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Susan S. Silbey

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Volume II

Regulation of Property, Practices, and Products

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Series Preface

The International Library of Essays in Law and Society is designed to provide a broad overview of this important field of interdisciplinary inquiry. Titles in the series will provide access to the best existing scholarship on a wide variety of subjects integral to the understanding of how legal institutions work in and through social arrangements. They collect and synthesize research published in the leading journals of the law and society field. Taken together, these volumes show the richness and complexity of inquiry into law's social life.

Each volume is edited by a recognized expert who has selected a range of scholarship designed to illustrate the most important questions, theoretical approaches, and methods in her/his area of expertise. Each has written an introductory essay which both outlines those questions, approaches, and methods and provides a distinctive analysis of the scholarship presented in the book. Each was asked to identify approximately 20 pieces of work for inclusion in their volume. This has necessitated hard choices since law and society inquiry is vibrant and flourishing.

The International Library of Essays in Law and Society brings together scholars representing different disciplinary traditions and working in different cultural contexts. Since law and society is itself an international field of inquiry it is appropriate that the editors of the volumes in this series come from many different nations and academic contexts. The work of the editors both charts a tradition and opens up new questions. It is my hope that this work will provide a valuable resource for longtime practitioners of law and society scholarship and newcomers to the field.

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Introduction

This second volume of exemplary scholarship on law and science focuses on the practices of scientists and the consequences of scientific production. If Volume I attended to science as it entered legal domains, primarily as evidence, Volume II collects accounts of law acting within the domains of science, primarily as resources and regulations.

When most people think of scientists, they conjure up images of white lab coats and incomprehensible formulae, medical miracles and electronic marvels, smelly substances and elaborate glass tubing, risks of environmental degradation and nuclear disaster. Laboratories appear as frightening as they are generative, elegant as they are messy. Most scientific laboratories are built from a limited set of templates, uniformly organizing space and equipment as standardized places with interchangeable cookie-cutter parts – architectural testaments to the universality of science and scientific knowledge (Gieryn; 1998, Silbey and Ewick, this volume, Chapter 11). Built with aspirations to disinterested, universal, collectively shared knowledge, science is also a terrain of raw competition and destructive jealousies driven by strong personalities. Although many scientific achievements have led to longer, richer, healthier and freer lives for many, scientific innovations have also produced increasingly effective surveillance and an abundance of instruments for raining pain and death on a scale heretofore unknown. Extending and enriching the lives of some, science also stokes the chasm between the haves and the have-nots. To talk about scientific miracles while attending to scientific dystopias requires looking under the surface of science, where history and sociology show it to be a contradictory human practice, born of both collective hope and individual ambition, both fuelling and feeding upon processes of capitalist accumulation.

Part I of this volume comprises a collection of essays addressing the ways in which modern science has been institutionalized in the United States with particular focus on the capitalization of science: the organizational and financial support from government, business, private philanthropy and public-interest organizations.[1] This institutional infrastructure is especially fragile because the exchanges and trade-offs among the various parties that constitute material support for science may be more cultural than economic, symbolic as well as instrumental (cf. Mukerji, 1989). For example, it is true that public funding supports most scientific research: in government laboratories, through contracts and grants to non-government scientists or through indirect support of higher education and industrial R&D. Nonetheless, 'good science is not exchanged for funds; [and] neither do scientists merely follow the political winds to scrape together the monies they need for research' (Mukerji, 1989). Rather, in exchange for the wherewithal to do science and develop scientific expertise, government secures a reserve labour force that can be mobilized, when needed, for advice, technical support and emergency response. Government trades material resources for the most effective form of modern legitimacy – knowledge. Because 'the power of science lies less in what scientists

[1] A weakness of this volume that should be acknowledged upfront is the paucity of materials on science in other nations. This should be remedied in a subsequent volume.

tell the government than in the cultural authority of science as an institution' (ibid., p. xi), the discoveries and inventions produced through government funding simultaneously legitimate both science and the state: 'For the money it allocates to support research, the state gets the right and ability to use that authority to legitimate its actions and for continuation of the soft-money funding systems, scientists give up control of their cultural power' (ibid., p. xi).

The institutionalization of modern science has been achieved not only through government and philanthropic largesse, but also through legal techniques that transform the search for knowledge into a profit-making activity. Part II of this volume addresses exactly that conjunction among legal, economic and scientific phenomena in the creation of intellectual property that makes markets *of* scientific knowledge *in* scientific practice. The final three Parts address law in one of its more commonplace functions as a means of confining action through rules and rule-based decision-making. There we look at the ways in which statutes and regulations, primarily, have been used to establish criteria for legitimate, ethical and safe science. The final chapter looks at some efforts to deal with the often uncertain human, material, and environmental consequences of scientific innovations.

State Institutionalization of Science

Part I begins, then, with Larry Owens's account of a legal engagement that, despite its failure, became a template for the rapid expansion of scientific research during and after the Second World War. Owens's essay, 'MIT and the Federal "Angel": Academic R & D and the Federal-Private Cooperation before World War II', is an appropriate opening for this volume as the text itself begins with quotes from legal scholars, Henry Maine and Lawrence Friedman, extolling the role of contract as the foundation of modern social and economic relations. Owens describes how, in 1933, the TVA and MIT attempted to set up a relationship in which MIT would invent a means for transmitting electric power over long distances – something not yet physically or technologically possible – while the federal government contributed to MIT's research and development costs. Long-distance power transmission would be established through the historic technique for long-distance transmission of human agency: contract.

The parties were not unfamiliar with contract negotiations; like their Pilgrim ancestors, they too conceived of social and political arrangements in terms of the tools of the marketplace. As Owens points out, the commodification of science that was successfully consolidated during and following the Second World War was 'only a recent and vigorous example of the commercializing propensities that have marked the development of the West over the last centuries' (p. 28) The contract form lay at the heart of the process of merging private and public capital with university research from the original bequests that established the universities to the government contracts for specific technologies and projects. As Karl Llewellyn and Roscoe Pound wrote at the time, in their entry in *The Encyclopedia of the Social Sciences*, the contract embodies 'the social and legal machinery appropriate to arranging affairs in any specialized economy which relies on exchange rather than tradition (the manor) or authority (the army) for apportionment of productive energy and of product' (Llewellyn and Pound, 1931, quoted on p. 28).

Despite the contract's familiarity and suitability as a social technique, the negotiations fell apart; the bargain was not struck. At the heart of the problem, Owens suggests, was the complexity of the contract that attempted to mix public interests in technological and economic development with historical commitments to private property, profit and small government. The contract was to be a three-party agreement between the university, the TVA and a private philanthropic organization that used the income from its members' patent licences to support science. MIT would conduct the research, the Research Corporation would hold the patents and the TVA would provide the funds, but, despite the clear division of labour, there was a lack of clarity at the heart of the bargain. In whose interest would the licences be awarded? How would public benefits be ensured? In 1933, university and philanthropic leaders were not yet ready to accept a major role for government nor was the Research Corporation willing to forego profit-making licences. The TVA was anxious to have the new technology offered by the university but was neither comfortable with the commercial self-interest implicit in the patenting agreement nor confident that either the university or the Research Corporation could forego self-interest in favour of a public good.

Although the federal angel failed to bless the Van de Graaff electric transmission system in 1933 – failed 'to establish … [a] precedent for the privatization of federal sponsorship' (p. 27) – by 1940, only seven years later, the university and the federal government had successfully created an '"arrangement" of committees and contracts that successfully mobilized for war the nation's private scientific resources' (p. 26) therein established the paradigm for post-war scientific development. The signing of the National Science Foundation Act by President Harry S. Truman on 5 May 1940 established a central core of that post-war institutionalization.

Standard histories of the seven-year struggle to establish the National Science Foundation (NSF) often depict a battle between populists and New Dealers seeking democratically accountable research and development against scientists seeking support for scientific autonomy through investigator-initiated research (Kevles, 1977; England, 1982). Daniel Kleinman, in 'Layers of Interests, Layers of Influence: Business and the Genesis of the National Science Foundation' (Chapter 2), enriches the conventional account with an analysis of the structural and sectoral bases for the various positions taken and the various forms of participation by business firms in the legislative debates over the establishment of the NSF. At the heart of the matter was the issue that could not be successfully negotiated between MIT and the TVA in 1933 – who would own the intellectual property of federally-funded scientific research: 'business generally opposed … efforts to prohibit exclusive licenses resulting from industrial research supported with government funds' (p. 34), seeking to benefit from federally-supported university research. As such, the National Association of Manufacturers actively lobbied to oppose the populist New Deal coalition that sought non-exclusive rights and favored support for both basic and applied research, as well as a proposal by Vannevar Bush for a scientist-controlled agency to fund basic, but not applied, scientific research, and opportunities for exclusive licensing. In the end, Kleinman argues, the NSF was a compromise among the various positions that becomes apparent only if one looks at the heterogeneity within the business community and among the forms of lobbying and influence business used.

Kelly Moore, in 'Organizing Integrity: American Science and the Creation of Public Interest Organizations 1955–1975' (Chapter 3), writes about another source of support for the institutionalization of American science. She describes a productive contradiction in which scientific authority and the autonomy to determine what is and is not science are sustained not by science's processes of knowledge production but by its alliances with distinctly nonscientific constituencies. 'To reap prestige and financial support ...', Moore writes, 'scientists must ... demonstrate that their work is ultimately ... useful to a broad constituency' (p. 54). In this effort, science must demonstrate not its distinctiveness, but its affinity with other interests, even those that might compromise its norms of disinterestedness, generality and scepticism (Merton, [1942]1957). From the 1950s through the 1970s, a period of social and political protest, scientists formed public-interest organizations that could speak politically with a scientific voice while keeping science pure and apolitical. Organizations, such as the Union of Concerned Scientists, Science for the People and the Scientists' Institute for Public Information, could speak out, lobby or advise on policy matters while research conducted by individual principal investigators (PIs) was shielded from inquiries about its political roots and implications.

The authority of science derives in good measure from this continuous monitoring of what does and does not constitute legitimate science, what is inside science and what lies beyond its sacred spaces. Scholars who study scientists and scientific research practices have adopted the term 'boundary work' to describe the social transactions that mediate between science and other institutions, including politics and law (Gieryn, 1995, 1999). Observers vary in the degree to which they see these boundaries as more or less given, or in the process of being built, maintained, defended and broken down (Miller, 2000). Nonetheless, 'recognizing that there is no unbridgeable chasm between science and non-science and that the flexibility of boundary work may threaten some important values and interests', some have suggested that standardized packages, and what some call boundary objects, stabilize this legitimating boundary work by creating shared practices (Guston, 2001, p. 400; Fujimura, 1991; Miller, 2001). The public-interest organizations that Moore describes fulfill these mediating functions, sustaining the autonomy and disinterestedness of science while performing its public utility. David Guston, in his essay 'Stabilizing the Boundary Between US Politics and Science' (Chapter 4), describes offices of technology transfer, specifically at the National Institutes of Health, as another set of organizations that mediates the divide between science and its public – here, the law and the market. The office of technology transfer, an organization we turn to more extensively in Part II, becomes an agent, Guston claims, for both political and scientific interests. Because the boundary organization serves two masters, Jasanoff (1996, p. 397) has labelled its work, 'co-production', the simultaneous production of knowledge and social order.

Making Markets of/in Science

Part II begins, as did Part I, with a problem in contract. Again, we encounter a controversy concerning title and property in scientific work. Once more, the right to benefit economically from scientific invention is entangled with the state funding of science – in this case, not the modern state through grants and contracting but an emperor's patronage in the employment of a court mathematician. Although the following four essays in this section address very contemporary issues concerning the patenting and licensing of biological matter and the expansion of the intellectual property regime since 1980, as well as a close look at how one technology licensing office manages its position at the boundary of science and the market, we begin with the story of Johannes Kepler's effort to capitalize on Tycho Brahe's work without constraint by, and compensation to, Brahe's heirs. In 'Publish or Perish: Legal Contingencies and the Publication of Kepler's *Astronomia nova*' (Chapter 5), James Voelkel describes the genesis and unusual shape of Kepler's historic narrative in a series of litigations from libel suits among competing scientists to a suit between the emperor and Brahe's heirs who sought back-pay from Emperor Rudolf II and compensation for Brahe's astronomical assets. Those who bemoan the development of a late twentieth-century litigious culture would do well to study the history of intellectual property litigations.

Kepler had not been the obvious successor to Tycho Brahe. Only two years before his death, Brahe's household laboratory had been employing a half-dozen or more assistants with various pecuniary relationships – some self-supported noblemen, some employed directly by Brahe, some on commission from collaborating courts. Because of a rapid and coincidental depletion of Brahe's staff immediately before his death, Kepler found himself in the role of the primary assistant with specific responsibility for completing the calculations for the *Rudolphine Tables* of planetary motion, the major project of the moment. When Kepler first wrote to Brahe, seeking access to Brahe's measurements to substantiate his own astronomical model, Brahe invited him to the laboratory, more interested in securing Kepler's co-operation in an ongoing libel litigation than in aiding Kepler's own work. Indeed, Brahe had become more than cautious regarding his assistants' interests, believing that two of his assistants had stolen his work and had published it as their own. Thus, when Kepler arrived to join Brahe's research group, Brahe attempted to confine Kepler's work, through a series of written pledges, to a narrow range focused exclusively on measurements of Mars. Only when the current assistants departed, for a variety of unrelated reasons, did Kepler rise in 1601 to the status of primary assistant. This role had been achieved as part of Brahe's efforts to secure additional funding from the emperor: 'The originality and significance of his ideas could translate into lavish support' (p. 39) from the emperor – much more than from the direct capitalization of his results or honoraria (which were relatively insignificant for this very wealthy man). Most of the emperor's largesse was bestowed on Brahe as a consequence of prestige rather than a direct purchase of intellectual property. The *Rudolphine Tables* were an exception, however. Here, Brahe sought to secure funds in exchange for writing the emperor into history by attaching his name to the best, most accurate astronomical data, just as King Alfonso X of Castile's name had been attached to the Ptolemaic data in the *Alfonsine Tables* and Duke Albrecht of Prussia's name had been attached to the Copernican *Prutenic Tables*. Unfortunately, Brahe died before the task had been hardly begun, and Kepler was immediately appointed as court mathematician with responsibility for 'caring for Tycho's instruments and completing his remaining publications' (p. 125). Thus Kepler was left in charge while the emperor negotiated with Brahe's family for title to the instruments and data. Although an agreement was finally reached to pay the family approximately one-fifth of their original demand, the emperor insisted that this be a government, rather than a personal, payment and that was not forthcoming. This inevitably led to extended litigation in which the family sought to recover the primary assets of the instruments and the observations, succeeding in due course in recovering the lucrative responsibility for the *Rudolphine Tables*. Consequently, to sustain the emperor's commission, Kepler was compelled to produce another work, which we know today as the *Astronomia nova*. To avoid conflicts with Brahe's family, Kepler first framed his findings in terms of an elaboration of his work on Mars, but this did not prove a sufficient strategy to withstand further litigation in which he was ultimately bound to allow Brahe's son-in-law, one of his earlier assistants, to edit and censor his work for publication. Out of respect and legal necessity, Kepler ended up interweaving the Ptolemaic, Tychonic and Copernican world systems in a 'long narrative of his [Kepler's] failures using classical mathematical techniques' (p. 136), so that the censor of the text would be unable to excise Kepler's particular contributions and essential reliance on celestial physics, rather than mathematics, to make his particular understanding and contribution. The context of Kepler's work is the stuff of a long, complex and compelling romance, but, as Voelkel concludes, 'beginning with the law, which determined in a quite specific way what Kepler could and could not publish, we can look at one of the masterpieces of modern science with new eyes' (p. 141).

We then skip more than 370 years to Stanford and Berkeley, California, to the first major patent of biological matter, with Sally Smith Hughes's essay, 'Making Dollars out of DNA' (Chapter 6), and to another scientifically significant litigation, *Moore* v. *Regents of the University of California*[2] which sustained the University of California's patent to a cell line derived from John Moore's spleen. Just as Kepler was forced by Tycho Brahe's heirs to establish his innovative astronomy by creating discontinuity between his work and that of his predecessors, in order to sustain the patent and licensing rights the University of California had to establish a discontinuity between natural biological matter and invented biological matter. Hannah Landecker's essay, 'Between Beneficence and Chattel: The Human Biological in Law and Science' (Chapter 7) unpacks this artfully constructed distance by displaying how the scientific process that is being patented as a discontinuous invention relies for its scientific validity on the establishment of continuity between the original cells and the line in use in subsequent experiments. She shows how arguments about the continuity of the person – John Moore – and the cell line were left out of the litigation which relied on government expertise that had originally been provided by the defendants in the case. Landecker's essay offers an example of the economic, legal and rhetorical practices that institutionalize contemporary science by lagitimating the resources and conditions of its practice.

The patenting of scientific procedures and products was resisted for most of the twentieth century, although 'by the 1920s hard-line opposition to patenting among academic scientists was beginning to be modified in favor of a more flexible approach' (Weiner, 1987, p. 50). Some felt that patenting was an efficient way of controlling the quality of products and protecting the public. That patenting could also provide revenue to support expanding academic research was, of course, an added incentive. Critics, however, argued that patenting undermined the free exchange of ideas essential for research, encouraged unhealthy competition and fed product development that was not always in the public interest. We have already encountered some of these issues in the opening essay, 'MIT and the Federal "Angel"'. Debates about academic patenting, consistent throughout most of the twentieth century, were most intense during periods of economic crisis and at times when new research seemed to make socially beneficial applications possible. In 1957 Seymour Melman, Professor of Industrial Engineering at Columbia University, completed a study initiated by the US Senate Subcommittee on Patenting, in which he suggested 'not only that there were problems with the way the patent system was running, but also that there were serious questions about the viability of the system per se' (Weiner, 1987, p. 57). Melman addressed the issues put forward by both the supporters and critics of patenting academic research. He found that the system was fundamentally incompatible with academic research. First, patenting law required a single inventor, or small

2 51 Cal. 3d 120, MC 1990.

number of named inventors, while modern scientific research and technology 'had become a group-based endeavor in which it was often difficult to identify the individual or individuals responsible for a discovery or invention' (Weiner, 1987, p. 57). Second, rather than spurring innovative research, Melman argued that patenting impeded research by inviting extended litigation about property rights, thereby reducing, rather than encouraging, further research. Aggressive patenting policies in academia (as well as industry) were backfiring because increased managerial control of research 'impeded the university scientist in the free pursuit of knowledge as an end in itself and thus weakened the universities as centers of basic research' (Weiner, 1987, p. 58). Third, information-sharing and rapid publication, which had become an engine of research productivity, was being limited by the secrecy required for the patenting process. Melman's report was basically ignored while the patent lawyers association independently published their own report challenging the claims, but they were unsuccessful in their attempt to rebut Melman's findings.

The passage of the 1980 Bayh-Dole Act by the US Congress transformed the landscape of academic research by permitting universities, non-profit institutions and small businesses to retain the property rights to inventions derived from federally-funded research. Although the intent of Congress was to encourage collaboration between commercial and non-profit organizations, the result was a profound change in the culture of academic research (Powell and Owen-Smith, 1998). Although the statutory change responded most directly to the development of biotechnology, the consequences spread beyond the biosciences to almost every discipline in science and engineering, with a growing divide between what Powell and Owen-Smith (1998) call the 'have' and 'have-not' universities. The chasm between haves and have-nots escalates because of a spiralling feedback loop of federal funding, lucrative licences for innovations produced from federally-funded research, and then additional research funding on the basis of prior productivity. Although federal funders provide incentives for young and minority investigators and special awards for educational, rather than research, institutions while attempting to geographically balance the distribution of funds, the number of patents and the volume of research support is concentrated in a small number of institutions.

In 'Dockets, Deals, and Sagas: Commensuration and the Rationalization of Experience in University Licensing' (Chapter 8) Jason Owen-Smith provides a close-up look at how science is transformed into property at the interface between university and market. Recent studies of scientific practice have described the heterogeneously assembled and contingent character of facts and artefacts (Bijker, 1995; Callon, 1986; Latour, 1987; Silbey, 2006), but Owen-Smith demonstrates how, in the effort to stabilize the scientific object so that it can be specified in a patent, the technology licensing office makes transparent the contingent, circumstantial character of scientific knowledge. The technology-licensing officers develop local epistemologies and rules of thumb for representing, distinguishing and comparing scientific results and inventions. There is little that is necessary or predetermined in the particular licences other than that they identify the specific technology in such a way as to ensure broad public access and benefit while securing revenue for the university. To achieve these purposes, the technology licensing officers sometimes combine disparate patents in a single licence; at other times they disentangle pieces of a single patent into distinctive licences. Owen-Smith shows the social and organizational arrangements that help constitute technologies, how the objects and processes 'take their form and acquire their attributes as a result of their relations with other entities' (Law, 1999, p. 3, quoted on p. 207), such as the technology licensing officers' discussion rituals, interpretations of university policies, or perceptions of potential public relations problems.

Governing Science: Law in the Lab

In a straightforward sense, patent law provides maps for the journey of science from the laboratory to the market. But this simple metaphor effaces a more complicated nexus between law and science. Law does not supply merely an environment surrounding the boundary of scientific spaces; it also inhabits science not only metaphorically, but also quite materially and behaviourally. However, the role of legal regulation within the procedures as well as in the spaces of science is perhaps one of the least explored or understood aspects of the relationship between law and science. Part III of this collection addresses this link between law and science within the very processes of data collection and analyses that are the hallmarks of empirical science.

Powerfully shaping contemporary life, science is perceived to be dangerous, both in terms of its potential to produce physical harm and in its insistence on an independent source of authority. Although legal regulations focus on material and physical dangers, most leave unchallenged the authority of scientists to determine what constitutes scientific knowledge (Gieryn, 1999). Of course, the history and development of modern science has not been a story of total immunity from the influences of competing social institutions. As the chapters in this volume and Volume I attest, the law has been constitutively present, sometimes centrally so, in the expansion and organization of modern science. 'But, in its efforts to promote (as well as contain) the development and consequences of science, the law has, over the centuries, certified areas of scientific autonomy, putting them beyond the law's reach' (Silbey and Ewick, this volume, p. 273). Since the middle of the twentieth century, however, the law's reach has increased considerably into all sorts of activities, relationships and spaces that had heretofore been privileged as private. By the end of the twentieth century, the regulatory state also included scientific spaces and practices within its embrace.

Under the mandate to secure the health and well-being of the nation, under the state's residual police powers, legal regulation has crept into just about every form of human action from the certification of health-protecting pharmaceuticals to the composition of children's pajamas or the construction of infants' cribs and carriages:

> *What* the law regulates, constrains, and enables is influenced, if not determined, in large part by science's methods and conclusions ...The law's deference to science's claim – to have access to something that is independent of its own activities – [thus] helps construct scientific authority and legitimacy at the same time as it instantiates and legitimates law's authority to regulate. (Silbey and Ewick, this volume, p. 273)

While science provides the impetus and justification for legal regulation in the name of health and safety,

> ... *how* that regulation takes place, through what sorts of procedures and sanctions, are the law's specific prerogative. Thus, we manage the dangers of radiation through an elaborate system of continuous surveillance that can lead to mandatory cessation of operation or

> personal exclusion from work. On the other hand, we respond to the dangers of smoking by requiring notices on cigarette packages, prohibit advertising and sale to minors, but taxing rather than prohibiting consumption for adults. And, in most American states, we respond to the dangers of sexually transmitted diseases not by providing or requiring surveillance or mandated notices, nor by monitoring the sexual practices of infected persons; we do, however, permit and certify marriages only after screening for disease. In each of these instances, the dangers have been identified through scientific research; the modes and forms of regulation are legal inventions. (Ibid.)

In the early twentieth century, chemistry laboratories began to install ventilation hoods to exhaust the chemical fumes. They were not required by law, at first, but were merely examples of good research practice. By the end of the Second World War, radioisotopes were familiar research substances, the control of which was delegated to the Atomic Energy Commission that later became the Nuclear Regulatory Commission. Under the auspices of these agencies, licences were issued to universities and other laboratories to work with radioactive materials. The licences specified safe conditions of operation through architecture, training and self-monitoring. Again, there was no regulatory surveillance or enforcement except when an accident was reported. Some universities established in-house offices to provide service to those using radioactive materials. These offices usually assumed the role of consulting advisors supporting researcher self-policing.

Thus, for most of the twentieth century, universities acquiesced to national priorities for research and development, in exchange for which the government funded the research and deferred to historic traditions of academic self-governance. By the end of the twentieth century, however, science's collaboration with the regulatory state led back, in an almost perfect feedback loop, into the sanctified spaces of science (the laboratories and research practices of scientists) through regulations concerning health, safety, environmental protection and conditions of employment. Although such regulations were, in principle, universal, with very few exempt categories, scientists and academic institutions nonetheless retained a good measure of the organizational autonomy they had been used to. In 1991 OSHA (Occupational Health and Safety Administration) enacted the lab standard, exempting research facilities from regulations designed for high-production enterprises. The new rules delegated to the regulated organizations themselves authority to determine how these more generally applicable federal and state regulations would be implemented within universities and research laboratories. Thus a compromise was struck between the regulator's interests in safety and the universities' interest in self-governance. This pattern of adaptive regulation would characterize the legal regulation of laboratory practices for at least the last quarter of the twentieth century and into the twenty-first.

Beginning in the 1970s this unspoken bargain between regulators and scientists began to wither in the face of a series of scientific inventions and embarrassments that awakened public notice and political institutions to what seemed like unnecessarily risky, if not evil, scientific enterprises. As a consequence, demands for more direct regulation of the processes of doing science escalated, beginning with attention to human subjects of and in research. Following the Second World War, the Nuremberg Code established voluntary consent by human subjects as the fundamental principle of ethical scientific or medical research. Nonetheless, for 40 years (1932–72) the US public health service had been conducting an experiment on 400 African-