines for programs like Medicare and Medicaid, judges do not shrink from active judicial review.[27] As a result, when agencies make individual determinations as to who is eligible for a particular benefit and the courts review that decision, the system continues to function. Of course there are controversies about the application of broad guidelines in many cases, but we do not see the system grinding to a halt as happens when an entire power plant or even an entire mode of energy production never makes it on-line.

Or consider zoning law. Zoning decisions, although they may affect the quality of life of many citizens, rarely have the broad, dramatic impact of, for example, a development in communications or energy. Yet initial zoning policy—broad, "theoretical" planning—undergoes far more public scrutiny than basic science policy. Comprehensive planning documents for various communities may be the subject of public forums, debates, and newspaper editorials that would be unheard of for, say, initial research in computer science. Moreover, there is a growing number of jurisdictions in which legislation provides that individual land use decisions must be consistent with broader zoning plans.[28] The "technology" must fit the "science." Thus, in zoning, although not everything proceeds smoothly, there is at least some reason to expect continuity between theory and practice.

There is no point arguing whether the regulatory gap in science is different in degree or in kind from the gap between theory and practice in other fields. The fact remains that the gap is vast. Moreover, it has tremendous consequences for public policy in America today. Perhaps the most dramatic example to date has been that of civilian nuclear energy.

The Case of Nuclear Fission

After World War II, an enormous government research effort was devoted to the development of nuclear reactors for the generation of electricity. Optimism was so high that President Eisenhower could say in 1953 that with adequate uranium resources nuclear energy "would rapidly be transformed into universal, efficient and economic usage."[29]

The fission reactors developed by the early government and industrial effort were largely acceptable to the scientific community. Tremendous support was placed behind one particular approach, the so-called light water reactor. Relatively little support was given to other approaches. Beginning in the 1970s, however, years before the 1979 accident at Three-Mile Island, public concerns over environmental, safety, and economic factors led to a tremendous slowdown in the civilian nuclear program. Regulatory issues came to the forefront, as countless lawsuits added to the licensing time for reactors. The nuclear industry was buffeted by complaints concerning cost, safety, waste disposal, vulnerability to terrorists, and the political costs of large, central power plants. State and federal regulation tightened in response to these public concerns.[30]

The nuclear industry did not lose every courtroom or legislative battle, but at times it must have seemed as though the battles would never cease. Consider state regulation of reactors. In 1976, California passed legislation placing a moratorium on certification of new nuclear plants until a state commission determined that there was a demonstrated way to dispose of high level nuclear waste. The industry went to court, arguing that the California law conflicted with federal laws pervasively regulating nuclear energy and setting up a process for the development of nuclear waste storage technologies. The U.S. Supreme Court ruled in favor of the California law, finding that federal law regulated the safety aspects of nuclear energy but not the economic aspects. The California law, the Court said, was motivated by concern that waste storage might make nuclear energy uneconomic.[31] The industry was, of course, disappointed with losing the case, but it felt that at least the court had established that the federal government regulated nuclear safety. The industry thus had reason to be confident when the Karen Silkwood case reached the Supreme Court.

Karen Silkwood was a laboratory analyst in a Kerr-McGee plant that fabricated plutonium fuel pins for nuclear reactors. She was contaminated by plutonium under controversial circumstances. After her death in an automobile accident, her estate sued under state law to recover damages due to her contamination. The jury awarded the Silkwood estate punitive damages, in effect punishing Kerr-McGee for endangering Silkwood. On review in the Supreme Court, Kerr-McGee argued that the Court's decision in the earlier California case established that federal law had sole authority in matters of nuclear safety. But the Court disagreed, finding that Congress intended federal regulation of nuclear safety to coexist with state tort laws. The Court concluded "there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a state may nevertheless award damages on its own law of liability," but the Court concluded that "Congress intended to stand by both concepts and to tolerate whatever tension there was between them."[32]

We saw before how disappointed grant applicants challenging actions by the dominant scientific community felt they were facing a Kafkaesque maze. Every corridor of potential judicial relief led to a dead end. Now, on the other side of the regulatory gap, it is the proponents of a new technology, often supported by the dominant scientific community, who themselves face an endless course of regulatory obstacles, where surmounting one leads only to another. The result is not that nuclear power suddenly stops. There is no public consensus to forbid new developments, however controversial. But there is a full dose of public control, slowing technological process.

The dramatic change in nuclear power's fortunes from the days of early research to the present is due in large part to the regulatory gap. More attention in the early years to social concerns that would accompany commercialization would have reduced later regulatory problems. As one scientist has written:

> As soon as we found a concept that worked reasonably well, powerful forces drove that machine, the L[ight] W[ater] R[eactor], to prominence. We did not take the time to test, modify, and finally choose the "best" nuclear reactor among many competitors. Now we know that safer, smaller, and probably cheaper fission reactors can be built.[33]

Some members of the public would have opposed nuclear energy in any form, but there is considerable evidence that other reactor designs, ignored in the early years, might have proven more acceptable to many citizens. In particular, early attention to waste disposal and to the health effects of radiation would have paid off. It appears possible, for example, that a design known as the modular high-temperature gas-cooled reactor, used in other countries for decades, might be socially superior to the conventional light water reactor.[34]

Another nuclear technology—the breeder reactor—is also a victim of the regulatory gap. The breeder is a fission reactor that runs on plutonium. While it is operating, it converts a relatively common form of uranium into more plutonium.[35] This increases the availability of fuel, but plutonium is a more dangerous fuel than that used in conventional reactors. Nonetheless, because of its fuel efficiency, the construction of breeder reactors was "an almost unanimous ambition of civilian nuclear scientists" after World War II.[36] Given its origins in the insulated world of science, it is not surprising that the Clinch River Breeder, a demonstration project that received billions of dollars before being slowed by litigation and stopped by Congress, represented a design far from optimal for meeting social concerns, such as the need to safeguard plutonium from terrorists who might fashion it into bombs.[37] Other designs, potentially superior in social terms, were slighted.[38] The breeder thus fell victim to the regulatory gap.

Computers and Regulation

If nuclear energy is the most dramatic example of the regulatory gap it is far from the only one. Virtually every technology that comes on-line must struggle with legal requirements that stem from a process-oriented system in which countless groups have a say. Perhaps the clearest way to see this is to consider the computer industry, one of the fast-growing segments of American technology. Here the regulatory gap has been nowhere near as destructive as with nuclear energy, yet it has taken a toll.

We tend to think of the computer industry today as a rapidly growing consumer-oriented portion of the private sector. But as with so many areas of modern technology, a major spur for initial research came from the federal government. The rising tide of immigration made the government's task of taking the 1880 census extremely difficult. It was becoming hard to complete one census in the ten-year period before the next had to begin. Thus in 1889, the superintendent of the 1890 census held a competition to find an improved way to handle census data. The winner was an electrically powered calculating machine developed by two men, John Billings and Herman Hollerith, who had previously worked for the census office. Computers were given a tremendous boost when this machine successfully handled the 1890 census.

The federal government continued to support developments in computer sciences, particularly because of the need for computers in World War II and in the immediate postwar era.[39] Today, an enormous private computer industry serves much of the American population in areas ranging from finances to communications. But having made the transition to the commercial sector, developments in computer science that are perfectly acceptable from a technical point of view have increasingly run into regulatory issues not on the agenda of the basic researchers. As a result, development of the computer industry, although still rapid, is not trouble-free.

A series of Supreme Court cases concerning the patentability of computer programs provides a classic illustration of the often rocky relationship between regulation and new technology. Patents give the inventor a seventeen-year monopoly for certain useful nonobvious inventions. Once you have a patent, your monopoly is good even against others who later come up with the same idea. Can a computer program be patentable? To a nonlawyer that might seem like a yes or no question. But it turns out to be a good deal more complicated, and thus the matter of providing incentives to those who write programs turns out to be a difficult regulatory issue.

In October 1963 the patent office received a patent application for a method of converting numbers from one form to another. The inventors, Gary Benson and Arthur Tabbott, had written an algorithm—a step-by-step procedure—for taking numbers written in a traditional format and converting them into binary numbers. In the binary system—which is often used in computers—all numbers are expressed as combinations of the two digits zero and 1. The number one for example, is expressed as 001, the number two is 010, the number three is 011, the number four is 100, and so on. The inventors' algorithm was designed for use in computers. In effect, the inventors were seeking to patent a particular computer program—one that used mathematical techniques to put numbers in binary form. The patent office rejected the application, and when the inventors' challenge to that decision reached the Supreme Court, it unanimously agreed with the patent office. The Court referred to the familiar rule that one cannot patent a law of nature or mathematics, and said that a patent for Benson and Tabbott would, in effect, preempt the use of a particular mathematical formula. The fact that the formula was set forth as a step-by-step computer program was irrelevant.[40]

But matters soon became more complicated. In 1978, the Court considered Dale Flook's application for a patent on a method for calculating "alarm limits." In oil refining and other industries, various operating conditions, such as temperature and pressure, are constantly monitored while certain chemical conversion processes take place. When the monitoring reveals that an inefficient or dangerous condition exists, the "alarm limit" is reached and an alarm goes off. Because conditions change as a chemical conversion process starts up or slows down, the "alarm limit" must be updated so that the alarm will only sound when there really is a problem. Flook sought a patent on a three-step method for updating alarm limits: (1) measure the present value of the variables, such as temperature; (2) use an algorithm, that is a step-by-step procedure, to calculate an updated alarm limit based on those variables; and (3) replace the old alarm limit with the updated value. The algorithm

Flook devised for step 2 was designed to be used by a computer—it was, in effect, a computer program.

A majority of the Supreme Court, in an opinion by Justice Stevens, held that no patent should be awarded to Flook. Stevens reasoned that the only new thing in Flook's process was step 2, the computer program for calculating the alarm limit. Allowing a patent for this program would be allowing the patenting of a mathematical formula, in contravention of the binary conversion case and earlier precedent.[41] But three members of the Court, in a dissent by Justice Stewart, saw it differently. To them, Flook was trying to patent a new three-step process. He should not be barred because one part of that process involved the use of a formula. After all, Stewart reasoned, thousands of processes involve, at some point, an unpatentable formula.[42]

Just three years later, the dissenters in the Flook case found themselves in the majority. The patent application of James Diehr and Theodore Lutton concerned a method for converting raw, uncured synthetic rubber into a cured and therefore usable final product. Their method involved using a mold to shape the uncured rubber under heat and pressure for just the right amount of time. Diehr and Lutton used a standard formula that revealed, based on the temperature, time, and so on, when to open the mold. They devised a way to constantly measure the conditions inside the mold, feed those figures into a computer, and have the computer continually update the standard formula until the formula indicated the mold should be opened. The patent office declined to grant a patent. However, this time, in 1981, the Supreme Court reversed. Justice Rehnquist, who had dissented in the Flook case, wrote for a majority of the Court that this patent application was different than Flook's. Whereas Flook was seeking simply to patent a formula, Diehr and Lutton had devised an entire improved process for curing rubber in which a computer program simply played a part.[43]

Justice Stevens, who had written the Flook opinion, was joined by three other justices in dissent. The dissenters saw no difference between Flook's method of calculating an alarm limit for chemical conversions and Diehr and Lutton's method for calculating how long to cure rubber.[44]

It is important to note that Rehnquist, in the rubber curing case, did not overrule the Flook case even though he had dissented there. The difference in the two cases, in terms of the attitudes of particular Justices, was that Justices White and Powell voted to deny Flook a patent but to grant one to Diehr and Lutton. By distinguishing rather than overruling Flook, Rehnquist won the support of White and Powell and left the Court room to maneuver in the future.

Before you become too critical of the Court's efforts in this area, consider the difficulties of the task. The patent monopoly is a tremendous incentive to inventors but it is costly to others who seek to enter a field. Precisely how much incentive is desirable in a field like computer programming? Moreover, what does it mean to allow or disallow patents for programs, when those programs are imbedded in complex products and processes? As the progression from binary number conversion to curing rubber indicates, these cases can become more and more difficult.

Today the issue of the patentability of computer software remains intensely controversial. Litigation is extensive, and the costs of that litigation include, at times, a slowing of the innovation process.[45] Companies like to know how they will protect their intellectual property rights before investing, and the uncertain state of the law makes that difficult. Moreover, many computer scientists believe that when computer software is involved, the patent process makes progress less rather than more likely.[46]

Indeed, the patent question is simply the tip of the iceberg of incentive issues for computer scientists. The computer field moves so rapidly that even when patents are available, getting one may be too slow a process to be worthwhile. And having one may provide little of value when the field rapidly shifts course. Accordingly, a good deal of attention, including regulatory attention, has shifted to copyright law, another way of protecting the computer scientists' intellectual property.

A copyright is much more easily obtained than a patent and the protection lasts longer. But a copyright, unlike a patent, does not protect you against someone who independently comes up with the same idea. Should copyrights be available for various types of computer programs? After much debate, Congress and the courts have generally said yes; however, regulatory issues remain, concerning, for example, whether and how copyrights should cover the "look and feel" of a program—its interface with the user—as well as its internal codes.[47] Here, as with patents, uncertainty has bred litigation and delays.[48]

Thus although the computer industry has moved fast, it has been slowed by legal disputes over intellectual property, and grumbling by computer scientists has inevitably followed. In principle, the regulatory gap here could have been narrowed. From the beginning, computer software did not easily fit into existing categories; indeed, it blurred the distinction between patent and copyright.[49] In recent years, scholars have suggested that a new form of intellectual property protection should be tailored precisely for software.[50] But these proposals come after years of litigation and delay and they plunge into a world in which caution and compromise inevitably rule. There is little support for having computer software "unregulated"—with no legal protection, thefts would be so common that the incentive to innovate and market would fade. But regulation when it comes is something of a cold shower to a new technology. Understandably, the early writers of computer software did not focus on the protection of intellectual property.

The Emergence of the Science Counselor

The regulatory gap is a deeply entrenched feature of the modern American legal landscape. It will never disappear entirely, because the difference in world view between scientists and lawyers will never disappear entirely. But can the gap be narrowed? Developments in recent years suggest that some narrowing will take place as an increasing number of scientists become what I call *science counselors*.[51]

Narrowing the regulatory gap is a matter of self-interest for the scientific community. When a technology slows or grinds to a halt after billions have been invested, the pessimism and discontent that follows is widespread. It could eventually poison public support for basic research itself. Pure scientists may love science for its own sake, but the public funds it because of potential payoffs.

Science counselors are scientists doing research who shape that research, early on, to increase the likelihood that the resulting commercial product will encounter a relatively calm regulatory climate. They are not cheerleaders who proclaim that science will solve the world's ills at no cost. They are cautious and prudent researchers who bring social factors into the research process.

Science counselors are not a panacea. Nothing can remove the pinch of regulation entirely. Any new product alters rights in ways that create disputes, but the most wasteful outcomes can often be avoided. Scientific research need not produce the type of product that is least acceptable to society. That outcome follows from the indifference of researchers to commercialization. If research is guided by a socially conscious hand from the outset, choices can be made that improve the product's chances of relatively smooth commercialization. Scientists increasingly realize that taking these steps is in the interests of science. Doing research today without concern for the ultimate legal consequences is like doing a high wire act without the wire.

"Science counselor" is not, of course, a precise job description. There have always been scientists more or less attuned to the social implications of their work. The trend, however, is in the direction of more researchers giving greater weight to those implications.

Perhaps the best way to understand the role of the science counselor is to contrast that role with the others scientists play when they seek to shape public policy.

For decades, American scientists have participated in public debate on large issues such as arms control and the environment. As recently as the immediate post-World War II era, relatively few played this role. For every J. Robert Oppenheimer there were thousands who stayed out of the limelight. As the years went by, more scientists (such as Edward Teller and Linus Pauling) became familiar figures in public debate. Today, on issues like global warming, scientists like Carl Sagan are increasingly prominent participants.

The activities of these "visible scientists,"[52] to use the term popularized by Rae Goodell, have not been free of controversy. Theoretically, scientists enter public debate as expert witnesses, advising politicians, legislatures, and citizens' groups on the technical aspects of public issues. In practice, it is often hard to separate technical advice from personal viewpoints as scientists sometimes offer views in areas far removed from their specialties and seem to arrive at those views through political rather than technical reasoning. Some have condemned scientists for seeking to expand their influence beyond their expertise, whereas others have praised them for going beyond narrow laboratory concerns and entering into wider moral and political discourse. A major motivation for some of these visible scientists has been a sense of moral obligation born of the scientists' role in building the atomic bomb.[53]

The visible scientists, so prominent on television and in other mass media today, tend to be senior figures in their fields, including Nobel laureates. They have often abandoned scientific research altogether as they devote essentially all their efforts to their current political concerns.

Akin to the visible scientists are the "regulatory scientists" analyzed by Sheila Jasanoff and others.[54] These individuals provide advice to government agencies through service on countless advisory committees. They are typically less prominent than the visible scientists, but their efforts are ubiquitous. Like the visible scientists, when they provide advice they are not doing research; they are attempting to provide input into social decisions. They also have to confront the question of whether one can really separate technical from political advice in the policy arena.

There is an inexorable progression from the few presidential science advisors of the World War II era to the scores of "visible" and "regulatory" scientists prominent today to the full-blown emergence of "science counselors." Science counselors, unlike visible and regulatory scientists, do not leave the scientific community to participate in public debate and decision making. They are ordinary researchers in government, in universities, and in private institutions who become informed about potential social issues raised by their work and shape their work in light of those issues. Whereas visible and regulatory scientists are doing policy work, science counselors are doing science.

Because of this difference, the closest analogue to the science counselor is not the visible or regulatory scientist. Rather, it is the science manager who is concerned with budgets and the laboratory's output.

Much research depends on government funding, so the writing of grant and budget requests has become an art. Budgetary decisions shape the type of research done, and science managers are often at the interface, urging their labs to do work that looks attractive and urging agencies to see the lab's work as irresistible. Science managers in government have considerable experience in dealing with the sometimes probing questions of the Office of Management and Budget. Managers in industry, by the same token, must show that scientific work will someday, somehow lead to profits.[55]

Scientists working on this borderline find the job difficult, but budgetary constraints act in a broadbrush manner. When cancer research became enormously popular, a great deal of science became known as cancer research. The science counselor is going a step beyond the traditional science manager who says "fund my lab—it will pay off." Science counselors tell their lab not to follow the road most likely to produce a new source of energy but to follow the road most likely to produce a new, nonpolluting source of energy using raw material available in America.

More fundamentally, science counselors may not head a lab or a research team. They may be ordinary scientists who have absorbed the notion of social constraint into their very concept of what a scientist does. Instead of grumbling about environmental or economic restrictions being imposed on their work by outside forces, they have made those restrictions part of their professional ethic.

Pursuing science for its utility, rather than for the pure expansion of knowledge, has always caused tension for scientists. The tension becomes greater as regulatory requirements sharply define the notion of utility.

The value system of the science counselor can be contrasted with the value systems of traditional scientists and lawyers. The traditional pure scientist is primarily concerned with testable knowledge about the natural world. Progress is defined as growth in our collection of that knowledge, and honors go to the scientist who establishes priority in adding something to that collection. The results of scientific research are ultimately put at the disposal of society for good or ill. When traditional scientists work on a mission-oriented project, their search is for the most scientifically attractive solution—the one that most quickly and neatly resolves the scientific problems presented. Traditional scientists may have strong moral concerns. They may, for example, decline to work in a field because of its implications for weaponry. But this is an all-or-nothing judgment—once scientific work begins, scientific values dominate.

Lawyers in a science policy dispute or elsewhere are primarily concerned with representing their client and protecting the integrity of the decision process itself. Progress in the scientific sense is not a major factor—lawyers are often indifferent to whether the world is better off if their client wins. They may even doubt whether "social progress" is a meaningful phrase. Lawyers believe, instead, that society can best peacefully resolve its disputes if process values are paramount.

The science counselor rejects the lawyer's agnosticism. There must be progress if science is to be worthwhile. But the science counselor also rejects the traditional scientist's notion of progress as simply the expansion of knowledge. For the science counselor, progress is social progress—the creation of socially acceptable technology that serves the public by making life, on balance, more comfortable and serves science by assuring a continued demand for research. The science counselor can argue at times that the search for socially acceptable progress will lead to interesting new areas of scientific research, but the desire for social acceptability may lead to an emphasis by scientists on areas that are scientifically not very interesting but socially quite important. The bottom line is that progress has been redefined away from the pure scientific model.

For generations, engineers have chided scientists for framing great theories with little concern for how they could be applied. In building a skyscraper, engineers are a lot more useful than scientists. The science counselor, in a sense, is responding to this kind of criticism, but from the legal not the engineering point of view. Science counselors are, in part, trying to make science fit social constraints.

Science counselors, nonetheless, must be scientists. A lawyer in this role would lack credibility with scientists, lack intimate knowledge of research, and lack the faith in progress, however dilute, that marks the work of the science counselor. The science counselor embraces, however reluctantly, the legal constraints that mark modern American society. By altering research to fit those constraints, the science counselor seeks to mesh science and society.

The science counselor's work should not be confused with technology assessment. As generally practiced, technology assessment comes too late.[56] Various early warning systems are used by technology assessment organizations to foresee and shape technological development. Scientists, engineers, lawyers, and social scientists engage in technology assessment, whereas Congress relies on technology assessment to narrow the regulatory gap.

Technology assessment, however, is caught in the middle. It comes after millions have been invested in research and development and momentum has begun behind various approaches. Moreover, by the time technology assessment gets underway, real regulation, whether through legislation or litigation, has often begun. Under these circumstances, it is not surprising that technology assessment organizations, such as the congressional Office of Technology Assessment, typically have only advisory powers. They do valuable studies and aid public debate, but the vital public decisions are made elsewhere. The science counselor, by coming onto the scene earlier and shaping the research itself, will avoid the irrelevance that is often the fate of technology assessment. As one public policy analyst has said, in the future the best scientists must master policy issues, even though this will "take time and energy away from their scientific work."[57]

Superconductivity and the Science Counselor

The emergence of the science counselor has been and will remain a gradual process. The origins of the modern science counselor can be traced most directly to the late 1960s when the regulatory gap grew and the threat to science sharpened, partly as a result of the environmental and antiwar movements. In recent years public debates on a variety of issues have been informed by the participation of science counselors. A good example is the emerging field of superconductivity.[58]

Superconductivity is electricity without resistance, the transmission of electrical current without energy loss. Discovered in 1911 by a Dutch physicist, superconductivity was for seventy-five years observed only at near absolute zero temperatures. By 1973, for example, the phenomenon was possible only at minus 418 degrees Fahrenheit, sharply limiting technological applications.

In April 1986, however, two physicists at the IBM Zurich Research Laboratory submitted for publication experimental results showing that in a ceramic compound superconductivity had been observed at minus 397 degrees Fahrenheit. Other scientists joined the search using similar compounds, and the relevant temperature began jumping upward. Although it is not certain, there is now hope that superconductivity may become available under proper conditions at temperatures achievable with ordinary commercial refrigerants, and perhaps even at room temperature.[59]

Various agencies of the federal government—including the Departments of Energy and Defense, and the National Science Foundation—had long funded superconductivity research. But with the recent advances, funding levels have increased sharply.[60]

The potential practical benefits of superconductivity are considerable. At present when electricity is transmitted, as much as 20 percent of the energy is lost in the form of heat generated by resistance in the wire. A superconductivity cable could eliminate that loss, reducing the cost of electricity. Eliminating the heat caused by resistance could also make possible smaller and faster computers, because presently efforts to scale down computers are limited by heat production. Superconductors could also be used in electromagnets to generate intense magnetic fields, opening up possibilities, including magnetically levitated trains.[61]

There has been no shortage of media excitement over superconductivity—the media typically emphasizes scientific breakthroughs and often presents them in the most glowing form.[62] And indeed, the race to make progress in superconductivity was an extraordinarily exciting human as well as scientific process, as ably conveyed in Robert Hazen's *The Breakthrough*. But there will, of course, be difficult decisions down the road as superconductivity moves into technological applications.

For example, some of the recent advances in superconductivity have relied on materials that contain yttrium, a so-called rare earth. Yttrium is not, in fact, rare, and increased uses of superconductivity will require increased production of it. Yttrium is often found in monazite ore, which is presently mined and processed for various purposes. If superconductivity turns out to mean increased work with monazite ore, a rather dramatic example of the regulatory gap is in the offing. Monazite ore is a low-level radioactive compound. In April 1986, the same month the IBM physicists submitted their findings on ceramic superconductors, a federal court handed down a decision in ongoing litigation brought by William Merklin, an employee of Raw Earths, Inc.[63] None of the breathless press accounts on superconductivity mention Mr. Merklin; indeed he did not work with superconductors or even with yttrium. But he did work on processing monazite ore and he did contract cancer of the larynx, throat, and lymph nodes, perhaps from his exposure to the radioactive ore. In the course of its decision, which held that Mr. Merklin might have a viable claim for damages, the court found that "radioactive monazite ore and its refined derivatives are dangerous products" for purposes of certain legal theories.[64]

Of course, this particular risk with superconductivity may never come to pass. But it is quite likely that in practice the applications of superconductivity will raise a variety of health and safety issues. Thallium and mercury, for example, are other possible components in commercial superconductors, and both are quite toxic.[65]

So unless something changes, the regulatory gap will take its toll once again. Some scientists do not see it coming; after all, some of them reacted to developments concerning mercury-based superconductors with enthusiasm, saying these materials have "both intrinsic scientific interest and overlapping technological potential" without ever mentioning the toxicity of mercury.[66] But there does appear to be change on the horizon. With superconductivity, science counselors have begun to emerge. In fact, with all the hyperbole surrounding superconductivity it is primarily scientists who have sounded notes of caution. Dr. John Hulm, for example, director of corporate research and planning at Westinghouse, has said that he had "never seen the country so hysterical about a new technology. It's puzzling and a little dangerous. We are creating expectations that may not be realized."[67] Consider as well the views of Massachusetts Institute of Technology (MIT) professor H. Kent Bowen and of Dr. Siegfried Hecker, director of the Los Alamos National Laboratory. Both have stressed that if the United States is to be competitive in end products using superconductivity we must link scientific progress with manufacturing technology to aid in ultimate commercialization. Bowen has stressed the need to minimize uncertainties about commercial applications, and Hecker has said explicitly that we cannot "disconnect" research from manufacturing and marketing.[68] In the same vein, R. J. Cava, a researcher at AT&T Bell Laboratories, has questioned whether toxic superconductors will ever be widely usable and has discussed the relative public acceptance of mercury as opposed to thallium.[69]

The most dramatic development concerning the social implications of superconductivity has been the creation of a consortium linking American Telephone & Telegraph, International Business Machines, the Massachusetts Institute of Technology, and the Lincoln Laboratories, a government-sponsored MIT lab. This organization is designed to give the United States the lead in commercializing superconductors. It grew out of the recommendation of a White House Science Council Committee, chaired by Ralph E. Gomory, IBM senior vice president for science and technology.[70] That White House committee concluded:

> We believe the optimal way to proceed is to take advantage of the scientific strength at universities and government laboratories and infuse it with detailed knowledge of applications. This knowledge is resident in industry. This is best done if the three institutions, university, industry and government, work together

to develop goals and to jointly support them, manage them, and review them for progress.[71]

Saying that we should take the scientific strength at universities and government and infuse "it" with a detailed appreciation of applications obscures a basic point. It is people—basic scientific researchers—who will be infused with this practical knowledge. And it is their work—their science—that will be altered.

Thus with superconductivity we are seeing the beginning of a system in which science counselors shape research for social ends. At present, we are in a transitional stage. In the chapters that follow, we will see scientific developments in genetics, fusion, and artificial intelligence that are heading for the regulatory gap. Although science counselors are attempting to soften the blow, it remains true that promises of dramatic technological impact far outstrip the reality. At the same time, these scientific advances are shaping our values even as their practical consequences remain surprisingly distant.